DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 147, 153, 155, 156 and 158

[CMS–9911–P]

RIN 0938–AU65

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023

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

ACTION: Proposed rule.

SUMMARY: This proposed rule includes proposed payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs, as well as proposed 2023 user fee rates for issuers offering qualified health plans (QHPs) through federally-facilitated Exchanges and State-based Exchanges on the Federal platform. This proposed rule also proposes requirements related to prohibiting discrimination based on sexual orientation and gender identity; guaranteed availability; the offering of QHP standardized options through Exchanges on the Federal platform; requirements for agents, brokers, web-brokers, and issuers assisting consumers with enrollment through Exchanges that use the Federal platform; verification standards related to employer sponsored coverage; Exchange eligibility determinations during a benefit year; special enrollment period verification; cost-sharing requirements; Essential Health Benefits (EHBs); Actuarial Value (AV); QHP issuer quality improvement strategies; accounting for quality improvement activity (QIA) expenses and provider incentives for medical loss ratio (MLR) reporting and rebate calculation purposes; re-enrollment, and requirements related to a new State Exchange improper payment measurement program. This proposed rule also seeks comment on how HHS can advance health equity through QHP certification standards and otherwise in the individual and group health insurance markets, and how HHS might address plan choice overload in the Exchanges.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 27, 2022.

ADDRESSES: In commenting, please refer to file code CMS–9911–P.

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

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

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9911–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–9911–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, Sara Rosta, (301) 492–4223, or Kaye Wells, (301) 492–4301, for general information.

Cam Moultrie Clemmons, (206) 615–2338, or Anthony Galace, (301) 492–4400, for matters related to past-due premiums.

Allison Yadsko, (410) 786–1740, John Barfield, (301) 492–4433, or Jacqueline Wilson, (301) 492–4286 for matters related to risk adjustment or risk adjustment data validation (HHS–RADV).

Aaron Franz, (410) 786- 8027, or John Barfield, (301) 492–4433, for matters related to federally-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE–FP) user fees.

Nora Simmons, (410) 786–1981, for matters related to advance payment of the premium tax credit (APTC) proration.

Aaron Franz, (410) 786- 8027, or Hi'ilei Haru, 301–492–4363, for matters related to cost-sharing reduction reconciliation.

Josh Van Drei, (410) 786–1659, for matters related to actuarial value (AV).

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

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

Susan Kalmus, (301) 492–4275, for matters related to agent, broker, and web-broker guidelines. Dena Nelson, 240–401–3535, or Carly Rhyne, 301–492–4188, for matters related to income calculation for eligibility for advance payments of premium tax credits.

Katherine Bentley, (301) 492–5209, or Ariel Kennedy, (301) 492–4306, for matters related to special enrollment period verification.

Leigha Basini, (301) 492–4380, for matters related to nondiscrimination based on sexual orientation and gender identity; and EHB nondiscrimination.

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

Nidhi Singh Shah, (301) 492–5110, for matters related to quality improvement strategy standards for Exchanges.

Erika Ourisman, (301) 492–4170, for matters related to downstream and delegated entities.

Nikolas Berkobien, (301) 492–4400, or Leigha Basini, (301) 492–4380 for matters related to standardized options.

Erika Melman, (301) 492–4348, Deborah Hunter, (443) 386–3651, or Whitney Allen, (667) 290–8748, for matters related to network adequacy and essential community providers.

Linus Bicker, (803) 931–6185, for matters related to State Exchange improper payment measurement.

Phuong Van, (202) 570–5594, for matters related to advancing health equity through qualified health plans (QHPs).

Angelica Torres-Reid, (410) 786–1721, and Robert Yates, (301) 492–5151, for matters related to State Exchange general program integrity and oversight requirements.

Zarah Ghiasuddin, (301) 492–4308, for matters related to re-enrollment in the Exchanges.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post 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 individual will take actions to harm the 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.

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I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges,'' are entities established under the Patient Protection and Affordable Care Act (ACA) [1] through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs). Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. The ACA also established the risk adjustment program, which transfers funds from issuers that attract lower-than-average risk populations to issuers that attract higher-than-average risk populations to reduce incentives for issuers to avoid higher-risk enrollees.

In previous rulemakings, we established provisions and parameters to implement many ACA requirements and programs. In this proposed rule, we propose to amend some of these provisions and parameters, with a focus on maintaining a stable regulatory environment. These proposed changes are intended to provide issuers with greater predictability for upcoming plan years (PYs), while simultaneously enhancing the role of states in these programs. The proposals would provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability.

On January 20, 2021, the President issued an Executive Order which stated the Administration's policy on preventing and combating discrimination on the basis of gender identity and sexual orientation.[2] This Executive Order instructed the Secretary of Health and Human Services (Secretary of HHS, or HHS Secretary) to review all existing regulations, guidance documents, and other agency actions to determine whether they are consistent with the aforementioned policy, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with it. In consideration of this Executive Order, and as a result of our review of certain regulations, we propose to amend HHS regulations such that Exchanges, issuers, and agents and brokers are prohibited from discriminating based on sexual orientation and gender identity. The provisions in this proposed rule reflect the aspects of the Executive Order 13988 and aligns with the HHS' Notice, released on May 10, 2021, that HHS interprets and enforces section 1557's and Title IX's prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity, based on the Supreme Court's decision in *Bostock* v. *Clayton County.*[3]

Risk adjustment continues to be a core program in the individual, small group, and merged markets both on and off Exchanges, and we propose recalibrated parameters for the HHS-operated risk adjustment methodology. We published a technical paper, the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes [4] in October 2021, and sought comment on potential updates to the risk adjustment models. Consistent with the model changes discussed in the October 2021 Risk Adjustment (RA) Technical Paper, in this rule, we propose the following three updates to the HHS risk adjustment models beginning with the 2023 benefit year: (1) Adding a two-stage weighted approach to the adult and child models; (2) removing the current severity illness factors from the adult models and adding an interacted hierarchical condition category (HCC) count model specification to the adult and child models; and (3) replacing the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors. These proposals are intended to improve prediction in the adult and child risk adjustment models for the lowest-risk enrollees, the highest-risk enrollees, and partial-year enrollees, whose plan liabilities are underpredicted in the

[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] Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, January 20, 2021, *see* 86 FR 7023.

[3] U.S. Dep't of Health & Hum. Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 FR 27984 (May 25, 2021). *Also see, Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020). *https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf.*

[4] Available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

current models. We also propose to recalibrate the 2023 benefit year risk adjustment models using the 2017, 2018, and 2019 enrollee-level External Data Gathering Environment (EDGE) data. We further propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models. We discuss our consideration of the targeted removal of the mapping of hydroxychloroquine sulfate to Immune Suppressants and Immunomodulators (RXC 09) in the 2018 and 2019 benefit year enrollee-level EDGE data used for the 2023 benefit year model recalibration,[5] as well as the targeted removal of Descovy® from mapping to Anti-HIV Agents (RXC 01) in all three benefit years' enrollee-level EDGE datasets used for the 2023 benefit year model recalibration. We also propose for the 2024 benefit year and beyond to recalibrate the adult models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration. We propose to begin to use this approach for recalibration of the 2023 adult risk adjustment models, with the exception of the 2017 enrollee-level EDGE data year, for which we propose to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018).

Additionally, we propose to repeal the ability of states to request a reduction in risk adjustment state transfers starting with the 2024 benefit year, while proposing to provide an exception for states that previously requested a reduction to transfers under § 153.320(d). In addition, we solicit comments on the requests from Alabama to reduce risk adjustment state transfers for the 2023 benefit year in the individual (including the catastrophic and non-catastrophic risk pools) and small group markets.

We also propose the 2023 benefit year risk adjustment user fee for states where HHS operates the risk adjustment program. We also propose to collect and extract five new data elements including ZIP code, race, ethnicity, individual coverage health reimbursement arrangement (ICHRA) indicator, and a subsidy indicator as part of the required risk adjustment data that issuers must make accessible to HHS in states where HHS is operating the risk adjustment program. We also propose to extract three new data elements issuers already provide to HHS as part of the required risk adjustment data submissions (plan ID, rating area, and subscriber indicator) and to expand the permitted uses of the risk adjustment data and reports. Finally, we propose that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans, actionable discrepancies, or successful appeals, the recouped funds would be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next applicable benefit year for which high-cost risk pool payments have not already been calculated.

We propose further refinements to the HHS–RADV error estimation methodology beginning with the 2021 benefit year to (1) extend the application of Super HCCs (which are currently based on the coefficient estimation groups defined in the applicable benefit year's ''Additional Adult Variables'' Table of the ''Do It Yourself (DIY)'' software (Table 6 in the 2021 Benefit Year DIY Software), which is published on the CCIIO website)[6] from their current application only in the sorting step that assigns HCCs to failure rate groups to broader application throughout the HHS–RADV error rate calculation process, (2) specify that Super HCCs will be defined separately according to the age group model to which an enrollee is subject, and (3) constrain to zero any failure rate group outlier with a negative failure rate, regardless of whether the outlier issuer has a negative or positive error rate.

As we do every year in the HHS notice of benefit and payment parameters, we propose updated parameters applicable in the individual and small group markets. We propose the PY 2023 user fee rates for issuers offering plans through the Exchanges using the Federal platform. We propose maintaining the Federal-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE–FP) user fees at the current PY 2022 rates, 2.75 and 2.25 percent of total monthly premiums, respectively, in order to preserve and ensure that the FFEs and Federal platform have sufficient funding to cover the cost of all special benefits provided to FFE and SBE–FP issuers during PY 2023. We also note that HHS will issue the 2023 benefit year premium adjustment percentage index and related payment parameters in guidance, consistent with the policy finalized in part 2 of the 2022 Payment Notice.

We also propose to require all Exchanges to prorate premiums and advance payments of the premium tax credit (APTC) when administering APTC for enrollees enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month.

We are proposing changes to clarify that the cost-sharing reduction (CSR) data submission process is mandatory only for those issuers that received CSR payments from HHS for any part of the benefit year, and voluntary for other issuers. We propose a technical correction to the definition of large group market in § 144.103 to delete the concluding phrase ''unless otherwise provided under state law.''

We propose new display requirements for web-broker non-Exchange websites, including requirements related to QHP comparative information and standardized disclaimer language; a prohibition on displaying QHP advertisements or otherwise providing favored or preferred display of QHPs based on compensation agents, brokers, or web-brokers receive from QHP issuers; and a requirement to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on web-broker non-Exchange websites to better inform and protect consumers using such websites.

We propose a number of policies to address certain agent, broker, and web-broker practices. These policies would be added as part of the FFE standards of conduct codified at § 155.220(j)(2), improving CMS's ability to enforce existing responsibilities agents, brokers, and web-brokers utilizing the Exchange are required to adhere to without substantially burdening other agents, brokers, and web-brokers, while also providing more detail about specific business practices that are prohibited. We believe the proposed new regulatory text would protect consumers, ensure the efficient operation of the Exchange, minimize the risk of future tax discrepancies, reduce unauthorized enrollments in Exchange coverage, and provide a stronger basis for CMS to take enforcement action against agents, brokers, and web-brokers for violations of these requirements.

We propose revising our interpretation of the guaranteed availability requirement to prohibit

[5] The same concern was not present for the 2016 or 2017 enrollee-level EDGE data because hydroxychloroquine was not included in the crosswalk until 2018.

[6] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.* The August 3, 2021 version of the 2021 DIY Software Tables is available at *https://www.cms.gov/files/document/cy2021-diy-tables-07092021.xlsx.*

issuers from applying a premium payment to an individual's or employer's past debt owed for coverage and refusing to effectuate enrollment in new coverage. We believe this proposal would have a positive impact on the risk pool by removing barriers to enrollment for low-income individuals who lost prior coverage due to nonpayment of premiums. In addition, this proposal would promote more equitable access to health insurance coverage by ensuring that enrollment is not delayed as a result of non-payment of past-due premiums to the same issuer or control group, regardless of an individual's or employee's status as an APTC recipient.

Stable and affordable Exchanges with healthy risk pools are necessary for ensuring consumers maintain stable access to health insurance options. In order to minimize the potential for adverse selection in the Exchanges, we propose to allow Exchanges to conduct risk-based employer sponsored coverage verification.

We propose to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We also propose to specify that only expenses directly related to activities that improve health care quality may be included as quality improvement activity (QIA) expenses for MLR reporting and rebate calculation purposes.

In addition, we propose to make a technical amendment to remove a reference to a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus, et al.* v. *Cochran,* 523 F. Supp. 3d 731 (D. Md. 2021), and thus deleted in part 2 of the 2022 Payment Notice final rule.

With regards to the essential health benefits (EHB), we propose an evergreen deadline for EHB-benchmark plan applications by states, as well as proposing to remove the ability for states to permit issuers to substitute benefits between EHB categories. In addition, we propose changed de minimis thresholds for the actuarial value (AV) for plans subject to EHB requirements, as well as narrower de minimis thresholds for individual market silver QHPs and income-based CSR plan variations. We also propose to remove the state annual reporting requirement to report state-required benefits in addition to the EHB to HHS. We believe there may be ways to achieve compliance with the defrayal policy without imposing the rigid submission requirements on states that exist under the annual reporting requirement.

We propose policies to strengthen and clarify our network adequacy standards, including expanding the provider specialty list for time and distance standards and adding appointment wait time standards. For plans with tiered networks, we propose that, to count toward the issuer's satisfaction of the network adequacy and essential community provider (ECP) standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. We also propose to require issuers to submit information about whether providers offer telehealth services. We propose to increase the ECP threshold from 20 percent to 35 percent.

We also propose to amend the current regulation, which provides that, notwithstanding any relationship or relationships a QHP issuer may have with delegated or downstream entities, the QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities with all applicable Federal standards related to Exchanges. Specifically, HHS proposes adding a requirement that all agreements between QHP issuers and their downstream and delegated entities include language stating that any Exchange authority, including State Exchanges, may demand and receive records related to the QHP issuers' obligations and compliance with applicable Federal standards related to Exchanges. We also propose other amendments to extend the obligation to oversee compliance of delegated and downstream entities to QHP issuers in all models of Exchange. These proposals would hold QHP issuers in all models of Exchange responsible for their downstream and delegated entities' adherence to applicable Federal standards, and make their oversight obligations, and the obligations of their downstream and delegated entities, explicit. We also propose to amend the title of subpart D of 45 CFR part 156 from ''Standards for Qualified Health Plan Issuers on Federally Facilitated Exchanges and State-Based Exchanges on the Federal platform'' to ''Standards for Qualified Health Plan Issuers on Specific Types of Exchanges'' to more accurately reflect the applicability of the regulations within the subpart.

We solicit comments on incorporating the net premium, maximum out-of-pocket (MOOP), deductible, and annual out-of-pocket costs (OOPC) of a plan into the Exchange re-enrollment hierarchy as well as additional criteria or mechanisms HHS could consider to ensure the Exchange hierarchy for re-enrollment aligns with plan generosity and consumer needs, such as, re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity offered by the same QHP issuer. We also propose to update the quality improvement strategy (QIS) standards to require QHP issuers to address health and health care disparities as a specific topic area within their QIS beginning in 2023.

We also propose to require issuers of QHPs in FFEs and SBE–FPs to offer through the Exchange standardized QHP options beginning in PY 2023.

Finally, we solicit comments regarding additional ways HHS could incentivize QHP issuers to design plans that improve health equity and health conditions in enrollees' environments, as well as how QHP issuers could address other social determinants of health (SDOH) outside of the QHP certification process.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health 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.[7]

Section 2702 of the PHS Act, as added by the ACA, establishes requirements for guaranteed availability of coverage in the group and individual markets.

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

Section 2791 of the PHS Act defines several terms, including ''large group market''.

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

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

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary 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. Section 1302(d) of the ACA describes the various levels of coverage based on their AV. Consistent with section 1302(d)(2)(A) of the ACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the ACA directs the Secretary of HHS to develop guidelines that allow for de minimis variation in AV calculations. Sections 1302(b)(4)(A) through (D) 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 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(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 establishes special enrollment periods and section 1311(c)(6)(D) of the ACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.[8]

Section 1311(c)(1)(E) of the ACA specifies that to be certified as a QHP, each health plan must implement a QIS, which is 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 to improve health outcomes of plan enrollees, to prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities.

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 qualified health plans offered through Exchanges and (2) assist individuals in applying for PTC and CSRs for qualified health plans sold through an Exchange.

Sections 1313 and 1321 of the ACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 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 general 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 1343 of the ACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees.

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

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

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 qualified health plans offered through the individual market Exchanges. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 1411(c) of the ACA requires the Secretary to submit certain information provided by applicants under section 1411(b) of the ACA to other federal officials for verification, including income and family size information to the Secretary of the Treasury. Section 1411(d) of the ACA provides that the Secretary must verify the accuracy of information provided by applicants under section 1411(b) of the ACA for which section 1411(c) does not prescribe a specific verification procedure, in such manner as the Secretary determines appropriate.

Section 1411(f) of the ACA requires the Secretary, in consultation with the Treasury and Homeland Security Department Secretaries and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations. Section 1411(f)(1)(B) of the 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 purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs, and limits the disclosure of such information.

Section 1557 of the ACA applies certain long-standing civil rights nondiscrimination requirements to ''any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive agency, or any entity established under'' Title I of the ACA (or amendments). It did so by referencing statutes that specify prohibited grounds of discrimination, namely, race, color, national origin, sex, age, or disability, in an array of federally funded and administered programs or activities.[9] In addition, HHS has previously finalized rules unrelated to section 1557 of the ACA to address populations that have historically been subject to discrimination.

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.[10] Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under §§ 155.305(h) and 156.155(a)(5).

1. Premium Stabilization Programs

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

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

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

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

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit year and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of our risk adjustment models, and amendments to the HHS–RADV process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

In the November 2, 2017 **Federal Register** (82 FR 51042), we published a proposed rule outlining the benefit and payment parameters for the 2019 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology and amendments to the HHS–RADV process (proposed 2019 Payment Notice). We published the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 16930). We published a correction to the 2019 risk adjustment coefficients in the 2019 Payment Notice final rule in the May 11, 2018 **Federal Register** (83 FR 21925). On July 27,

[9] 42 U.S.C. 18116.

[10] Public Law 115–97, 131 Stat. 2054 (2017).

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

2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level External Data Gathering Environment (EDGE) dataset.[12]

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). That final rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. That final rule also permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of the final rule.[13]

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

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

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

In the June 2, 2020 **Federal Register** (85 FR 33595), we published a proposed rule that proposed updates to various aspects of the HHS–RADV methodologies and processes. We published a final rule titled, the 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) in the December 1, 2020 **Federal Register** (85 FR 76979). That final rule revised the failure rate grouping algorithm, finalized a sliding scale adjustment in HHS–RADV error rate calculation, and a constraint on risk score adjustments for low-side failure rate outliers. The final rule also established a transition from the prospective application of HHS–RADV adjustments to apply HHS–RADV results to risk scores from the same benefit year as that being audited.

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

In the January 20, 2021 **Federal Register** (86 FR 6138), HHS issued a final rule containing certain policy and regulatory revisions related to the risk adjustment program (hereinafter referred to as ''part 1 of the 2022 Payment Notice final rule''). In the May 5, 2021 **Federal Register** (86 FR 24140), HHS issued another final rule containing policy and regulatory revisions related to the risk adjustment program, including approval of the request from Alabama to reduce risk adjustment transfers by 50 percent in the individual and small group markets for the 2022 benefit year (hereinafter referred to as ''part 2 of the 2022 Payment Notice final rule''). In addition, part 2 of the 2022 Payment Notice 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.

2. Program Integrity

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

3. Market Rules

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

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and guaranteed renewability. In the Market Stabilization final rule that was published in the April 18, 2017 **Federal Register** (82 FR 18346), we further interpreted the guaranteed availability provision. In the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 17058), we clarified that certain exceptions to the special enrollment periods only apply with respect to coverage offered outside of the Exchange in the individual market.

[12] ''Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[13] ''Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf.*

In the Nondiscrimination in Health and Human Education Programs or Activities final rule on section 1557 of the ACA, published in the June 19, 2020 **Federal Register** (85 FR 37160), we removed nondiscrimination protections on the basis of gender identity and sexual orientation from the guaranteed availability regulation.

In part 2 of the 2022 Payment Notice final rule in the May 5, 2021 **Federal Register** (86 FR 24140), we made additional amendments to the guaranteed availability regulation regarding special enrollment periods and finalized new special enrollment periods related to untimely notice of triggering events, cessation of employer contributions or government subsidies to COBRA continuation coverage, and loss of APTC eligibility. In the final rule Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond published in the September 27, 2021 **Federal Register** (86 FR 53412) (part 3 of the 2022 Payment Notice) by HHS and the Department of the Treasury, HHS finalized additional amendments to the guaranteed availability regulations regarding special enrollment periods.

4. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and Small Business Health Options Program (SHOP), eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges, as well as network adequacy and ECP certification standards, was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

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

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

In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period.

In the February 6, 2020 **Federal Register** (85 FR 7088), we published a proposed rule (proposal 2021 Payment Notice). We published the final rule in the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice).

In the December 4, 2020 **Federal Register** (85 FR 78572), we issued a proposed rule containing certain policy and regulatory revisions related to user fees (proposed 2022 Payment Notice). In the January 19, 2021 **Federal Register** (86 FR 6138), HHS issued a rule finalizing certain of the provisions in the proposed 2022 Payment Notice (part 1 of the 2022 Payment Notice final rule). In the May 5, 2021 **Federal Register** (86 FR 24140), HHS published a second final rule addressing the remainder of the proposed provisions (part 2 of the 2022 Payment Notice final rule). In the July 1, 2021 **Federal Register** (86 FR 35156), HHS and the Department of the Treasury released a proposed rule proposing to amend certain policies in part 1 of the 2022 Payment Notice final rule, and finalized the rule in the September 27, 2021 **Federal Register** (86 FR 53412) (part 3 of the 2022 Payment Notice final rule).

5. Essential Health Benefits

On December 16, 2011, HHS released a bulletin that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework.[14] A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for PYs 2020 and beyond.

6. Medical Loss Ratio (MLR)

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the May 14, 2020 **Federal Register** (85 FR 29164), and the May 5, 2021 **Federal Register** (86 FR 24140), and an interim final rule that was published in the September 2, 2020 **Federal Register** (85 FR 54820).

7. Quality Improvement Strategy

We promulgated regulations in 45 CFR 155.200(d) to direct Exchanges to evaluate quality improvement strategies, and 45 CFR 156.200(b) that direct QHP issuers to implement and report on a quality improvement strategy or strategies consistent with section 1311(g) standards as a QHP certification criteria for participation in an Exchange. In the 2016 Payment Notice, published in the February 27, 2015 **Federal Register** (80 FR 10749), we finalized

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

regulations at § 155.1130 to establish standards and the associated timeframe for QHP issuers to submit the necessary information to implement QIS standards for QHPs offered through an Exchange.

8. Nondiscrimination

Section 1311(b) and section 1321(b) of the ACA provide that each state has the opportunity to establish an Exchange. In the July 15, 2011 **Federal Register** (76 FR 41866), HHS published the ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans'' proposed rule to implement section 1311(b) and section 1321(b) of the ACA. In the March 27, 2012 **Federal Register** (77 FR 18310), HHS published the ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers'' final rule and interim final rule (hereinafter referred to as the ''Exchange Standards final rule''), which included nondiscrimination protections.

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHB and actuarial value requirements. In the November 26, 2012 **Federal Register** (77 FR 70644), HHS published the ''Patient Protections and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation'' proposed rule to implement section 1302 of the ACA. In the February 25, 2013 **Federal Register** (78 FR 12834), HHS published the ''Patient Protections and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation'' final rule, which included nondiscrimination protections.

Sections 2701, 2702, and 2703 of the PHS Act and Section 1312(c) of the ACA provide protections to individuals and employers in obtaining health insurance coverage. In the November 26, 2012 **Federal Register** (77 FR 70584), HHS published the ''Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review'' proposed rule to implement sections 2701, 2702, and 2703 of the PHS Act and section 1312(c) of the ACA. In the February 27, 2013 **Federal Register** (78 FR 13406), HHS published the ''Patient Protections and Affordable Care Act; Health Insurance Market Rules; Rate Review'' final rule, which included nondiscrimination protections.

In the HHS Notice of Benefit and Payment Parameters for 2017 proposed rule, published in the December 2, 2015 **Federal Register** (80 FR 75488), HHS proposed policies for nondiscrimination protections into the relevant notice of benefit and payment parameters. In the March 8, 2016 **Federal Register** (81 FR 12204), HHS published the HHS Notice of Benefit and Payment Parameters for 2017 final rule, which included nondiscrimination protections.

In the Nondiscrimination in Health and Human Education Programs or Activities final rule on section 1557 of the ACA, published in the June 19, 2020 **Federal Register** (85 FR 37160), HHS removed nondiscrimination protections on the basis of gender identity and sexual orientation from various CMS nondiscrimination regulations. In the HHS Notice of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, published in the May 25, 2021 **Federal Register** (86 FR 27984), HHS informed the public that HHS will interpret and enforce section 1557's and Title IX's prohibition on discrimination on the basis of sex to include discrimination based on sexual orientation and gender identity.

B. Stakeholder Consultation and Input

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

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 144, 147, 153, 155, 156 and 158.

The proposed changes to 45 CFR part 144 would remove superfluous language from the definition of large group market.

The proposed changes to 45 CFR part 147 would prohibit issuers from discriminating against individuals in issuer marketing practices and benefit designs based on sexual orientation and gender identity. We also propose to reinterpret the guaranteed availability requirements in § 147.104 such that issuers could not refuse to effectuate new coverage based on failure of an individual or employer to pay premiums owed for prior coverage.

The proposed changes to 45 CFR part 153 would recalibrate the 2023 benefit year risk adjustment models using the 2017, 2018, and 2019 enrollee-level External Data Gathering Environment (EDGE) data. We also propose to update the adult and child risk adjustment models for 2023 and beyond to better predict plan liability for certain subpopulations. We propose to update the adult risk adjustment models by removing the current severity illness factors and replacing the current enrollment duration factors with enrollment duration factors contingent on the enrollee having at least one HCC. In addition, we propose to update the adult and child risk adjustment models by adding a two-stage weighted approach to model recalibrations and an interacted HCC count model specification for 2023 and beyond. We propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models. We discuss removing the mapping of hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) in the 2018 and 2019 benefit year enrollee-level EDGE data used for the annual recalibration of the HHS risk adjustment models. We also propose for the 2024 benefit year and beyond to recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration. We propose using this approach for recalibration of the 2023 adult risk adjustment models with the exception of the 2017 enrollee-level EDGE data year, for which we propose to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018).We also propose to collect and extract five new data elements including ZIP code, race, ethnicity, ICHRA indicator, and a subsidy indicator as part of the required risk adjustment data that issuers must make accessible to HHS in states where HHS is operating the risk adjustment program. We also propose to extract three new data elements issuers already

provide to HHS as part of the required risk adjustment data submissions (plan ID, rating area, and subscriber indicator) and to expand the permitted uses of the risk adjustment data and reports. Additionally, we propose an amendment to § 153.730 to address situations when April 30 does not fall on a business day and to provide that when this occurs, the deadline for issuers to submit the required risk adjustment data in states where HHS operates the program would be the next applicable business day.

The proposals in part 153 also relate to risk adjustment state flexibility requests. We propose to repeal the ability of states to request a reduction in risk adjustment transfers calculated by HHS under the state payment transfer formula starting with the 2024 benefit year, while proposing to create an exception for any state that has requested a reduction in prior benefit years. In addition, we solicit comments on the requests from Alabama to reduce risk adjustment state transfers for the 2023 benefit year in the individual (including the catastrophic and non-catastrophic risk pools) and small group markets.

In part 153 we also propose the risk adjustment user fee for the 2023 benefit year and modifications to the error estimation methodology applied in HHS–RADV. We propose updating the HHS–RADV error estimation process to extend the application of Super HCCs beyond the sorting step that assigns HCCs to failure rate groups to also apply throughout the HHS–RADV error rate calculation processes and to specify that Super HCCs will be defined separately according to the model (infant, child, adult) to which an enrollee is subject. We also propose to constrain to zero any failure rate group outlier negative failure rate, regardless of whether the outlier issuer has a negative or positive error rate. Finally, we propose that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans, an actionable discrepancy, or a successful administrative appeal, the recouped high-cost risk pool funds will be used to reduce high-cost risk pool charges for that national high-cost risk pool beginning for the next benefit year for which a high cost risk pool payment has not already been calculated.

In addition, the proposals regarding part 153 also relate to MLR reporting requirements and clarify how issuers should report certain ACA program amounts that could be subject to reconsideration for MLR reporting purposes. We propose to separately address and reference HHS–RADV adjustments to make clear that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts.

The proposed changes to 45 CFR part 155 would allow Exchanges to implement a verification process for enrollment in or eligibility for an eligible employer sponsored plan based on the Exchange's assessment of risk for inappropriate payments of APTC/CSR. In part 155 we also propose to require all Exchanges to prorate when administering APTC for enrollees enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. We also propose new requirements in part 155 related to the QHP comparative information and standardized disclaimer required to be displayed on web-broker non-Exchange websites, a prohibition on displaying QHP advertisements or otherwise providing favored or preferred placement in the display of QHPs on web-broker non-Exchange websites based on compensation agents, brokers, or web-brokers receive from QHP issuers, and a requirement regarding the prominent display of a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on web-broker non-Exchange websites to better inform and protect consumers using such websites. We also propose changes to part 155, to clarify the FFE standards of conduct and what it means for agents, brokers, and web-brokers to provide the Exchange with correct information under section 1411(b) of the ACA, including ensuring that accurate consumer information is being entered on Exchange applications. Finally, we propose changes to part 155 to set forth prohibited agent, broker, and web-broker business practices commonly observed by HHS and to create enforceable standards under which HHS may take enforcement action against agents, brokers, and web-brokers when these prohibited business practices are discovered.

In 45 CFR part 156, as we do every year in the HHS notice of benefit and payment parameters, we propose to update the user fee rates for the 2023 benefit year for all issuers participating on the Exchanges using the Federal platform. We note that we intend to publish the 2023 premium adjustment percentage index and related payment parameters in guidance as finalized in part 2 of the 2022 Payment Notice. The proposed changes to part 156 also include technical amendments to § 156.50 to conform the user fee regulations with the repeal of Exchange Direct Enrollment (DE) option finalized in part 3 of the 2022 Payment Notice.[15] We are proposing changes to § 156.430 to clarify that the CSR data submission process is mandatory only for those issuers that receive CSR payments from HHS for any part of the benefit year as a result of HHS possessing a valid appropriation to make CSR payments, and voluntary for other issuers.

In part 156, we also propose an evergreen deadline for EHB-benchmark plan applications by states, as well as proposing to remove the ability for states to permit issuers to substitute benefits between EHB categories, proposing to change de minimis thresholds for the AV of plans subject to the AV requirements, as well as narrower de minimis thresholds for individual market silver QHPs and income-based CSR plan variations; and proposing to remove the annual reporting requirement on states to report state-required benefits in addition to the EHB to HHS.

In part 156, we also propose to require issuers of QHPs in FFEs and SBE–FPs to offer through the Exchange standardized QHP options beginning in PY 2023. We also propose to update the QIS standards in part 156 to require QHP issuers to address health and health care disparities as a specific topic area within their QIS beginning with PY 2023.

The proposed changes to part 158 would clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. The proposed changes to part 158 would also specify that only expenses directly related to activities that improve health care quality may be included as QIA expenses for MLR reporting and rebate calculation purposes. In addition, the proposed changes to part 158 would make a technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus, et al.* v.

[15] 86 FR 53412.

Cochran,[16] and thus deleted in part 2 of the 2022 Payment Notice final rule.

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2023

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

We propose to remove superfluous language from the definition of large group market. The definition currently provides that ''Large group market'' means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer, unless otherwise provided under State law. We propose to amend the definition by deleting the phrase ''unless otherwise provided under State law.'' The phrase has no meaning or application, and does not appear in the statutory definition of the term in section 2791(e)(3) of the PHS Act. That phrase was initially included in the PHS Act regulatory definitions of large group market, large employer, and small employer adopted by HHS under HIPAA.[17] However, in final rules published on October 30, 2013 (78 FR 65045), we amended the definitions of large employer and small employer to make them consistent with PHS Act section 2791(e), as amended by the ACA, and in so doing, removed that phrase from the definitions. At that time, we inadvertently neglected to delete the phrase from the regulatory definition of large group market, and we now propose to do so, in order to align these definitions and make the regulatory definition for large group market consistent with the definition under the ACA.

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability of Coverage (§ 147.104)

a. Past-Due Premiums

We propose to re-interpret the guaranteed availability requirement at section 2702 of the PHS Act and its implementing regulation at § 147.104 to require issuers to accept individuals and employers who apply for coverage, even where the individual or employer owes past-due premiums for coverage from the same issuer or another issuer in the same controlled group. On January 28, 2021, President Biden issued Executive Order 14009, ''Strengthening Medicaid and the Affordable Care Act'' (E.O. 14009).[18] Section 3 of E.O. 14009 directs HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether they are inconsistent with policy priorities described in Section 1 of E.O. 14009, to include protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals. Consistent with E.O. 14009, specifically section 3(iv), this proposal intends to remove an unnecessary barrier to individuals and families attempting to enroll into health coverage in the individual market.

Specifically, we propose to redesignate § 147.104(i) as § 147.104(j) and add a new § 147.104(i) to specify that a health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates § 147.104(a). The guaranteed availability provisions require health insurance issuers offering non-grandfathered coverage in the individual or group market to accept every individual and employer in the state that applies for such coverage unless an exception applies. Individuals and employers typically are required to pay the first month's premium to effectuate coverage. Under the current interpretation of the guaranteed availability requirement stated in the Market Stabilization final rule, to the extent permitted by applicable state law, an issuer does not violate the guaranteed availability requirements under § 147.104 where the issuer attributes a premium payment made for new coverage to any past-due premiums owed for coverage from the same issuer or another issuer in the same controlled group within the prior 12-month period before effectuating enrollment in the new coverage. This policy addressed concerns that individuals might take unfair advantage of the rules regarding grace periods.[19] However, in part 3 of the 2022 Payment Notice proposed rule, we stated our intention to reassess this interpretation to analyze whether this policy presents unnecessary barriers to accessing health coverage.[20]

After reevaluating our interpretation of the guaranteed availability requirement, we propose reinstating our previous interpretation of the guaranteed availability rules with respect to non-payment of premiums.[21] Under this interpretation, an issuer may not apply any premium payment made for new coverage in the same or a different plan or product to any outstanding debt owed from any previous coverage and then refuse to effectuate the new enrollment based on failure to pay premiums. Thus, the guaranteed availability requirement would prohibit issuers from refusing to effectuate new coverage due to failure to pay outstanding premium debt from the previous year.

Based on HHS' experience since we codified the currently-effective interpretation of guaranteed availability, we believe the current policy, has the unintended consequence of creating barriers to health coverage that disproportionately affect low-income individuals, and is therefore inconsistent with the intent of the guaranteed availability statutory requirements. The current policy heightens the risk of economic hardships for low-income individuals enrolled in health insurance coverage with APTC. Individuals stop paying premiums (and lose coverage due to nonpayment of premiums) for a variety of reasons throughout the year. For example, commenters to the Market Stabilization proposed rule stated that individuals who are victims of crime, or those grappling with domestic violence,

[16] 523 F. Supp. 3d 731 (D. Md. 2021).

[17] 62 FR 16894 (April 8, 1997) and 69 FR 78720 (Dec. 30, 2004).

[18] E.O. 14009; 86 FR 7793 (Feb. 2, 2021).

[19] QHP issuers are required, under § 156.270, to provide a grace period of 3 consecutive months for an enrollee, who, when failing to timely pay premiums, is receiving APTC. If the enrollee exhausts the grace period without paying all outstanding premiums, subject to a premium payment threshold implemented under § 155.400(g), then the QHP issuer must terminate the enrollee's enrollment back to the last day of the first month of the 3-month grace period. As a result, an individual receiving APTC whose coverage is terminated after the exhaustion of a grace period would owe at most 1 month of premiums, net of any APTC paid on their behalf to the issuer; however, an individual who attempts to enroll in new coverage while in a grace period, and whose coverage has not yet been terminated, could owe up to 3 months of premium, net of any APTC paid on their behalf to the issuer.

[20] 86 FR 35156, 36071.

[21] Federally-facilitated Marketplace (FFM) and Federally-facilitated Small Business Health Options Program Enrollment Manual, Section 6.3 Terminations for Non-Payment of Premiums, *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ENR_FFMSHOP_Manual_080916.pdf* (describing operational requirements effective as of July 19, 2016, which were superseded by subsequent publications).

medical emergencies, incarceration, or other urgent circumstances are often forced to make difficult financial decisions that may lead to failure to pay their health insurance premiums. Even for some middle-income families, the high cost of health care for multiple family members with chronic health conditions may result in non-payment of premiums.[22] Requiring such individuals to pay back past-due premium plus a binder payment prior to enrollment may present an insurmountable barrier leading to gaps in coverage. For this reason, HHS is of the view that the current interpretation of the guaranteed availability requirement creates unnecessary barriers to accessing health coverage.

HHS is also concerned that the barriers created by the current interpretation of guaranteed availability disproportionately affect low-income enrollees for whom APTC is paid. Under federal law governing grace periods for enrollees for whom APTC is paid, QHP issuers must provide a 3-month grace period before they are allowed to terminate an enrollee's coverage for non-payment of premiums and must continue to provide coverage during the first month of the grace period. As a result, those enrollees who are unable to satisfy outstanding premium payments by the end of the 3-month grace period generally may owe at least one month of past due premium after their coverage is terminated. In contrast, grace period rules for individuals who are not eligible for APTC are governed by state law. Many state laws allow for termination back to the end of the period for which an enrollee paid premium, in which case an enrollee without APTC whose coverage is terminated for nonpayment would not owe past-due premium when they attempt to enroll in coverage during a subsequent open enrollment or special enrollment period. Enrollees for whom APTC is paid generally may have household incomes as low as 100 percent of the federal poverty level (FPL) (which, for the 2021 benefit year, is $12,760 for a single person household).[23] Thus, premium payment policies that require payment of past-due premiums prior to effectuation of new coverage are likely to disproportionately affect low-income enrollees with APTC, the individuals who may be least able to pay all outstanding premium debt among those seeking coverage in the individual market.

Conditioning health insurance enrollment on the payment of past-due premiums could disincentivize health insurance enrollment altogether, reducing the rate of enrollment for low-income individuals. The economic burden associated with being required to pay past-due premiums prior to enrolling in new coverage may prevent low-income individuals from enrolling in coverage and affect the demographics of the risk pool. Various studies have found that low-income families often struggle to balance out-of-pocket health care costs alongside rent or mortgage payments, and other necessary living expenses.[24] Maintaining the current interpretation of the guaranteed availability rules would uphold barriers to health insurance coverage for low-income individuals, who face a greater risk of poorer health outcomes.[25] Reverting to the previous interpretation of the guaranteed availability rules would ensure individuals who stand to benefit the most from health insurance coverage can enroll in coverage, and would promote more equitable access to health insurance coverage. In addition, the public health and economic crises caused by the COVID–19 pandemic exacerbated the hardships facing low-income individuals and families. The resulting financial and health insecurity caused by the pandemic underscores the critical role that access to continuous health coverage will continue to play during the ongoing and often unpredictable challenges of the pandemic and beyond. Returning to the previous interpretation of the guaranteed availability rule would remove a barrier to accessing health coverage that compounds the economic challenges from the COVID–19 crisis.

In the Market Stabilization rule, we noted concern that enrollees with APTC may take advantage of guaranteed availability by declining to make premium payments for coverage at the end of a benefit year without losing coverage. Although this remains possible, we are of the view that the disparate negative impact on low-income populations outweighs the possible deterrent effect on individuals who may try taking advantage of the guaranteed availability rules. We seek comment regarding the frequency of any potential gaming behavior, as well as information on the primary diagnoses and services that may be involved in suspected gaming situations so that we may better assess any contributing causes of such non-payment. For example, non-payment may not be the result of gaming, but could be indicative of contextual challenges individuals face in satisfying payment obligations. We are particularly interested in comments from issuers that have not adopted a premium payment policy that requires payment of past-due premiums prior to effectuating enrollment. In addition, we note that issuers are generally not permitted to forgive past-due premium debt, and can pursue other mechanisms to collect past-due premiums. We believe this mitigates the risk that some enrollees may take advantage of the guaranteed availability rules.

We seek comment on this proposal.

b. Nondiscrimination Based on Sexual Orientation and Gender Identity

We propose to amend 45 CFR 147.104(e) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 147.104(e), but amendments made in 2020 to § 147.104(e) removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 147.104(e) to the pre-2020 nondiscrimination protections.

Section 147.104(e) states that a health insurance issuer and its officials, employees, agents, and representatives must not employ marketing practices or benefit designs that would have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions. Previously, in the 2014 Market Rules, we finalized § 147.104(e) to also prohibit discrimination based on sexual orientation and gender

[22] John Tozzi. (March 2018). ''Why Some Americans Are Risking It and Skipping Health Insurance.'' *Bloomberg News.* Retrieved from *https://www.bloomberg.com/news/features/2018-03-26/why-some-americans-are-risking-it-and-skipping-health-insurance.*

[23] See 2021 Poverty Guidelines for the 48 Contiguous States and the District of Columbia, available at *https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines/prior-hhs-poverty-guidelines-federal-register-references/2020-poverty-guidelines.*

[24] Tim Thomas, Ph.D.; Jose Hernandez, Ph.D.; et al. (2019). The Evictions Study. *The University of California Berkeley and the University of Washington.* Retrieved from *https://evictions.study/index.html.*

[25] P.J. Cunningham; T.L. Green; R.T. Braun. (February 2018). Income Disparities in the Prevalence, Severity, and Costs of Co-Occurring Chronic and Behavioral Health Conditions. *Medical Care.* Retrieved from *https://www.commonwealthfund.org/publications/journal-article/2018/feb/income-disparities-prevalence-severity-and-costs-co-occurring.*

identity.[26] However, in the 2020 final rule that revised regulations implementing section 1557 of the ACA, HHS also revised certain CMS regulations, including those at § 147.104(e), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[27] The 2020 section 1557 final rule is the subject of ongoing litigation.[28]

Pursuant to section 1311(c)(1)(A) of the ACA, the HHS Secretary was required to establish by regulation criteria for certification that require QHP issuers to meet marketing requirements and not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs. Under the authority of section 1321(a) of the ACA, which provides the HHS Secretary broad rulemaking authority with respect to the establishment and operation of Exchanges and the offering of QHPs through such Exchanges, in the 2012 Exchange Standards final rule, CMS codified a regulation implementing this requirement at § 156.225. Under the general rulemaking authority in section 2792 of the PHS Act, which provides the HHS Secretary broad rulemaking authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act, the 2014 Market Rules adopted a similar standard in § 147.104(e), applying this requirement to the group and individual health insurance markets. Furthermore, in order to ensure consistency against employing discriminatory marketing practices and benefit designs, HHS finalized § 147.104(e) to align with other prohibitions on discrimination that HHS had already codified at that time with respect to EHB in § 156.125, with respect to standards applicable to QHPs under § 156.200(e) that included protections against discrimination on the basis of sexual orientation and gender identity, and with respect to marketing standards in § 156.225. The 2014 Market Rules further clarified that discriminatory marketing practices or benefit designs represent a failure by issuers to comply with the guaranteed availability requirements in PHS Act section 2702, as such practices or designs can have the effect of discouraging or preventing the enrollment of individuals in health insurance coverage.

In the 2020 section 1557 final rule, HHS revised the section 1557 implementing regulation. Among other things, the rule removed the definition of ''on the basis of sex,'' which included gender identity, and instead purported to rely upon the ''plain meaning'' of the word ''sex'' in the underlying Title IX regulation.[29] However, as HHS noted in the 2020 section 1557 final rule, CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in the group and individual markets.[30]

Following public posting of the 2020 section 1557 final rule on the agency's website, the Supreme Court held in Bostock v. Clayton County, 140 S. Ct. 1731 (2020), that discrimination on the basis of sex under Title VII of the Civil Rights Act of 1964 includes discrimination on the basis of sexual orientation and gender identity. On January 20, 2021, the President signed Executive Order 13988 stating that it is the Administration's policy to prevent and combat discrimination on the basis of gender identity and sexual orientation, and that under Bostock's reasoning, laws that prohibit sex discrimination also prohibit discrimination on the basis of gender identity and sexual orientation, so long as the laws do not contain sufficient indications to the contrary.[31] The Executive Order (E.O.) also instructed all agency heads, including the HHS Secretary, to review all existing regulations, guidance documents, and other agency actions to determine whether they are consistent with the aforementioned policy, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with it. The Department of Justice (DOJ) issued a memorandum on March 26, 2021 that determined the court's reasoning in Bostock applies to Title IX and thus that Title IX's prohibition on discrimination on the basis of sex includes discrimination on the basis of gender identity and sexual orientation.[32] Following the E.O. and DOJ's memorandum, HHS released on May 10, 2021 a Notice that HHS will interpret and enforce section 1557's and Title IX's prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity.[33]

Likewise, CMS is not relying on authority from section 1557 of the ACA for the proposal at § 147.104(e) or the parallel proposals to nondiscrimination regulations at §§ 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b). We will further elaborate in the respective preambles to §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) the specific ACA authority CMS is relying on to prohibit discrimination in the group and individual markets. CMS proposes to exercise the same authority as it exercised in the 2014 Market Rules to amend § 147.104(e) to again prohibit a health insurance issuer and its officials, employees, agents, and representatives from discriminating in its marketing practices or benefit designs on the basis of sexual orientation and gender identity. Specifically, CMS proposes to again rely on section 2702 of the PHS Act, as well as section 2792 of the PHS Act, which provides the HHS Secretary broad rulemaking authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act. These are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 147.104(e). Utilizing these same authorities to again prohibit discrimination based on sexual orientation and gender identity would be consistent with the authority CMS relies upon for those existing protections at § 147.104(e) that currently prohibit discrimination on the basis of race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions.

People who identify as part of the lesbian, gay, bisexual, transgender, and

[26] 78 FR 13406 (February 27, 2013).

[27] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[28] The 2020 section 1557 final rule is the subject of several lawsuits and court orders. For more information, *see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html.*

[29] 85 FR 37160, 37166 (June 19, 2020). The 2016 and 2020 section 1557 final rules are the subject of several lawsuits and court orders. For more information, *see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html, https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html.*

[30] 85 FR 37160, 37219, 37218–21 (June 19, 2020).

[31] Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 FR 7023 (Jan. 20, 2021).

[32] U.S. Dep't of Justice, Memorandum on Application of Bostock v. Clayton County to Title IX of the Education Amendments of 1972 (Mar. 26, 2021), *https://www.justice.gov/crt/page/file/1383026/download.* On June 16, 2021, the Department of Education's Office for Civil Rights issued a similar Notice explaining that it too will enforce Title IX's prohibition on discrimination on the basis of sex to include: (1) Discrimination based on sexual orientation; and (2) discrimination based on gender identity (*available at https://www2.ed.gov/about/offices/list/ocr/docs/202106-titleix-noi.pdf*).

[33] 86 FR 27984.

queer (LGBTQI+) community face pervasive health and health care disparities, and are at higher risk for many concomitant conditions, including substance use and [34] mental health disorders, sexually transmitted infections,[35] HIV,[36] cancer, cardiovascular disease, and obesity.[37] Overall, LGBTQI+ people report being in poorer health than non-LGBTQI+ individuals. LGBTQI+ people of all genders are more likely to become disabled at a younger age than heterosexual individuals.[38] In addition to disparities in health outcomes, LGBTQI+ people face barriers to obtaining appropriate health care and transgender people who can access insurance may nonetheless be denied coverage for needed services. For example, nearly half of transgender respondents in one survey said their health insurance company denied them gender affirming surgery,[39] and a similar proportion reported that they were denied coverage for hormone therapy.[40] Beyond health coverage issues, LGBTQI+ people may struggle to access care because of cost barriers. LGBTQI+ people are also more likely than others to report postponing or forgoing health care due to costs, and costs were an even greater obstacle for younger LGBTQI+ people and those who are transgender—especially transgender people of color.[41]

We believe that prohibiting discrimination based on sexual orientation or gender identity can lead to improved health outcomes for this community [42] and that the removal of such protections in the 2020 section 1557 final rule frustrated not only guaranteed availability requirements, but also the broader aim of improving health equity. Without protection from discrimination, individuals may continue to face barriers to accessing medically necessary health care. For example, without protection from discrimination, transgender individuals may face barriers or be denied medically necessary gender-affirming care. We believe amending the nondiscrimination protections as proposed at § 147.104(e) to again explicitly prohibit discrimination based on sexual orientation and gender identity is warranted in light of the existing trends in health care discrimination and to better address barriers to health equity for LGBTQI+ individuals.[43] As proposed, such revisions to § 147.104(e) would also support the original objective of ensuring consistency against employing discriminatory marketing practices and benefit designs, as we are proposing parallel changes to nondiscrimination regulations at §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b).

If any of the provisions at §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) are held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances. In enforcing the nondiscrimination provisions in the corresponding CMS regulations, HHS will comply with laws protecting the exercise of conscience and religion, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb–4) and all other applicable legal requirements.

We seek comment on this proposal.

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

In subparts A, 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 lower-than-average risk, risk adjustment covered plans to 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.[44] HHS did not receive any requests from states to operate risk adjustment for the 2023 benefit year. Therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2023 benefit year.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2022, the permanent risk adjustment program is subject to the fiscal year 2022 sequestration.[45] The federal government's 2022 fiscal year begins October 1, 2021. Therefore, the risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from fiscal year 2022 resources (that is, funds collected during the 2022 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 (Pub. L. 99–177, enacted December 12, 1985), as

[34] Hilary Daniel et al, Annals of Internal Med. Position Papers, *Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians* (July 21, 2105), *https://www.acpjournals.org/doi/full/10.7326/M14-2482?journalCode=aim.*

[35] Hilary Daniel et al, Annals of Internal Med. Position Papers, *Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians* (July 21, 2105), *https://www.acpjournals.org/doi/full/10.7326/M14-2482?journalCode=aim.*

[36] U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control and Prevention, *HIV Surveillance Report, 2019; Vol. 32* (May 2021), *https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-updated-vol-32.pdf.*

[37] *See, for example,* Lesbian, Gay, Bisexual, and Transgender Health, Healthy People 2020, *https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health#:~:text=Research%20suggests%20that%20LGBT%20individuals,%2C%2C%203%20and%20suicide;* Hafeez, Hudaisa et al. ''Healthcare Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review.'' *Cureus* vol. 9,4 e1184. 20 Apr. 2017, doi:10.7759/cureus.1184 (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215/*); Fredriksen-Goldsen KI, Kim H–J, Barkan SE, Muraco A and Hoy-Ellis CP (2013) Health disparities among lesbian, gay, and bisexual older adults: Results from a population-based study. *American Journal of Public Health* 103, 1802–1809; Billy A. Caceres et al. ''A Systematic Review of Cardiovascular Disease in Sexual Minorities'', American Journal of Public Health 107, no. 4 (April 1, 2017): pp. e13–e21.

[38] Hilary Daniel et al, Annals of Internal Med. Position Papers, *Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians* (July 21, 2105), *https://www.acpjournals.org/doi/full/10.7326/M14-2482?journalCode=aim.*

[39] For purposes of this preamble, the term ''gender affirming care'' means gender affirming care for transgender individuals. This may also be referred to as ''transition related care.''

[40] Sharita Gruberg et al, Center for American Progress, *The State of the LGBTQ Community in 2020* (Oct. 6, 2020), *https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/.*

[41] Sharita Gruberg et al, Center for American Progress, *The State of the LGBTQ Community in 2020* (Oct. 6, 2020), *https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/.*

[42] Ward, BW, Dahlhamer, JM, Galinsky, AM, and Joestl, SS. Sexual Orientation & Health Among U.S. Adults: National Health Interview Survey, CDC National Health Statistics Report 77, 2014.

[43] Nguyen, T.T., Vable, A.M., Glymour, M.M. et al. Trends for Reported Discrimination in Health Care in a National Sample of Older Adults with Chronic Conditions. J GEN INTERN MED 33, 291–297 (2018). *https://doi.org/10.1007/s11606-017-4209-5.*

[44] Also see 42 U.S.C. 18041(c)(1).

[45] *https://www.whitehouse.gov/wp-content/uploads/2021/05/BBEDCA_251A_Sequestration_Report_FY2022.pdf.*

amended, and the underlying authority for the risk adjustment program, the funds that are sequestered in fiscal year 2022 from the risk adjustment program will become available for payment to issuers in fiscal year 2023 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 Coronavirus Aid, Relief, and Economic Security (CARES) Act amended section 251A(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 and extended sequestration for the risk adjustment program through fiscal year 2030 at a rate of 5.7 percent per fiscal year.[46]

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 HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXCs) beginning with the 2018 benefit year.[47] Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a CSR 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) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the state transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable state market risk pool. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

a. Data for Risk Adjustment Model Recalibration for 2023 Benefit Year and Beyond

We are proposing to recalibrate the 2023 benefit year risk adjustment models with the 2017, 2018, and 2019 enrollee-level EDGE data. Consistent with the approach outlined in the 2020 Payment Notice to no longer rely upon MarketScan® data for recalibrating the risk adjustment models, we will recalibrate the risk adjustment models for the 2023 benefit year using only enrollee-level EDGE data, and we will continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2023 benefit year model recalibration.[48] Additionally, as outlined in the 2022 Payment Notice, we will 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 coefficients published in the proposed rule for the applicable benefit year,[49] and will not update the coefficients between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available for incorporation.[50] We believe this promotes stability, better meets the goal of the risk adjustment program, and allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year.

As such, we propose to determine coefficients for the 2023 benefit year based on a blend of separately solved coefficients from the 2017, 2018, and 2019 benefit years' enrollee-level EDGE data.[51] The draft coefficients listed in Tables 1 through 6 reflect the use of 2017, 2018, and 2019 benefit year enrollee-level EDGE data, as well as other risk adjustment model updates proposed in this proposed rule (including changes to the model specifications, the pricing adjustment to Hepatitis C drugs, and the removal of the mapping of hydroxychloroquine sulfate to an RXC). However, we note that the coefficients could change if we identify an error or if some or all of the proposed model changes are not finalized or are modified in response to comments. In addition, consistent with § 153.320(b)(1)(i), if we are unable to finalize the final coefficients in time for publication in the final rule, we would publish the final coefficients for the 2023 benefit year in guidance soon after the publication of the final rule. We seek comment on the proposal to determine 2023 benefit year coefficients based on a blend of separately solved coefficients from the 2017, 2018, and 2019 enrollee-level EDGE data.

We also solicit comments on the future use of the 2020 enrollee-level EDGE data due to the COVID–19 PHE. Under current policy, 2020 enrollee-level EDGE data would be used in recalibration of the HHS risk adjustment models for the 2024 benefit year and that data would continue to be used for the 2025 and 2026 benefit year models.[52] Although HHS has not analyzed the 2020 enrollee-level EDGE data yet, we solicit comment on the future use of the 2020 enrollee-level EDGE data for the annual recalibration of the HHS risk adjustment models.

b. Risk Adjustment Model Updates

Beginning with the 2023 benefit year, we are proposing three modeling updates to the risk adjustment models. Consistent with the potential model updates discussed in the 2021 RA Technical Paper, we propose the following model updates, which are the same as those proposed but not finalized in the 2022 Payment Notice:[53] (1) Adding a two-stage weighted model specification to the adult and child models; (2) removing the severity illness factors in the adult models and

[46] *https://www.congress.gov/116/bills/s3548/BILLS-116s3548is.pdf.*

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

[48] 84 FR 17463 through 17466.

[49] While 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 risk adjustment model recalibration.

[50] 86 FR 24140 at 24152.

[51] As discussed later in this proposed rule, we propose to remove the mapping of hydroxychloroquine to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions.

[52] Consistent with the approach finalized in the 2022 Payment Notice, use of the 3 most recent consecutive years of enrollee-level EDGE data would result in the use of 2018, 2019, and 2020 enrollee-level EDGE data for the recalibration of the 2024 benefit year models; the use of 2019, 2020, and 2021 enrollee-level EDGE data for recalibration of the 2025 benefit year models; and the use of 2020, 2021, and 2022 enrollee-level EDGE data for recalibration of the 2026 benefit year models.

[53] See 85 FR 78572 at 78583–78586. In the 2022 Payment Notice Final Rule, in response to comments, we did not finalize the proposed updates and announced that we would publish a technical paper on the proposed model changes; see 86 FR 24140 at 24151–24162. See also the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

replacing them with new severity and transplant indicators interacted with HCC count factors in the adult and child models; and (3) replacing the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors in the adult models.

As described in prior rulemakings and in the 2021 RA Technical Paper, the current HHS–HCC models, which are linear models, underpredict plan liability for enrollees without HCCs and the lowest expected expenditures, underpredict plan liability for enrollees with the highest HCC counts and the highest expected expenditures, and underpredict plan liability for partial-year enrollees with HCCs.[54] The proposals in this proposed rule are intended to improve the risk adjustment adult and child models' prediction for these subpopulations. We released the 2021 RA Technical Paper in response to stakeholder requests for more information on the impacts of these proposals before they were adopted and released simulated transfer estimates reflecting the combination of these proposed changes in December 2021.[55] We continue to believe the combination of these proposed model changes will improve the current models' predictive accuracy for the lowest-risk enrollees, certain partial-year adult enrollees, and the very highest-risk enrollees, while limiting trade-offs in other areas of model performance and complexity. As such, we are re-proposing these combined model specification changes in this rule, and the following sections describe these proposed model specification changes in detail.

i. Two-Stage Weighted Model Specification

We propose to use a two-stage weighted model specification to recalibrate the adult and child risk adjustment models starting with the 2023 benefit year to improve the underprediction of plan liability for the lowest-risk enrollees (that is, enrollees in low risk deciles and enrollees without HCCs).[56] Since approximately 80 percent of enrollees in the individual and small group (or merged) markets do not have HCCs, this underprediction, while small in magnitude, represents a large number of enrollees.[57]

To improve prediction for the lowest-risk enrollees, we explored calibrating the adult and child models in two stages to reweight the healthier enrollees more heavily. In the first-stage estimation, the model coefficients would be estimated using the current model specifications; and in the second stage, we would re-estimate the model weighting enrollees in the recalibration sample by the capped reciprocal of the predicted values of relative expenditures from the first step estimation with the same model specification. More specifically, the first stage of this proposed weighted estimation method for the adult models involves a linear regression (weighted by the person-specific eligibility fraction of the number of months enrolled divided by 12) of simulated plan liability[58] on age-sex factors, payment HCC factors, severity illness factors,[59] the enrollment duration factors,[60] and RXCs. For the child models, the first stage of the proposed weighted estimation method involves a linear regression of simulated plan liability on age-sex factors and payment HCC factors.[61] The methodology for conducting the proposed first stage regression would be essentially identical to the current adult and child risk adjustment recalibrations. The second stage of the proposed two-stage weighted model specification involves using recalibration sample enrollees' inverse (also referred to as reciprocal) capped predictions from the first stage as weights for a second linear regression. As such, this step has the material effect of weighting healthier enrollees more heavily so that the statistical model predicts their expenditures more accurately. It also systematically reduces the influence of very expensive enrollees on the final model factors.

To help provide stability to the proposed two-stage weighted model specification, we imposed lower and upper bound caps on the first-stage predictions at the 2.5th and 97.5th percentiles in the adult models, and the 2.5th and 99.5th percentiles in the child models. This capped weighted approach avoids excessively large or small weights for any observations for the second stage estimation, and therefore mitigates the potential to underpredict at the high end for expensive enrollees, as well as any possible low-end overprediction of healthier enrollees. We tested various caps for the weights based on the distribution of costs and found these lower and upper bound caps achieved better prediction on average.[62]

Additionally, in our consideration of the two-stage weighted model specification, we tested various methods of determining weights for the second stage, including reciprocals of the square root of predictions, log of predictions, and residuals from the first stage estimation, but the reciprocal of the capped predictions from the first stage resulted in better predictive ratios for low-cost enrollees compared to any of these alternative weighting functions.[63]

Our conceptual reasoning for pursuing the two-stage weighted model specification is to retain the simple linear, additive structure of the current models while forcing the model to better predict lowest-risk enrollees, who our analyses identified as underpredicted in the current adult and child models. Based on analyses using 2018 enrollee-level EDGE data, the two-stage weighted approach significantly improves the predictive ratios (PRs) of the lower deciles and the PRs for enrollees without HCCs compared to the current models.[64] Similar results were also seen when using 2016 and 2017 enrollee-

[54] See, for example, 85 FR 29164 at 29188–29190; 85 FR 78572 at 78583–78586; and 86 FR 24140 at 24151–24162. See also the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[55] See the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.* Issuers that participated in the simulation also received issuer-specific data, including risk score and transfer estimates for the simulated results.

[56] When we refer to the enrollees without HCCs, we are referring to enrollees without payment HCCs.

[57] See Chapter 2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf,* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

[58] We simulate plan liability expenditures for each metal level for each enrollee in the recalibration dataset (that is, we apply different standardized benefit design parameters to the same sample for each metal level). See *https://www.cms.gov/mmrr/Downloads/MMRR2014_004_03_a03.pdf.*

[59] We are also proposing to remove the current severity illness indicators in the adult models and add new severity and transplant indicators interacted with HCC count factors in the adult and child models, as described elsewhere in this proposed rule.

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

[61] See supra note 58.

[62] See Section 2.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* Also see 85 FR at 78667 and 86 FR at 24283.

[63] Ibid.

[64] See Figure 2.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

level EDGE data.[65] In addition, the two-stage weighted approach eliminated the overprediction observed in risk decile 8.[66] We also found that the two-stage weighted approach did not meaningfully change factor coefficients for most HCCs, providing stability to the risk adjustment model factors.

At the same time, we also considered whether the two-stage weighted approach worsens the fit of the models along other dimensions, identifying three areas that had minor, negative impacts on the model fit. First, the two-stage weighted approach predicts plan liability by age-sex factor less accurately than the current models, especially for younger and older women. Overall, we considered this to be an acceptable trade-off, because across all age and sex factors, most PRs were within a tolerable threshold of +/−5 percent (for example, 0.95 to 1.05), and the two-stage weighted approach has the major benefit of more accurately predicting the age-sex factors for the enrollees without HCCs, which is a much larger population than enrollees with HCCs. Second, the two-stage weighted approach is somewhat less accurate at predicting certain HCCs, with the two-stage weighted approach worsening adult model silver plan PRs by at least 5 percentage points for 14 (out of 91) ungrouped HCCs and 3 (out of 18) grouped HCCs. For the vast majority of HCCs, the impact is very small and most affected HCCs or HCC groups have small sample sizes.[67] Again, we considered this reduced accuracy to be an acceptable trade-off because most of the PRs for the two-stage weighted approach were within a tolerable threshold of +/−5 percent (for example, 0.95 to 1.05), most enrollees do not have HCCs, and the two-stage weighted approach predicts plan liability better for those no HCC enrollees. Third, the two-stage weighted approach had lower R-squared values compared to the current models. However, the decrease in R-squared is at most 0.1 percentage points for all metal levels, which is a minor reduction in fit across models.[68] Similar to the worsening of the age-sex cell and the HCC PRs, we were not concerned about the lower R-squared as the reduction in fit was minor at all metal levels, the values remained within the range of R-squared statistics of other concurrent models predicting expenditures for commercial insurance enrollees,[69] and the proposed two-stage weighted model specification better predicts plan liability for enrollees with no HCCs, which is the majority of enrollees. After considering the impact of the approach on model performance, we determined that the proposed two-stage weighted model specification does not have material unintended consequences in model performance and achieves the aim of improving the predictive accuracy of the current adult and child models for enrollees in the lowest risk deciles and for enrollees without HCCs. For these reasons, we believe that the two-stage weighted approach can improve prediction for lowest-risk enrollees with limited trade-offs in other parts of the models' performance. Therefore, we are proposing to add the two-stage weighted model specification to the adult and child models beginning with the 2023 benefit year in combination with the proposed interacted HCC counts model specification and the updated adult model enrollment duration factors described later in this proposed rule.

In the 2021 RA Technical Paper, we explained that we believe that by addressing the underprediction of costs associated with lowest-risk enrollees in the adult and child models, we could further encourage the retention and offering of plans that enroll a higher proportion of this subpopulation of enrollees. We believe issuers offering these types of plans are at greater risk of exiting the market if transfers calculated under the state payment transfer formula undercompensate for the true plan liability of the lowest-risk enrollees. We received stakeholder comments in this regard, noting that the underprediction of the lowest-risk enrollees could disincentivize issuers from attracting healthy enrollees to their plans, thereby undermining the goals of developing a healthy and stable market and encouraging competition on the basis of high quality rather than risk selection. However, other stakeholders have questioned if we should focus model changes on improving prediction for the lowest-risk enrollees when the risk adjustment program is intended to reduce incentives for issuers to avoid enrolling individuals with higher risk.

We also received comments concerned that the two-stage weighted model would be redundant of other elements in the state payment transfer formula, which stated that the administrative cost adjustment to statewide average premium[70] already addresses some of the underprediction of the lowest-risk enrollees in the risk adjustment models. We clarify that the proposed two-stage weighted model specification and existing administrative cost adjustment to statewide average premium are not redundant and address separate considerations. As detailed in the 2018 Payment Notice, the purpose of the administrative cost adjustment to statewide average premium is to exclude fixed administrative costs that are not dependent on enrollee risk, such as taxes.[71] In contrast, and as previously described elsewhere,[72] the purpose of the proposed two-stage weighed model specification is to improve the current adult and child models' prediction for the lowest risk enrollees.

We seek comment on the two-stage weighted model specification proposal, specifically regarding whether we should implement the proposed two-stage weighted model specification alone, independent of the other proposed model specification changes outlined in this rule, beginning with the 2023 benefit year; whether we should implement the proposed two-stage weighted model specification in conjunction with these other proposals; or whether we should not implement the two-stage weighted model specification at all. Additionally, given the stakeholder comments we received

[65] The PRs calculated in the 2021 RA Technical Paper are calculated using the same samples on which the models were calibrated. However, as is common practice in evaluating model fit, we also tested splitting the sample for calibration and validation purposes and the results were unchanged. Further, for purposes of the analysis in the 2021 RA Technical Paper, we calculated PRs for at least three data years and the results always appear the same. We therefore generally only reported results in the 2021 RA Technical Paper from the 2018 data year, which was the most recently available dataset at the time that we ran these analyses in preparation for announcing the proposed model changes in the proposed 2022 Payment Notice.

[66] See Figure 2.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[67] For example, only one HCC or HCC group whose PR was identified in our analysis as worsening by at least 5 percentage points was present in greater than 1 percent of the adult silver plan enrollees in the 2018 enrollee-level EDGE dataset (HCC 142 *Specified Heart Arrhythmias*). Our analysis found that all other HCCs had recalibration dataset frequencies of less than 0.5 percent of enrollees. See Chapter 2.3 and Table 2.1 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[68] See Figure 2.6 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[69] See Winkelman, R., & Mehmud, S. (2007). A Comparative Analysis of Claims-Based Tools for Health Risk Assessment. Schaumberg, IL: Society of Actuaries.

[70] 81 FR at 94099–94100.

[71] See 81 FR at 61488–61489. Also see 81 FR at 94099–94100.

[72] See Section 2.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* Also see 85 FR at 78667 and 86 FR at 24283.

questioning the need for this type of model update, we also generally solicit comments on whether we should seek to improve the current models' prediction for the lowest-risk enrollees.

ii. Interacted HCC Counts Model Specification

In addition to the two-stage weighted approach, we are proposing to add an interacted HCC counts model specification to the adult and child risk adjustment models starting with the 2023 benefit year to address the current models' underprediction of plan liability for the very highest-risk enrollees (that is, those in the top risk percentile and those enrollees with the most HCCs). While this highest-risk subpopulation represents a small number of enrollees, it represents a large portion of expenditures. As described in the 2021 RA Technical Paper, enrollees in risk decile 10 represent roughly 74.29 percent of actual plan liability, compared to only 1.36 percent for enrollees in risk decile 1.[73] We found that for enrollees with a high HCC count, there is an increasing, non-linear effect that leads to higher costs than are currently predicted by adding up the incremental effects of each HCC.

Therefore, to address the underprediction of the highest-cost enrollees, we explored the addition of severity and transplant factors interacted with HCC counts in the adult and child models, wherein a factor flagging the presence of at least one severe or transplant payment HCC is interacted with counts of the enrollee's payment HCCs.[74] The purpose of adding severity and transplant factors interacted with HCC count factors to the adult and child models is to address the underprediction of the highest risk enrollees (as the proposed two-stage-weighted model specification addresses the underprediction of the healthiest enrollees) by accounting for the fact that costs of certain HCCs rise significantly when they occur with multiple other HCCs. Specifically, the goals of this approach were to:

1. Address the non-linearity in costs between enrollees without HCCs or with very low costs and enrollees with multiple HCCs or with high costs;

2. Empirically incorporate the cost impact of multiple complex diseases; and

3. Reduce incentives for coding proliferation to mitigate the gaming concerns with HCC counts models.

In developing this interacted HCC counts approach, we identified common HCCs for enrollees with extremely high costs, as well as HCCs that were being underpredicted in the current risk adjustment adult and child models. We found that many of the HCCs that were flagged as being underpredicted were the current severe illness HCCs, the transplant HCCs, and other HCCs related to the severity of disease. Therefore, we considered dropping the current severity illness factors in the adult models and replacing them with severity and transplant factors interacted with HCC count factors in the adult models, as well as adding the severity and transplant factors interacted with HCC count factors to the child models.

We propose the inclusion of the factors in Tables 1 and 2 as the interacted severity and transplant factors in the adult and child models starting with the 2023 benefit year. We separated out transplant HCCs and severity HCCs into their own separate set of interacted factors, as expressed in Tables 1 and 2, because we found that this approach improved prediction for high-cost enrollees better than an approach that combined severity and transplant HCCs into a single set of factors. Furthermore, under the current risk adjustment models, adult severity illness interaction factors are collapsed into a single binary variable indicating the presence of any severity illness interaction. In contrast, the proposed severity factors would not be collapsed and would instead be separated out by the HCC count with which the severity or transplant illness indicator was interacted.

We defined the new proposed interaction factors such that an enrollee would receive one or more of these factors if they had any HCCs in the severity or transplant indicator groups in Table 3 and according to how many HCCs were recorded in the enrollee's data in total. As such, the proposed severity and transplant interaction factors would express the presence of one or more of the selected severity or transplant HCCs in Table 3. That is, an enrollee must have at least one HCC in the ''severity'' or ''transplant'' indicator groups in Table 3 to receive the interacted HCC count factor toward their risk score, but would not receive any additional flags for having more than one of the ''severity'' or ''transplant'' HCCs in an indicator group beyond the total HCC count.

The proposed severity-HCC-count-interaction factors were calculated as 10 separate factors for the adult models, and seven separate factors for the child models. In the adult models, the first nine factors specified the presence of (1) an HCC in the severity list in Table 3 and (2) exactly one payment HCC in the enrollee's data, exactly two, exactly three, and so on, up to exactly nine payment HCCs. The tenth factor specified the presence of (1) an HCC in the severity list in Table 3 and (2) ten or more payment HCCs in the enrollee's data. For the child models, the first five factors represented the presence of (1) an HCC in the severity list in Table 3 and (2) exactly one payment HCC in the enrollee's data, exactly two, exactly three, and so on, but the sixth factor represents the presence of (1) an HCC in the severity list in Table 3 and (2) six to seven payment HCCs, and the seventh factor represents the presence of (1) an HCC in the severity list in Table 3 and (2) eight or more payment HCCs in the enrollee's data.

The proposed transplant-HCC-count-interaction factors were calculated similarly. However, the transplant factors were calculated using a different range of HCC counts. In the adult models, five separate transplant interaction factors were created, representing the presence of (1) an HCC in the transplant list in Table 3 and (2) payment HCC counts of exactly four, exactly five, exactly six, exactly seven, and eight or more payment HCCs in the enrollee's data. For the child models, we created only one transplant interaction factor indicating the presence of (1) an HCC in the transplant list in Table 3 and (2) a total of four or more payment HCCs in the enrollee's data. As detailed later in this section, this treatment of transplant-HCC-count-interaction factors stabilized the child model estimates by increasing the sample size used to estimate the factor coefficients.

To illustrate how the proposed severity- (or transplant-) HCC-count-interaction factors would be assigned to an enrollee, consider an adult enrollee with four payment HCCs, one of which is HCC 34 ''Liver Transplant Status/Complications''. Because HCC 34 appears in both the severity and transplant indicator groups in Table 3, this enrollee would receive the following factor coefficients toward their risk score in the adult models: (1) The four factor coefficients for their individual HCCs (the three non-transplant HCC factors and the HCC 34

[73] See Table 4.1 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[74] For HCCs in a coefficient estimation group, the group is counted at most once. These groups of HCCs in the HHS risk adjustment adult and child models are detailed in the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software ''Additional Adult Variables'' and ''Additional Child Variables'' table logic (Tables 6 and 7 in the 2021 Benefit Year DIY Software). The August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.*

transplant HCC factor), (2) the factor coefficient for the severity-HCC-count-interaction indicating four payment HCCs, and (3) the factor coefficient for the transplant-HCC-count-interaction indicating four payment HCCs.[75] The child model would operate similarly. For a child enrollee with a transplant HCC in the transplant factor group and three other payment HCCs, the following would be used to calculate the enrollee's risk score: (1) The factor coefficients for all four HCCs (that is, the three non-transplant HCCs and the transplant HCC), (2) the factor coefficient for the severity-HCC-count-interaction indicating four payment HCCs, and (3) the factor coefficient for the transplant-HCC-count-interaction indicating four or more payment HCCs.

To implement the severity- and transplant-HCC-count-interaction factors in the regression model and estimate the value of their factor coefficients, we are proposing to remove the current severity illness factors in the adult models, and add severity- and transplant-HCC-count-interaction factors for the adult and child models beginning with the 2023 benefit year. Although the severity (or transplant) HCC-count-interaction factor coefficients may be estimated as having negative values, the combination of these interaction factor coefficients with the factor coefficient of the HCC that triggered the severity factor will always be positive. For example, the proposed adult silver metal level model factor coefficient for Viral or Unspecified Meningitis (HCC 04), which is proposed as a severe illness HCC, is 6.914, when combined with the proposed severity-HCC-count-interaction factor coefficient for one HCC of −4.603 (indicating that the enrollee only has HCC 04 present in their data), would increase the enrollee's risk score by 2.311. Moreover, an increase in the count of HCCs would lead to a monotonic increase in the enrollee risk score, because the severity-HCC-count-interaction factor coefficients are less negative (and sometimes positive) with a larger number of payment HCCs.

One potential concern with this proposed model specification change is that the severity- and transplant-HCC-count-interaction factor coefficients might be based on small sample sizes. In recognition of this issue, we considered sample sizes of the various interacted HCC count factors when developing this proposal and the proposed factor coefficients. We explored alternative methods of interacting HCC counts with severity and transplant HCCs, including interacting the HCC counts with individual selected severity and transplant HCCs, but found that interacting the HCC counts with a factor indicating the presence of at least one of the selected HCCs in each group produced PR improvements and sufficient sample sizes for reasonably stable factor coefficient estimates. To that end, we analyzed 2016, 2017, and 2018 enrollee-level EDGE data and chose the model specifications that grouped the HCC counts interacted with individual severity and transplant HCCs into two sets of aggregated factors to maximize sample size, reduce concerns of overfitting the model, and reduce the number of factors being added to the models. More specifically, in the adult models, we found that starting with 4+ HCCs for the transplant interacted factors improved predictions of enrollees at the very high end in terms of risk and cost and ending at 8+ HCCs for the transplant interacted factors, instead of 10+ HCCs, addressed the small sample sizes of enrollees with a transplant and 9 or more HCCs. For the child models, we found having one transplant interacted factor for 4+ HCCs provided more stable estimates given the smaller sample sizes for children than those for adults. With the proposed structure for transplant and severity interacted factors in place, the resulting sample sizes for both proposed sets of factors in the child and adult models in the proposed 2022 Payment Notice and in this rule are consistent with the sample sizes used for individual HCCs in the adult and child risk adjustment models.

We also considered potential gaming concerns in developing the proposed interacted HCC counts factors. We believe that the proposal to restrict the incremental risk score adjustment to enrollees with at least one severe illness HCC, which accounts for less than 2 percent of the adult enrollee-level EDGE data population across the 2016, 2017, and 2018 benefit years, helps mitigate the concern that issuers may attempt to inflate HCC counts to influence their transfers under the state payment transfer formula. In other words, the scope for potentially inflating HCC coding frequency under this proposal would be limited to a small fraction of total enrollees, in contrast to an approach that would interact HCC counts for any payment HCC, where a payment HCC is present in approximately 20 percent of the adult enrollee population across the same three benefit years of enrollee-level EDGE data.[76] We also note that enrollees with interacted HCCs are likely to have more HCCs and higher risk scores and therefore are more likely to be sampled and have their risk scores reviewed in the HHS-operated risk adjustment data validation (HHS–RADV) process due to our use of stratified sampling and application of the Neyman allocation.[77]

Our analysis of the proposed interacted HCC counts factors combined with the proposed HCC-contingent enrollment duration factors in the adult models (discussed in the following section) significantly improves predictions across most deciles and HCC counts for the very highest-risk enrollees, as well as the lowest-risk enrollees without HCCs. Specifically, as described in the 2021 RA Technical Paper, the proposed interacted HCC counts approach improves the PRs for enrollees across most HCC counts, with significant improvements for enrollees with high numbers of HCCs (greater than 6).[78] The proposed interacted HCC counts approach also demonstrated improved R-squared statistics across all metal levels in the adult and child models using 2016, 2017, and 2018 enrollee-level EDGE data.[79]

Some commenters on the 2021 RA Technical Paper were concerned about potential data bias because of the exclusion of enrollees with capitated claims from the analytic sample used to test the model specification changes. As previously stated in the 2016 RA White Paper,[80] we have historically excluded enrollees with capitated claims from the recalibration sample due to concerns that methods for computing and reporting derived amounts from capitated claims would not result in

[75] This is in addition to other factors that the adult enrollee has that are used to calculate their risk score (such as the applicable demographic factors, RXCs (if any), and the applicable enrollment duration factors).

[76] This analysis was based on 2016, 2017, and 2018 enrollee-level EDGE data. See Chapter 4.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[77] For a discussion of our use of stratified sampling and application of the Neyman allocation, see 79 FR at 13756–13758; and 84 FR at 17494–17495.

[78] See Figure 4.3 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[79] See Figure 4.4 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[80] See the March 2016 Risk Adjustment Methodology White 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.*

reliable data for recalibration or analysis.[81]

Beyond the predictive improvements, an additional benefit of the proposed interacted HCC count model specification is that it would not overhaul the existing risk adjustment factors and would instead build upon the current models. Additionally, the factors would remain fairly stable, could be used in combination with other refinements and model updates, and could be easily modified, adjusted, expanded, or constrained in the future to include additional HCCs or to remove HCCs. For all of these reasons, we are proposing to add the proposed interacted HCC counts model specification as outlined above to the adult and child risk adjustment models beginning with the 2023 benefit year.

We seek comment on this proposal, specifically regarding whether we should implement the proposed interacted HCC counts model specification alone, independent of the other proposed model specification changes outlined in this rule, beginning with the 2023 benefit year; whether we should implement the proposed interacted HCC counts model specification in conjunction with these other proposals; or whether we should not implement the proposed interacted HCC counts model specification at all. We also seek comment on the variations on the HCC counts model specification discussed in this section, including whether we should interact severity or transplant factors with individual HCCs, or should interact HCC counts with individual selected severity and transplant HCCs, rather than interacting HCC counts with only an indicator of the presence of severity or transplant HCCs, as proposed. Finally, we seek comment on the proposed list of severity and transplant HCCs in Table 3 that would be used to calculate the proposed interacted HCC count factor coefficients and whether other HCCs should be to added to the proposed list that trigger the interacted HCC count factor coefficients or whether any of the HCCs on the proposed list should be removed.

iii. Changes to the Adult Model Enrollment Duration Factors [82]

In addition to the proposed two-stage weighted model specification and the interacted HCC counts model specification, we are also proposing to change the enrollment duration factors in the adult risk adjustment models to improve the prediction for partial-year adult enrollees with and without HCCs. Although the value for the factors change from year to year as part of the annual recalibration of the adult models, we have not made changes to the structure of the enrollment duration factors since they were first adopted for the 2017 benefit year. To develop the current enrollment duration factors for the adult models, we reviewed the annualized predicted expenditures, actual expenditures, and PRs by enrollment duration groups (for each: 1 month, 2 months, and so on up to 12 months) for our risk adjustment concurrent modeling sample, which was made up of adults in the 2014 MarketScan® data.[83] This analysis found that actuarial risk for adult enrollees with short enrollment periods tended to be underpredicted in our methodology, and actuarial risk for adult enrollees with full enrollment periods (12 months) tended to be overpredicted. We therefore proposed and finalized in the 2018 Payment Notice that, beginning for the 2017 benefit year, the adult models would include enrollment duration factors that apply to all adults with partial-year enrollment.[84] The value for the enrollment duration factors have generally decreased since they were first introduced in the adult models for the 2017 benefit year, reflecting a reduced impact of enrollment duration on risk scores of partial year enrollees. After a slight increase between 2017 and 2018, the factors have decreased significantly from 2018 to 2021, and in some cases (the 10- and 11-month factors) the factors are now 0.000, relative to a 12-month enrollment baseline.[85]

As described in prior rulemakings and the 2021 RA Technical Paper, we have been considering potential adjustments to the enrollment duration factors and our more recent analysis of enrollee-level EDGE data found that the current adult model enrollment duration factors underpredicted plan liability for partial-year adult enrollees with HCCs and overpredicted plan liability for partial-year adult enrollees without HCCs.[86] [87] More specifically, our analysis of 2017 and 2018 enrollee-level EDGE data found that the current enrollment duration factors are driven by enrollees with HCCs.[88] That is, partial-year enrollees with HCCs had higher per member, per month (PMPM) expenditures on average as compared to full-year enrollees with HCCs, and partial-year enrollees without HCCs were not significantly different in PMPM expenditures compared to full-year enrollees without HCCs.[89]

Therefore, beginning with the 2023 benefit year, we are proposing to eliminate the current monthly enrollment duration factors of up to 11 months for all enrollees in the adult models, and replace them with new monthly enrollment duration factors of up to 6 months that would apply only to adult enrollees with HCCs. If finalized as proposed, this would mean there would be no enrollment duration factors for adult enrollees without HCCs starting with the 2023 benefit year nor would there be enrollment duration factors for adult enrollees with HCCs and more than 6 months of enrollment.

While we considered other enrollment duration factor structures, we are proposing to limit the enrollment duration factors to 6 months because we found that the monthly average cost variation by number of months enrolled is meaningfully reduced after 6 months for adult enrollees with HCCs, and enrollment duration factors beyond 6 months did not meaningfully improve

[81] See Chapter 1.4 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

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

[83] See pages 35–39 of the March 2016 Risk Adjustment Methodology White 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.*

[84] 81 FR 94058 at 94071–94074.

[85] In unconstrained models, these factors are negative; therefore, we constrained them to zero because we do not believe negative enrollment duration factors are appropriate, as this would create inappropriate incentives. See Figure 3.1 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[86] See 85 FR 29164 at 29188–29190.; 86 FR 24140 at 24151–24162.; and the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[87] When we refer to the enrollees with and without HCCs, we are referring to enrollees without payment HCCs.

[88] See, for example, Chapters 1.4 and 3.2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* Also see 85 FR at 7103–7104 and 85 FR at 78585–78586.

[89] See Chapter 1.4 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

prediction for the adult models. As part of our analysis of enrollment duration factor options, we also considered adoption of enrollment duration factors by market, but we did not find a meaningful distinction in relative costs between markets on average once we implemented the proposed enrollment duration factors of up to 6 months for adult enrollees with HCCs.[90] We also considered HCC-type contingent enrollment duration factors. Specifically, we found that the distribution of enrollment duration and PMPM allowed charges by enrollment duration is similar for adults with any acute HCCs versus adults with only chronic HCCs.[91] We therefore determined that, on balance, it would add unnecessary complexity to introduce enrollment duration factors by market type or that are contingent on types of HCCs with little benefit. Therefore, we are not proposing enrollment duration factors for the adult models by market type or that are contingent on types of HCCs at this time.

We also considered previous comments we received that expressed concerns that certain issuers—particularly small group market issuers, small issuers, or Medicaid issuers—may have partial-year enrollees with HCCs that are not coded. These commenters expressed concerns that these issuers may have difficulty obtaining diagnoses for these enrollees, creating cases where the issuer may pay claims, and incur costs, for services associated with a condition for the partial-year enrollee, but the issuer's limited time with the partial-year enrollee may not be adequate to capture the diagnosis code associated with the HCC.[92] [93] In response to the 2021 RA Technical Paper, we got further comment from stakeholders who questioned whether the HCC-contingent enrollment duration factors would have negative impacts on small group market issuers that offer non-calendar year coverage and take on new business later in the year. As we noted in the 2021 RA Technical Paper, our analysis did not find evidence that issuers are unable to capture cost-meaningful HCCs for partial-year enrollees in the individual or small group (including merged) market.[94]

We solicit comments on the proposed changes to the enrollment duration factors for the adult models. We also solicit comments regarding whether we should implement the proposed changes to enrollment duration factors alone, independent of the other proposed model specification changes outlined in this rule, beginning with the 2023 benefit year; whether we should implement the proposed changes to enrollment duration factors in conjunction with these other proposals; or whether we should not implement the proposed changes to enrollment duration factors at all and maintain the current structure for these factors.

iv. Combined Impact of the Proposed Model Changes

In sum, we are proposing to modify the HHS risk adjustment model specifications for the adult and child models beginning with the 2023 benefit year by combining a two-stage weighted approach with the removal of the current adult model severe illness interaction factors and the addition of new severe illness and transplant interacted HCC count factors to the adult and child models. We are also proposing to replace the current enrollment duration factors in the adult models. For the two-stage weighted approach, we propose calibrating the adult and child models in two stages. The first stage of the weighted estimation method would involve a linear regression of simulated plan liability on age-sex factors and payment HCC factors for the adult and child models, with the addition of RXCs and the new proposed enrollment duration factors for the adult models. The second stage would use the reciprocal of prediction from the first step to weight a second stage linear regression. To stabilize the weights from the first stage predictions, we propose lower and upper bound caps on the predictions used as weights at the 2.5th and 97.5th percentiles in the adult models and the 2.5th and 99.5th percentiles in the child models. This two-stage weighted approach would be combined with the new severity and transplant indicators from the interacted HCC count factors. For the severity indicator group, we propose to add separate count factors for one to 10+ payment HCCs (1, 2, . . . , 10+) for the adult models and one to 5, 6 or 7, and 8+ payment HCCs (1, 2, . . . 5, 6 or 7, 8+) for the child models. The proposed HCCs that would flag the severity indicator are listed in Table 3. For the transplant HCCs, we propose to incorporate factors for 4 to 8+ payment HCCs (4, 5, 6, 7, 8+) for the adult models and one factor for 4+ payment HCCs for the child models. The proposed HCCs that would flag the transplant indicator are listed in Table 3. The severity- (and transplant-) HCC-count-interaction factors would be included in both stages of the regressions. We propose to incorporate the two-stage weighted approach and the interacted HCC count specification updates beginning with the 2023 benefit year HHS risk adjustment adult and child models. We also propose to remove the current severity illness factors in the adult models beginning with the 2023 benefit year. Lastly, we propose to remove the current 11 enrollment duration factors for all enrollees in the adult models and replace them with new monthly enrollment duration factors of up to 6 months that only apply to enrollees with HCCs. We propose to incorporate the new HCC-contingent enrollment duration factors beginning with the 2023 benefit year adult models.

We tested combining these model specifications into an approach that incorporated the two-stage weighted approach, the severity and transplant factors interacted with HCC count factors, and the HCC-contingent enrollment duration factors. We found that, together, these changes are expected to improve model performance in comparison to the current models. Our analysis found this combined approach generally improved prediction for enrollees at both the low and high ends of expected expenditures and had higher R-squared statistics across metal levels than the current models, indicating a better individual-level fit.[95] Our analysis also found general improvement in PRs for the models with the combined proposed model specification changes across each decile of predicted plan liability, by age-sex factor for adult enrollees with and without HCCs, and by enrollment

[90] See Chapter 3.3.2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[91] See Chapter 3.3.3 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[92] See Chapter 3.4 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[93] This issue differs from situations where issuers may not have a complete diagnostic profile for a partial-year enrollee because the services received were not related to the diagnoses that were not captured. For example, if an enrollee received services due to a condition while enrolled with a different issuer, then the current issuer may not have all diagnosis codes for a partial-year enrollee. However, such cases do not have cost implications for the current issuer since the partial-year enrollee received no services associated with that diagnosis.

[94] See Chapter 3.4 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[95] See Chapter 5.1 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

length.[96] We also found that the mean absolute error did not materially differ between the current adult and child models and the proposed adult and child models with the combined proposed model specification changes incorporated.[97] These observations support our belief that the best way to comprehensively improve the predictive accuracy of the current models across the risk spectrum is to implement all three proposed model specification changes together. To further assist issuers and other stakeholders with analyzing the impact of the combination of these proposed model specification changes, HHS also conducted a transfer simulation and provided summary-level and issuer-specific risk score and transfer estimates.[98] [99]

As detailed in the 2021 RA Technical Paper, this transfer simulation applied the proposed model specification changes to 2020 benefit year EDGE data to illustrate and estimate what 2020 benefit year risk adjustment transfers would have been if the combined model specification changes were applied.[100] The transfer simulation provided issuers with detailed, plan-level simulated results.[101] The coefficients values presented in Tables 1 and 2 incorporate the combination of these proposed model specification changes and Table 3 provides the list of the proposed severity and transplant HCCs that would apply for the proposed interacted HCC counts factors. We seek comment on the combination of these proposed model changes and the adoption of these changes beginning with the 2023 benefit year.

We seek comment on finalizing each of these proposed model specification changes as a whole, in part, or in combination or for example, whether we should finalize the proposed interaction HCC counts model specification and the proposed changes to the adult model enrollment duration factors without the proposed two stage weighted model specification. Finally, we seek comment on finalizing the 2023 models without the proposed model specification changes, but with updates to the data years used for recalibration, (that is, to use 2017, 2018, and 2019 enrollee-level EDGE data, as detailed elsewhere in this proposed rule); or, alternatively, using the updated final 2022 risk adjustment model coefficients [102] for the 2023 benefit year risk adjustment models, trended forward to project 2023 costs or not trended forward to project 2023 costs.

c. Pricing Adjustment for the Hepatitis C Drugs

For the 2023 benefit year, we propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models.[103] Since the 2020 benefit year risk adjustment models, we have been making a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the models.[104] This market pricing adjustment has been necessary to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year. We also continue to be cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim, and therefore, make the transfer results more favorable for the issuer. We have committed to reassessing this pricing adjustment with additional years of enrollee-level EDGE data, as data become available. As part of the 2023 benefit year model recalibration, we reassessed the Hepatitis C RXC using available enrollee-level EDGE data (including 2019 benefit year data) to consider whether the adjustment was still needed and if it is still needed, whether it should be modified. We found that the data for the Hepatitis C RXC that would be used for the 2023 benefit year recalibration (that is, the 2017, 2018, and 2019 enrollee-level EDGE data) still do not account for the significant pricing changes due to the introduction of new Hepatitis C drugs and, therefore, do not precisely reflect the average cost of Hepatitis C treatments applicable to the benefit year in question.

Specifically, we are proposing to recalibrate the 2023 benefit year risk adjustment models with the 2017, 2018, and 2019 enrollee-level EDGE data. Generic Hepatitis C drugs did not become available on the market until 2019.[105] Due to the lag between the data years used to recalibrate the risk adjustment models and the applicable benefit year of risk adjustment, we do not believe that the data used for recalibrating the models precisely reflect the average cost of Hepatitis C treatments expected in the 2023 benefit year. Therefore, we continue to believe a market pricing adjustment for the 2023 benefit year is necessary to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year. We intend to continue to assess this pricing adjustment in future benefit year recalibrations using additional years of enrollee-level EDGE data. We seek comment on our proposal to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs for the 2023 benefit year.

d. Risk Adjustment RXC Mapping for Recalibration

i. Inclusion and Exclusion Criteria for Drugs in RXC Mapping and Recalibration

This section provides an overview of the inclusion and exclusion criteria HHS uses to identify drugs for mapping to RXCs in the adult risk adjustment models, reviews what version of the RXC mapping document HHS uses when processing the enrollee-level EDGE data for a benefit year for recalibration of the adult risk adjustment models, and outlines the criteria that warrant consideration for changes to the incorporation (or

[96] Ibid.

[97] Ibid.

[98] See the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* See also the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.* Issuers that participated in the simulation also received detailed issuer-specific data, including risk score and transfer estimates for the simulated results.

[99] If an issuer wishes to use the simulation results to assist in assessing the impact of these model specification changes on future benefit year transfer amounts, it should do so with caution and in combination with other significant data.

[100] See Chapter 5.2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[101] See the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

[102] See ''Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients.'' May 12, 2020. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

[103] See, for example, 84 FR 17463 through 17466.

[104] 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.

[105] See *https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv.* See also *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.*

exclusion) of particular drugs from the RXC mappings in future benefit year recalibrations. We also propose a change to the approach for identifying the version of the RXC mapping document HHS would use to process a given benefit year's enrollee-level EDGE data for recalibration of the adult risk adjustment models.

In accordance with § 153.320, HHS develops and publishes the risk adjustment methodology applicable in states where HHS operates the program, including the draft factors to be employed in the models for the benefit year. This includes the annual recalibration of the adult risk adjustment models' RXC coefficients using data from the applicable prior benefit years trended forwarded to reflect the applicable benefit year of risk adjustment. Drugs that appear on claims data, either through National Drug Codes (NDCs) or Healthcare Common Procedural Coding System (HCPCS), are cross walked to RxNorm Concept Unique Identifiers (RXCUIs).[106] RXCUI mappings are always matched to the NDCs and HCPCS applicable to the particular EDGE data year as the NDC and HCPCS reflect the drugs that were available in the market during the benefit year.[107] Currently, we use the most recent RXC mappings (RXCUIs that map to RXCs) that are available when we first process the enrollee-level EDGE data for a benefit year for recalibration of the adult risk adjustment models. For example, for the 2022 benefit year, we recalibrated the adult risk adjustment models using 2016, 2017, and 2018 enrollee-level EDGE data and applied the second quarter (Q2) 2018 RXC mapping document for both 2016 and 2017,[108] and applied the Q2 2019 mapping document for 2018 for recalibration of the adult risk adjustment models RXC factors.[109]

As noted in the 2022 Payment Notice, we also continuously assess the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment models.[110] More specifically, during a benefit year, HHS conducts quarterly reviews of RXCUIs that map to RXCs in the adult risk adjustment models for that benefit year. During our annual review of enrollee-level EDGE data for recalibration purposes, and to a certain extent during quarterly reviews of RXCUIs that map to RXCs in the adult risk adjustment models, HHS evaluates the inclusion and exclusion of RXCUIs based on criteria such as: (1) Whether costs for an individual drug are comparable to the costs of other drugs in the same class, (2) whether a drug is a good predictor of the presence of the diseases that map to the HCCs that an RXC indicates (which can be evaluated through clinical expert review in the absence of data), (3) whether clinical expert reviews of the pharmacological properties and prescribing patterns are consistent with treatment of a particular condition, and (4) stakeholder feedback.[111] As a result of this on-going assessment, we may make quarterly updates to the RXC Crosswalk, which identifies the list of NDCs and HCPCS indicating the presence of an RXC in the current benefit year DIY and EDGE reference data, to ensure drugs are mapped to RXCs, where appropriate. This can include the addition or removal of drugs based on market availability and the other criteria identified above. As such, the risk adjustment mapping of RXCUIs to RXCs, along with the list of NDCs and HCPCS that crosswalk to each RXCUI, may be updated throughout a particular benefit year of risk adjustment. HHS provides information to issuers on these updates through the DIY software, which is published on the CCIIO website,[112] as well as through the EDGE global reference updates, which are published on the Distributed Data Collection program page on the Registration for Technical Assistance Portal (REGTAP).[113]

This ongoing updating process occurs on a different timeline than the annual model recalibration activities for a given benefit year.

In this rule, we propose to change the approach for identifying the version of the RXC mapping document HHS would use to process a given benefit year's enrollee-level EDGE data for the annual recalibration of the adult risk adjustment models. More specifically, we propose to recalibrate the adult risk adjustment models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the applicable benefit year's model recalibration, while continuing to engage in annual and quarterly review processes using the inclusion and exclusion criteria described above. For example, if we recalibrate the 2024 benefit year adult risk adjustment models using 2018, 2019, and 2020 benefit years of enrollee-level EDGE data, we would use the Q4 RXC mapping document for each of those benefit years (that is, Q4 2018, Q4 2019, and Q4 2020, respectively) for recalibration purposes. We would also use the criteria described above to evaluate the inclusion and exclusion of RXCUIs and may make other updates to the 2024 benefit year RXC Crosswalk to ensure drugs are mapped to RXCs, where appropriate.

We propose to begin to use this approach for recalibration of the 2023 adult risk adjustment models with the exception of the 2017 enrollee-level EDGE data year, for which we propose to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018). We propose to use the applicable benefit year's Q4 RXC mapping documents for both the 2018 and 2019 benefit years of enrollee-level EDGE data for the recalibration of the adult risk adjustment models for the 2023 benefit year. Under this proposal, we would hold those mappings constant when using the 2018 and 2019 enrollee level EDGE data years in future benefit year model recalibrations—meaning that we would use the applicable benefit year's Q4 RXC mapping documents when the 2018 or 2019 benefit year of enrollee-level EDGE data is used for future benefit year model recalibrations.[114]

[106] See, for example, 81 FR at 94074–94080.

[107] See, for example, Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk Memorandum at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf*.

[108] RXCs were not added to the risk adjustment models until 2018 benefit year; therefore, we used 2018 RXC mappings for both 2016 and 2017 enrollee-level EDGE data as there were no 2016 and 2017 RXC mapping documents. Note that, even though 2018 RXC mappings were applied to these earlier years, they were cross walked to the NDCs and HCPCS that describe the applicable drugs during those earlier years.

[109] Although the recalibration proposals are typically released towards the end of the calendar year, we generally receive the prior benefit year enrollee-level EDGE data in the summer or fall, at which point we apply the most recently available mapping document as we begin to prepare the data to recalibrate the models for the applicable benefit year. This is why, for example, we used the 2019 Q2 mapping document when processing the 2018 enrollee-level EDGE data for recalibration of the 2022 benefit year adult models.

[110] See 86 FR at 26164.

[111] See, for example, the Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk (September 17, 2017), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf*.

[112] The August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance*.

[113] Available at *https://www.regtap.info/reg_library.php?libfilter_topic=3*.

[114] Consistent with the approach finalized in the 2022 Payment Notice, the 2018 and 2019 enrollee-level EDGE data would be used for the recalibration

The purpose of maintaining a specific version of the same RXC mapping document for future recalibrations under this proposal is to limit the volatility of some coefficients from year-to-year and to ensure that we are capturing the utilization and costs observed for the underlying drugs in use in that year for the condition. Because the final DIY software update contains the Q4 list, this approach would also have the added benefit of providing issuers the opportunity to see the mappings/crosswalk that will be applied to that data year in the final DIY software release before it is used for recalibration.

For purposes of the 2023 benefit year recalibration, we are proposing an exception for the 2017 benefit year enrollee-level EDGE data and would instead use the most recent RXC mapping document that was available when we first processed the benefit year's enrollee-level EDGE data for recalibration purposes (that is, Q2 2018). We are proposing this approach for the 2017 benefit year enrollee-level EDGE data because we did not include RXCs in the adult risk adjustment models until 2018 [115] and therefore, we do not have a Q4 RXC mapping for the 2017 benefit year. Thus, we propose to use the Q2 2018 RXC mapping document for the 2017 benefit year enrollee-level EDGE data year for 2023 model recalibration, consistent with the mapping used for processing the 2017 data for recalibration of the 2021 and 2022 adult models. We seek comment on this proposal to change the approach for identifying the version of the RXC mapping document that would be used to process a given benefit year's data for the annual recalibration of the adult models, as well as the proposed applicability beginning with the 2023 benefit year model recalibration and the proposed exception for the mapping document for the 2017 benefit year enrollee-level EDGE data.

Alternatively, we seek comment on whether we should take a different approach to recalibration of the RXC mappings for the adult risk adjustment models. Under this alternative, we would use the latest RXC mapping document available at the time that we recalibrate the adult risk adjustment models and apply it to all three underlying EDGE data years used to recalibrate the models for the benefit year. This alternative is in contrast to the current approach of using the most recent RXC mappings (RXCUIs that map to RXCs) that are available when we *first process* the enrollee-level EDGE data for recalibration of the applicable benefit year's adult models and the above proposed approach to use the final Q4 RXC mappings that was applicable for each benefit year of data included in the applicable benefit year's model recalibration. More specifically, under this alternative approach, we would instead use the most recent RXCUI to RXC mapping document available at the time of developing a benefit year's proposed model factors for publication in the applicable benefit year's Payment Notice. As the recalibration process typically begins several months prior to the proposed Payment Notice being released, the most recently available RXCUI to RXC mapping document available at the time of developing a benefit year's proposed model factors would generally be either the Q4 mapping from the prior benefit year (for 2023 benefit year (BY) model recalibration that would have been the Q4 mapping for BY 2020), or the Q1 or Q2 mapping document from the year in which recalibration is occurring (for 2023 benefit year model recalibration that would have been the Q1 or Q2 mapping for BY 2021). Under this approach, the RXCUI to RXC mappings applied to the underlying data years used in model recalibration would be updated each year of model recalibration to reflect the most recently available decisions in the quarterly mapping document about which RXCUIs map to RXCs in the adult models. While this approach would represent what is most likely to map to the RXCs in the upcoming benefit year of risk adjustment, the RXC mapping document used would still lag behind what the RXC mapping document will be in the applicable benefit year due to the inherent time lag between when recalibration occurs for a benefit year and the actual benefit year.[116] Also, while we believe that the impact will likely be minimal, this approach to remapping the RXCs every year may contribute to volatility of some coefficients, as the RXC mappings for the underlying data years would be updated each year during the annual model recalibration. Another drawback of this approach is that the most recent RXC mappings will be reflective of similarly recent costs, clinical relevancies, and prescribing patterns. If changes to any of these have occurred between an earlier data year and the most recent year, RXC mappings reflecting the latter will generally be applied to the former.[117] We seek comment on all aspects of this alternative approach.

ii. Targeted Changes to RXC Mappings for Recalibration

Regardless of the version of the RXC mapping document we use during the annual adult risk adjustment model recalibration, there may be a relatively small number of drugs that still require additional analysis and consideration given the changes that can occur in the market between the data year and the applicable benefit year of risk adjustment. The targeted changes to particular drugs' mappings would typically occur when performing recalibration for future benefit years. Based on our experience since the incorporation of RXCs into risk adjustment models in the 2018 benefit year, we do not believe that the removal or addition of an RXCUI from the RXC mappings (and the associated removal of the NDCs and HCPCS associated with that RXCUI) are typically material to recalibration because most drug removals are not associated with utilization and cost levels that would have a meaningful impact on model coefficients.[118] However, in extenuating circumstances where HHS believes there will be a significant impact from a change in an RXCUI to RXC mapping, such as: (1) Evidence of significant off-label prescribing (as was the case with hydroxychloroquine sulfate [119]); (2) abnormally large changes in clinical indications or practice patterns associated with drug usage; or (3) certain situations in which the cost of a drug (or biosimilars) become much higher or lower than the typical cost of drugs in the same prescription drug category, HHS will consider whether changes to the RXCUI to RXC mapping from the applicable data year crosswalk are needed for future benefit year recalibrations. In the following sections of this proposed rule, we illustrate cases where we believe extenuating

of the 2024 benefit year models and the 2019 enrollee-level EDGE data would be used for the recalibration of the 2025 benefit year models. See, supra, note 47.

[115] See 81 FR at 94075.

[116] For example, the current recalibration activities (in calendar year 2021) relate to the 2023 benefit year risk adjustment models.

[117] As noted elsewhere in this rule, in certain circumstances, HHS may consider changes to the RXCUIs from the applicable data year crosswalk as part of future benefit year model recalibration and quarterly review processes.

[118] For example, the average effect of the removal of a single therapeutic drug ingredient in the 2019 Drug Removal Review on 2020 Q1 was an approximate decrease of 0.14% percent in total pharmacy claims spending among RXC drugs, and the average effect of the removal of a single non-hydroxychloroquine therapeutic drug ingredient in the 2020 Drug Removal Review on 2021 Q1 was an approximate decrease of 0.68 percent in total pharmacy claims spending among RXC drugs.

[119] See, for example, 86 FR at 24180.

circumstances existed and our evaluation of whether to make targeted changes to the mapping of select RXCUIs to RXCs due to those extenuating circumstances as part of the annual recalibration process for the 2023 benefit year adult models. In particular, we consider the cases of RXCUI to RXC mapping of Descovy® and hydroxychloroquine sulfate. We also note that, as discussed above, HHS may make other exception-based adjustments during the recalibration process to reflect changes in clinical practice and prescribing between recalibration and the benefit year, such as the adjustment for Hepatitis C drugs, where HHS determines it is necessary and appropriate to do so. We are not proposing changes to this approach or the criteria used for these reviews, but are sharing these examples to further promote transparency about the process for targeted changes to mapping of select RXCUI to RXCs.[120]

(a) Descovy®

Descovy® has been included in RXC 01 (Anti-HIV Agents) since RXCs were initially added to the adult risk adjustment models for the 2018 benefit year because it met the inclusion criteria of being a reliable predictor of the presence of HIV and being representative of the costs of other drugs associated with the treatment of HIV. However, in October 2019, Descovy® was approved by the Food and Drug Administration (FDA) for pre-exposure prophylaxis (PrEP).[121] As noted in the 2022 Payment Notice, HHS removed Descovy® from the Q4 2020 RXCUI to RXC mappings for consistency with the treatment of other PrEP drugs.[122] [123] The 2023 benefit year model recalibration, however, is the first benefit year recalibration that will use the 2019 benefit year enrollee-level EDGE data. HHS therefore considered removal of Descovy® from the RXC mappings applied to the 2019 benefit year enrollee-level EDGE data year. The reason for this consideration was that some enrollees in 2019 would have used Descovy® for PrEP, which would have an impact on the recalibration of the coefficients for RXC 01 (Anti-HIV Agents) and was in keeping with the previously mentioned criteria of changes in clinical indications or practice patterns associated with drug usage for further evaluation for potential exception. However, our internal analysis of available enrollee-level EDGE data indicated that most Descovy® users in 2019 were using the drug as part of active HIV treatment, rather than PrEP.[124] This, supported by the fact that Descovy® was approved for PrEP late in the calendar year of 2019, suggested that the benefits of keeping Descovy® mapped to RXC 01 (Anti-HIV Agents) outweighed the tradeoffs of removing it.[125] Similarly, the 2019 approval and subsequent change in Descovy® use that triggered its removal from the crosswalk in Q4 BY 2020 was not applicable to its use in 2017 or 2018 when it was not approved PrEP. Therefore, we are not proposing to make an exception to the RXCUI to RXC mappings to remove Descovy® from mapping to RXC 01 in 2017, 2018 and 2019 benefit year enrollee-level EDGE datasets used for the 2023 benefit year recalibration of the adult models. We further note that, regardless of the mapping approach adopted for Descovy®, enrollees in risk adjustment covered plans that use Descovy® (or other PrEP drugs) in combination with another HIV treatment drug that maps to RXC 01 would still receive credit for RXC 01 in the 2023 benefit year of risk adjustment. If we adopt the alternative mapping approach of using the latest RXC mapping document available at the time that we recalibrate adult risk adjustment models and apply it to all three underlying EDGE data years used to recalibrate the models for the benefit year, Descovy® would not map to RXC 01 and we would have to make an exception to include it in the mapping. We seek comment on whether we should make such an exception to include and map Descovy® to RXC 01 in the datasets used to recalibrate the 2023 benefit year adult models, should the alternative approach be finalized.

(b) Hydroxychloroquine Sulfate

Hydroxychloroquine sulfate was initially mapped to RXC 09 (Immune Suppressants and Immunomodulators) in the Q3 BY 2018 review because it was believed to be a reliable predictor of the presence of conditions associated with RXC 09. However, HHS removed the RXCU for hydroxychloroquine sulfate from mapping to RXC 09 (Immune Suppressants and Immunomodulators) in the Q4 BY 2020 RXC mappings because of concerns regarding unrepresentative expenditures and off-label prescribing during the COVID–19 PHE.[126] This meant that beginning with the 2020 benefit year of risk adjustment, hydroxychloroquine sulfate no longer mapped to RXC 09.

Then, in part 2 of the 2022 Payment Notice final rule, we finalized proposals for the 2022 benefit year model recalibration, including the targeted removal of hydroxychloroquine sulfate for recalibration of the adult models.[127] As we explained, our analysis of pre-2020 data showed that the cost of hydroxychloroquine sulfate drugs were much lower than the costs of other drugs taken by enrollees assigned RXC 09.[128] However, even though hydroxychloroquine sulfate was no longer mapping to the RXC 09 in the Q4 2020 DIY software, hydroxychloroquine sulfate was still mapping to RXC 09 in the 2018 enrollee-level EDGE data that would be used for the 2022 benefit year model recalibration.[129] Additionally, after hydroxychloroquine sulfate was removed from mapping to RXC 09 in the

[120] As noted above, HHS also conducts quarterly reviews of RXCUIs that map to RXCs in the adult models and may make targeted changes to RXC mappings during a benefit year as a result of these reviews. We are not proposing any changes to the quarterly update process or the criteria used for such reviews.

[121] See *https://www.fda.gov/news-events/press-announcements/fda-approves-second-drug-prevent-hiv-infection-part-ongoing-efforts-end-hiv-epidemic*.

[122] See 86 FR at 24164. Also see HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software Instructions for the 2020 Benefit Year (April 15, 2021 Update), available at *https://www.cms.gov/files/document/cy2020-diy-instructions04132021.pdf*.

[123] We further explained that enrollees that use Descovy® (or other PrEP drugs) in combination with other HIV treatment drugs would still receive credit for RXC 01. See 86 FR at 24164.

[124] Assessing the use of Descovy® for PrEP involved identifying instances of the use of Descovy® without an accompanying HIV diagnosis (as defined by the presence of HCC01) or use of any other anti-HIV agent (as defined by the use of any drug in RXC01 other than Descovy®). The reason the latter helps to identify non-PrEP Descovy® use is because Descovy® for active HIV–1 treatment is required to be co-administered with other anti-HIV agents.

[125] Consistent with the approach outlined in this rule, Descovy® was mapped to RXC 01 in the Q4 2019 RXC mapping applied to enrollee-level EDGE data that was used to develop the proposed 2023 benefit year factors for the adult models in this rule. If the alternative approach to RXC mapping is adopted, such that the Q4 2020 RXC mapping is applied for the 2023 benefit year recalibration of the adult models, Descovy® would not map to RXC 01 unless an exception is made.

[126] 85 FR at 24180. Also see the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software Instructions for the 2020 Benefit Year, April 15, 2021 Update, available at *https://www.cms.gov/files/document/cy2020-diy-instructions04132021.pdf*.

[127] 86 FR at 24180.

[128] 86 FR at 24180.

[129] The same concern was not present for the 2016 or 2017 enrollee-level EDGE datasets used for the 2022 benefit year model recalibration because hydroxychloroquine sulfate was not mapped to RXC 09 until the Q3 2018 crosswalk.

Q4 2020 RXC mapping, stakeholders expressed concern about the impact on the coefficients for RXC 09, and associated interaction terms, of including hydroxychloroquine sulfate in RXC mapping for recalibration given that these drugs were such low-cost. After consideration of these issues, HHS determined that hydroxychloroquine sulfate met the criteria of significant off-label prescribing, changes in clinical practice patterns associated with drug usage, and the cost of the drug being much lower than the typical cost of drugs in the same prescription drug category that warrants further consideration of whether an exception is appropriate. After determining that hydroxychloroquine sulfate met those criteria and considering the feedback from stakeholders, HHS made the determination that it should be removed. Therefore, to effectuate the targeted removal of hydroxychloroquine sulfate for the recalibration of the 2022 benefit year adult risk adjustment models, we only used 2016 and 2017 enrollee-level EDGE data, where hydroxychloroquine sulfate was not mapped to RXC 09, for the limited purpose of developing the coefficients for RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions (RXC 09 × HCC056 or 057 and 048 or 041; RXC 09 × HCC056; RXC 09 × HCC057; RXC 09 × HCC048, 041).[130]

Our consideration of the targeted removal of select drugs from RXC mappings for purposes of the 2023 benefit year model recalibration similarly identified hydroxychloroquine sulfate as a drug for further consideration. It continues to meet the criteria of significant off-label prescribing, changes in clinical practice patterns associated with drug usage, and the cost of the drug being much lower than the typical cost of drugs in the same prescription drug category. However, unlike the 2022 benefit year model recalibration, the 2023 benefit year updates involve two years of enrollee-level EDGE data (2018 and 2019 data years) where the inclusion of hydroxychloroquine sulfate could impact the annual model recalibration updates to the coefficients and associated interaction terms for RXC 09. Therefore, we determined that the targeted removal of this drug from mapping to RXC 09 was again appropriate, but to effectuate the targeted removal of this drug for purposes of the 2023 benefit year recalibration of the adult models, we would adopt a different approach than 2022 risk adjustment model recalibration and would remove the RXCUI to RXC mapping in the 2018 and 2019 enrollee-level EDGE data for hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions (RXC 09 x HCC056 or 057 and 048 or 041; RXC 09 x HCC056; RXC 09 x HCC 057; RXC 09 x HCC048, 041). We would adopt a similar approach for any future year that uses the enrollee-level EDGE data for the 2018 and 2019 benefit years for purposes of the annual model recalibration.[131] We note that the same concern was not present for the 2017 benefit year enrollee-level EDGE data—the other benefit year of data that will be used for the 2023 benefit year model recalibration—because hydroxychloroquine was not included in the RXC crosswalk until the 2018 benefit year.

We seek comment on these proposals.

e. List of Factors To Be Employed in the Risk Adjustment Models

The proposed 2023 benefit year risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2017, 2018, and 2019 enrollee-level EDGE data, including all of the model specification changes and recalibration proposals detailed above, are shown in Tables 1 through 6. The adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the $1 million threshold.[132] Table 1 contains factor coefficients for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, interacted HCC counts, and enrollment duration coefficients. Table 2 contains the factor coefficients for each child model, including the age-sex, HCCs, and interacted HCC counts coefficients. Table 3 lists the proposed HHS–HCCs that have been selected for the proposed interacted HCC counts factors that would apply to the adult and child models. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant models' maturity and severity categories, respectively.

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[130] 86 FR at 24180.

[131] Consistent with the approach finalized in the 2022 Payment Notice, the 2018 and 2019 benefit year enrollee-level EDGE datasets would continue to be used for recalibration of the 2024 benefit year models; and the 2019 benefit year enrollee-level EDGE dataset would also be used for recalibration of the 2025 benefit year models.

[132] We are not proposing changes to the high-cost risk pool parameters for the 2023 benefit year. Therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.

TABLE 1: Proposed Adult Risk Adjustment Model Factors for 2023 Benefit Year

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21-24, Male	0.178	0.131	0.096	0.070	0.070
	Age 25-29, Male	0.184	0.137	0.101	0.076	0.075
	Age 30-34, Male	0.212	0.158	0.117	0.087	0.086
	Age 35-39, Male	0.242	0.181	0.134	0.098	0.097
	Age 40-44, Male	0.271	0.205	0.153	0.111	0.110
	Age 45-49, Male	0.301	0.229	0.172	0.126	0.125
	Age 50-54, Male	0.381	0.301	0.236	0.184	0.182
	Age 55-59, Male	0.433	0.344	0.272	0.214	0.212
	Age 60-64, Male	0.509	0.409	0.328	0.262	0.260
	Age 21-24, Female	0.291	0.219	0.164	0.125	0.123
	Age 25-29, Female	0.315	0.236	0.178	0.135	0.134
	Age 30-34, Female	0.367	0.280	0.212	0.161	0.159
	Age 35-39, Female	0.418	0.324	0.248	0.189	0.187
	Age 40-44, Female	0.476	0.374	0.291	0.223	0.221
	Age 45-49, Female	0.498	0.391	0.302	0.229	0.227
	Age 50-54, Female	0.554	0.445	0.351	0.275	0.272
	Age 55-59, Female	0.557	0.447	0.353	0.276	0.274
	Age 60-64, Female	0.602	0.487	0.390	0.311	0.309
Diagnosis Factors						
HCC001	HIV/AIDS	1.171	1.037	0.949	0.888	0.886
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	8.763	8.379	8.064	7.677	7.660
HCC003	Central Nervous System Infections, Except Viral Meningitis	7.668	7.366	7.042	6.580	6.558
HCC004	Viral or Unspecified Meningitis	7.586	7.267	6.914	6.411	6.388
HCC006	Opportunistic Infections	6.894	6.657	6.346	5.847	5.823
HCC008	Metastatic Cancer	23.803	23.352	23.257	23.273	23.274
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	14.250	13.933	13.836	13.798	13.797
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors	5.798	5.612	5.525	5.459	5.457
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.679	3.472	3.351	3.255	3.252
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.444	2.287	2.185	2.099	2.096
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.077	0.961	0.838	0.715	0.711
HCC018	Pancreas Transplant Status	4.972	4.824	4.603	4.209	4.187
HCC019	Diabetes with Acute Complications	0.357	0.294	0.237	0.185	0.184
HCC020	Diabetes with Chronic Complications	0.357	0.294	0.237	0.185	0.184
HCC021	Diabetes without Complication	0.357	0.294	0.237	0.185	0.184
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19-21	0.278	0.247	0.203	0.138	0.136
HCC023	Protein-Calorie Malnutrition	10.190	9.956	9.733	9.422	9.407
HCC026	Mucopolysaccharidosis	27.310	27.073	27.002	26.980	26.979
HCC027	Lipidoses and Glycogenosis	27.310	27.073	27.002	26.980	26.979
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	7.525	7.375	7.287	7.213	7.210

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	1.260	1.153	1.052	0.951	0.948
HCC034	Liver Transplant Status/Complications	6.981	6.706	6.358	5.888	5.861
HCC035_1 [133]	Acute Liver Failure/Disease, Including Neonatal Hepatitis	7.175	7.010	6.973	6.985	6.985
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	2.731	2.530	2.426	2.345	2.342
HCC036	Cirrhosis of Liver	1.231	1.124	1.026	0.919	0.915
HCC037_1	Chronic Viral Hepatitis C	0.680	0.585	0.492	0.402	0.399
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.680	0.585	0.492	0.402	0.399
HCC041	Intestine Transplant Status/Complications	19.349	19.028	18.825	18.506	18.490
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	10.418	10.050	9.776	9.429	9.413
HCC045	Intestinal Obstruction	4.639	4.411	4.317	4.249	4.248
HCC046	Chronic Pancreatitis	2.993	2.854	2.895	3.033	3.043
HCC047	Acute Pancreatitis	2.748	2.521	2.388	2.305	2.304
HCC048	Inflammatory Bowel Disease	0.778	0.677	0.568	0.445	0.440
HCC054	Necrotizing Fasciitis	9.043	8.839	8.772	8.734	8.732
HCC055	Bone/Joint/Muscle Infections/Necrosis	4.470	4.264	4.204	4.194	4.194
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	1.266	1.152	1.046	0.947	0.944
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.823	0.728	0.609	0.479	0.474
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.288	2.119	2.006	1.907	1.903
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.288	2.119	2.006	1.907	1.903
HCC063	Cleft Lip/Cleft Palate	1.555	1.416	1.311	1.217	1.215
HCC066	Hemophilia	71.880	71.564	71.483	71.476	71.476
HCC067	Myelodysplastic Syndromes and Myelofibrosis	12.239	12.101	12.041	11.997	11.994
HCC068	Aplastic Anemia	12.239	12.101	12.041	11.997	11.994
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	12.239	12.101	12.041	11.997	11.994
HCC070	Sickle Cell Anemia (Hb-SS)	2.192	2.074	1.979	1.889	1.886
HCC071	Beta Thalassemia Major	2.192	2.074	1.979	1.889	1.886
HCC073	Combined and Other Severe Immunodeficiencies	3.744	3.636	3.600	3.611	3.613
HCC074	Disorders of the Immune Mechanism	3.744	3.636	3.600	3.611	3.613
HCC075	Coagulation Defects and Other Specified Hematological Disorders	1.692	1.596	1.516	1.436	1.433
HCC081	Drug Use with Psychotic Complications	1.946	1.774	1.620	1.450	1.444
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	1.946	1.774	1.620	1.450	1.444
HCC083	Alcohol Use with Psychotic Complications	1.151	1.023	0.908	0.796	0.792

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.151	1.023	0.908	0.796	0.792
HCC087_1	Schizophrenia	2.331	2.130	1.995	1.886	1.883
HCC087_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	2.223	2.035	1.898	1.771	1.768
HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	1.167	1.036	0.904	0.767	0.762
HCC090	Personality Disorders	0.771	0.658	0.524	0.382	0.377
HCC094	Anorexia/Bulimia Nervosa	1.957	1.821	1.716	1.614	1.610
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	7.189	6.981	6.684	6.181	6.153
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.071	0.981	0.892	0.785	0.778
HCC102	Autistic Disorder	0.895	0.786	0.667	0.548	0.544
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	0.771	0.658	0.524	0.382	0.377
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	9.152	8.994	8.931	8.905	8.905
HCC107	Quadriplegia	9.152	8.994	8.931	8.905	8.905
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	6.565	6.448	6.400	6.356	6.355
HCC109	Paraplegia	6.565	6.448	6.400	6.356	6.355
HCC110	Spinal Cord Disorders/Injuries	4.872	4.668	4.585	4.534	4.533
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	5.292	5.066	4.914	4.779	4.774
HCC112	Quadriplegic Cerebral Palsy	2.348	2.184	2.084	1.996	1.992
HCC113	Cerebral Palsy, Except Quadriplegic	0.826	0.739	0.656	0.570	0.567
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.471	1.347	1.236	1.129	1.125
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	4.849	4.761	4.732	4.703	4.700
HCC117	Muscular Dystrophy	1.659	1.531	1.411	1.280	1.275
HCC118	Multiple Sclerosis	2.305	2.156	2.045	1.937	1.933
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	1.659	1.531	1.411	1.280	1.275
HCC120	Seizure Disorders and Convulsions	1.207	1.083	0.971	0.860	0.856
HCC121	Hydrocephalus	8.794	8.572	8.329	7.970	7.954
HCC122	Coma, Brain Compression/Anoxic Damage	9.137	8.866	8.603	8.235	8.218
HCC123	Narcolepsy and Cataplexy	5.885	5.703	5.583	5.478	5.474
HCC125	Respirator Dependence/Tracheostomy Status	19.391	19.095	18.890	18.665	18.655
HCC126	Respiratory Arrest	8.094	7.750	7.451	7.070	7.053
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	8.094	7.750	7.451	7.070	7.053
HCC128	Heart Assistive Device/Artificial Heart	18.956	18.635	18.352	17.977	17.961

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC129	Heart Transplant Status/Complications	18.956	18.635	18.352	17.977	17.961
HCC130	Heart Failure	1.946	1.836	1.762	1.694	1.693
HCC131	Acute Myocardial Infarction	5.518	5.227	5.150	5.147	5.147
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	4.282	4.015	3.907	3.849	3.849
HCC135	Heart Infection/Inflammation, Except Rheumatic	7.915	7.652	7.325	6.837	6.815
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	1.730	1.625	1.530	1.440	1.438
HCC138	Major Congenital Heart/Circulatory Disorders	1.730	1.625	1.530	1.440	1.438
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.730	1.625	1.530	1.440	1.438
HCC142	Specified Heart Arrhythmias	1.721	1.591	1.481	1.365	1.368
HCC145	Intracranial Hemorrhage	10.077	9.762	9.496	9.152	9.136
HCC146	Ischemic or Unspecified Stroke	1.547	1.406	1.307	1.214	1.212
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.342	2.190	2.084	1.982	1.979
HCC150	Hemiplegia/Hemiparesis	3.111	2.980	2.948	2.949	2.949
HCC151	Monoplegia, Other Paralytic Syndromes	2.198	2.068	1.979	1.888	1.885
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	7.661	7.504	7.481	7.487	7.487
HCC154	Vascular Disease with Complications	5.122	4.991	4.954	4.937	4.938
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	6.904	6.608	6.237	5.677	5.650
HCC158	Lung Transplant Status/Complications	11.241	10.954	10.742	10.479	10.464
HCC159	Cystic Fibrosis	4.913	4.768	4.705	4.655	4.654
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.779	0.680	0.571	0.459	0.455
HCC161_1	Severe Asthma	0.779	0.680	0.571	0.459	0.455
HCC161_2	Asthma, Except Severe	0.779	0.680	0.571	0.459	0.455
HCC162	Fibrosis of Lung and Other Lung Disorders	1.692	1.571	1.469	1.364	1.361
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.292	6.048	5.729	5.238	5.213
HCC174	Exudative Macular Degeneration	1.386	1.237	1.096	0.948	0.944
HCC183	Kidney Transplant Status/Complications	6.706	6.492	6.310	5.891	5.861
HCC184	End Stage Renal Disease	21.049	20.604	20.584	20.575	20.577
HCC187	Chronic Kidney Disease, Stage 5	0.988	0.901	0.842	0.783	0.780
HCC188	Chronic Kidney Disease, Severe (Stage 4)	0.988	0.901	0.842	0.783	0.780
HCC203	Ectopic and Molar Pregnancy	2.154	1.940	1.722	1.472	1.464
HCC204	Miscarriage with Complications	0.908	0.798	0.641	0.433	0.424
HCC205	Miscarriage with No or Minor Complications	0.908	0.798	0.641	0.433	0.424
HCC207	Pregnancy with Delivery with Major Complications	3.918	3.614	3.339	3.041	3.036
HCC208	Pregnancy with Delivery with Complications	3.918	3.614	3.339	3.041	3.036

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC209	Pregnancy with Delivery with No or Minor Complications	2.796	2.577	2.305	1.925	1.913
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications	1.221	1.081	0.900	0.691	0.683
HCC211	(Ongoing) Pregnancy without Delivery with Complications	0.893	0.779	0.623	0.462	0.456
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.334	0.265	0.179	0.113	0.111
HCC217	Chronic Ulcer of Skin, Except Pressure	1.471	1.348	1.257	1.172	1.169
HCC218	Extensive Third -Degree Burns	21.774	21.387	21.092	20.726	20.709
HCC219	Major Skin Burn or Condition	2.417	2.278	2.184	2.106	2.103
HCC223	Severe Head Injury	16.806	16.566	16.369	16.139	16.129
HCC226	Hip and Pelvic Fractures	7.986	7.739	7.691	7.688	7.689
HCC228	Vertebral Fractures without Spinal Cord Injury	4.055	3.873	3.763	3.662	3.659
HCC234	Traumatic Amputations and Amputation Complications	4.788	4.611	4.554	4.529	4.528
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	20.991	20.797	20.488	20.005	19.981
HCC253	Artificial Openings for Feeding or Elimination	5.803	5.684	5.657	5.654	5.654
HCC254	Amputation Status, Upper Limb or Lower Limb	1.685	1.522	1.403	1.302	1.299
Interacted HCC Counts Factors						
	Severe illness, 1 payment HCC	-4.972	-4.824	-4.603	-4.209	-4.187
	Severe illness, 2 payment HCCs	-4.958	-4.824	-4.594	-4.209	-4.187
	Severe illness, 3 payment HCCs	-3.796	-3.665	-3.329	-2.788	-2.763
	Severe illness, 4 payment HCCs	-2.837	-2.627	-2.160	-1.445	-1.413
	Severe illness, 5 payment HCCs	-2.036	-1.708	-1.094	-0.196	-0.157
	Severe illness, 6 payment HCCs	-1.576	-1.091	-0.319	0.768	0.814
	Severe illness, 7 payment HCCs	-0.606	0.108	1.082	2.407	2.463
	Severe illness, 8 payment HCCs	-0.399	0.377	1.415	2.829	2.889
	Severe illness, 9 payment HCCs	1.675	2.727	3.986	5.656	5.726
	Severe illness, 10 or more payment HCCs	10.392	12.008	13.694	15.874	15.966
	Transplant severe illness, 4 payment HCCs	3.563	3.539	3.534	3.560	3.567
	Transplant severe illness, 5 payment HCCs	6.997	6.977	6.968	7.011	7.018
	Transplant severe illness, 6 payment HCCs	13.244	13.242	13.276	13.385	13.396
	Transplant severe illness, 7 payment HCCs	18.237	18.225	18.266	18.387	18.397
	Transplant severe illness, 8 or more payment HCCs	33.690	33.890	34.117	34.474	34.495
Enrollment Duration Factors						
	Enrolled for 1 month, at least one payment HCC	9.276	7.861	6.698	5.524	5.483
	Enrolled for 2 months, at least one payment HCC	3.425	2.687	2.120	1.647	1.631
	Enrolled for 3 months, at least one payment HCC	1.925	1.475	1.118	0.838	0.829
	Enrolled for 4 months, at least one payment HCC	1.039	0.747	0.506	0.327	0.321

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Enrolled for 5 months, at least one payment HCC	0.693	0.485	0.310	0.173	0.169
	Enrolled for 6 months, at least one payment HCC	0.454	0.304	0.172	0.075	0.071
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	8.084	7.444	7.084	6.752	6.745
RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	7.280	6.771	6.640	6.685	6.689
RXC 03[134]	Antiarrhythmics	0.103	0.094	0.086	0.063	0.039
RXC 04	Phosphate Binders	1.491	1.608	1.568	1.643	1.631
RXC 05	Inflammatory Bowel Disease Agents	1.553	1.314	1.127	0.879	0.870
RXC 06	Insulin	1.196	0.976	0.736	0.496	0.487
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.725	0.618	0.502	0.384	0.380
RXC 08	Multiple Sclerosis Agents	22.757	21.749	21.373	21.176	21.176
RXC 09[135]	Immune Suppressants and Immunomodulators	16.519	15.829	15.703	15.737	15.740
RXC 10	Cystic Fibrosis Agents	16.556	16.178	16.118	16.167	16.171
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 and HCC 001	2.676	2.811	3.123	3.539	3.550
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)	-0.680	-0.585	-0.492	-0.402	-0.399
RXC03xHCC142	Additional effect for enrollees with RXC 03 and HCC 142	0.000	0.000	0.000	0.000	0.000
RXC04xHCC184, 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
RXC05xHCC048, 041	Additional effect for enrollees with RXC 05 and (HCC 048 or 041)	-0.644	-0.458	-0.379	-0.300	-0.297
RXC06xHCC018, 019, 020, 021	Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021)	0.647	0.718	0.814	0.878	0.881
RXC07xHCC018, 019, 020, 021	Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021)	-0.180	-0.128	-0.096	-0.106	-0.106
RXC08xHCC118	Additional effect for enrollees with RXC 08 and HCC 118	0.015	0.510	0.888	1.249	1.257

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC09xHCC056 or 057and048 or 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057)	0.884	0.776	0.832	0.877	0.878
RXC09xHCC056	Additional effect for enrollees with RXC 09 and HCC 056	-1.266	-1.152	-1.046	-0.947	-0.944
RXC09xHCC057	Additional effect for enrollees with RXC 09 and HCC 057	-0.823	-0.728	-0.609	-0.479	-0.474
RXC09xHCC048, 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041)	0.431	0.774	0.884	1.018	1.023
RXC10xHCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	49.790	49.773	49.829	49.924	49.926

TABLE 2: Proposed Child Risk Adjustment Model Factors for 2023 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2-4, Male	0.273	0.202	0.153	0.116	0.115
Age 5-9, Male	0.192	0.133	0.095	0.068	0.067
Age 10-14, Male	0.224	0.163	0.120	0.094	0.093
Age 15-20, Male	0.267	0.202	0.152	0.118	0.117
Age 2-4, Female	0.225	0.163	0.126	0.100	0.099
Age 5-9, Female	0.166	0.111	0.081	0.060	0.059
Age 10-14, Female	0.212	0.154	0.116	0.091	0.091
Age 15-20, Female	0.337	0.257	0.195	0.149	0.148
Diagnosis Factors					
HIV/AIDS	6.429	5.960	5.765	5.649	5.647
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	14.096	13.866	13.726	13.622	13.621
Central Nervous System Infections, Except Viral Meningitis	13.094	12.934	12.866	12.837	12.837
Viral or Unspecified Meningitis	11.331	11.241	11.109	10.995	10.994
Opportunistic Infections	15.156	15.121	15.054	14.969	14.965
Metastatic Cancer	31.899	31.609	31.506	31.464	31.463
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	8.432	8.188	8.073	7.991	7.988
Non-Hodgkin Lymphomas and Other Cancers and Tumors	6.783	6.561	6.434	6.329	6.326
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.961	3.790	3.658	3.530	3.525
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.961	3.790	3.658	3.530	3.525
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.014	0.878	0.759	0.617	0.613
Pancreas Transplant Status	14.250	14.144	14.055	13.989	13.985
Diabetes with Acute Complications	2.502	2.226	1.938	1.636	1.628
Diabetes with Chronic Complications	2.502	2.226	1.938	1.636	1.628
Diabetes without Complication	2.502	2.226	1.938	1.636	1.628
Protein-Calorie Malnutrition	17.721	17.613	17.580	17.574	17.573
Mucopolysaccharidosis	38.371	38.095	38.005	37.967	37.966

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Lipidoses and Glycogenosis	38.371	38.095	38.005	37.967	37.966
Congenital Metabolic Disorders, Not Elsewhere Classified	5.598	5.463	5.374	5.298	5.295
Amyloidosis, Porphyria, and Other Metabolic Disorders	5.598	5.463	5.374	5.298	5.295
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.772	6.502	6.396	6.346	6.345
Liver Transplant Status/Complications	14.250	14.144	14.055	13.989	13.985
Acute Liver Failure/Disease, Including Neonatal Hepatitis	10.018	9.833	9.778	9.776	9.775
Chronic Liver Failure/End-Stage Liver Disorders	9.546	9.360	9.278	9.240	9.239
Cirrhosis of Liver	2.657	2.549	2.455	2.373	2.374
Chronic Viral Hepatitis C	1.774	1.629	1.541	1.506	1.506
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.693	0.589	0.484	0.385	0.383
Intestine Transplant Status/Complications	13.918	13.773	13.667	13.578	13.576
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	17.163	16.863	16.788	16.799	16.801
Intestinal Obstruction	3.430	3.214	3.061	2.912	2.907
Chronic Pancreatitis	11.310	11.100	11.034	11.016	11.017
Acute Pancreatitis	4.408	4.138	3.969	3.820	3.816
Inflammatory Bowel Disease	10.270	9.855	9.687	9.584	9.581
Necrotizing Fasciitis	3.164	2.937	2.798	2.693	2.690
Bone/Joint/Muscle Infections/Necrosis	3.164	2.937	2.798	2.693	2.690
Rheumatoid Arthritis and Specified Autoimmune Disorders	5.297	5.022	4.885	4.795	4.793
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.300	1.170	1.038	0.911	0.906
Osteogenesis Imperfecta and Other Osteodystrophies	1.188	1.076	0.989	0.952	0.950
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.188	1.076	0.989	0.952	0.950
Cleft Lip/Cleft Palate	1.348	1.157	0.959	0.771	0.765
Hemophilia	72.572	72.060	71.904	71.853	71.853
Myelodysplastic Syndromes and Myelofibrosis	12.112	11.943	11.864	11.812	11.811
Aplastic Anemia	12.112	11.943	11.864	11.812	11.811
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	12.112	11.943	11.864	11.812	11.811
Sickle Cell Anemia (Hb-SS)	4.650	4.438	4.306	4.201	4.197
Beta Thalassemia Major	4.650	4.438	4.306	4.201	4.197
Combined and Other Severe Immunodeficiencies	4.084	3.920	3.820	3.728	3.724
Disorders of the Immune Mechanism	4.084	3.920	3.820	3.728	3.724
Coagulation Defects and Other Specified Hematological Disorders	3.254	3.117	3.002	2.895	2.892
Drug Use with Psychotic Complications	2.069	1.882	1.730	1.578	1.573
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.069	1.882	1.730	1.578	1.573
Alcohol Use with Psychotic Complications	1.256	1.112	0.971	0.815	0.810
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.256	1.112	0.971	0.815	0.810
Schizophrenia	4.160	3.861	3.673	3.518	3.514
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.217	2.957	2.762	2.574	2.569

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Major Depressive Disorder, Severe, and Bipolar Disorders	2.404	2.188	1.999	1.813	1.807
Personality Disorders	0.506	0.411	0.304	0.219	0.218
Anorexia/Bulimia Nervosa	2.260	2.088	1.960	1.844	1.840
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	11.538	11.458	11.385	11.331	11.329
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.541	1.388	1.245	1.096	1.089
Autistic Disorder	2.404	2.188	1.999	1.813	1.807
Pervasive Developmental Disorders, Except Autistic Disorder	0.506	0.411	0.304	0.219	0.218
Traumatic Complete Lesion Cervical Spinal Cord	9.534	9.288	9.170	9.099	9.098
Quadriplegia	9.534	9.288	9.170	9.099	9.098
Traumatic Complete Lesion Dorsal Spinal Cord	8.988	8.747	8.655	8.602	8.601
Paraplegia	8.988	8.747	8.655	8.602	8.601
Spinal Cord Disorders/Injuries	3.486	3.281	3.131	2.982	2.975
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	48.007	47.749	47.629	47.534	47.531
Quadriplegic Cerebral Palsy	3.118	2.961	2.881	2.822	2.821
Cerebral Palsy, Except Quadriplegic	1.411	1.269	1.123	0.968	0.962
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.616	1.469	1.357	1.248	1.244
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	9.977	9.787	9.721	9.697	9.697
Muscular Dystrophy	5.687	5.505	5.380	5.258	5.254
Multiple Sclerosis	12.134	11.693	11.573	11.551	11.552
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	5.687	5.505	5.380	5.258	5.254
Seizure Disorders and Convulsions	1.551	1.413	1.266	1.129	1.124
Hydrocephalus	11.308	11.280	11.259	11.254	11.254
Coma, Brain Compression/Anoxic Damage	11.213	11.150	11.071	11.028	11.026
Narcolepsy and Cataplexy	5.298	5.103	4.953	4.799	4.793
Respirator Dependence/Tracheostomy Status	27.709	27.451	27.357	27.326	27.325
Respiratory Arrest	14.691	14.404	14.285	14.230	14.230
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	14.691	14.404	14.285	14.230	14.230
Heart Assistive Device/Artificial Heart	13.918	13.773	13.667	13.578	13.576
Heart Transplant Status/Complications	13.918	13.773	13.667	13.578	13.576
Heart Failure	4.805	4.702	4.634	4.582	4.580
Acute Myocardial Infarction	1.458	1.316	1.201	1.094	1.091
Unstable Angina and Other Acute Ischemic Heart Disease	1.458	1.316	1.201	1.094	1.091
Heart Infection/Inflammation, Except Rheumatic	15.257	15.116	15.014	14.897	14.892
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	2.816	2.592	2.403	2.194	2.181
Major Congenital Heart/Circulatory Disorders	0.974	0.842	0.703	0.571	0.568
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.698	0.593	0.496	0.430	0.428
Specified Heart Arrhythmias	2.605	2.419	2.291	2.169	2.165
Intracranial Hemorrhage	12.911	12.812	12.746	12.660	12.654

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Ischemic or Unspecified Stroke	1.877	1.766	1.705	1.648	1.647
Cerebral Aneurysm and Arteriovenous Malformation	2.557	2.380	2.267	2.129	2.119
Hemiplegia/Hemiparesis	4.097	3.963	3.877	3.782	3.777
Monoplegia, Other Paralytic Syndromes	2.562	2.401	2.266	2.127	2.122
Atherosclerosis of the Extremities with Ulceration or Gangrene	12.054	11.811	11.700	11.637	11.635
Vascular Disease with Complications	7.002	6.852	6.796	6.764	6.763
Pulmonary Embolism and Deep Vein Thrombosis	19.955	19.813	19.737	19.693	19.692
Lung Transplant Status/Complications	13.918	13.773	13.667	13.578	13.576
Cystic Fibrosis	54.075	53.528	53.389	53.377	53.377
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.973	1.798	1.651	1.502	1.497
Severe Asthma	1.310	1.149	0.982	0.800	0.794
Asthma, Except Severe	0.371	0.288	0.198	0.124	0.121
Fibrosis of Lung and Other Lung Disorders	1.310	1.149	0.982	0.800	0.794
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	10.858	10.819	10.800	10.793	10.793
Kidney Transplant Status/Complications	14.250	14.144	14.055	13.989	13.985
End Stage Renal Disease	35.540	35.287	35.230	35.234	35.234
Chronic Kidney Disease, Stage 5	3.500	3.273	3.093	2.995	2.987
Chronic Kidney Disease, Severe (Stage 4)	3.500	3.273	3.093	2.995	2.987
Ectopic and Molar Pregnancy	2.005	1.788	1.554	1.287	1.276
Miscarriage with Complications	0.867	0.737	0.556	0.329	0.319
Miscarriage with No or Minor Complications	0.867	0.737	0.556	0.329	0.319
Pregnancy with Delivery with Major Complications	3.599	3.289	2.974	2.581	2.568
Pregnancy with Delivery with Complications	3.599	3.289	2.974	2.581	2.568
Pregnancy with Delivery with No or Minor Complications	2.570	2.339	2.035	1.585	1.567
(Ongoing) Pregnancy without Delivery with Major Complications	0.942	0.797	0.594	0.378	0.371
(Ongoing) Pregnancy without Delivery with Complications	0.942	0.797	0.594	0.378	0.371
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.447	0.344	0.227	0.135	0.134
Chronic Ulcer of Skin, Except Pressure	1.312	1.190	1.080	0.988	0.986
Extensive Third -Degree Burns	19.825	19.594	19.501	19.461	19.461
Major Skin Burn or Condition	1.901	1.739	1.609	1.491	1.488
Severe Head Injury	19.825	19.594	19.501	19.461	19.461
Hip and Pelvic Fractures	3.488	3.241	3.079	2.963	2.959
Vertebral Fractures without Spinal Cord Injury	3.451	3.235	3.067	2.894	2.888
Traumatic Amputations and Amputation Complications	3.540	3.302	3.128	2.950	2.943
Stem Cell, Including Bone Marrow, Transplant Status/Complications	13.918	13.773	13.667	13.578	13.576
Artificial Openings for Feeding or Elimination	6.793	6.599	6.560	6.565	6.566
Amputation Status, Upper Limb or Lower Limb	3.540	3.302	3.128	2.950	2.943
Interacted HCC Counts Factors					
Severe illness, 1 payment HCC	-9.888	-9.970	-10.057	-10.158	-10.162
Severe illness, 2 payment HCCs	-9.814	-9.827	-9.906	-10.003	-10.006
Severe illness, 3 payment HCCs	-8.266	-8.306	-8.198	-8.090	-8.086
Severe illness, 4 payment HCCs	-7.829	-7.855	-7.707	-7.515	-7.506
Severe illness, 5 payment HCCs	-5.539	-5.425	-5.125	-4.779	-4.766

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Severe illness, 6 or 7 payment HCCs	-0.942	-0.645	-0.200	0.273	0.290
Severe illness, 8 or more payment HCCs	15.918	16.769	17.562	18.301	18.326
Transplant severe illness, 4 or more payment HCCs	16.762	16.867	16.917	16.950	16.952

TABLE 3: HCCs Selected for the Proposed HCC Interacted Counts Variables for the Adult and Child Models Beginning with the 2023 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 18 Pancreas Transplant	X	X
HCC 23 Protein-Calorie Malnutrition	X	
HCC 34 Liver Transplant Status/Complications	X	X
HCC 41 Intestine Transplant Status/Complications	X	X
HCC 42 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	X	
HCC 96 Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	X	
HCC 121 Hydrocephalus	X	
HCC 122 Coma, Brain Compression/Anoxic Damage	X	
HCC 125 Respirator Dependence/Tracheostomy Status	X	
HCC 135 Heart Infection/Inflammation, Except Rheumatic	X	
HCC 145 Intracranial Hemorrhage	X	
HCC 156 Pulmonary Embolism and Deep Vein Thrombosis	X	
HCC 158 Lung Transplant Status/Complications	X	X
HCC 163 Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	X	
HCC 183 Kidney Transplant Status/Complications	X	X
HCC 218 Extensive Third -Degree Burns	X	
HCC 223 Severe Head Injury	X	
HCC 251 Stem Cell, Including Bone Marrow, Transplant Status/Complications	X	X
G13 (Includes HCC 126 Respiratory Arrest and HCC 127 Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes)	X	
G14 (Includes HCC 128 Heart Assistive Device/Artificial Heart and HCC 129 Heart Transplant Status/Complications)	X	X

TABLE 4: Proposed Infant Risk Adjustment Model Factors for 2023 Benefit Year

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	211.839	210.253	209.766	209.650	209.649
Extremely Immature * Severity Level 4	148.689	146.914	146.263	145.989	145.984
Extremely Immature * Severity Level 3	33.465	32.024	31.445	31.172	31.166
Extremely Immature * Severity Level 2	33.465	32.024	31.445	31.172	31.166
Extremely Immature * Severity Level 1 (Lowest)	33.465	32.024	31.445	31.172	31.166
Immature * Severity Level 5 (Highest)	114.339	112.648	112.101	111.930	111.927
Immature * Severity Level 4	68.723	67.058	66.498	66.297	66.293
Immature * Severity Level 3	33.465	32.024	31.445	31.172	31.166
Immature * Severity Level 2	30.547	29.122	28.535	28.241	28.233

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Immature * Severity Level 1 (Lowest)	25.485	24.145	23.552	23.233	23.224
Premature/Multiples * Severity Level 5 (Highest)	101.847	100.436	99.969	99.809	99.806
Premature/Multiples * Severity Level 4	28.534	27.101	26.508	26.227	26.221
Premature/Multiples * Severity Level 3	13.748	12.735	12.108	11.610	11.594
Premature/Multiples * Severity Level 2	7.676	6.953	6.336	5.695	5.672
Premature/Multiples * Severity Level 1 (Lowest)	5.767	5.141	4.569	4.022	4.004
Term * Severity Level 5 (Highest)	78.537	77.271	76.765	76.525	76.520
Term * Severity Level 4	15.369	14.386	13.769	13.290	13.278
Term * Severity Level 3	5.921	5.324	4.752	4.173	4.153
Term * Severity Level 2	3.667	3.171	2.610	2.020	1.999
Term * Severity Level 1 (Lowest)	1.898	1.532	1.094	0.778	0.769
Age1 * Severity Level 5 (Highest)	63.541	62.812	62.524	62.386	62.383
Age1 * Severity Level 4	12.611	12.090	11.787	11.574	11.567
Age1 * Severity Level 3	2.978	2.695	2.472	2.291	2.285
Age1 * Severity Level 2	1.969	1.732	1.508	1.303	1.296
Age1 * Severity Level 1 (Lowest)	0.573	0.489	0.433	0.392	0.391
Age 0 Male	0.534	0.491	0.451	0.386	0.384
Age 1 Male	0.112	0.096	0.077	0.058	0.058

TABLE 5: HHS HCCs Included in Infant Model Maturity Categories

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

TABLE 6: HHS HCCs Included in Infant Model Severity Categories

Severity Category	HCC/Description
Severity Level 5 (Highest)	Metastatic Cancer
Severity Level 5	Pancreas Transplant Status
Severity Level 5	Liver Transplant Status/Complications
Severity Level 5	Intestine Transplant Status/Complications
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Severity Level 5	Respirator Dependence/Tracheostomy Status
Severity Level 5	Heart Assistive Device/Artificial Heart
Severity Level 5	Heart Transplant Status/Complications
Severity Level 5	Heart Failure
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
Severity Level 5	Lung Transplant Status/Complications
Severity Level 5	Kidney Transplant Status/Complications
Severity Level 5	End Stage Renal Disease
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia
Severity Level 4	Mucopolysaccharidosis
Severity Level 4	Adrenal, Pituitary, and Other Significant Endocrine Disorders
Severity 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 Category	HCC/Description
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis
Severity Level 4	Aplastic Anemia
Severity Level 4	Combined and Other Severe Immunodeficiencies
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord
Severity Level 4	Quadriplegia
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease
Severity Level 4	Quadriplegic Cerebral Palsy
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy
Severity Level 4	Coma, Brain Compression/Anoxic Damage
Severity Level 4	Respiratory Arrest
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
Severity Level 4	Acute Myocardial Infarction
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic
Severity Level 4	Major Congenital Heart/Circulatory Disorders
Severity Level 4	Intracranial Hemorrhage
Severity Level 4	Ischemic or Unspecified Stroke
Severity Level 4	Vascular Disease with Complications
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections
Severity Level 4	Chronic Kidney Disease, Stage 5
Severity Level 4	Artificial Openings for Feeding or Elimination
Severity Level 3	HIV/AIDS
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis
Severity Level 3	Opportunistic Infections
Severity Level 3	Non-Hodgkin Lymphomas and Other Cancers and Tumors
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers
Severity Level 3	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors
Severity Level 3	Lipidoses and Glycogenosis
Severity Level 3	Intestinal Obstruction
Severity Level 3	Necrotizing Fasciitis
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies
Severity Level 3	Cleft Lip/Cleft Palate
Severity Level 3	Hemophilia
Severity Level 3	Disorders of the Immune Mechanism
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders
Severity Level 3	Drug Use with Psychotic Complications
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
Severity Level 3	Alcohol Use with Psychotic Complications
Severity Level 3	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord
Severity Level 3	Paraplegia
Severity Level 3	Spinal Cord Disorders/Injuries
Severity Level 3	Cerebral Palsy, Except Quadriplegic
Severity Level 3	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies
Severity Level 3	Muscular Dystrophy
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders
Severity Level 3	Hydrocephalus
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders
Severity Level 3	Specified Heart Arrhythmias
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation

Severity Category	HCC/Description
Severity Level 3	Hemiplegia/Hemiparesis
Severity Level 3	Cystic Fibrosis
Severity Level 3	Extensive Third -Degree Burns
Severity Level 3	Severe Head Injury
Severity Level 3	Hip and Pelvic Fractures
Severity Level 3	Vertebral Fractures without Spinal Cord Injury
Severity Level 2	Viral or Unspecified Meningitis
Severity Level 2	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors
Severity Level 2	Diabetes with Acute Complications
Severity Level 2	Diabetes with Chronic Complications
Severity Level 2	Diabetes without Complication
Severity Level 2	Protein-Calorie Malnutrition
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders
Severity Level 2	Cirrhosis of Liver
Severity Level 2	Chronic Pancreatitis
Severity Level 2	Acute Pancreatitis
Severity Level 2	Inflammatory Bowel Disease
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn
Severity Level 2	Sickle Cell Anemia (Hb-SS)
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes
Severity Level 2	Seizure Disorders and Convulsions
Severity Level 2	Monoplegia, Other Paralytic Syndromes
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis
Severity Level 2	Severe Asthma
Severity Level 2	Fibrosis of Lung and Other Lung Disorders
Severity Level 2	Chronic Kidney Disease, Severe (Stage 4)
Severity Level 2	Chronic Ulcer of Skin, Except Pressure
Severity Level 2	Major Skin Burn or Condition
Severity Level 1 (Lowest)	Chronic Viral Hepatitis C
Severity Level 1	Chronic Hepatitis, Except Chronic Viral Hepatitis C
Severity Level 1	Beta Thalassemia Major
Severity Level 1	Autistic Disorder
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder
Severity Level 1	Multiple Sclerosis
Severity Level 1	Asthma, Except Severe
Severity Level 1	Traumatic Amputations and Amputation Complications
Severity Level 1	Amputation Status, Upper Limb or Lower Limb

f. Cost-Sharing Reduction Adjustments

We propose to continue including an adjustment for the receipt of CSRs in the risk adjustment models in all 50 states and the District of Columbia. While we continue to study and explore ways to update the CSR adjustments to improve prediction for CSR enrollees,[136] for the 2023 benefit year, to maintain stability and certainty for issuers, we are proposing to maintain the CSR adjustment factors finalized in the 2019, 2020, 2021, and 2022 Payment Notices.[137] See Table 7. We also propose to continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent.[138] We seek comment on these proposals.

[136] See Appendix A of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[137] See 83 FR 16930 at 16953; 84 FR 17454 at 17478 through 17479; 85 FR 29164 at 29190; and 86 FR 24140 at 24181.

[138] See 81 FR 12203 at 12228.

TABLE 7: Cost-Sharing Reduction Adjustment Factors

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

g. Model Performance Statistics

Each benefit year, to evaluate risk adjustment model performance, we examine each model's R-squared statistic and 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 risk adjustment models.[139] As detailed in the 2021 RA Technical Paper, the proposed model specification updates, when taken together, generally demonstrate improvements in R-squared as well as PRs.[140] Because we propose to blend the coefficients from separately solved models based on the 2017, 2018, and 2019 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 2023 benefit models are shown in Table 8.

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

R-Squared Statistic			
Models	2017 Enrollee level EDGE Data	2018 Enrollee-level EDGE Data	2019 Enrollee-level EDGE Data
Platinum Adult	0.4501	0.4467	0.4475
Gold Adult	0.4438	0.4400	0.4407
Silver Adult	0.4405	0.4366	0.4371
Bronze Adult	0.4376	0.4337	0.4340
Catastrophic Adult	0.4374	0.4336	0.4339
Platinum Child	0.3487	0.3527	0.3535
Gold Child	0.3453	0.3494	0.3501
Silver Child	0.3430	0.3470	0.3476
Bronze Child	0.3405	0.3444	0.3451
Catastrophic Child	0.3404	0.3443	0.3450
Platinum Infant	0.3311	0.3112	0.3146
Gold Infant	0.3272	0.3073	0.3107
Silver Infant	0.3252	0.3053	0.3087
Bronze Infant	0.3237	0.3037	0.3073
Catastrophic Infant	0.3236	0.3037	0.3072

[139] Hileman, Geof and Spenser Steele. ''Accuracy of Claims-Based Risk Scoring Models.'' Society of Actuaries. October 2016.

[140] See, for example, Chapter 5.1 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

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

In part 2 of the 2022 Payment Notice final rule, 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.[141] We explained that under this approach, we will no longer republish these formulas in future annual HHS notice of benefit and payment parameter 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 would continue to apply the formula as finalized in the 2021 Payment Notice in the states where HHS operates the risk adjustment program in the 2023 benefit year.[142] Additionally, as finalized in the 2020 Payment Notice, we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking.[143] We are not proposing any changes to the high-cost risk pool parameters for the 2023 benefit year; therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.

4. Risk Adjustment State Flexibility Requests (§ 153.320(d))

We propose to repeal the ability of states to request a reduction in risk adjustment state transfers starting with the 2024 benefit year, with an exception for states that have requested such reductions in prior benefit years. We also solicit comments on requests from Alabama to reduce risk adjustment state transfers for the 2023 benefit year in the individual (including the catastrophic and non-catastrophic risk pools) and small group markets. In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the applicable risk adjustment state transfers calculated by HHS using the state payment transfer formula for the state's individual (catastrophic or non-catastrophic risk pools), small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's markets.[144] We finalized that any requests we received would be published in the applicable benefit year's proposed HHS notice of benefit and payment parameters, and the supporting evidence provided by the state in support of its request would be made available for public comment.[145]

In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, states must submit such requests with the supporting evidence and analysis outlined under § 153.320(d)(1) by August 1st of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year. If approved by HHS, state reduction requests will be applied to the plan PMPM payment or charge state payment transfer amount (Ti in the state payment transfer formula).[146] For the 2020 and 2021 benefit years, the state of Alabama submitted a 50 percent risk adjustment transfer reduction request for its small group market and HHS approved both requests.[147] For the 2022 benefit year, the state of Alabama submitted 50 percent risk adjustment transfer reduction requests for its individual (including catastrophic and non-catastrophic risk pools) and small group markets, and HHS approved both requests.[148]

a. Requests To Reduce Risk Adjustment Transfers for the 2023 Benefit Year

For the 2023 benefit year, HHS received requests from Alabama to reduce risk adjustment state transfers for its individual and small group markets by 50 percent.[149] Alabama asserts that the state payment transfer formula produces imprecise results in Alabama because of the extremely unbalanced market share in the individual and small group markets. Specifically, Alabama asserts that the presence of a dominant issuer in the individual and small group markets precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share, which Alabama believes precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the individual market for the 2023 benefit year would not exceed 1 percent, the de minimis premium increase threshold set forth in § 153.320(d)(1)(iii) and (d)(4)(i)(B).

In the small group market request, Alabama states that its review of the issuers' financial data from the 2020 benefit year suggests that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2023 benefit year would exceed the de minimis threshold. However, Alabama asserts that HHS should consider data for years prior to 2021 to analyze its small group market request for the 2023 benefit year because the COVID–19 PHE renders an analysis based on 2020 data unreliable. Alabama further notes that there is no regulatory requirement to analyze the request using the most recent available year of data. Alabama further states that the de minimis regulatory threshold does not work when a small issuer receives a risk adjustment payment, and that the test should instead be based on what percentage market share the large issuer in Alabama holds compared to the other issuers in the market.

We seek comment on the requests to reduce risk adjustment state transfers in the Alabama individual and small group markets by 50 percent for the 2023 benefit year. The requests and additional documentation submitted by Alabama are posted under the ''State Flexibility Requests'' heading at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html.*

b. Repeal of Risk Adjustment State Flexibility To Request a Reduction in Risk Adjustment State Transfers (§ 153.320(d))

We propose to generally repeal the flexibility for states to request reductions of transfers calculated by HHS under the state payment transfer formula in all state market risk pools starting with the 2024 benefit year, with an exception for states that previously requested a reduction in risk adjustment state transfers under § 153.320(d). Section 3 of E.O. 14009 directs HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related

[141] See 86 FR at 24183–24186.

[142] For an illustration and further details on the state payment transfer formula, see 86 FR at 24183–24186.

[143] See 84 FR at 17466–17468.

[144] 83 FR 16955–16960.

[145] If the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence. See 45 CFR 153.320(d)(3).

[146] For an illustration of the state payment transfer formula, see 86 FR at 24184.

[147] See 84 FR 17484–17485 and 85 FR 29193–29194.

[148] See 86 FR 24187–24189.

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

to Medicaid and the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether they are inconsistent with policy priorities described in Section 1 of E.O. 14009, to include protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals.[150] Consistent with this directive, we have been considering whether the risk adjustment state flexibility under § 153.320(d) is inconsistent with policies described in Sections 1 and 3 of E.O. 14009.

In prior rulemakings, we received comments stating that this policy does not strengthen the ACA and requesting that HHS repeal this policy, as risk adjustment state flexibility may result in risk selection, market destabilization, increased premiums, smaller networks, and worse plan options. Specifically, these commenters stated that reducing transfers to plans with higher-risk enrollees could create incentives for issuers to avoid enrolling high-risk enrollees in the future through distorting plan offering and designs, including by avoiding broad network plans, not offering platinum plans at all, and only offering limited gold plans. Commenters further stated that issuers could also distort plan designs by excluding coverage or imposing high cost sharing for certain drugs or services. Some commenters stated that the risk adjustment state payment transfer formula already adjusts for differences in types of individuals enrolled in different states and aggregate differences in prices and utilization by using the statewide average premium as a scaling factor, so state flexibility to account for state-specific factors is unnecessary.[151] The commenters also generally noted that states that believe the HHS risk adjustment methodology does not work properly in their markets have the option, if they operate their Exchange, to operate a state-based risk adjustment program.

Moreover, since HHS finalized the risk adjustment state flexibility policy in the 2019 Payment Notice, there have been changes in Administration policy priorities. This Administration's stated priorities include protecting and strengthening the ACA, of which the risk adjustment program is an integral part, and supporting protections for people with pre-existing conditions;[152] in contrast, past Administration priorities included reducing economic burden on states and other entities and maximizing state flexibility.[153] Market participation has also stabilized in recent years, with new issuers entering the market and premiums remaining stable since 2019.[154]

Following our further consideration of this policy consistent with the instructions in the E.O., prior comments on this policy, and the earlier described changes, as well as the general low level of interest states have expressed in the policy, we propose, beginning for the 2024 benefit year, to repeal the ability for states to request a reduction in risk adjustment state transfers of up to 50 percent in any state market risk pool with an exception for states who previously requested this flexibility in prior benefit years. We propose to effectuate this change by amending the introductory text to § 153.320(d) to reflect that this flexibility was available from the 2020 through 2023 benefit years for all states and to add a new second sentence to the introductory text in § 153.320(d) to capture the proposal to permit states that previously participated to request these reductions beginning with the 2024 benefit year.

In addition, we propose to add new § 153.320(d)(5) to define prior participants as any state that previously submitted a risk adjustment state flexibility request for any market risk pool. We are proposing to create an exception for states that previously participated because there is one state, Alabama, that requested this flexibility since 2020 (the first benefit year these requests were permitted). Alabama has generally been able to demonstrate a de minimis impact on the market risk pool in which the reduction in transfers was requested, meaning any impacted issuer would not need to increase their premiums by more than 1 percent to account for the reduction to risk adjustment transfers. As explained in the state's requests, Alabama has unique state characteristics, in which there is an extremely unbalanced market share in both its individual and small group markets, with one very dominant issuer and a few very small competitors that produces imprecise results under the HHS risk adjustment methodology, which is calibrated on a national dataset.[155] We do not believe that continuing to permit a reduction in risk adjustment transfers in this state, given its unique characteristics, undermines the efficacy of risk adjustment. In addition, we believe that any minimal impact on transfers in this state is outweighed by the benefit of maintaining and taking steps to support the state's effort to maximize participation in its state market risk pools that have developed as a result of this flexibility in prior years, and that might otherwise only have a single issuer offering coverage in the absence of this flexibility.

We note that this proposal to retain this flexibility for prior participants is only intended to permit such states to continue to request risk adjustment state flexibility in benefit year 2024 and beyond, not to automatically apply previously approved transfer reductions to future benefit years. Under this proposal, a prior participant will still be required to submit its request(s) to reduce risk adjustment state transfers each year in the timeframe, form, and manner set forth in § 153.320(d)(1) and (2), and HHS will continue to evaluate risk adjustment state flexibility requests for approval as set forth in § 153.320(d)(4). If state requests do not meet the applicable approval criteria, HHS will not approve the requests. The flexibility for HHS to approve a reduction amount that is lower than the amount requested by the State in § 153.320(d)(4)(ii) would also be retained.

Finally, for reduction requests for the 2024 benefit year and beyond, we also propose to remove the option for the state to demonstrate the state-specific factors that warrant an adjustment to more precisely account for relative risk differences in the state individual catastrophic, individual non-catastrophic, small group, or merged

[150] E.O. 14009; 86 FR 7793 (Feb. 2, 2021).

[151] See *https://www.brookings.edu/wp-content/uploads/2020/12/FiedlerLaytonCommentLetterNBPP2022.pdf.*

[152] Executive Order 14009; 86 FR 7793 (Feb. 2, 2021).

[153] Executive Order 13765; 82 FR 8351 (Jan. 24, 2017).

[154] See, for example, the 2019, 2020, and 2021 Unified Rate Review Public Use Files, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/ratereview.* See also the Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.* See also the Summary Report on Permanent Risk Adjustment Transfers for the 2019 Benefit year, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2019.pdf.*

[155] See Alabama requests for 2020 through 2022 under the Risk Adjustment State Flexibility Requests heading at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.* Some of the information in these requests is redacted in accordance with 45 CFR 153.320(d)(3). If the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence.

market risk pool as one of the justifications for the state's request and one of the criteria for HHS approval. Instead, we propose to require prior participants to meet the other existing criterion that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments, as the sole justification for the state's request and criterion for HHS approval beginning with 2024 benefit year requests. To effectuate this change, we propose to amend paragraph (d)(1)(iii) of § 153.320 to add the phrase ''For the 2020 through 2023 benefit years'' to reflect that state requests submitted for those benefit years must include a justification for the reduction requested demonstrating either of the existing criteria, that is, the state-specific factors that warrant an adjustment to more precisely account for relative risk differences in the state individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, or that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments. We also propose to add a new § 153.320(d)(1)(iv) to capture the requirement that prior participant requests beginning with the 2024 benefit year must include a justification demonstrating the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments. We similarly propose to amend the standards for HHS approval under § 153.320(d)(4)(i) to create a new paragraph (d)(4)(i)(A) to capture the existing options available for 2020 through 2023 benefit year requests and a new paragraph (d)(4)(i)(B) to capture the new proposed option that would apply to prior participants' requests beginning with the 2024 benefit year. Retaining the de minimis standard as the only option for prior participants to justify the reduction and for HHS to approve a request would help ensure that consumers would not experience an increase in premiums greater than 1 percent as the result of a state requested reduction in transfers, which aligns with the priorities under E.O. 14009 to ensure that health care remains affordable for consumers. HHS would continue to publish any requests submitted under this revised framework, make them available for public comment, and announce any approved or denied reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters, as set forth in § 153.320(d)(3).

We seek comment on this proposal to generally repeal the state flexibility to request reductions in the transfers calculated by HHS under the state payment transfer formula beginning with 2024 benefit year, with the exception of states that previously submitted a risk adjustment state flexibility request for any market risk pool. We also seek comment on whether we should limit this repeal to the individual market catastrophic and non-catastrophic risk pools (including merged market states whose issuers report risk adjustment data in the individual market) and continue to permit the submission of these requests in the small group market only (including merged market states whose issuers report risk adjustment data in the small group market). We further seek comment on the proposed prior participant exception, including the proposed definition for prior participants. We also seek comment on the proposal to retain as the only option for state justification and HHS approval of requested reductions beginning with the 2024 benefit year the demonstration that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments, and to remove the criterion related to the state demonstrating the state-specific factors that warrant an adjustment to more precisely account for relative risk differences in the applicable state market risk pool. Finally, we seek comment on the health equity impacts of these proposals, especially for underserved and minority communities.

5. Risk Adjustment Issuer Data Requirements (§§ 153.610, 153.700, and 153.710)

In this section, we propose that issuers collect and make available for HHS' extraction from issuers' EDGE servers five new data elements—ZIP code,[156] race, ethnicity, an ICHRA indicator, and a subsidy indicator (APTC indicator at the policy-level)—as part of the required risk adjustment data that issuers must make accessible to HHS in states where HHS operates the risk adjustment program,[157] beginning with the 2023 benefit year. We also propose that beginning with the 2022 benefit year, HHS would extract from issuers' EDGE servers the following three data elements that issuers already are required to make accessible to HHS as part of the required risk adjustment data: Plan ID (which represents the HIOS ID, state, product ID, standard component number, and variant), rating area, and subscriber indicator. We also propose to exclude plan ID, ZIP code, and rating area from the limited data set HHS makes available to requestors for research purposes, but include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in that limited data set once available. Lastly, we propose to expand and clarify the scope of permissible HHS uses for the data and the reports extracted from issuer EDGE servers (including data reports and ad hoc query reports). Related to these proposals, we also consider the burden associated with the proposed collection and extraction of these data elements and whether there are any policies that HHS could pursue to encourage the consistent use and reporting of ICD–10–CM z codes. The following subsections provide further discussion of these proposals.

a. Background

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 risk adjustment program in any state that fails to do so.[158] 45 CFR 153.610(a) requires that health insurance issuers of risk adjustment covered plans submit or make accessible all required risk adjustment data in accordance with the data collection approach established by HHS [159] in states where HHS operates the program on behalf of a state. In the 2014 Payment Notice, HHS established an approach for obtaining the necessary data for risk adjustment calculations in states where HHS operates the program through a distributed data collection model that prevented the transfer of individuals' personally identifiable information (PII).[160] Since the 2016 benefit year, HHS required issuers of risk adjustment covered plans to submit 95 data elements to their EDGE servers

[156] ZIP code™ is a trademark of the United States Postal Service.

[157] HHS has been operating the risk adjustment program in all 50 states and the District of Columbia since the 2017 benefit year.

[158] 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.

[159] Also see 45 CFR 153.700–153.740.

[160] See 78 FR at 15497–15500 and 45 CFR 153.720.

to support the HHS' calculation of risk adjustment transfers.[161]

Then, in the 2018 Payment Notice, we finalized policies for the extraction and use of enrollee-level EDGE data beginning with the 2016 benefit year.[162] The purpose of collecting and extracting enrollee-level EDGE data was to provide HHS with more granular data to use to recalibrate the HHS risk adjustment models and to use actual data from issuers' individual and small group (and merged) market populations, as opposed to the MarketScan® commercial database that approximates these populations, for model recalibration purposes. We also finalized the use of the extracted enrollee-level EDGE data to inform development of the AV Calculator and methodology and noted the data could be a valuable source for calibrating other HHS programs in the individual and small group markets. In the 2020 Payment Notice, we expanded the permitted uses of the extracted enrollee-level EDGE data to provide that HHS may use these data and the reports extracted from issuers' EDGE servers (including data reports and ad hoc query reports) to calibrate and operationalize our individual and small group (including merged) market programs, including to recalibrate the HHS risk adjustment models, to inform updates to the AV Calculator, and to conduct policy analysis for the individual and small group (including merged) markets.[163] These additional uses of the enrollee-level EDGE data and reports enhance HHS' ability to develop and set policy for the individual and small group (including merged) markets and avoid the need to pursue alternative burdensome data collections from issuers.[164]

b. Proposed Collection and Extraction of New Data Elements and Extraction of Current Data Elements

Based on our experience accessing EDGE server data for the risk adjustment model recalibration and analytics purposes, and as part of our ongoing efforts to continuously improve HHS programs, we propose to collect and extract new data elements from issuers' EDGE servers through issuers' EDGE Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files, specifically: (1) ZIP code, (2) race, (3) ethnicity, (4) subsidy indicator, and (5) ICHRA indicator. For race and ethnicity data, we propose to require issuers to report race and ethnicity in accordance with the October 30, 2011 HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status (2011 HHS Data Standards),[165] which is collected at a granular level that would allow HHS to better analyze more subpopulations than our current data allows us to do, thereby allowing us to consider more areas of health equity, as well as to better address discrimination in health care and health disparities.[166] We propose to require issuers of risk adjustment covered plans to submit and make accessible these new data elements to HHS in states where HHS operates the risk adjustment program beginning with the 2023 benefit year. Extraction of these new five data elements as part of the enrollee-level EDGE data and the reports extracted from issuers' EDGE servers (including data reports and ad hoc query reports) would begin with the 2023 benefit year.[167] In addition to collecting and extracting these new data elements, we also propose to extract plan ID, rating area, and subscriber indicator as part of the enrollee-level EDGE data beginning with the 2022 benefit year data and reports extracted from issuers' EDGE servers. For the plan ID, rating area, and subscriber indicator, we note that issuers are already required under current HHS program requirements to submit these data elements to their EDGE servers.[168]

Collecting and extracting these new and current data elements would allow HHS to further assess and analyze actuarial risk and risk patterns in the individual, small group, and merged markets, and determine if, based on future analysis, any refinements to the HHS risk adjustment methodology, the AV Calculator, or other HHS individual or small group (including merged) market programs should be proposed through notice-and-comment rulemaking. For example, we propose to collect and extract the ICHRA indicator to conduct analyses on whether there are any unique actuarial characteristics of the ICHRA population[169] and to examine if employers with sicker enrollees are more attracted to offering ICHRAs, and if ICHRA enrollment is impacting state individual (or merged) market risk pools. We similarly want to examine whether there are any risk patterns or impacts when analyzing risk adjustment data using ZIP codes, race, ethnicity, and the subsidy indicator. For example, we are interested in conducting analysis on whether there are any cost differentials for certain conditions based on race, ethnicity or subsidy indicator. For the three current data elements that we are proposing to newly extract, our purpose would be to similarly use these data to further assess risk patterns and the impact of risk adjustment policies. For example, the extraction of rating area data would provide HHS with more granular data to assess risk patterns and impacts based on geographic differences. In addition, the proposal to newly extract plan ID and subscriber indicator from issuers' EDGE servers would allow HHS to be able to simulate transfers using the enrollee-level data, which is currently not possible without the plan ID.[170]

We believe these proposed data collections and extractions would serve the compelling government interest of promoting equity in health coverage and care, as well as the ACA's goal of making high-quality health care accessible and affordable for all individuals. Specifically, we believe that the collection and extraction of these new data elements would allow HHS to analyze and assess health equity

[161] The full list of required data elements can be found in Appendix A of OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401)), which is currently being updated. The current Appendix A is available at *https://omb.report/icr/201712-0938-015/doc/79644301.pdf.* The previous version is available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201712-0938-015.*

[162] 81 FR 94058 at 94101.

[163] 84 FR 17454, 17488.

[164] We also clarified that our policies regarding HHS uses of the enrollee-level EDGE data apply to the HHS components that currently receive and use such data for purposes of the HHS risk adjustment program. See *ibid* at 17488.

[165] *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.*

[166] As detailed further later in this preamble, issuers would have the option of selecting ''unknown'' for this data element if they do not have this information for a particular enrollee.

[167] The deadline for submission of 2023 benefit year risk adjustment data submissions is April 30, 2024. See 45 CFR 153.730.

[168] The full list of required data elements can be found in Appendix A of OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401)), which is currently being updated. The current Appendix A is available at *https://omb.report/icr/201712-0938-015/doc/79644301.pdf.* The previous version is available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201712-0938-015.*

[169] Currently, HHS only collects information on an enrollee's ICHRA status in connection with a special enrollment period eligibility determination for Exchanges, which does not provide us with complete data.

[170] For the transfer simulation of the combined model specification changes, HHS was not able to use the available enrollee-level EDGE datasets. Instead, issuers needed to run multiple EDGE Ad Hoc commands on their respective EDGE servers for the simulation to be successful. See Section 5.2 of the 2021 RA Technical Paper, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

impacts more than current data allow. Consistent with Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [171] we believe this proposal would facilitate our ability to assess the extent to which specific communities experience barriers or challenges in accessing benefits and opportunities available related to our individual, small group, and merged market programs. This proposed data collection could also facilitate our ability to assess whether new policies, regulation, or guidance may be necessary or appropriate to further advance equity within our programs in the individual, small group and merged markets. We believe that the proposed collection and extraction of these data elements is narrowly tailored to serve this compelling government interest because this is the minimum data anticipated at this time that would allow HHS to further assess and analyze actuarial risk and risk patterns in the individual, small group, and merged markets. Consistent with the policy adopted in the 2020 Payment Notice regarding the use of data and reports extracted from issuer EGDE servers (including data reports and ad hoc query reports), and our proposal below to expand the permissible HHS uses of such data and reports, we would collect, extract and use these new and current data elements to conduct policy analysis for HHS programs in the individual and small group (including merged) markets and to inform policy analyses and improve the integrity of other HHS federal health-related programs to the extent such use is otherwise authorized by, required under, or not inconsistent with applicable federal law.

In the proposed 2020 Payment Notice, we sought comment on the advantages and disadvantages of extracting state and rating area data as part of the enrollee-level EDGE data for use to recalibrate the HHS-operated risk adjustment models, to inform updates to the AV Calculator and methodology, and to conduct policy analyses for other HHS individual and small group (including merged) market programs.[172] We explained that extracting these geographic details could enable HHS to assess the impact of differences in geographic factors in the HHS risk adjustment methodology and to better estimate the AV of plans based on cost differences across regions. We also noted that extraction of geographic details (state and rating area) could help support other HHS programs and policy priorities, as well as provide additional data elements for researchers. However, after consideration and review of the public comments received on the proposed 2020 Payment Notice, we did not finalize the proposed extraction of these data elements. We explained that, at that time, in response to stakeholder feedback, we did not believe that the benefits of these additional data element extractions would outweigh the potential increased risk to issuers' proprietary information and increased issuer burden.[173]

However, in light of E.O. 13985 and E.O. 14009, we have continued to consider whether extraction of these data elements would support and enhance HHS' policy analysis capabilities with regard to the HHS risk adjustment program, as well as other HHS individual and small group (including merged) market programs that seek to provide access to health care to consumers. Based on this further analysis and consideration, HHS has determined that the proposed extraction of rating area data, along with the proposed collection and extraction of the other data elements discussed in this proposal, align with the policy goals in E.O. 13985 and E.O. 14009 and would provide HHS with more granular data to help improve HHS' analytical capacity to assess equity impacts of programs impacted by this proposed rule, including our capacity to identify potential refinements to the HHS risk adjustment methodology, consider policy and operational changes to improve other HHS individual and small group (including merged) market programs, and identify ways to address health equity issues in these programs. For example, HHS believes that analysis of the additional data elements proposed for collection and extraction from issuers' EDGE servers would help HHS better monitor trends in the health insurance markets, inform HHS analyses of whether updates to the QHP certification review processes would be necessary or appropriate,[174] and inform QHP compliance reviews and subregulatory guidance. HHS also is of the view that the additional data elements proposed for collection and extraction from EDGE servers could be valuable in assessing policy and operational issues in connection with programs that are not centered around the individual or small group (including merged) commercial health insurance markets, such as the wrap-around QHP coverage offered to Medicaid expansion populations in some states [175] and coverage offered by non-federal governmental plans.[176]

Additionally, HHS continually considers methods and mechanisms to identify discriminatory practices in the commercial health insurance markets and HHS federal health-related programs. The additional data we propose to collect and extract from issuers' EDGE servers also would inform future policy to better address discrimination and other systemic barriers in health care and health disparities that may exist in connection with coverage offered in the commercial health insurance markets, as well as in other HHS federal health-related programs that do not focus on commercial health insurance.

For all of the reasons discussed in this section, HHS proposes to collect and extract the proposed five new data elements outlined above as part of the required risk adjustment data issuers must make accessible to HHS through their respective EDGE servers beginning with the 2023 benefit year. We also propose to extract plan ID, rating area, and subscriber indicator as part of the EDGE enrollee-level data set beginning with the 2022 benefit year.[177] We note that any changes to the risk adjustment methodology or other policies based on HHS's analysis of these data would be set forth in notice and comment rulemaking.

We seek comments on these proposals, including feedback specifically on whether we should extract only certain portions of the plan ID, such as the five-digit HIOS ID, two-character state ID, three-digit product number, four-digit standard component

[171] E.O. 13985 is 86 FR 7009 available at *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[172] 84 FR 227 at 251.

[173] 84 FR 17454 at 17488.

[174] Each year, HHS provides an overview of its QHP certification review processes in the annual Letter to Issuers in the FFEs. The 2022 Final Letter to Issuers in the FFEs is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2022-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces.pdf.*

[175] See, *e.g., https://www.medicaid.gov/medicaid/downloads/wraparound-benefits.pdf.*

[176] Non-federal governmental plans are subject to many PHS Act federal market reform requirements. See, *e.g.,* 42 U.S.C. 300gg–21(a)(1)(A). Also see 42 U.S.C. 300bb–1, *et seq.* HHS is generally responsible for enforcement of provisions of the PHS Act that apply to non-federal governmental plans. See, *e.g.,* 42 U.S.C. 300gg–22(b)(1)(B) and 45 CFR 150.301, *et seq.*

[177] We propose to extract plan ID, rating area, and subscriber indicator for the 2022 benefit year, which is one year earlier than we propose to extract the other five new data elements, because issuers already submit plan ID, rating area, and subscriber indicator to their EDGE servers.

number, two-digit variant ID, or any combination thereof.[178]

c. Limited Data Set

In conjunction with the proposed collection and extraction of the new and current data elements in this proposed rule, we propose to exclude plan ID, ZIP code, and rating area from the limited data set containing enrollee-level EDGE data that HHS makes available to qualified researchers.[179] However, we propose to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in the limited data set once they are available.[180] In the 2020 Payment Notice, we finalized our proposal to create on an annual basis a limited data set file using masked enrollee-level data submitted to HHS from issuers' EDGE servers. The limited data set file is made available to requestors who seek the data for research purposes only.[181] We adopted this policy because we believed making the limited data set file available to qualified researchers upon request would increase understanding of these markets and contribute to greater transparency. HHS strictly adheres to all the requirements and CMS guidelines related to providing the limited data set to qualified researchers, including requiring the recipient of the limited data set to enter into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information. We believe that including race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator would enhance the usefulness of the limited data set for research and would continue to protect enrollees' PII and issuers' proprietary information. Although we believe that including plan ID, ZIP code, and rating area in the limited data set similarly would enhance the usefulness of the limited data set, we believe this would raise significant concerns for issuers given previous comments noting the competitive and proprietary nature of these geographic identifiers. We therefore propose to not include these geographic identifiers as part of the limited data set that HHS makes available to qualified researchers upon request. We seek comments on the proposal to exclude plan ID, ZIP code, and rating area, and to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator as part of the enrollee-level EDGE limited data set made available to qualified researchers upon request. We seek comment on this proposal, including about whether collecting race and ethnicity data in accordance with the 2011 HHS Data Standards would require systems changes and about any costs associated with such changes. If finalized as proposed, race, ethnicity, the ICHRA indicator, and the subsidy indicator would be included beginning with the 2023 benefit year enrollee-level EDGE limited data set. Subscriber indicator would be included beginning with the 2022 benefit year enrollee-level EDGE limited data set if the proposal to extract that data element is finalized as proposed. We appreciate the sensitivities related to enrollee-level EDGE data and the importance of ensuring that our policies continue to safeguard enrollees' privacy and security and issuers' proprietary information. Thus, we are particularly interested in feedback on any privacy or confidentiality concerns with including these elements in the limited data set made available to qualified researchers upon request.

d. Proposal To Expand Permissible Uses of EDGE Data

We also propose to expand the permitted uses of the data and reports (including data reports and ad hoc query reports) extracted from issuers' EDGE servers to include other HHS federal health-related programs outside of the commercial individual and small group (including merged) markets. This proposed expansion would apply to data that HHS already collects as well as the proposed collection and extraction of ZIP code, race, ethnicity, subsidy indicator, ICHRA indicator, plan ID, rating area, and subscriber indicator as outlined in this rule. The proposed expansion to the permitted uses of the EDGE data and reports would apply as of the effective date of the final rule. Specifically, HHS proposes to expand the uses of the data and reports HHS extracts from issuers' EDGE servers to include not only the specific uses for purposes we identified in the 2020 Payment Notice[182]—that is, to calibrate and operationalize our individual and small group (including merged) market programs (including assessing risk in the market for risk adjustment purposes and informing updates to the AV Calculator), and to conduct policy analysis for the individual and small group (including merged) markets—but also for the purposes of informing policy analyses and improving the integrity of other HHS federal health-related programs, to the extent such use of the data is otherwise authorized by, required under, or not inconsistent with applicable federal law. For example, certain states have wrap-around coverage that include enrolling their Medicaid expansion populations in QHPs and those enrollees are currently reflected in the enrollee-level EDGE data. Under this proposal to expand the permitted uses of EDGE data and reports, it would be clear that HHS could use this information to inform policy analyses and improve the integrity of these Medicaid expansion population approaches. Similarly, to the extent appropriate, this proposal would allow HHS to use the EDGE data and reports to inform policy analyses related to PHS Act requirements enforced by HHS that are applicable market-wide[183] and those that are applicable to non-federal governmental plans.[184] Consistent with our current policy, the proposals in this rule related to HHS use of the enrollee-level EDGE data and reports would apply to the HHS components that currently receive and use such data for purposes of the HHS risk adjustment program. Other government components would be able to request the enrollee-level EDGE limited data set file for research, as that term is defined under § 164.501. We also note that the enrollee-level EDGE data, including the data elements proposed for collection and extraction in this rule, may be subject to disclosure as otherwise required by law.[185]

[178] For additional explanation of the plan ID components, see pg. 42 of the CMS Standard Companion Guide Transaction Information: Instructions related to the ASC X12 Benefit Enrollment and Maintenance (834) transaction, based on the 005010X220 Implementation Guide and its associated 005010X220A1 addenda for the FFE, available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/companion-guide-for-ffe-enrollment-transaction-v15.pdf.*

[179] See 84 FR at 17487.

[180] As proposed, the subscriber indicator would be included in the enrollee-level data HHS extracts from issuer EDGE servers beginning with the 2022 benefit year; therefore, this new data field would be included beginning with the 2022 benefit year limited data set. As proposed, race, ethnicity, ICHRA indicator, and subsidy indicator would be included in the enrollee-level data HHS extracts from issuer EDGE servers beginning with the 2023 benefit year; therefore, these data fields would be included beginning with the 2023 benefit year limited data set.

[181] As explained in the 2020 Payment Notice, we do not currently make the limited data set available to requestors for public health or health care operation activities. See 84 FR at 17488.

[182] See 84 FR 17488.

[183] See, for example, 42 U.S.C. 300gg–300gg–28.

[184] Non-federal governmental plans are subject to many PHS Act federal market reform requirements. See, *e.g.,* 42 U.S.C. 300gg–21(a)(1)(A). Also see 42 U.S.C. 300bb–1, *et seq.* HHS is generally responsible for enforcement of provisions of the PHS Act that apply to non-federal governmental plans. See, *e.g.,* 42 U.S.C. 300gg–22(b)(1)(B) and 45 CFR 150.301, *et seq.*

[185] See, for example, 2 U.S.C. 601(d).

We note that any changes to our policies that result from analysis of these data, such as using the data to modify the state payment transfer formula, would be subject to notice and comment rulemaking. Furthermore, we would not use the additional data elements or any analysis of them to pursue changes to our policies until we conduct thorough data quality checks. For example, in submitting data on race and ethnicity, issuers would have the option of selecting ''unknown'' for these data elements and we would ensure an adequate response rate before conducting analyses that could inform policy decisions. We would similarly ensure an adequate response rate with respect to submission of the ICHRA indicator before conducting analyses that could inform policy decisions.[186] We solicit comment on this proposal to expand the permitted uses of the enrollee-level EDGE data.

e. Burden for Collecting and Extracting Additional Data Elements

As stated above, we propose to extract plan ID, rating area, and subscriber indicator from issuers' EDGE servers to consider for use in risk adjustment model recalibration and other potential refinements to the HHS-operated risk adjustment program, as well as to conduct policy analysis for HHS federal health-related programs, including those related to the individual and small group (including merged) health insurance markets and HHS non-commercial market programs, beginning with the 2022 benefit year. While collecting additional data elements may represent increased burden for issuers, there would be little to no additional issuer burden related to extracting these three proposed data elements because HHS extracts and stores the data, and issuers would only be required to execute a command provided by HHS to generate the EDGE report(s) containing all required data elements. Since issuers are already required to include these three data elements (plan ID, rating area, and subscriber indicator) as part of the required risk adjustment submissions to their respective EDGE servers, we believe there would be little to no additional burden associated with the proposed extraction of these three data elements beginning with the 2022 benefit year.

As stated above, we also propose to require issuers to include five new data elements—ZIP code, race, ethnicity, an ICHRA indicator, and a subsidy indicator—as part of their risk adjustment submissions to issuer EDGE servers beginning with the 2023 benefit year. We believe issuers currently collect ZIP codes; therefore, the burden associated with the proposed collection of this data element through issuer EDGE servers would only be the additional effort and expense for issuers to compile and submit this additional data element to their EDGE servers, as well as to retain this data element as part of their risk adjustment records as required under § 153.620(b). Because the subsidy indicator is derived from existing data,[187] we believe the burden would again only be the additional effort and expense for issuers to compile and submit this data element to their EDGE servers, as well as to retain this data element as part of their risk adjustment records as required under § 153.620(b). In contrast, we do not believe information to populate the ICHRA indicator is routinely collected by all issuers at this time; therefore, in recognition of the burden that collection of this new data element potentially would pose for some issuers, we propose to make submission of the ICHRA indicator on issuers' EDGE servers optional for the 2023 and 2024 benefit years. This transitional approach for the ICHRA indicator would be similar to how we have handled other new data collection requirements[188] and would allow issuers additional time to develop processes for collection, validation and submission of this new data field before it is required.

We believe that most issuers currently collect race and ethnicity data in some manner, and therefore the burden associated with the collection of this information through issuer EDGE servers would only be the additional effort and expense for issuers to compile and submit these additional data elements to their EDGE servers and retain these data elements as part of their risk adjustment records as required under § 153.620(b). However, we are interested in comments on the collection of these data elements, issuers' rate of collections of these data elements in accordance with the 2011 HHS Data Standards[189] and whether there are any considerations about the availability and current collection of these data elements that HHS should be aware of, given that these data fields are often an optional field on health insurance application and enrollment forms.[190] We also acknowledge that some of these new proposed data elements, such as race and ethnicity and the ICHRA indicator, may be collected by HHS from FFE or SBE–FP enrollees through the QHP application process and from State Exchange enrollees through the State Exchange enrollment and payment files and our intention would be to structure these data elements similar to current collections, where possible. However, this proposal would require all issuers of risk adjustment covered plans to make these data elements accessible to HHS through their EDGE servers as part of the required risk adjustment data submissions in states where HHS operates the risk adjustment program. The data that issuers submit to their EDGE servers would be more uniform and comprehensive than information submitted by FFE and SBE–FP enrollees on a QHP application and by State Exchange enrollees through enrollment and payment files, as it would represent all enrollees in risk adjustment covered plans, including coverage offered inside and outside of Exchanges. By collecting these data as part of the required risk adjustment data issuers submit to their respective EDGE servers, HHS would also have the ability to extract and aggregate these data elements with other claims and enrollment data accessible through issuer EDGE servers, which would not be possible with the data collected from consumers through other processes because the EDGE data is masked[191] and therefore cannot be linked with other sources. We considered the possibility of using data imputation methods with existing *HealthCare.gov* application data to construct a simulated dataset and conduct preliminary exploratory analysis, but once again determined that

[186] As detailed later, we propose to adopt a transition approach for the ICHRA indicator, which would make this data field optional for the 2023 and 2024 benefit years.

[187] Subsidy indicator is derived from the Marketplace enrollment data communicated to issuers where this data provides the APTC amount for an enrollee. Issuers would be able to use this information to derive the subsidy indicator for each enrollee.

[188] For example, HHS did not penalize issuers for temporarily submitting a default value for the in/out-of-network indicator for the 2018 benefit year in order to give issuers time to make the necessary changes to their operations and systems to comply with the new data collection requirement, but required issuers to provide full and accurate information for the in/out-of-network indicator beginning with the 2019 benefit year.

[189] HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status | ASPE *See* HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status | ASPE, available at *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.*

[190] Race and ethnicity questions, for example, are optional on the *HealthCare.gov* application. See *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=201903-0938-016* (Attachment A, page 27–28).

[191] 45 CFR 153.720.

we would be unable to impute data from the applications due to the EDGE data being masked. We therefore do not view this as a duplicative data collection. Our proposal also would ensure HHS has access to the same information in the same format for on- and off-Exchange enrollments, as well as across all Exchange types—FFEs, SBE–FPs and State Exchanges—for the individual, small group and merged markets.

To fully assess the additional issuer burden resulting from this proposal, we seek comment on the relative value of the additional data elements we propose to require when compared to other data elements we could propose to collect. For instance, we seek comment on whether HHS should consider collecting county data in lieu of ZIP code, and also solicit comment on whether HHS should consider requiring issuers to report census tract data, instead of ZIP codes or county data. Specifically, we understand that five-digit ZIP codes can change on a regular basis, which could limit the usefulness of this data element when comparing data across benefit years. Census tract data or county data, therefore, may be more useful. We also clarify that, while race and ethnicity would be required data submission elements under these proposals, issuers would have the option of selecting ''unknown'' for this data element, which aligns with the approach taken for application and enrollment forms. In other words, issuers would not be penalized if they did not have the data for a particular enrollee. Instead, this proposal is designed to require the submission of race and ethnicity data if a particular enrollee provided it to their respective issuer. We also seek comment on how issuers may already be collecting data on race and ethnicity in order to identify alternatives that HHS could consider to further ease the burden of this collection while also meeting the stated goals of collecting data to analyze more subpopulations than the current data allows, consider more areas of health equity, and better address discrimination in health care and health disparities.

f. Encouraging the Use of Z Codes

We seek comment on the collection and extraction of z codes (particularly Z55–Z65), a subset of ICD–10–CM encounter reason codes used to identify, analyze, and document social determinants of health.[192] We are currently collecting z codes in the enrollee-level EDGE data and have started analyzing those codes.[193] However, we understand there have been reports of a lack of consistent use of z codes by providers [194] and we want to encourage consistent use of z codes to help further assess risk in the individual, small group and merged market risk pools. We solicit comment on whether there are policies that HHS should pursue that could encourage consistent use of z codes by providers to support collection and use of the data for the HHS-operated risk adjustment program. In light of E.O. 13985 and E.O. 14009, HHS is interested in analyzing z code data to learn about the relationship between risk and the social determinants of health. Finally, we seek comment on whether there are other data elements HHS should consider collecting and extracting to support the operation of the HHS-operated risk adjustment program.

6. Risk Adjustment User Fee for 2023 Benefit Year (§ 153.610(f))

HHS proposes a risk adjustment user fee for the 2023 benefit year of $0.22 per member per month (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. As noted previously in this proposed rule, for the 2023 benefit year, HHS will be operating the risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS' operation of risk adjustment on behalf of states is funded through a risk adjustment user fee.[195] Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a state, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

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

In part 2 of the 2022 Payment Notice final rule, we calculated the federal administrative expenses of operating the risk adjustment program for the 2022 benefit year to result in a risk adjustment user fee rate of $0.25 PMPM based on our estimated costs for risk adjustment operations and estimated billable member months for individuals enrolled in risk adjustment covered plans.[196] For the 2023 benefit year, HHS proposes to use the same methodology to estimate our administrative expenses to operate the risk adjustment program. These costs cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment program activities. To calculate the user fee, we divided HHS' projected total costs for administering the risk adjustment program on behalf of states by the expected number of billable member months in risk adjustment covered plans in states where the HHS-operated risk adjustment program will apply in the 2023 benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states for the 2023 benefit year will be approximately $60 million, and therefore, the proposed risk adjustment user fee is $0.22 PMPM. The risk adjustment user fee costs for the 2023 benefit year are expected to remain steady from the prior 2022 benefit year estimates. However, we project a small increase in billable member months in the individual and small group (including merged) markets overall in the 2023 benefit year based on the enrollment increases observed in the 2020 benefit year prior to implementation of the ARP in 2021. The

[192] See CMS Infographic: *Using Z Codes: The Social Determinants of Health; Data Journey to Better Outcomes,* available at *https://www.cms.gov/files/document/zcodes-infographic.pdf,* last accessed Nov. 5, 2021. See also *Utilization of Z Codes for Social Determinants of Health Among Medicare Fee-for-Service Beneficiaries, 2019,* available at *https://www.cms.gov/files/document/zcodes-infographic.pdf.*

[193] Using the 2019 enrollee-level EDGE data, we found that only 0.49 percent of the population had a code within Z55–Z65 range. These enrollees had higher costs than enrollees without a Z55–Z65 code across all age/sex and market/metal/CSR categories.

[194] See *https://journals.lww.com/lww-medicalcare/Fulltext/2020/12000/Utilization_of_Social_Determinants_of_Health.2.aspx.*

[195] 78 FR 15409 at 15416–15417.

[196] 86 FR 24140 at 24195–24196.

assumption that the enhanced premium tax credit subsidies in section 9661 of the ARP will expire after the 2022 benefit year significantly influenced our development of the 2023 enrollment and premium projections used to develop the proposed risk adjustment user fee for the 2023 benefit year. We expect the expiration of this ARP provision to revert enrollment projections to the pre-ARP level observed in the 2020 benefit year. We seek comment on the proposed risk adjustment user fee for the 2023 benefit year.

7. Compliance With Risk Adjustment Standards; High-Cost Risk Pool Funds—Audits of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

HHS proposes that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii), the high-cost risk pool funds recouped from an issuer in an applicable national high-cost risk pool [197] would be used to reduce high-cost risk pool charges for that national high-cost risk pool beginning for the current benefit year, if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for the current benefit year, we propose to use the recouped high-cost risk pool funds to reduce the next applicable benefit year's high-cost risk pool charges for all issuers owing high-cost risk pool charges for that national high-cost risk pool.

In part 2 of the 2022 Payment Notice final rule, HHS codified several requirements related to the audits and compliance reviews of risk adjustment covered plans.[198] We did not finalize our disbursement proposal for high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan under § 153.620(c), but stated our intention to address this issue in future rulemaking.[199] As such, we are proposing here that any high-cost risk pool funds recouped through an audit under § 153.620(c)(5)(ii) would be disbursed in the next benefit year for which high-cost risk pool payments have not already been calculated, in the form of reduced charges for all issuers owing high-cost risk pool charges in the applicable national high-cost risk pool. If HHS recoups high-cost risk pool funds after the current benefit year's high-cost risk pool payments have been calculated, we propose to apply the high-cost risk pool funds recouped through an audit under § 153.620(c)(5)(ii) to reduce the next applicable benefit year's high-cost risk pool charges for all issuers owing high-cost risk pool charges for the applicable national high-cost risk pool. For example, if a 2018 high-cost risk pool audit results in funds being recouped for the national high-cost risk pool for the individual market in March 2022, then these recouped funds would be disbursed in the form of reduced 2021 benefit year high-cost risk pool charges for issuers in the national high-cost risk pool for the individual market because high-cost risk pool payments for the 2021 benefit year are not calculated until June 2022. Notwithstanding any reduction to a national high-cost risk pool's charges for a given benefit year, this proposed policy would not impact the amount of high-cost risk pool payments made to eligible issuers, because the reduction in charges is due to the recoupment of funds as the result of an audit of a prior benefit year rather than a change in payments for the given benefit year. In addition, the calculation of high-cost risk pool charges and payments will continue to be calculated in accordance with the established policies, terms and factors.[200] [201] We believe this proposal is consistent with our general policy that HHS would not rerun or otherwise recalculate high-cost risk pool charges and payments for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c).[202]

We also clarify that when HHS recoups high-cost risk pool funds as a result of an audit, the issuer subject to the audit would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in § 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of recouped audit funds, issuers whose charge amounts are reduced would report the high-cost risk pool charges paid for that benefit year net of recouped audit funds in the next MLR reporting cycle consistent with § 153.710(h).

We also propose that any high-cost risk pool funds recouped as a result of an actionable discrepancy or successful administrative appeal filed pursuant to §§ 153.710(d) and 156.1220, respectively, would be treated the same way, that is, any high-cost risk pool funds recouped based on an actionable discrepancy or successful appeal would be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next benefit year for which high-cost risk pool payments have not already been calculated. Additionally, issuers would similarly be responsible for reporting any high-cost risk pool related adjustments that result from the recoupment of funds due to an actionable discrepancy or successful administrative appeal in the next MLR reporting cycle consistent with § 153.710(h).

We seek comment on these proposals.

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

To ensure the integrity of the HHS-operated risk adjustment program, HHS conducts risk adjustment data validation (HHS–RADV) under §§ 153.350 and 153.630 in any state where HHS is operating risk adjustment on a state's behalf. [203] The purpose of HHS–RADV is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and proper functioning of the HHS-operated risk adjustment program. HHS–RADV also ensures that risk adjustment transfers reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor data quality, thereby helping to ensure that the HHS-operated risk adjustment program 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 IVA and an SVA. Under § 153.630, each issuer of a risk

[197] The high-cost risk pool calculation under the HHS risk adjustment methodology involves two national risk pools—one for the individual market (including catastrophic and non-catastrophic plans, and merged market plans), and another for the small group market. See, for example, 81 FR at 94080–94082.

[198] See 86 FR 24140 at 24287.

[199] We proposed that any high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis to other issuers in the relevant national high-cost risk pool in the form of a reduced high-cost risk pool charge in the applicable benefit year. See 85 FR 78572 at 78604.

[200] See 81 FR 94058, 94081. Also see 84 FR 17454, 17467 (We are finalizing the $1 million threshold and 60 percent coinsurance rate for 2020 benefit year and beyond without requiring notice and comment on the high-cost risk pool thresholds each year.). We are not proposing changes to the high-cost risk pool parameters for the 2023 benefit year. Therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.

[201] For a visual illustration of the high-cost risk pool terms and factors, see 86 FR at 24184–24185.

[202] 86 FR 24140 at 24193.

[203] HHS has operated the risk adjustment program in all 50 states and the District of Columbia since the 2017 benefit year.

adjustment covered plan must engage an independent IVA entity. The issuer provides demographic, enrollment, prescription drug, and medical record documentation for a sample of enrollees selected by HHS to the issuer's IVA entity. 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 and SVA as applicable, HHS conducts error estimation to calculate an error rate.

In the 2020 HHS–RADV Amendments Rule,[204] we described and finalized the error rate calculation methodology for HHS–RADV applicable for benefit years 2019 and onward. In this rule, we propose further refinements to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year and beyond to: (1) Extend the application of Super HCCs to also apply to coefficient estimation groups throughout the HHS–RADV error rate calculation processes, (2) specify that the Super HCC will be defined separately according to the age group model to which an enrollee is subject, and (3) constrain to zero any outlier negative failure rate in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate.

HHS is committed to ensuring the integrity and reliability of HHS–RADV and continuously improving the error rate calculation methodology and program requirements. As part of our ongoing efforts to explore potential modifications to the HHS–RADV error rate calculation methodology, we have identified through our own analysis, and through feedback from stakeholders, these areas for further refinement. We believe these proposals will better align the calculation and application of error rates with the intent of the HHS–RADV program, thereby enhancing the integrity of HHS–RADV and the HHS-operated risk adjustment program.

a. Coefficient Estimation Groups in Error Estimation

First, we propose to modify our process for grouping coefficient estimation groups in error estimation. In the 2020 HHS–RADV Amendments Rule,[205] we finalized a policy to ensure that HCCs that share a coefficient estimation group used in the risk adjustment models are sorted into the same failure rate groups by first aggregating any HCCs that share a coefficient estimation group into Super HCCs before applying the HHS–RADV failure rate group sorting algorithm. Since implementing the Super HCC policy, we found there are rare occasions where there is a minor misalignment between the calculation of risk adjustment plan liability risk score (PLRS) values and HHS–RADV error estimation. To address these rare situations, in this rule we propose to modify the Super HCC policy to apply the coefficient estimation group logic as expressed in the applicable benefit year's DIY software throughout the HHS–RADV error rate calculation methodology, as they are in risk adjustment. We propose to adopt these changes beginning with the 2021 benefit year of HHS–RADV.

The majority of HCCs in a coefficient estimation group are in the same hierarchy, but in rare instances an individual enrollee may be recorded on an issuer's EDGE server as having multiple HCCs in an HCC coefficient estimation group that do not have a direct hierarchical relationship to one another. For example, based on the 2021 DIY software Tables 4 and 6,[206] HCC 61 Osteogenesis Imperfecta and Other Osteodystrophies shares coefficient estimation group G04 with HCC 62 Congenital/Developmental Skeletal and Connective Tissue Disorders in the adult risk adjustment models, but the two HCCs are not hierarchically related. However, even if an enrollee has both unrelated conditions, the enrollee only receives the coefficient for one of those conditions in the enrollee's risk adjustment risk score calculation because both conditions share the same coefficient estimation group.

To further explain, when such HCCs share a direct hierarchical relationship, the presence of the more severe condition nullifies the presence of the less severe condition; that is, the enrollee will receive credit in risk adjustment and HHS–RADV for only the most severe of the two conditions. Similarly, in risk adjustment, when HCCs that share a coefficient estimation group do not share a direct hierarchical relationship, an enrollee will have both HCCs nullified and replaced with a single instance of a variable indicating the presence of HCCs in that coefficient estimation group, as seen in DIY software Tables 6 and 7, leading to the enrollee only receiving one indicator of risk across both conditions. However, in this latter case, the process of nullifying and replacing the HCCs with the variable representing the coefficient estimation group is not currently replicated in the calculation of HHS–RADV failure rates, group adjustment factors, or enrollee adjustment factors, so it is possible for an enrollee to be recorded in their EDGE, IVA, or SVA data as having both conditions for the purposes of HHS–RADV.

The nullification and replication process in the risk adjustment risk score calculation de-duplicates conditions in coefficient estimation groups in the same way that multiple HCCs that share a hierarchical relationship are de-duplicated. However, there is no analogous de-duplication process for coefficient estimation groups in HHS–RADV.[207] As such, it is possible for an enrollee to be recorded as having multiple conditions in a coefficient estimation group for HHS–RADV, requiring the issuer to be able to validate both conditions to avoid receiving an HHS–RADV adjustment to the enrollee's risk score, even though the enrollee only received the coefficient for one of those conditions in the enrollee's risk adjustment risk score calculation. Therefore, beginning with the 2021 benefit year of HHS–RADV, we are proposing to extend the Super HCC policy finalized in the 2020 HHS–RADV Amendments Rule, such that HHS will apply the coefficient estimation group logic as expressed in the applicable benefit year's DIY software[208] throughout HHS–RADV error estimation, rather than just at the sorting step that assigns HCCs to failure rate groups. This change would mean that an issuer would only need to validate one HCC in a coefficient estimation group to avoid further impacting an adjustment to an enrollee's risk score in HHS–RADV, aligning with how an enrollee's risk score[209] would be calculated under the state payment transfer formula.

[204] 85 FR 76979.

[205] See 85 FR 76979 at 76984–76989.

[206] See, for example, the August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.*

[207] It is rare for an enrollee to have two HCCs in the same coefficient estimation group that are not also in a hierarchical relationship. This situation occurred in no more than 0.1 percent of enrollees sampled for 2017 and 2018 HHS–RADV.

[208] In section III.C.8.b. of this proposed rule, we propose how the coefficient estimation group logic would be applied to adult, child, and infant enrollees and discuss alternative application methodologies.

[209] In the application of the coefficient estimation group logic to HHS–RADV, the definition of coefficient estimation groups for the infant models depends upon proposals in section III.C.8.b. of this proposed rule. If the approach in section III.C.8.b. is finalized as proposed, Super HCCs for the infant models would be based on the calculated model factors used for the infant models, as described in the applicable benefit year's DIY software ''Additional Infant Variables'' table logic (Table 8 of the 2021 Benefit Year DIY Software). In section III.C.8.b. of this rule, we also briefly describe alternative approaches wherein Super HCCs for infants would be identical to those for the child

If finalized as proposed, this update to the Super HCC policy would necessitate a change to the policy finalized in the 2021 Payment Notice [210] which amended the outlier identification process to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 HCCs.[211] That policy was developed based on results of analysis that showed that if the number of EDGE HCCs per sample of enrollees was below 30 HCCs, the implied alpha of our statistical tests for outliers was higher than our 5 percent target, thereby failing to meet the threshold for statistical significance. Moreover, statistical practice often relies on a standard recommendation regarding the determination of sample size, which states that sample sizes below 30 observations are often insufficient to assume that the sampling distribution is normally distributed.[212]

The 2021 Payment Notice policy was developed when individual HCCs were the unit of analysis for calculating failure rates. However, the proposed policy in this rule to de-duplicate coefficient estimation groups in HHS–RADV would alter the unit of analysis of failure rates to be de-duplicated Super HCCs,[213] rather than individual HCCs. Although the unit of analysis would have changed, the underlying issue with sample size in the outlier identification process would remain the same. As such, as a part of this proposal, we propose to generally maintain the outlier identification approach adopted in the 2021 Payment Notice and propose 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 (which would include, as proposed below, maturity-severity factors for infant enrollees) beginning with 2021 benefit year HHS–RADV. Consistent with the policies adopted in the 2021 Payment Notice,[214] we also propose to continue to include data from an issuer who has fewer than 30 de-duplicated EDGE Super HCCs in a failure rate group in the calculation of national metrics for that failure rate group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. However, the issuer would not have its risk score adjusted for that group, even if the magnitude of its failure rate appeared to otherwise be very large relative to other issuers. In addition, we clarify that under this proposal this issuer may be considered an outlier in other failure rate groups in which it has 30 or more de-duplicated EDGE Super HCCs.

We seek comment on this proposal and whether HCCs in coefficient estimation groups should be de-duplicated before they are sorted into failure rate groups and in all subsequent stages of HHS–RADV error estimation.

b. Defining Super HCCs Separately for Adults, Children, and Infants

In conjunction with our proposal to modify the application of coefficient estimation groups in section III.C.8.a. of this proposed rule, we also propose to modify the Super HCC policy to apply coefficient estimation groups to enrollees according to the risk adjustment model to which they are subject. Under the current Super HCC policy, coefficient estimation group logic from the adult models is applied to all enrollees, including those subject to the child and infant models.[215] As detailed in the 2020 HHS–RADV Amendments Rule, we adopted this approach because the adult models' HCC coefficient estimation groups will be applicable to the vast majority of enrollees [216] and our belief that the use of HCC coefficient estimation groups present in the adult risk adjustment models sufficiently balances the representativeness and accuracy of HCC failure rate estimates across the entire population in aggregate.[217]

However, there are some differences in the structure of the risk adjustment model coefficient estimation groups between the adult, child, and infant models that the current approach does not take into account. For example, the child and adult risk adjustment models' coefficient estimation groups for the 2021 benefit year and onward [218] are almost identical with the exception of two adult-only coefficient estimation groups and five child-only coefficient estimation groups (Table 9).

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models, or identical to those for the adult models, and would involve additional steps analogous to those described in Chapter 11.3.4 of the 2020 Benefit Year HHS–RADV Protocols, available at *https://www.regtap.info/uploads/library/2020_RADV_Protocols__042921_5CR_060421.pdf*. These additional steps would not be necessary if the Super HCCs proposals in this rule to define Super HCCs separately for adults, children, and infants are finalized as proposed.

[210] 85 FR at 29196 through 29198.

[211] Under the outlier identification policy finalized in the 2021 Payment Notice, data from an issuer who has fewer than 30 HCCs in a failure rate group is included in the calculation of national metrics for that failure rate group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. However, the issuer does not have its risk score adjusted for that group, even if the magnitude of its failure rate appeared to otherwise be very large relative to other issuers. In addition, we clarified that this issuer may be considered an outlier in other failure rate groups in which it has 30 or more HCCs.

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

[213] If the approach in section III.C.8.b. is finalized as proposed, Super HCCs for the infant models would be based on the calculated model factors used for the infant models, as described in the applicable benefit year's DIY software ''Additional Infant Variables'' table logic (Table 8 of the 2021 Benefit Year DIY Software). In section III.C.8.b. of this rule, we also briefly describe alternative approaches under which Super HCCs for infants would be identical to those for the child models, or identical to those for the adult models, and would involve additional steps analogous to those described in Chapter 11.3.4 of the 2020 Benefit Year HHS–RADV Protocols (available at). These additional steps would not be necessary if the Super HCCs proposals in this rule proposed to define Super HCCs separately for adults, children, and infants are finalized as proposed.

[214] 85 FR at 29196 through 29198.

[215] See 85 FR at 76984 through 76900.

[216] The majority of the population with HCCs in the HHS–RADV samples are subject to the adult models (88.3 percent for the 2017 benefit year; 88.7 percent for the 2018 benefit year). For 2017, this was calculated after removing issuers in Massachusetts and incorporating cases where issuers failed pairwise and the SVA subsample was used.

[217] See 85 FR at 76987.

[218] Starting in 2021 benefit year, the HHS risk adjustment models use Version 07 for the HHS–HCC classification. Prior to the 2021 benefit year, the HHS risk adjustment models used Version 05 for HHS–HCC classification.

TABLE 9: Comparison of V07 Coefficient Estimation Groups Used in the Adult and Child Models

Coefficient Estimation Group	Used in Model		HCC	Description
	Adult	Child		
G01	✔	✔	HCC 19	Diabetes with Acute Complications
			HCC 20	Diabetes with Chronic Complications
			HCC 21	Diabetes without Complication
G02B	✔	✔	HCC 26	Mucopolysaccharidosis
			HCC 27	Lipidoses and Glycogenosis
G02D		✔	HCC 28	Congenital Metabolic Disorders, Not Elsewhere Classified
			HCC 29	Amyloidosis, Porphyria, and Other Metabolic Disorders
G03		✔	HCC 54	Necrotizing Fasciitis
			HCC 55	Bone/Joint/Muscle Infections/Necrosis
G04	✔	✔	HCC 61	Osteogenesis Imperfecta and Other Osteodystrophies
			HCC 62	Congenital/Developmental Skeletal and Connective Tissue Disorders
G06A	✔	✔	HCC 67	Myelodysplastic Syndromes and Myelofibrosis
			HCC 68	Aplastic Anemia
			HCC 69	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn
G07A	✔	✔	HCC 70	Sickle Cell Anemia (Hb-SS)
			HCC 71	Beta Thalassemia Major
G08	✔	✔	HCC 73	Combined and Other Severe Immunodeficiencies
			HCC 74	Disorders of the Immune Mechanism
G09A	✔	✔	HCC 81	Drug Use with Psychotic Complications
			HCC 82	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
G09C	✔	✔	HCC 83	Alcohol Use with Psychotic Complications
			HCC 84	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications
G10	✔	✔	HCC 106	Traumatic Complete Lesion Cervical Spinal Cord
			HCC 107	Quadriplegia
G11	✔	✔	HCC 108	Traumatic Complete Lesion Dorsal Spinal Cord
			HCC 109	Paraplegia
G12	✔	✔	HCC 117	Muscular Dystrophy
			HCC 119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders
G13	✔	✔	HCC 126	Respiratory Arrest
			HCC 127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
G14	✔	✔	HCC 128	Heart Assistive Device/Artificial Heart
			HCC 129	Heart Transplant Status/Complications
G15A	✔		HCC 160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis
			HCC 161_1	Severe Asthma
			HCC 161_2	Asthma, Except Severe
G16	✔	✔	HCC 187	Chronic Kidney Disease, Stage 5
			HCC 188	Chronic Kidney Disease, Severe (Stage 4)
G17A	✔	✔	HCC 204	Miscarriage with Complications
			HCC 205	Miscarriage with No or Minor Complications
G18A	✔	✔	HCC 207	Pregnancy with Delivery with Major Complications

			HCC 208	Pregnancy with Delivery with Complications
G19B		✔	HCC 210	(Ongoing) Pregnancy without Delivery with Major Complications
			HCC 211	(Ongoing) Pregnancy without Delivery with Complications
G21	✔		HCC 137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
			HCC 138	Major Congenital Heart/Circulatory Disorders
			HCC 139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders
G22		✔	HCC 234	Traumatic Amputations and Amputation Complications
			HCC 254	Amputation Status, Upper Limb or Lower Limb
G23		✔	HCC 131	Acute Myocardial Infarction
			HCC 132	Unstable Angina and Other Acute Ischemic Heart Disease

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The infant models also are composed of variables that function analogously to coefficient estimation groups in that they can represent the presence of a large number of HCCs, or just a single HCC. However, these variables in the infant models, the severity-maturity interaction factors, are structured completely differently from the coefficient estimation groups in the adult and child models. We have continued to consider these issues as we gained more experience with operating HHS–RADV and had access to additional years of HHS–RADV data to analyze.

In recognition of the differences in each age group model's definitions, and based on the results of further analysis on the year-over-year stability of sorting Super HCCs into three failure rate groups, described below, we propose to define Super HCCs as:

- The HCC-derived adult model variables after the application of the relevant rows in the applicable benefit year's DIY software adult variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software,[219] the ''HCC group'' rows in Table 6: Additional Adult Variables),
- The HCC-derived child model variables after the application of the relevant rows in the applicable benefit year's DIY software child variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software, the ''HCC group'' rows in Table 7: Additional Child Variables), and
- The HCC-derived infant model variables after the application of the relevant rows in the applicable benefit year's DIY software infant variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software, the ''Severity level'', ''Maturity level'', ''Assign as IHCC AGE1 if needed'', ''Impose hierarchy'', and ''Maturity x severity level interactions'' rows in Table 8: Additional Infant Variables).

Under this approach, we would sort the adult and child coefficient estimation groups into failure rate groups together, when they are identical in definition between the adult and child models, and independently from one another when they are not identical. For infant enrollees, rather than have individual HCCs sorted into failure rate groups, or use the adult or child coefficient estimation group (Super HCC) definitions, we would sort the infant enrollees' maturity-severity level interaction factors themselves into failure rate groups as Super HCCs after they have been de-duplicated. In short, for the risk adjustment models for 2021 benefit year and onward, using each age group's model factors to define Super HCCs, and sorting adult and child Super HCCs together when they have identical definitions, would increase the number of factors used in sorting from 110 under the current Super HCC grouping policy established in the 2020 RADV Amendments Rule to 146 under this approach. We propose to adopt these changes to the Super HCC policy beginning with the 2021 benefit year of HHS–RADV.

When we established the current Super HCC grouping policy in the 2020 HHS–RADV Amendments Rule,[220] we acknowledged the possibility of defining Super HCCs based on each model separately. Nevertheless, we proposed and finalized Super HCCs based on only the adult models due to concerns that using the child and infant models separately would result in some infant model Super HCCs with very small sample sizes, leading to less stable failure rate group assignments year-over-year. We also finalized a policy to use the adult models to create Super HCCs because the adult models' HCC coefficient estimation groups will be applicable to the vast majority of enrollees (including most children, considering the strong overlap between the structure of the adult and child models) and our belief that the use of HCC coefficient estimation groups present in the adult risk adjustment models sufficiently balances the representativeness and accuracy of HCC failure rate estimates across the entire population in aggregate. However, simulations run using 2018 HHS–RADV data[221] have shown that if we were to use each model's factor definitions separately as proposed in this rule, with adult and child coefficient estimation groups that have identical definitions being sorted together, we would expect 93.4 percent of factors for one benefit year of HHS–RADV to be sorted into the same failure rate group for the subsequent benefit year of HHS–RADV. Similarly, according to our simulation of 1,000 subsequent years of HHS–RADV, if we were to base Super HCCs on the adult models for adults and the child models for children and infants, the percentage of factors whose sorting would remain stable between subsequent years would be 93.2 percent. In contrast, and contrary to expectations, if Super HCCs were only based on the definitions in the adult

[219] See, for example, the August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.*

[220] See 85 FR at 76984–76900.

[221] The 2018 risk adjustment models, to which the 2018 HHS–RADV data were subject, were based on the V05 HHS–HCC classification for the HHS risk adjustment models, which is the version of the HHS–HCC classification that applies through the 2020 benefit year. The 2021 risk adjustment models, to which the 2021 HHS–RADV data will be subject, were based on the V07 HHS-Condition Categories, which applies for the 2021 benefit year and beyond.

models, we would expect only 91.4 percent of factors to remain in the same failure rate group across subsequent benefit years.

This analysis demonstrates that the very small sample sizes for enrollees subject to the infant models would not lead to more overall instability if the Super HCC policy was modified to use each age group's model factor definitions separately, except for where child and adult coefficient estimation groups have identical definitions, to define Super HCCs. In fact, our continued study of these issues found that using each model's factor definitions separately, except for where child and adult coefficient estimation groups have identical definitions, to define Super HCCs could provide more stability than using only the adult models, or a combination of the child and adult models. In addition, we note that beginning with the 2021 benefit year, the risk adjustment models were updated based on Version 07 (V07) of the HHS–HCC classification.[222] When the Super HCC policy was first implemented in the 2020 HHS–RADV Amendments Rule,[223] the risk adjustment models for the earliest HHS–RADV benefit years to which the policy was effective (HHS–RADV benefit years 2019 and 2020) were based on Version 05 (V05) of the HHS–HCC classification.[224] Due to the change in the HHS–HCC hierarchies in the V07 classification,[225] the structure of the coefficient estimation groups for the child models for the 2021 benefit year and beyond differs further from the structure of the coefficient estimation groups for the adult models than it did for the 2019 and 2020 benefit years. For these reasons, we are proposing to define Super HCCs based on each age group's model factor definitions separately, except for where child and adult coefficient estimation groups have identical definitions, as described in the relevant rows in the applicable benefit year's DIY software adult variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software,[226] the ''HCC group'' rows in Table 6: Additional Adult Variables), the relevant rows in the applicable benefit year's DIY software child variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software, the ''HCC group'' rows in Table 7: Additional Child Variables), and the relevant rows in the applicable benefit year's DIY software infant variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software, the ''Severity level'', ''Maturity level'', ''Assign as IHCC AGE1 if needed'', ''Impose hierarchy'', and ''Maturity x severity level interactions'' rows in Table 8: Additional Infant Variables).

These relevant rows of the applicable benefit year's DIY software tables would be applied such that each instance of a Super HCC is only counted once per enrollee, even if that enrollee has multiple HCCs in that Super HCC. Furthermore, any payment HCCs that are not modified by the DIY software table logic rows referenced above would be treated as individual Super HCCs, such that all Super HCCs are aligned with how their component HCCs are treated in the risk adjustment models for the applicable benefit year. We propose to apply this change beginning with the 2021 benefit year of HHS–RADV.

We seek comment on these proposals and whether Super HCCs should continue to be defined for all enrollees based on only the adult models,[227] should be defined for adult enrollees based on the adult models and for child and infant enrollees based on the child models,[228] or should be defined for each age group according to the age group risk adjustment model to which they are subject, as proposed.

c. Negative Failure Rate Constraint

In the 2020 HHS–RADV Amendments Rule,[229] we finalized a policy to constrain outlier issuers' error rate calculations to zero in cases when an issuer is a negative error rate outlier and its failure rate is negative, beginning with 2019 benefit year HHS–RADV. We finalized this policy in order to distinguish between low failure rates due to accurate data submission and failure rates that have been depressed through the presence of HCCs in the audit data that were not present in the EDGE data. If a negative failure rate is due to a large number of found HCCs, it does not reflect accurate reporting through the EDGE server for risk adjustment.

In this rule, we propose modifying the application of that policy beginning with the 2021 benefit year of HHS–RADV to constrain to zero the failure rate of any issuer who is a negative failure rate outlier in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate. We believe this proposed policy is appropriate and necessary to account for the fact that, because there are three failure rate groups in HHS–RADV, it is possible for a positive error rate outlier issuer to have a negative failure rate in one failure rate group and a positive failure rate in another failure rate group. To address those cases, we propose to amend the application of the negative failure rate constraint policy such that, for the purposes of calculating the group adjustment factor (GAF), we would constrain to zero the failure rate of any failure rate group in which an issuer is a negative failure rate outlier, regardless of whether the outlier issuer has an overall negative or positive error rate. We propose to adopt this policy beginning with the 2021 benefit year HHS–RADV. Although our experience to date leads us to believe that this scenario is unlikely to occur often, this refinement is consistent with the intent of the policy to reduce potential incentives for issuers to use HHS–RADV to identify more HCCs than were reported to their EDGE servers for an applicable benefit year.

We seek comment on this proposal.

9. Disbursement of Recouped High-Cost Risk Pool Funds—Discrepancies of Issuers of Risk Adjustment Covered Plans (§ 153.710(d))

HHS proposes that any funds recouped as a result of an actionable high-cost risk pool-related discrepancy under § 153.710(d) would be used to reduce high cost-risk pool charges for that national high-cost risk pool for the current benefit year if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for that benefit year, we propose to use the high-cost risk pool funds recouped based on an actionable

[222] 85 FR 29164.

[223] See 85 FR 76984–76990.

[224] See Table 4 of the 2019 DIY software tables, available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/DIY-Tables-2019.04.2020.xlsx.* See also Table 4 of the 2020 DIY software tables, available at *https://www.cms.gov/files/document/hhs-hcc-software-v0520128q2-tables-04132021.xlsx.*

[225] For a discussion of these changes, see 85 FR at 7098–7101 and 85 FR at 29175–29185. Also see the Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program (June 17, 2019), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.*

[226] The August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.*

[227] If this alternative approach is adopted, for infant enrollees, Super HCCs would not align with the structure of the infant risk adjustment models, as such the HHS–RADV process would involve additional steps analogous to those described in Chapter 11.3.4 of the 2020 Benefit Year HHS–RADV Protocols (available at *https://www.regtap.info/uploads/library/2020_RADV_Protocols__042921_5CR_060421.pdf*). The additional steps described in Chapter 11.3.4 of the 2020 Benefit Year HHS–RADV Protocols would not be necessary if the Super HCCs proposals in this rule are finalized as proposed such that infant enrollee Super HCCs are based on the calculated model factors used for the infant models.

[228] Ibid.

[229] 85 FR at 76994–76998.

discrepancy to reduce the next applicable benefit year's high-cost risk pool charges for all issuers owing high-cost risk pool charges for that national high-cost risk pool. As elsewhere discussed in this preamble, under ''High-Cost Risk Pool Funds—Audits of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))'' and ''Disbursement of Recouped High-Cost Risk Pool Funds—Administrative Appeals of Issuers of Risk Adjustment Covered Plans (§ 156.1220),'' we also propose similar disbursement policies for high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii) and successful administrative appeals under § 156.1220(a)(1)(ii). We propose to treat funds recouped as a result of an actionable high-cost risk pool-related discrepancy the same way. That is, the recouped discrepancy funds would be used to reduce high-cost risk pool charges for that market for the next benefit year for which high-cost risk pool payments have not already been calculated. We also clarify that when HHS recoups high-cost risk pool funds as a result of an actionable discrepancy, the issuer that filed the discrepancy would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in § 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of high-cost risk pool funds recouped as a result of an actionable discrepancy, issuers whose charge amounts are reduced would be required to report the high-cost risk pool charges paid for that benefit year net of recouped audit funds in the next MLR reporting cycle consistent with § 153.710(h).

We seek comment on this proposal.

10. Medical Loss Ratio Reporting Requirements (§ 153.710(h))

HHS established a framework in prior rulemakings to guide issuer treatment of certain payments and charges that could be subject to reconsideration for purposes of risk corridors and MLR reporting.[230] For example, because risk adjustment transfer amounts are factors in an issuer's MLR calculations, a delay in resolving final risk adjustment payments and charges, including HHS–RADV adjustments to transfers, could make it difficult for issuers to comply with reporting requirements under the MLR program. A delay in resolving final risk adjustment transfer amounts could occur due to audits, actionable discrepancies, or successful appeals. Therefore, we clarified in § 153.710(h)[231] how issuers should report certain ACA program amounts that could be subject to reconsideration for risk corridors and MLR reporting purposes. In this rule, we propose to amend the introductory sentence in § 153.710(h)(1) and to add a proposed new paragraph (h)(1)(v) to separately address and explicitly capture a reference to HHS–RADV adjustments to make clear that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts (including high-cost risk pool payments and charges). That is, notwithstanding any HHS–RADV discrepancy filed under § 153.630(d)(2), or any HHS–RADV request for reconsideration under § 156.1220(a)(1)(vii) and (viii), unless the dispute has been resolved, issuers must report, as applicable, the HHS–RADV adjustment to a risk adjustment payment or charge as calculated by HHS in the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers.[232] We also propose to add a reference to HHS–RADV discrepancies under § 153.630(d)(2) to the introductory sentence in § 153.710(h)(1).

We propose conforming amendments to paragraph (h)(2) to add a reference to HHS–RADV adjustments to address situations where there could be subsequent changes to HHS–RADV adjustments calculated by HHS in the applicable benefit year's HHS–RADV Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers, such as modifications resulting from an actionable discrepancy or successful appeal. In these situations, an issuer would be required to report during the current MLR reporting year any adjustment to an HHS–RADV adjustment made or approved by HHS before August 15, or the next applicable business day, of the current reporting year unless otherwise instructed by HHS. Issuers would be required to report any adjustment to an HHS–RADV adjustment made or approved by HHS where such adjustment has not been accounted for in a prior MLR Reporting Form, in the following reporting year. For example, if an issuer's successful administrative appeal results in changes to HHS–RADV adjustments for a state market risk pool and issuers in that state market risk pool are notified of those modifications in September, those issuers would be required to report these adjusted amounts in the next MLR reporting cycle, after the appeal has been resolved and they receive notice of the adjusted amounts. However, if an appeal is resolved and issuers are notified about modifications to HHS–RADV adjustments for a given benefit year as a result of that appeal before August 15, or the next applicable business day, those issuers must report the adjusted amounts in the current MLR reporting year.

Recognizing that flexibility is often needed in reporting these amounts on MLR forms, consistent with existing framework in § 153.710(h)(3), HHS would have the ability to modify these instructions in guidance in cases where HHS reasonably determines that these reporting instructions would lead to unfair or misleading financial reporting. Our intent in issuing any such guidance would be to avoid having the application of the instructions in exceptional circumstances lead to unfair or misleading financial reporting.[233]

Finally, we propose a technical amendment to § 153.710(h)(3) to replace the current cross-reference to paragraph (g)(1) and (2) of this section with a reference to paragraph (h)(1) and (2) of this section to point to the correct sections that contain the relevant reporting instructions. We inadvertently omitted this update as part of the amendments in the 2022 Payment Notice to incorporate an EDGE materiality threshold as part of § 153.710 that redesignated the risk corridors and MLR reporting instructions provisions from paragraph (g) to paragraph (h).[234]

We seek comments on these proposals.

11. Deadline for Submission of Data (§ 153.730)

A risk adjustment covered plan must submit data to HHS in states where HHS is operating the risk adjustment program that is necessary for HHS to calculate

[230] See 45 CFR 153.710(h). Also see 79 FR at 13789–13790 and 81 FR at 12235–12236.

[231] These instructions were previously codified in 45 CFR 153.710(g) and recently redesignated to 45 CFR 153.710(h). See 79 FR at 13789–13790 and 86 FR at 24194–24195.

[232] See Table 9 in the part 2 of the 2022 Payment Notice, 86 FR at 24201. For example, the 2019 and 2020 benefit year HHS–RADV Summary Report for non-exiting issuers will be published in early summer of 2022 and those issuers would be expected to report those amounts in their 2021 MLR Reports (filed by July 31, 2022).

[233] See, for example, Treatment of Risk Corridors Recovery Payments in the Medical Loss Ratio and Rebate Calculations (December 30, 2020), available at *https://www.cms.gov/files/document/mlr-guidance-rc-recoveries-and-mlr-final.pdf.*

[234] See 85 FR at 78604–78605 and 86 FR at 24194–24195.

risk adjustment payments and charges.[235] [236] In the 2014 Payment Notice, HHS established that the deadline for issuers to submit the required risk adjustment data is April 30 of the year following the applicable benefit year.[237] For example, the deadline for issuers of risk adjustment covered plans to submit the required 2020 benefit year risk adjustment data was April 30, 2021. HHS explained that this deadline provides ample time to allow for claims run-out from the prior benefit year to ensure that diagnoses for the benefit year are captured, while also providing HHS sufficient time to calculate payments and charges and meet the June 30 deadline for notifying issuers of risk adjustment transfer amounts at § 153.310(e).[238]

We are not proposing to change this deadline but propose to amend § 153.730 to address situations when April 30 does not fall on a business day. Currently, when April 30 falls on a non-business day, HHS has exercised enforcement discretion to extend the deadline to the next applicable business day.[239] This occurred in the past for the 2016 and 2017 benefit year data submissions and will occur again for the 2022 benefit year data submissions. Recognizing there will be future benefit years when April 30 does not fall on a business day, HHS proposes to amend § 153.730 to provide that when April 30 of the year following the applicable benefit year falls on a non-business day, the deadline for issuers to submit the required risk adjustment data would be the next applicable business day. We solicit comments on this proposal.

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

1. Non-Interference With Federal Law and Non-Discrimination Standards (§ 155.120(c))

We propose to amend 45 CFR 155.120(c) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 155.120(c), but amendments made in 2020 to § 155.120(c) removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 155.120(c) to the pre-2020 nondiscrimination protections.

Section 155.120(c) currently provides that in order to avoid interference and comply with applicable non-discrimination statutes, the states and the Exchanges must not discriminate based on race, color, national origin, disability, age, or sex. Previously, in the final rule ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers'' (Exchange Standards final rule), pursuant to the authority provided in section 1321(a)(1)(A) of the ACA to regulate the establishment and operation of an Exchange, we finalized § 155.120(c) to also prohibit discrimination based on sexual orientation and gender identity.[240] However, in the 2020 final rule related to section 1557 of the ACA, HHS revised certain CMS regulations, including those at § 155.120(c), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[241]

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in Exchanges pursuant to the authority to establish requirements with respect to the operation of Exchanges in section 1321(a)(1)(A) of the ACA.[242] Pursuant to this authority, HHS finalized in the Exchange Standards final rule that a State must comply with any applicable non-discrimination statutes, specifically finalizing that a State must not operate an Exchange in such a way as to discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. CMS proposes to exercise that same authority here to amend § 155.120(c) to again prohibit states and Exchanges carrying out Exchange requirements from discriminating based on sexual orientation and gender identity. Section 1321(a)(1)(A) of the ACA is the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 155.120(c). Utilizing this same authority to again prohibit discrimination based on sexual orientation and gender identity at § 155.120(c) would be consistent with the authority CMS relies upon for the existing protections at § 155.120(c) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex. We believe such amendments are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing these amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer back to § 147.104 under section III.B.1.b. of the preamble rather than restating the issues here.

We seek comment on this proposal.

3. Civil Money Penalties for Violations of Applicable Exchange Standards by Consumer Assistance Entities in Federally-Facilitated Exchanges (§ 155.206)

We propose to make a technical correction to 45 CFR 155.206(i) to add language that would cross-reference to the authority to implement annual inflation-related increases to civil money penalties (CMPs) pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act).[243] Because of an oversight, this language was not added to § 155.206(i) as part of prior efforts and rulemaking to implement the 2015 Act.[244] Additionally, a reference to § 155.206 and any accompanying CMP amounts have not been included in HHS's annual inflation update

[235] See 45 CFR 153.610 and 153.710. Since the 2017 benefit year, HHS has operated the risk adjustment program in all 50 states and the District of Columbia.

[236] Issuers of reinsurance-eligible plans in states where HHS operated the reinsurance program were similarly required to submit the data necessary for HHS to calculate reinsurance payments. See, for example, 45 CFR 153.420 and 153.710. The reinsurance program under section 1341 of the ACA was a temporary program that applied to the 2014–2016 benefit years. The risk adjustment program under section 1343 of the ACA is a permanent program and therefore is the primary focus of this discussion.

[237] See 78 FR 15410 at 15434.

[238] Ibid.

[239] See 81 FR 12204 at 12234 n.20; see also Evaluation of EDGE Data Submissions for 2016 Benefit Year at 1 (Dec. 23, 2016), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2016-Q_Q-Guidance_20161222v1.pdf.*

[240] 77 FR 18310 (March 27, 2012).

[241] 85 FR 37160 (June 19, 2020). *See also id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, and 156.1230).

[242] 85 FR 37218–21 (June 19, 2020).

[243] Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114–74, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, 104 Stat. 890 (1990).

[244] See, *e.g.,* Department of Health and Human Services; Adjustment of Civil Monetary Penalties for Inflation; Interim Final Rule, 81 FR 61538 (Sept. 6, 2016), available at *https://www.govinfo.gov/content/pkg/FR-2016-09-06/pdf/2016-18680.pdf.*

rulemakings.[245] Therefore, in this rule, we propose to amend § 155.206(i) to add the phrase ''as adjusted annually under 45 CFR part 102'' after the phrase ''$100 for each day'' in order to correct this oversight. The associated CMP table in 45 CFR 102.3 is updated annually, and § 155.206(i) will be included in the next annual update. To date, no CMPs have been imposed under this authority, but any that are will reflect the current inflationary adjusted amount as required by the 2015 Act and will be calculated in accordance with applicable OMB guidance to all Executive Departments on the implementation of the 2015 Act.

4. 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. Required QHP Comparative Information on Web-Broker Websites and Related Disclaimer

We propose to amend § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(1) through (c)(3)(i)(A)(5) a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We also propose to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website.

Currently, § 155.220(c)(3)(i)(A) requires that a web-broker non-Exchange website must disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c). To the extent that not all information required under § 155.205(b)(1) is displayed on the web-broker's website for a QHP, the web-broker's website must prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website, and provide a link to the Exchange website. The preamble in the proposed [246] and final [247] rules that established the current text in § 155.220(c)(3)(i)(A) explained the intent of this requirement was that a web-broker website must display all information required under § 155.205(b)(1) unless the information was not available to the web-broker, in which case the web-broker website must display the standardized disclaimer. Section 155.220(c)(3)(i)(D) similarly requires web-brokers to display all QHP data provided by an Exchange on its non-Exchange website used to participate in the FFE direct enrollment (DE) program (whether Classic DE or enhanced direct enrollment (EDE)).

In the early years of Exchange operations, we released a data file with limited QHP details (the QHP limited file) that provided web-brokers with a basic set of QHP information that could be used to satisfy the display requirements. Display of the data elements from the QHP limited file, in combination with a standardized disclaimer (the plan detail disclaimer), became the de facto minimum required to satisfy the web-broker's obligation to display QHP information on its non-Exchange website. In adopting this approach, we recognized that the Exchange may not have been able to provide web-brokers with certain data elements necessary to meet the § 155.205(b)(1) requirements, such as premium information, due to confidentiality requirements, web-broker appointments with QHP issuers, and state law. We also recognized some of the data elements, such as quality rating information, were not going to be available in the initial years of the Exchanges' operation.[248]

In the proposed 2022 Payment Notice, we proposed to establish an exception to the web-broker display requirements captured at paragraphs (c)(3)(i)(A) and (D).[249] We proposed to revise paragraph (c)(3)(i)(A) to require a web-broker non-Exchange website to disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), except when a web-broker's website does not support enrollment in a QHP. We proposed a similar revision to § 155.220(c)(3)(i)(D). A web-broker's non-Exchange website may not support enrollment in a QHP if the web-broker does not have an appointment with a QHP issuer and therefore is not permitted under state law to enroll consumers in the coverage offered by that QHP issuer. In such circumstances, we proposed that the web-broker's non-Exchange website would not be required to provide all the information identified under § 155.205(b)(1). Instead, we proposed to require web-brokers to display the following limited, minimum information for such QHPs: Issuer marketing name, plan marketing name, product network type, metal level, and premium and cost-sharing information. To take advantage of this proposed flexibility, we also proposed that web-broker non-Exchange websites would be required to identify to consumers the QHPs, if any, for which the web-broker websites did not facilitate enrollment by prominently displaying the plan detail disclaimer provided by the Exchange. The plan detail disclaimer explains that the consumer can get more information about such QHPs on the Exchange website, and includes a link to the Exchange website. We noted that we believed this proposal struck an appropriate balance by recognizing that web-brokers may not be permitted to assist with enrollments in QHPs for which they do not have an appointment while still providing key information about all QHPs on web-broker non-Exchange websites to allow consumers to window shop and identify whether they may want to explore other QHP options. We noted that it also would minimize burdens for web-brokers by not requiring them to develop processes to display all of the required comparative information listed in § 155.205(b)(1) for those QHPs for which they do not have an appointment to sell. We invited comments on the proposed limited, minimum QHP details that would be required to be displayed for those QHPs that the web-broker does not facilitate enrollment in through its non-Exchange website. We sought comment on whether to require display of any additional elements identified under § 155.205(b)(1) among the limited, minimum information, such as summaries of benefits and coverage.[250]

[245] See, *e.g.,* the Department of Health and Human Services; Annual Civil Monetary Penalties Inflation Adjustment; Final Rule, 85 FR 2869 (Jan. 17, 2020), available at *https://www.govinfo.gov/content/pkg/FR-2020-01-17/pdf/2020-00738.pdf.* See also the Department of Health and Human Services; Adjustment of Civil Monetary Penalties for Inflation and the Annual Civil Monetary Penalties Inflation Adjustment for 2021, 86 FR 62928 (Nov. 15, 2021), available at *https://www.govinfo.gov/content/pkg/FR-2021-11-15/pdf/2021-24672.pdf* and 45 CFR 102.3.

[246] See 78 FR at 37046.

[247] See 78 FR at 54077.

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

[249] See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations; Proposed Rule, 85 FR 78572 at 78614 (December 4, 2020).

[250] 45 CFR 155.205(b)(1) references the following comparative QHP information: Premium and cost-sharing information, the summary of benefits and coverage, metal level, results of enrollee satisfaction surveys, quality ratings, medical loss ratio

Continued

Almost all public comments received in response to the proposal in the proposed 2022 Payment Notice advocated for requiring that web-broker non-Exchange websites display more QHP information than the rule proposed to require, even in cases in which the web-broker non-Exchange website does not support enrollment in a QHP. The vast majority of commenters either advocated for requiring web-broker non-Exchange websites to display all available QHP information for all available QHPs, or generally supported making it easier for consumers to obtain comparative information for all available QHPs when consumers are using web-broker non-Exchange websites. After consideration of the comments received, we did not finalize the proposed amendments to § 155.220(c)(3)(i)(A) and (c)(3)(i)(D). We agreed that the display of more QHP information on web-broker non-Exchange websites is in the best interest of consumers to aid them in comparing QHP options without having to potentially navigate to multiple websites, consistent with the views of a majority of commenters who advocated for requiring that web-broker non-Exchange websites display all of the comparative information listed in § 155.205(b)(1). We also noted our belief that requiring web-broker non-Exchange websites to display additional QHP information is reasonable given that QHP information has been more readily accessible for some time, both through public use files and the Marketplace API.

As a result, we communicated in the preamble of part 2 of the 2022 Payment Notice final rule our intent, pending future rulemaking when these issues could be further clarified, to limit our current use of enforcement discretion that permits web-brokers to only display issuer marketing name, plan marketing name, product network type, and metal level for all available QHPs, beginning with the PY 2022 open enrollment period.[251] We stated that web-broker non-Exchange websites would be required to display all QHP information consistent with § 155.205(b)(1) and (c), with the exception of MLR information and transparency of coverage measures under § 155.205(b)(1)(vi) and (vii), for all available QHPs, beginning with the PY 2022 open enrollment period. We indicated we would not deem a web-broker non-Exchange website out of compliance with § 155.220(c)(3)(i)(A) and (D) with respect to the display of MLR information and transparency of coverage measures if the web-broker non-Exchange website displays the other required standardized comparative information consistent with § 155.205(b)(1) and (c). We also explained that prior to the start of the open enrollment period for PY 2022, if a web-broker's non-Exchange website did not display all QHP information consistent with the requirements of § 155.205(b)(1) and (c), other than MLR information and transparency of coverage measures, it would be required to prominently display the plan detail disclaimer and provide a link to the Exchange website. We noted that this interim approach did not establish new requirements and instead represented a change in the exercise of enforcement discretion regarding the standardized comparative information web-brokers are required to display under existing regulations following our consideration of comments on the proposed changes to the web-broker QHP display requirements in the proposed 2022 Payment Notice.

We now propose to revise § 155.220(c)(3)(i)(A) to incorporate a general requirement that web-broker non-Exchange websites display the QHP comparative information from § 155.205(b)(1), consistent with our forecast in the preamble of part 2 of the 2022 Payment Notice final rule.[252] Specifically, we propose to codify new §§ 155.220(c)(3)(i)(A)(1) through (5) to require web-broker websites to display premium and cost-sharing information, the summary of benefits and coverage established under section 2715 of the PHS Act; identification of the metal level of the QHP as defined by section 1302(d) of the ACA or whether it is a catastrophic plan as defined by section 1302(e) of the ACA; the results of the enrollee satisfaction survey as described in section 1311(c)(4) of the ACA; quality ratings assigned in accordance with section 1311(c)(3) of the ACA; and the provider directory made available to the Exchange in accordance with § 156.230 as the minimum QHP comparative information web-broker non-Exchange websites must display for all available QHPs. Including this information within § 155.220, instead of through a cross-reference to § 155.205(b)(1), would provide better clarity and ease of reference and establish a list of required QHP comparative information consistent with our current enforcement approach, which, as discussed above, does not require the display of MLR information and transparency of coverage measures.

In addition, we propose to modify the language in § 155.220(c)(3)(i)(A) that served as the basis for the plan detail disclaimer requirement to instead require web-broker non-Exchange websites that do not support enrollment in all available QHPs to provide notice to consumers of that fact, and direct consumers to the Exchange website where they may obtain enrollment support. We propose to revise § 155.220(c)(3)(i)(A) to state that web-broker websites must disclose and display the following QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c), and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a web link to the Exchange website. Historically the plan detail disclaimer served as the mechanism and visual cue to convey to consumers where they may find additional information about particular QHPs and how they may enroll in those QHPs (that is, using *HealthCare.gov*). However, requiring the continued display of the plan detail disclaimer is unnecessary and would be confusing as the plan detail disclaimer states more information about QHPs is available on *HealthCare.gov* when in fact web-broker non-Exchange websites will be displaying the same QHP comparative information as *HealthCare.gov*.[253] In the absence of the plan detail disclaimer, the secondary function of conveying those QHPs for which enrollment support is not available through the web-broker's non-Exchange website and how consumers may obtain enrollment support is lost. This proposal to modify the disclaimer requirement in § 155.220(c)(3)(i)(A) to convey to consumers those QHPs for which a web-broker website does not provide enrollment support and to direct them to where they can obtain enrollment support would serve the function lost by

information, transparency of coverage measures, and the provider directory.

[251] See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Final Rule, 86 FR 24140 at 24206 (May 5, 2021).

[252] Ibid.

[253] The Plan Detail Disclaimer states: ''[Name of Company] isn't able to display all required plan information about this Qualified Health Plan at this time. To get more information about this Qualified Health Plan, visit the Health Insurance Marketplace® website at *HealthCare.gov*.'' See p.53 *Federally-Facilitated Exchanges (FFEs) and Federally-Facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual*, section 5.3.2, August 18, 2021, available at *https://www.regtap.info/uploads/library/ENR_FFEFFSHOPEnrollmentManual2020_5CR_090220.pdf https://www.cms.gov/files/document/ffeffshop-enrollment-manual-2021.pdf*.

the elimination of the plan detail disclaimer requirement.

We seek comment on these proposals.

b. Prohibition of QHP Advertising on Web-Broker Websites

Section 155.220(c)(3)(i)(L) prohibits web-broker non-Exchange websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers. We propose to amend § 155.220(c)(3)(i)(L) to make clear that web-broker non-Exchange websites are also prohibited from displaying QHP advertisements, or otherwise providing favored or preferred placement in the display of QHPs, based on compensation agents, brokers, or web-brokers receive from QHP issuers. We have observed a web-broker marketing to QHP issuers on its website the option for their QHPs to receive ''preferred placement'' on the web-broker website for a fee. The marketing materials indicated preferred placement on the web-broker's website would position selected QHPs at the forefront of the user experience on the website. The marketing materials also suggested that users would not be made aware that preferred plan placements were purchased for a fee, and such placements were not assigned based on the specific attributes of the plans in relation to other available plans for which issuers did not purchase preferred placement.

We believe QHP advertising on web-broker websites, whether or not characterized as such or using other terms such as ''preferred placement,'' is not in the best interest of consumers. QHP advertisements on web-broker websites could be perceived by consumers, and agents and brokers assisting consumers, as permissible QHP recommendations by the web-broker based on the best interests of the consumer rather than on the basis of payment from the QHP issuer to the web-broker. Consumers, and agents and brokers assisting consumers, may also inadvertently perceive advertisements placing a QHP in a favored position on a web-broker's website as the result of a neutrally applied filter of all available QHPs. These risks are substantially increased if the advertisements are not clearly identified as advertisements. However, even if QHP advertisements are clearly identified, we believe it is not in the interest of consumers to allow them on web-broker websites. In light of the many different approaches to advertising that exist now or may be adopted in the future, we do not believe that attempting to identify which advertising practices are permissible and which are not is practical or sufficiently protective of consumers' interests. Advertising is intended to bias consumer, agent, or broker perceptions in a way that benefits the advertiser, rather than the consumer or client. QHP advertisements on web-broker websites could take forms other than favored or preferred placement among a list of other QHPs (for example, obscuring the availability of other QHPs), including forms that could be more confusing or deceptive to consumers, in particular those consumers who may have limited familiarity with health insurance products and terminology and may be easily misled by advertising claims.

Although § 155.220(c)(3)(i)(L) prohibits web-broker websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers, it does not explicitly prohibit QHP advertising, or otherwise providing favored or preferred placement in the display of QHPs, based on compensation an agent, broker, or web-broker receives from QHP issuers. Therefore, we propose to amend § 155.220(c)(3)(i)(L) to make clear that when a web-broker website is used to complete the QHP selection, the website must not display QHP advertisements or recommendations, or otherwise provide favored or preferred placement in the display of QHPs, based on compensation the agent, broker, or web-broker receives from QHP issuers. For purposes of this proposal, we intend for advertisements to include any form of marketing or promotion of QHPs based on compensation from QHP issuers, as opposed to the application of a neutral filter or sorting methodology that may promote particular QHPs and that are not based on compensation an agent, broker, or web-broker receives from QHP issuers.

We seek comment on this proposal.

c. Explanation of Rationale for QHP Recommendations on Web-Broker Websites

We propose to amend § 155.220 to add a proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on plan name, from lowest to highest premium, etc.). We believe this proposed new requirement would provide consumers with a better understanding of the information being presented to them on web-broker websites, thereby enabling them to make better informed decisions and shop for and select QHPs that best fit their needs.

Web-broker websites typically begin their consumer experiences with a series of screening questions. Often these screening questions are intended to assist consumers with determining whether they may qualify for insurance affordability programs (for example, APTC or Medicaid). Sometimes the screening questions request additional information unrelated to potential eligibility for insurance affordability programs, such as asking about preferred providers, prescription drug needs, or expected need for health care services in the coming year. Some web-brokers use the information collected in response to the preliminary screening questions to recommend one or more QHPs to consumers, or to rank all available QHPs from most to least recommended. Web-broker websites may recommend QHPs so long as they do not do so based on compensation an agent, broker, or web-broker receives from QHP issuers, consistent with § 155.220(c)(3)(i)(L), as described above. Current rules do not require web-broker websites to include an explanation of the rationale for QHP recommendations. All web-broker websites must adopt a default display of QHPs by virtue of providing consumers a list of available QHPs, and the default display implicitly recommends those QHPs displayed at the top of the list.[254] In addition, many web-broker websites offer filtering tools that consumers may use to adjust the default display of QHPs (for example, reordering the QHPs from lowest to highest deductible or limiting the display to silver metal level QHPs). In cases in which QHP display filtering tools are available and prominently displayed on a web-broker website, and when the default application of a filter produces the default ordering of QHPs displayed, the methodology for the default QHP display may be apparent. However, in other cases, consumers may not realize the implications of the default display of QHPs or may find it difficult to understand the methodology underlying the default display. Current rules do not require web-broker websites to include an explanation of the methodology used for their default displays of QHPs.

We support web-broker websites' use of innovative decision-support tools for consumers to help them shop for and select QHPs that best fit their needs. However, web-broker websites that explicitly recommend or rank QHPs do

[254] 45 CFR 155.220(c)(3)(i)(B) requires web-broker websites to provide consumers the ability to view all QHPs offered through the Exchange.

not always provide an explanation for their recommendations or rankings. Similarly, web-broker websites may not include an explanation of the methodology used for their default displays of QHPs, and it may not otherwise be apparent what methodologies are used. The absence of such explanations may cause some consumers to misunderstand the bases for the recommendations displayed to them on web-broker websites (whether explicit or implicit), or may prevent them from assessing the value of the recommendations (for example, whether a recommendation is based on the factors most important to them). In addition, the lack of explanations for QHP recommendations on web-broker websites may obscure that the web-broker is recommending QHPs based on compensation the web-broker receives from QHP issuers in violation of § 155.220(c)(3)(i)(L). For these reasons, we propose to amend § 155.220 to add proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for QHP recommendations and the methodology for its default display of QHPs.

We seek comment on this proposal.

d. Federally-Facilitated Exchange Standards of Conduct (§ 155.220(j))

We propose to amend § 155.220(j)(2)(i) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 155.220(j), but amendments made in 2020 to § 155.220(j) removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 155.220(j) to the pre-2020 nondiscrimination protections.

Section 155.220(j)(2)(i) describes that an individual or entity described in paragraph (j)(1) must provide consumers with correct information, without omission of material fact, regarding the FFE, QHPs offered through the FFE, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex. Previously, in the 2017 Payment Notice final rule, we finalized § 155.220(j)(2)(i) to also prohibit discrimination based on sexual orientation and gender identity.[255] However, in the 2020 final rule related to section 1557 of the ACA, HHS revised certain CMS regulations, including § 155.220(j)(2)(i), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[256]

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in the group and individual market pursuant to the Secretary's authority to establish procedures for States to permit agents and brokers to enroll consumers in QHPs through the FFEs, as described in sections 1312(e) of the ACA,[257] and the authority to establish requirements with respect to the operation of Exchanges, the offering of QHPs through such Exchanges, and other requirements as the Secretary determines appropriate under sections 1321(a)(1)(A), (B), and (D) of the ACA. Pursuant to this authority, in the 2017 Payment Notice final rule, HHS finalized at § 155.220 standards of conduct for agents and brokers that assist consumers to enroll in coverage through the FFEs to protect consumers and ensure the proper administration of the FFEs, including nondiscrimination standards at § 155.220(j)(2)(i) that prohibited agents, brokers and web-brokers described in paragraph (j)(1) from discriminating based on sexual orientation and gender identity. CMS further explained that such standards of conduct were necessary to protect against agent and broker conduct that is harmful towards consumers, or that prevents the efficient operation of the FFEs. CMS proposes to exercise that same authority here to amend § 155.220(j)(2)(i) to again prohibit an individual or entity described in paragraph (j)(1) from discriminating based on sexual orientation and gender identity. Sections 1312(e) and 1321(a)(1)(A), (B), and (D) of the ACA are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 155.220(j)(2)(i). Utilizing these same authorities to again prohibit discrimination based on sexual orientation and gender identity at § 155.220(j)(2)(i) would be consistent with the authority CMS relies upon for the existing protections at § 155.220(j)(2)(i) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex. We believe such amendments are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer back to § 147.104 under section III.B.1.b. of the preamble rather than restating the issues here.

We seek comment on this proposal.

i. Providing Correct Information to the FFEs

Section 155.220(j)(2) sets forth the standards of conduct for agents, brokers, or web-brokers that 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 that assist individuals in applying for APTC and CSRs for QHPs sold through an FFE. As explained in the 2017 Payment Notice proposed rule, these standards are designed to protect against agent, broker, and web-broker conduct that is harmful towards consumers or prevents the efficient operation of the FFEs.[258] Pursuant to § 155.220(j)(2)(ii), agents, brokers, or web-brokers must provide the FFEs with ''correct information under section 1411(b) of the Affordable Care Act.'' Section 1411(b) of the ACA details the information required to be provided by applicants to the Exchange to determine eligibility for Exchange coverage, APTC, CSRs, and individual responsibility exemptions, including the applicant's name, address, and information regarding household income.[259] Section 1411(h) of the ACA provides for the imposition of civil penalties if any person fails to provide correct information under section 1411(b) to the Exchange. Consistent with § 155.220(l), agents, brokers and web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in states with SBE–FPs must comply with all applicable FFE standards. This includes, but is not limited to, compliance with the FFE standards of conduct in § 155.220(j). We propose to amend § 155.220(j)(2)(ii) to add proposed new § 155.220(j)(2)(ii)(A) through (D) to codify additional details regarding the requirement that agents,

[255] 80 FR 12204 (March 8, 2016).

[256] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[257] 85 FR 37218–21 (June 19, 2020).

[258] 80 FR at 75526–75527.

[259] Also see 45 CFR 155.285(a)(1)(i) and (ii).

brokers, and web-brokers provide correct information to FFEs and SBE–FPs. More specifically, we propose to capture specific examples of what it means to provide correct information to the FFEs and SBE–FPs with respect to the consumer's email address, mailing address, telephone number, and household income projection based on our experience operating the FFEs and the Federal platform on which certain State-based Exchanges rely.

HHS has frequently observed applications submitted to the FFEs that contain incorrect consumer information, including applications that contain incorrect email addresses, telephone numbers, and mailing addresses. As administrator of the FFEs, HHS also has received applications that contain incorrect consumer household income projections that do not accurately reflect future consumer household income. These practices can harm consumers and prevent the efficient operation of the FFEs. Therefore, we propose to add language to § 155.220(j)(2)(ii) to address these common problems occurring on Exchange applications and provide clear standards intended to substantially reduce the occurrence of those problems to protect consumers and the efficient operation of the Exchanges. We also propose to amend § 155.220(j)(2)(ii) to make clear that the proposed standards of conduct related to agents, brokers, and web-brokers providing the FFEs and SBE–FPs with correct information that are listed in proposed new § 155.220(j)(2)(ii)(A) through (D) are not exhaustive, but are simply the areas where HHS has thus far identified a need for more direct and clear guidance.

First, we propose to add proposed new § 155.220(j)(2)(ii)(A), which would provide that an agent, broker, or web-broker may only enter an email address on an application for Exchange coverage or for APTC and CSRs for QHPs sold through an FFE or SBE–FP that is secure, not disposable, and belongs to the consumer or the consumer's authorized representative designated in compliance with § 155.227. We also propose to clarify that email addresses may only be entered on Exchange applications with the consent of the consumer or the consumer's authorized representative, and that properly entered email addresses would be required to adhere to the following guidelines pursuant to proposed new § 155.220(j)(2)(ii)(A)(1) through (3): (1) The consumer's email addresses may not have domains that remove email from an inbox after a set period of time; (2) the consumer's email address must be accessible by the consumer, or the consumer's authorized representative designated in compliance with § 155.227, and may not be accessible by the agent, broker, or web-broker, and (3) the consumer's email addresses may not have domains that belong to the agent, broker, or web-broker or their business or agency. These proposed standards align with existing guidance provided to agents, brokers, and web-brokers.[260]

HHS is proposing to codify these standards because it has observed numerous Exchange applications that contain email addresses that are disposable (where emails disappear after a set number of days), unsecure (where emails may be accessed without a password), or temporary (where the email address will cease to receive messages after a set time). HHS' concern arises from the fact that it has observed agents, brokers, and web-brokers submitting unauthorized Exchange applications on behalf of consumers without their knowledge or consent that contain these types of email addresses. HHS recognizes that such email addresses may be used by consumers to avoid receiving spam emails to a main inbox, but the use of these email addresses on Exchange applications defeats the purpose of entering an email address and occurs at a higher rate on applications assisted by agents, brokers, and web-brokers, many of which are unauthorized. Consumers who wish to avoid receiving emails from the Exchange and who are being assisted by an agent, broker, or web-broker may simply omit a contact email address from their Exchange application.

The email address provided as part of an Exchange application should provide a secure place for a consumer to receive vital information from the Exchange about their application. Emails sent to consumers through the Exchange often contain important information. As such, the consumer's email address entered on an Exchange application should be secure and only accessible by the consumer or the consumer's authorized representative designated in compliance with § 155.227. Allowing the use of email addresses that are disposable, unsecure, or temporary may harm the consumer by preventing the consumer from receiving important information from the Exchange regarding their Exchange application. It also could prevent the efficient operation of the Exchange. We therefore propose in this rule to clarify and codify that if an email address is included on the Exchange application, it must be the consumer's, or that of the consumer's authorized representative designated in compliance with § 155.227, to comply with the FFE standard of conduct under § 155.220(j)(2)(ii) to provide correct information to the Exchange.

Second, we propose to add proposed new § 155.220(j)(2)(ii)(B), which would provide that an agent, broker, or web-broker may only enter a telephone number on an application for Exchange coverage or an application for APTC and CSRs for QHPs that belongs to the consumer or their authorized representative designated in compliance with § 155.227. We also propose to provide that telephone numbers entered on Exchange applications may not be the personal number or business number of the agent, broker, or web-broker assisting with or facilitating enrollment through an FFE or assisting the consumer in applying for APTC and CSRs for QHPs, or their business or agency, unless the telephone number is actually that of the consumer or their authorized representative. These proposed standards align with existing guidance provided to agents, brokers, and web-brokers.[261]

Similar to email addresses, a telephone number belongs to the consumer if they, or their authorized representative, are accessible at the number and have access to the number. A telephone number provides a way for the consumer or their authorized representative to be contacted if there is an issue or question with the Exchange application. Allowing an agent, broker, or web-broker to list their telephone number or a telephone number associated with their business or agency in the place of the consumer's telephone number would not serve or benefit the consumer, but may harm the consumer by preventing the consumer from receiving important information from the Exchange regarding their Exchange application. It also could prevent the efficient operation of the Exchange. In addition, unlike email addresses, a telephone number is a required field when creating and submitting an Exchange application. We therefore propose in this rule to clarify and codify that the telephone number included on the Exchange application must be the consumer's, or that of the consumer's authorized representative as designated in compliance with § 155.227, to comply with the FFE standard of conduct under § 155.220(j)(2)(ii) to provide correct information to the Exchange.

[260] *https://www.regtap.info/uploads/library/AB_Slides_Compliance_052021_5CR_062221.pdf* See Compliance with Marketplace Requirements: Reminders for Agents and Brokers, May 20, 2021, available at *https://www.regtap.info/uploads/library/AB_Slides_Compliance_052021_5CR_062221.pdf.*

[261] *Ibid.*

Third, we propose to add proposed new § 155.220(j)(2)(ii)(C), which would provide that an agent, broker, or web-broker may only enter a mailing address on an application for Exchange coverage or an application APTC and CSRs for QHPs that belongs to, or is primarily accessible by, the consumer or their authorized representative designated in compliance with § 155.227. Further, the mailing address entered on the Exchange application must not be for the exclusive or convenient use of the agent, broker, or web-broker, and must be an actual residence or a secure location where the consumer or their authorized representative may receive correspondence, such as a P.O. Box or homeless shelter. These proposed standards align with existing guidance provided to agents, brokers, and web-brokers.[262] We also propose to provide that mailing addresses entered on Exchange applications may not be that of the agent, broker, or web-broker, or their business or agency, unless it is the rare situation where that address is the actual residence of the consumer or their authorized representative. HHS is proposing this change because it has observed numerous instances in which agents, brokers, or web-brokers have engaged in unauthorized enrollments of consumers in Exchange coverage without their knowledge or consent that involve the use of the same common mailing address on multiple Exchange applications that are not the actual residence of the consumer or their authorized representative.

As with telephone numbers, Exchange applications must provide a mailing address where the consumer or their authorized representative may be reached. Application or plan information may be sent to this mailing address, which is why it is important that the mailing address be the actual residence or a secure location where the consumer or their authorized representative may receive correspondence. Entering an incorrect mailing address on a consumer's Exchange application would result in situations where the consumer would not receive this information. This would harm consumers and prevent the efficient operation of the Exchange. We therefore propose in this rule to clarify and codify that the mailing address included on the Exchange application must be the consumer's, or the consumer's authorized representative as designated in compliance with § 155.227, to comply with the FFE standard of conduct under § 155.220(j)(2)(ii) to provide correct information to the Exchange.

Fourth, to minimize consumer harm stemming from the IRS reconciliation process, as well as to protect Exchange operations from inaccurate APTC and CSR determinations, we propose to add proposed new § 155.220(j)(2)(ii)(D), which would provide that when submitting household income projections on applications submitted to the Exchange to determine a tax filer's eligibility for APTC in accordance with § 155.305(f) or CSRs in accordance with § 155.305(g), an agent, broker, or web-broker may only enter a household income projection for a consumer that the consumer or the consumer's authorized representative designated in compliance with § 155.227, has authorized and confirmed is an accurate estimate. We propose to require that household income projections on Exchange applications must be attested to by the consumer or their authorized representative, and clarify that the agent, broker, or web-broker may answer questions posed by the consumer or their authorized representative related to household income projection, such as helping determine what qualifies as household income.

HHS is proposing this change because it has observed several instances in which agents, brokers, and web-brokers have provided inaccurate consumer household income projections on Exchange applications to obtain the lowest monthly premium rate for QHP coverage. This is problematic in situations when consumers are enrolled without their knowledge or consent because if a consumer is enrolled in an Exchange policy with a zero-dollar monthly payment, the consumer may not be aware they have been enrolled because there would not be a monthly bill. HHS has observed several instances where consumers have gone months without realizing they are enrolled in a QHP with APTC, typically finding out about the unauthorized enrollment when the IRS contacts them regarding money they owe due to not qualifying for all or part of the APTC paid for this coverage or when the IRS delays release of a tax refund.

Pursuant to § 155.305(f), a tax filer is, in general, not eligible for APTC unless the Exchange determines that the tax filer is expected to have household income, as defined in 26 CFR 1.36B–1(e), of greater than or equal to 100 percent but not more than 400 percent of the FPL for the year for which coverage is requested.[263] It is crucial that consumers applying for a QHP or applying for APTC and CSRs for QHPs provide an estimate of their projected household income that is as accurate as possible for an Exchange to be able to determine their eligibility for APTC. Failure to provide correct information on household income can harm consumers by creating liability during the reconciliation process or delaying the issuance of a tax refund, as well as prevent the efficient operation of the Exchange. More specifically, although eligible consumers may use APTC to lower their monthly premiums for QHP coverage through an Exchange if a consumer's projected household income on his or her Exchange application submission is inaccurate and lower than the actual household income, the consumer is likely to have excess APTC (the extent to which APTC exceeds the allowed PTC), all or a portion of which must be repaid when the consumer files his or her federal income tax return for the year of coverage as required under 26 U.S.C. 36B(f) and 26 CFR 1.36B–4. Each year, consumers for whom APTC is paid must submit Form 8962 with their annual federal income tax return to the IRS. On Form 8962, the consumer must reconcile the APTC paid on his or her behalf with the PTC[264] the consumer is allowed. Generally, consumers whose projected household annual income at enrollment is less than the actual annual household income will have excess APTC that must be repaid, subject to a repayment limit for consumers with household income below 400 percent of the FPL. Consumers are required to repay excess APTC by increasing their tax liability for the year by all or a portion of the excess APTC. Good-faith income projections, versus an income projection designed to achieve the lowest monthly rate, better protect the consumer from the unexpected cost and burden of repaying large amounts of APTC. Additionally, per § 155.305(b), Exchange enrollees must report changes that may impact their eligibility for financial assistance or coverage, including their projected annual household income, within 30 days of the change.

CSRs are similarly tied to a consumer's household income and they lower the amount that certain eligible individuals have to pay for deductibles, copayments, and coinsurance. Incorrect projections of a consumer's household income would also lead to incorrect CSR determinations, which would harm

[262] Ibid.

[263] Section 9661 of the American Rescue Plan Act of 2021 makes individuals with household incomes above 400 percent of the FPL who meet all other eligibility criteria eligible for APTC, but only through PY 2022.

[264] *https://www.irs.gov/pub/irs-pdf/p974.pdf.*

QHP issuers and prevent the efficient operation of the Exchange.

An estimate of a consumer's household income is required on the Exchange application if the consumer is applying for APTC and CSRs. As outlined above, agents, brokers, or web-brokers who are intentionally or negligently entering inaccurate household income projections on a consumer's Exchange application can harm consumers and prevent the efficient operation of the Exchange. We therefore propose in this rule to clarify and codify that if household income projections are included on the Exchange application, the estimate must be attested to by the consumer or the consumer's authorized representative as designated in compliance with § 155.227 to comply with the FFE standard of conduct under § 155.220(j)(2)(ii) to provide correct information to the Exchange.

As noted previously in this rule, the proposal to amend § 155.220(j)(2)(ii) to add proposed new § 155.220(j)(2)(ii)(A) through (D) is not intended to constitute an exhaustive list of practices that govern providing correct information to the Exchange under § 155.220(j)(2)(ii); rather, these are areas where HHS has thus far identified a need for more direct and clear guidance to protect consumers and the efficient operation of the Exchanges.

We seek comment on these proposals.

ii. Prohibited Business Practices

We propose to amend § 155.220(j)(2) to add several new standards of conduct for agents, brokers, and web-brokers that assist consumers with applying for and enrolling in coverage through an FFE or SBE–FP, with or without APTC and CSRs. Similar to the standards first established in the 2017 Payment Notice, these additional standards are also intended to protect against agent, broker, and web-broker conduct that is harmful towards consumers or frustrates the efficient operation of the Exchange. More specifically, we propose to codify standards related to the use of scripting and other automation interactions with CMS Systems or the DE Pathways (including both Classic DE and EDE), identity proofing consumer accounts on *HealthCare.gov,* and providing assistance with SEP enrollments. HHS is proposing these new FFE standards of conduct for agents, brokers, and web-brokers assisting consumers in FFEs and SBE–FPs because it has observed practices in these areas that have caused or can cause harm to consumers, as well as impede the efficient operation of the Exchange.

iii. Prohibited Automated Interactions With CMS Systems

In order to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and assist individuals in applying for APTC and CSRs for QHPs, agents, brokers, and web-brokers must comply with the regulatory requirements contained in § 155.220, including the requirement that such agents, brokers, and web-brokers comply with the terms of applicable agreements between the agent, broker, or web-broker and the Exchange.[265] One such agreement, the ''Agent Broker General Agreement for Individual Market Federally-Facilitated Exchanges and State-Based Exchanges on the Federal platform (IM General Agreement),'' [266] sets forth requirements related to automation. Specifically, section IV(c)(i)(4) of the IM General Agreement provides that scripting and other automation of interactions with CMS Systems or the DE Pathways are strictly prohibited, unless approved in advance by CMS. While these requirements are addressed in the IM General Agreement, they are not currently explicitly set forth in regulation. Therefore, we propose to amend § 155.220(j)(2) to add proposed new § 155.220(j)(2)(vi) to codify requirements and limitations on the use of automation and align the regulation with the IM General Agreement. New proposed § 155.220(j)(2)(vi) would provide that an agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through an FFE or SBE–FP, or assists individuals in applying for APTC and CSRs for QHPs sold through an FFE, or SBE–FP must not engage in scripting and other automation of interactions with CMS Systems or DE Pathways, unless approved in advance in writing by CMS.

CMS Systems to which CMS-registered agents, brokers, and web-broker may have access include *HealthCare.gov,* and the CMS Enterprise Portal. Codifying a regulation that addresses the use of automation in relation to these systems and platforms would help to establish clear and enforceable standards that would govern the behavior of agents, brokers, and web-brokers when assisting Exchange applicants. It would also clarify CMS' authority to take enforcement action against agents, brokers, and web-brokers for violations of these requirements.

HHS is proposing this standard of conduct because it has observed instances where unauthorized automated browser-based interactions with Exchange systems have led to unauthorized enrollments, unauthorized application changes, or unauthorized access to consumer PII. The risk of harm to consumers and the efficient operation of the Exchange is heightened when automated interactions occur because more consumer information can be downloaded using automation than through a manual process. Automated browser-based interactions with Exchange systems can lead to increases in unauthorized enrollments, unauthorized application changes, or unauthorized access to consumer PII because agents, brokers, and web-brokers could find far more consumer information using automation, which could result in the unauthorized taking, use, or sale of significant amounts of consumer PII for unlawful purposes. Allowing automation would also create significant traffic in the system, which could result in increased risk of system speed slowdowns and stability issues, as these automated interactions would cause a lot more system activity per user than anticipated and planned for. We seek comments on these concerns and this proposal. While this proposed rule is under consideration, CMS will continue to take appropriate enforcement action in response to situations resulting from unauthorized use of automation in connection with CMS Systems.[267]

We note that certain web-broker interactions with the Exchange were created with the intention of being automated, including the plan finder Application Program Interface (API) and Marketplace API. Thus, this proposal to prohibit use of automation in other circumstances is sufficiently narrowly tailored to accommodate these limited instances when automation is permitted in connection with CMS Systems or DE Pathways when approved in advance in writing by CMS. CMS believes that other uses of automation beyond what is currently approved may have appropriate business use cases. We therefore seek comment on appropriate uses of automation that may contribute to the efficient operation of the FFEs and SBE–FPs, and the DE Pathways.

iv. Identity Proofing

HealthCare.gov utilizes identity proofing to verify the identity of a consumer when a new Exchange

[265] 45 CFR 155.220(d).

[266] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ab_py2020_im_general_agreement_final_1.pdf.*

[267] See 45 CFR 155.220(g), (k), and (m).

account is created. We propose to amend § 155.220(j)(2) to add proposed new § 155.220(j)(2)(vii), which would provide that when identity proofing accounts on *HealthCare.gov,* agents, brokers, or web-brokers must only use an identity that belongs to the consumer. Currently, identity proofing is required when a consumer creates an account on *HealthCare.gov* via an EDE site, and when a consumer works with an agent or broker in person.[268] When a consumer creates an account on *HealthCare.gov* or an EDE site, they go through a remote identity proofing (RIDP) process. The RIDP process is an Experian service that takes basic demographic information regarding the consumer and requires the consumer to answer multiple choice questions correctly to proceed. This is done to ensure the consumer is a real person, to protect the consumer's personal information, and to prevent someone else from creating an Exchange account and applying for Exchange coverage in another's name without their knowledge or consent.

We are proposing this amendment to § 155.220(j)(2), as we have observed situations in which agents have used the same identity information to complete the identity proofing process for multiple consumer Exchange accounts, which can harm to consumers and prevent the efficient operation of the Exchange, undermines the purpose of identity proofing consumers and is often associated with unauthorized enrollments, identity theft, and fraud.

We seek comment on this proposal.

v. Providing Information to Federally-Facilitated Exchanges in Connection With Special Enrollment Periods

Finally, § 155.420(a)(1) provides that the Exchange must provide SEPs during which qualified individuals may enroll in QHPs and enrollees may change QHPs. We propose to amend § 155.220(j)(2) to add proposed new § 155.220(j)(2)(viii), which would state that when providing information to FFEs that may result in a determination of eligibility for an SEP under § 155.420, agents, brokers, and web-brokers must obtain authorization from the consumer to submit the request for a determination of eligibility for a SEP (although this authorization does not need to be in writing) and make the consumer aware of the specific triggering event and SEP for which the agent, broker, or web-broker will be submitting an eligibility determination request on the consumer's behalf. Under this new proposed standard of conduct, agents, brokers, and web-brokers providing assistance with SEP enrollments would be required to make reasonable, good faith efforts to ascertain the consumer's eligibility for the SEP, consistent with the existing standard under § 155.220(j)(3). We propose this requirement to address circumstances HHS has observed under which consumers who apply for QHP enrollment through an SEP with the assistance of an agent, broker, or web broker are not made aware of the basis upon which their QHP application claims entitlement to an SEP, or who otherwise did not authorize an agent, broker, or web-broker to enroll them in a QHP or make a change to their current QHP enrollment.

The purpose of SEPs is to promote access to health insurance coverage and continuous coverage by allowing individuals to enroll outside of the open enrollment period only if they experience certain SEP triggering events; this helps to avoid and control against adverse selection that would destabilize the Exchanges. The purpose of proposing to codify this requirement in proposed new § 155.220(j)(2)(viii) is to ensure the validity and integrity of the SEP process, avoid Exchange destabilization, and to create clear, enforceable standards to help mitigate consumer harm by establishing that agents, brokers, and web-brokers are responsible for providing information to the FFE that is accurate to the best of their knowledge, and to which the consumer has attested.

We seek comment on these proposals.

5. Premium Calculation (§ 155.240(e))

HHS proposes to add language at § 155.240(e)(2) to apply the premium calculation methodology currently applicable in the FFEs and SBE–FPs to all Exchanges, beginning with PY 2024. This proposed amendment to § 155.240(e), along with the proposed amendments to §§ 155.305(f)(5) and 155.340, support HHS's proposal to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. We further discuss these proposed changes in the Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340) section of this proposed rule where we propose to require all Exchanges to prorate premium and APTC amounts in cases where an enrollee is enrolled in a particular policy for less than the full coverage month. We seek comment on these proposals.

6. Eligibility Standards (§ 155.305)

We are proposing a technical amendment to § 155.305(f)(1)(i) to clarify that the income eligibility standards used by the Exchange for determining whether an individual is an applicable taxpayer for purposes of APTC eligibility are the same as the income thresholds at IRS regulation 26 CFR 1.36B–2(b). Whereas the current regulation states expected household income must be ''greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested,'' the proposed amendment specifies the individual must have an expected household income which will qualify the tax filer as an applicable taxpayer according to 26 CFR 1.36B–2(b). In turn, 26 CFR 1.36B–2(b) outlines the FPL percentage thresholds that are used for determining PTC eligibility. In practice, the federal and state Exchanges have always relied on thresholds outlined in 26 CFR 1.36B–2(b) to determine APTC eligibility, but we note that this proposed change allows for greater regulatory consistency and minimizes the need to update § 155.305(f)(1)(i) in response to legislative changes that may alter FPL percentage thresholds, as occurred for certain years under the ARP.

7. Eligibility for Advance Payments of the Premium Tax Credit (§ 155.305(f)(5))

HHS proposes to amend § 155.305(f)(5) to require that APTC must be calculated in accordance with 26 CFR 1.36B–3 and would be subject to the prorating methodology at proposed § 155.340(i). This proposed amendment to § 155.305(f)(5), along with the proposed amendments at §§ 155.240(e), and 155.340, detailed elsewhere in this rule, support HHS's proposal to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. We further discuss these proposals in the Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340) section of this proposed rule. We seek comment on this proposal.

[268] Section 1411(g)(1) of the ACA.

8. Verification Process Related to Eligibility for Insurance Affordability Programs—Employer Sponsored Plan Verification (§ 155.320)

Strengthening program integrity with respect to subsidy payments in the individual market continues to be a top HHS priority. Accordingly, we propose to revise § 155.320(d)(4) to provide each Exchange with the flexibility to tailor its employer sponsored plan verification process based on its assessment of the risk of inappropriate payments of APTC and CSRs as a result of associated risk and composition of their enrolled population.

Currently, Exchanges must verify whether an applicant for APTC and CSRs is eligible for or enrolled in an eligible employer sponsored plan for the benefit year for which coverage is requested using available data sources, if applicable, as described in § 155.320(d)(2). For any coverage year that an Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii), an alternate procedure applies. Specifically, Exchanges must select a random sample of applicants and meet the requirements under § 155.320(d)(4). For benefit years 2016 through 2019, Exchanges also could use an alternative process approved by HHS.

In the 2021 Payment Notice final rule, we finalized the policy that for PYs 2020 and 2021, HHS would not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4), when the Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii). This policy was designed to reduce burden on Exchanges while HHS finalized the results of a study to determine the potential risk and risk factors, if any, that may be associated with applicants that choose to enroll in an Exchange QHP with APTC/CSRs, rather than coverage offered through their employer. In the 2022 Payment Notice Final Rule, we extended this non-enforcement to PY 2022.

As we will discuss later in this preamble, HHS reviewed the results of the 2019 study and found that the risk for inappropriate eligibility or payment of APTC and CSRs based on applicant eligibility for or enrollment in qualifying employer sponsored coverage was low. Therefore, we are now proposing a new optional alternate procedure to replace the current procedures under § 155.320(d)(4). Under this proposed option, an Exchange would have flexibility to design its verification process based on the Exchange's assessment of risk for inappropriate eligibility or payment for APTC or CSRs. Until a new alternate procedure becomes effective, Exchanges must continue to use the procedures set forth under § 155.320(d)(4)(i), subject to the enforcement policy in effect for PYs 2021 and 2022.

HHS' experience conducting random sampling revealed that the burden associated with the verification activity far outweighed the activity's value to the integrity of the program. We found that employer response rates to HHS' requests for information were low. We further found that the manual verification process described in § 155.320(d)(4)(i) requires significant resources and government funds, and the value of the results ultimately did not appear to outweigh the costs of conducting the work because only a small percentage of sampled enrollees had been determined by HHS to have received APTC or CSRs inappropriately. Based on our experiences with the random sampling methodology under § 155.320(d)(4)(i), HHS concluded that the methodology may not be the best approach for all Exchanges to assess the risk for inappropriate payment of APTC/CSRs associated with applicants who may be eligible for or enrolled in qualifying employer sponsored coverage.

As a result, in 2019, HHS conducted a study to: (1) Determine the unique characteristics of the population with offers of employer sponsored coverage that meets minimum value and affordability standards, (2) compare premium and out-of-pocket costs for consumers enrolled in affordable employer sponsored coverage to Exchange coverage, and (3) identify the incentives, if any, that drive consumers to enroll in Exchange coverage rather than coverage offered through their current employer. The results of this study were finalized in early 2020 and aligned with HHS' previous findings from past studies that there is likely a very low volume of applicants with offers of affordable coverage through their employer that choose to inappropriately enroll in an Exchange QHP with APTC and CSRs.

Specifically, the study found that no more than 2 percent of enrollees received APTC/CSR inappropriately, and that lower income individuals and families had the most incentive to enroll in an Exchange QHP with APTC/CSR rather than coverage offered through an employer. HHS is therefore of the view that the risk for inappropriate payment of APTC and CSRs is low; thus, we propose to provide each Exchange with the flexibility to tailor its verification process based on its assessment of the risk of inappropriate payments of APTC/CSRs as a result of associated risk and composition of their enrolled population. This includes the ability of State Exchanges that operate their own eligibility and enrollment platform and have implemented, or are finalizing their implementation of, the current random sampling requirements under § 155.320(d)(4)(i), to continue employing the random sampling process and requirements and refining the process, as needed, under the proposed risk-based approach under § 155.320(d)(4)(i). HHS believes that these changes will serve to protect the integrity of the Exchange program by allowing all Exchanges to proactively identify risk factors attendant to QHP enrollees' receipt of APTC/CSRs for which they may not be eligible.

Specifically, we propose to allow Exchanges to implement a verification method that utilizes an approach based on a risk assessment identified through analysis of an Exchange's experience in relation to APTC/CSRs payments. HHS expects that this risk assessment would be informed by and identified through research and analysis of an Exchange's experiences with current and past enrollments, and not solely based on previously published research or literature. Furthermore, there are certain standards that HHS requires that all Exchanges adhere to when designing a risk-based approach to verify an applicant's offer of employer sponsored coverage. As such, HHS requires that any risk-based verification process be reasonably designed to ensure the accuracy of the data and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data. For example, if an Exchange's experience is that applicants from large companies that have different classes of employees, who may or may not qualify for employer sponsored coverage due to the number of hours they work per week, represent a higher risk of improper APTC/CSR payments, then the Exchange may implement a risk-based verification process to confirm whether applicants employed by such companies appropriately received APTC/CSRs.

Given that the proposed risk-based approach to verify whether an applicant has received an offer of coverage through an employer or is enrolled in employer sponsored coverage depends largely on an Exchange's assessment of risk and unique populations, HHS believes that there are various ways in which a risk-based approach can be

operationalized. Below we outline a few scenarios to provide illustrative examples of the procedures an Exchange may follow.

The first scenario concerns Exchanges that do not have access to an approved trusted data source that provides accurate and up-to-date information regarding enrollment or pre-enrollment in coverage offered through an employer and have determined that manual verification, such as conducting random sampling of enrollees to determine if any had an offer of affordable coverage through their employer but chose to enroll in an Exchange QHP with APTC/CSR instead, requires significant resources to conduct and have determined that the risk for improper APTC/CSR payment is low. In this scenario, Exchanges may make a reasonable determination and decide to accept a consumer(s)' attestation without any further manual verification, similar to current procedures to accept attestation only for residency and incarceration status. Conversely, if an Exchange has determined a high risk for improper APTC/CSR payment exists within its enrolled population, but also doesn't have access to an approved trusted data source for electronic verification, an Exchange may make a reasonable determination that conducting manual verification as part of its risk-based approach, such as conducting random sampling, is the appropriate risk-based approach to conduct employer sponsored coverage verification. Finally, there may be Exchanges that have determined that they do have access to an approved, accurate, and up-to-date trusted data source that allows for electronic verification of offers of employer sponsored coverage. In this scenario, an Exchange may choose to conduct electronic verification of their entire population through that trusted data source to verify offers of employer sponsored coverage. HHS believes that any of these approaches will serve to satisfy the requirement to conduct employer sponsored coverage verification using a risk-based approach while providing flexibility for all Exchanges to determine the process that best meets the needs of their populations.

Because HHS found that the risk for improper APTC payment is low in Exchanges using the federal eligibility and enrollment platform, such Exchanges would leverage the current attestation questions on the single, streamlined application and accept attestation without further verification against other trusted data sources. The attestation questions include, ''Are any of these people currently enrolled in health coverage?'' and ''Will any of these people be offered health coverage through their job, or through the job of another person, like a spouse or parent?''. HHS would also accept attestations related to employer sponsored coverage because HHS currently lacks access to another approved data source to verify whether an applicant has an offer of employer sponsored coverage that is affordable and meets minimum value standards. In the 2019 study referenced earlier in the preamble, HHS examined whether the use of other data sources would be feasible to verify offers and affordability of employer sponsored coverage, such as the National Directory of New Hires (NDNH) database. HHS determined that all available data sources were insufficient and did not provide the necessary information to satisfy the requirement, or would require legislative changes to give Exchanges permission to access and use them for verification of employer sponsored coverage. CMS notes that additional data source access, such as the NDNH, would improve accuracy and reduce administrative burden to consumers for the income verification step during the eligibility process.

Finally, under this proposal, we clarify that since SBE–FPs use the *HealthCare.gov* platform for eligibility and enrollment determinations, SBE–FPs would be required to follow the approach outlined above consistent with CMS regulations and the agreements SBE–FPs sign with CMS. Current Federal platform agreements require that SBE–FPs adhere to the same policy and operations as Exchanges that use the federal eligibility and enrollment platform regarding eligibility for and enrollment in QHP coverage.

Furthermore, in accordance with § 155.120(c), an Exchange's verification program cannot be discriminatory in nature, and State Exchange's verification processes will be monitored by HHS in accordance with its authority under §§ 155.1200 and 155.1210. In designing their verification program, Exchanges should pay special attention to known risks, including risk pool manipulation or steering high risk employees from the group health market into the Exchanges. The goal of this proposed policy is to ensure that only applicants eligible to receive APTC/CSRs receive these subsidies, and we would exercise our oversight authorities to ensure an Exchange's verification policies are not used to prevent any particular class of applicants from enrolling in QHP coverage with APTC/CSRs. We believe this approach would allow Exchanges to proactively identify and target applicants who may, for example, have an incentive to enroll in Exchange coverage with APTC/CSRs rather than their employer sponsored plan that meets minimum value and affordability standards. Further, we believe that a risk-based approach for verification of eligibility for employer sponsored eligibility or coverage verification would allow Exchanges to identify a larger population of Exchange enrollees who would be ineligible for APTC/CSRs due to an offer of employer sponsored coverage, as compared to the random sampling method. We believe the new policy we propose would more effectively protect the integrity of Exchange programs, as Exchanges would be able to mitigate the risk of improper federal payments in the form of APTC during the year more effectively.

Therefore, we propose to revise § 155.320(d)(4) by removing the requirement that the Exchange select a random sample of applicants for whom the Exchange does not have data as specified in § 155.320(d)(2)(i) through (iii) effective upon the finalization of the final rule. we encourage State Exchanges to submit comments on the proposed timing, especially if the proposal causes operational challenges or undue hardship as a result. We propose adding new language at § 155.320(d)(4) under which an Exchange would be permitted to design its verification process for enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan based on the Exchange's assessment of risk for inappropriate payment of APTC/CSRs or eligibility for CSRs, as appropriate. The proposed language at § 155.320(d)(4) would provide all Exchanges with the flexibility to determine the best means to design and implement a process to verify an applicant's enrollment in or eligibility for employer sponsored coverage, through analyses of relevant Exchange data, research, studies, and other means appropriate and necessary to identify risk factors for inappropriate payment of APTC or eligibility for CSRs. As previously discussed earlier in this rule, Exchanges must continue to use the procedures set forth in § 155.320(d)(4)(i) until a new alternate procedure becomes effective. We also propose to retain the current requirement at § 155.320(d)(4)(i)(A) that the Exchange provide notice to the applicant, but amend it such that it is contingent on whether the Exchange will be contacting the employer of an applicant to verify whether an applicant is enrolled in an

eligible employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan for the benefit year for which coverage is requested. Second, to provide more flexibility for Exchanges, we propose no longer applying the requirement at § 155.320(d)(4)(i)(D), which requires the Exchange to make reasonable attempts to contact an employer listed on an applicant's Exchange application to verify whether an applicant is enrolled in an employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan.

As we explained above, HHS' experience has been that employer compliance with these notices was low, which led to the proposal to remove the random sampling requirement. However, Exchanges may continue to send notification to employers as part of their risk-based verification processes if they so choose. Third, we propose removing the requirement at § 155.320(d)(4)(i)(F), which states that after 90 days from the date on which the Exchange first provides notice to an applicant as described in § 155.320(d)(4)(i)(A), the Exchange must redetermine eligibility for APTC and CSRs if the Exchange is unable to obtain the necessary information from an applicant's employer regarding enrollment in or eligibility for qualifying coverage in an employer sponsored plan. We believe these proposed changes provide Exchanges with the flexibility to implement a verification process for enrollment in or eligibility for an employer sponsored plan that is tailored to risks observed in their respective populations. As previously discussed earlier in preamble, Exchanges must continue to use the procedures set forth in § 155.320(d)(4)(i) until a new alternate procedure becomes effective.

Finally, we propose to remove the option for Exchanges to follow the procedures outlined in § 155.320(d)(4)(ii) to develop an alternative verification process that is approved by HHS. The revisions to § 155.320(d)(4)(i) provide enough flexibility for Exchanges to develop a risk-based verification process for eligibility for or enrollment in employer sponsored coverage. Therefore, extending § 155.320(d)(4)(ii) indefinitely would prove to be redundant in light of the proposed changes discussed earlier in preamble.

We seek comment on these proposals.

9. Annual Eligibility Redetermination (§ 155.335)

We solicit comments on incorporating the net premium, MOOP, deductible, and annual out-of-pocket costs (OOPC) of a plan into the re-enrollment hierarchy as well as additional criteria or mechanisms HHS could consider to ensure the Exchange hierarchy for re-enrollment aligns with plan generosity and consumer needs, such as, re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity offered by the same QHP issuer.

In the Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges final rule, we established the renewal and re-enrollment hierarchy at § 155.335(j) to minimize potential enrollment disruptions. Under § 155.335(j), we modified the standards for re-enrollment in coverage through Exchanges by proposing, in paragraph (j)(1), that if an enrollee remains eligible for enrollment in a QHP through the Exchange upon annual redetermination, and the product under which the QHP in which he or she was enrolled remains available for renewal, consistent with § 147.106 such enrollee will have his or her enrollment in a QHP through the Exchange under the product renewed unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. In this situation, we proposed that the QHP in which the enrollee will be renewed will be selected according to the following order of priority: (1) In the same plan as the enrollee's current QHP; (2) if the enrollee's current QHP is not available, the enrollee's coverage will be renewed in a plan at the same metal level as the enrollee's current QHP; (3) if the enrollee's current QHP is not available and the enrollee's product no longer includes a plan at the same metal level as the enrollee's current QHP, the enrollee's coverage will be renewed in a plan that is one metal level higher or lower than the enrollee's current QHP; and (4) if the enrollee's current QHP is not available and the enrollee's product no longer includes a plan that is at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee's coverage will be renewed in any other plan offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll.

Under paragraph (j)(2), we finalized standards to address re-enrollment in situations in which no plans under the product under which an enrollee's QHP is offered are available through the Exchange for renewal, consistent with § 147.106. In this situation, the enrollee may be enrolled in a QHP under a different product offered by the same issuer, to the extent permitted by applicable state law, unless the enrollee terminates coverage including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. In such cases, the re-enrollment will occur according to the following order of priority: (1) In a QHP through the Exchange at the same metal level as the enrollee's current QHP in the product offered by the issuer that is the most similar to the enrollee's current product; (2) if the issuer does not offer another QHP through the Exchange at the same metal level as the enrollee's current QHP, the enrollee will be re-enrolled in a QHP through the Exchange that is one metal level higher or lower than the enrollee's current QHP in the product offered by the issuer through the Exchange that is the most similar to the enrollee's current product; and (3) if the issuer does not offer another QHP through the Exchange at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee will be re-enrolled in any other QHP offered through the Exchange by the QHP issuer in which the enrollee is eligible to enroll.

In the 2017 Payment Notice, we finalized the rule that provides for auto-reenrollment in a QHP offered by another issuer through the Exchange, as opposed to permitting a QHP issuer that no longer has a QHP available to an enrollee through an Exchange to reenroll the enrollee outside the Exchange in order to maintain coverage with APTC and CSRs for the majority of Exchange enrollees who are receiving these subsidies. Under this rule, we established, beginning in PY 2017, that if no QHP from the same issuer is available to enrollees through the Exchange, then to the extent permitted by applicable State law, the Exchange could direct alternate enrollments for such enrollees into a QHP from a different issuer unless the enrollee terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. If the applicable State regulatory authority declines to act to direct this activity, such alternate enrollments would be directed by the Exchange. With regard to how Exchanges will determine which plans such enrollees should be auto-

reenrolled into, we noted that this policy provided considerable flexibility to Exchanges to implement this rule, in recognition of the operational realities of implementing a re-enrollment hierarchy in the often unique circumstances in which an issuer no longer has QHPs available to an enrollee through the Exchange.

HHS is aware of stakeholder concerns that the enrollees in the FFEs may fail to return to the Exchange to make an active plan selection in situations in which changing plans could be beneficial to the enrollee, and that re-enrollment rules may default enrollees into less beneficial plans than other available plans.

We solicit comments on whether factors such as net premium, MOOP, deductible, and OOPC should be reflected in a revised re-enrollment hierarchy for all Exchanges, with consideration for the potential impact of the actuarial value de minimis guidelines proposed in this rule at §§ 156.135 and 156.140 on cost-sharing. For example, HHS could consider re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity offered by the same QHP issuer. Additionally, HHS could consider re-enrolling a current silver QHP enrollee into another available silver QHP, under the enrollee's current product and with a service area that is serving the enrollee that is issued by the same QHP issuer, that has lower OOPC. We also solicit comments on additional criteria or mechanisms HHS could consider to ensure the hierarchy for re-enrollment in all Exchanges takes into account plan generosity and consumer needs beyond merely the retention of the most similar plan available.

10. Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340)

HHS is proposing to amend §§ 155.240(e), 155.305(f)(5), and 155.340 to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of the APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. HHS would require all Exchanges, including the Exchanges on the Federal platform and State Exchanges that operate their own eligibility and enrollment platforms to implement the proposed proration methodology in the PY 2024 benefit. HHS is limiting this proposed requirement to individual market policies because many SHOP Exchanges, particularly those that operate in a leaner fashion, like the federally-facilitated SHOP Exchanges, do not calculate premiums. Additionally, APTC are not available through SHOPs.

Currently, Exchanges apply APTC to an applicable taxpayer's monthly premium based on calculation, eligibility, and administration requirements from two sources: (1) IRS regulations at 26 CFR 1.36–B–1 through 1.36B–3, and (2) HHS regulations at 45 CFR part 155. IRS regulation at 26 CFR 1.36B–3(d) calculates PTC eligibility for a partial month of coverage as the lesser of the premiums for the month (reduced by any amount of such premiums refunded), or the monthly premium for the second lowest cost silver plan (SLCSP) reduced by the taxpayer's monthly contribution amount. Although 26 CFR 1.36B–3(d) defines the calculation of the premium assistance amount for a coverage month, and thus defines the calculation of the maximum APTC amount an applicable taxpayer may apply to their monthly premium, it does not describe how APTC is administered, which is regulated by HHS. When administering APTC, Exchanges must adhere to requirements at 45 CFR 155.305(f), which establishes eligibility and calculation requirements for APTC, 45 CFR 155.310(d)(2)(i), which requires the Exchange to permit an applicable taxpayer to accept less than the full amount of APTC for which they are eligible, and 45 CFR 155.340, which defines how Exchanges must administer and allocate APTC amounts applied to enrollees' monthly premiums.

Calculating maximum APTC as required under § 155.305(f) obligates the Exchange to calculate payments of the APTC in accordance with the way PTC is calculated at 26 CFR 1.36B–3. The IRS methodology described at 26 CFR 136.B–3 is appropriate for PTC, as PTC is calculated retrospectively and can account for the changes in an applicable taxpayer's premium across the entire tax year before the applicable final amount is calculated at the time of tax filing. Conversely, Exchanges administer APTC prospectively to issuers by advancing premium assistance to issuers based on enrollees' eligibility determinations and elections, which could change month-to-month before final reconciliation occurs. Currently, HHS regulations governing APTC eligibility and administration do not contain specific requirements on how APTC should be administered for a policy in which an enrollee is enrolled for less than the full coverage month. While the FFEs and SBE–FPs already prorate APTC and premium amounts, State Exchanges presently handle this scenario inconsistently, which may result in over-payment of APTC to issuers that exceeds the monthly PTC amount for which an applicable taxpayer will be eligible, thereby potentially triggering a federal income tax liability for the applicable taxpayer.[269]

By amending §§ 155.240(e), 155.305(f)(5) and 155.340 to require that the Exchange prorate the calculation of premiums and APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, HHS would provide needed clarification for all Exchanges, resulting in greater consistency in APTC administration and the consumer experience.

As explained earlier in this preamble, HHS proposes to add language at § 155.240(e)(2) to apply the methodology currently applicable in the FFEs and SBE–FPs to all Exchanges, beginning with PY 2024. This proposed amendment to § 155.240(e) would support the accurate and consistent calculation of partial-month enrollment premium amounts in a way that aligns with the method of administering the APTC that we propose in §§ 155.305(f)(5) and 155.340.

HHS also proposes to amend § 155.305(f)(5) by adding that APTC must be calculated in accordance with 26 CFR 1.36B–3, subject to the prorating methodology at proposed § 155.340(i). This would create uniform standards for taxpayers on how the APTC will be calculated for months in which an enrollee is enrolled in a particular policy for less than the full coverage month.

Finally, HHS proposes to amend § 155.340 by adding paragraph (i) to establish that, beginning with the PY 2024 benefit, all Exchanges would be required to calculate applied APTC when an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, as equal to the product of (1) the APTC applied on the

[269] HHS notes that an applicable taxpayer's excess APTC and accompanying tax liability for such excess APTC is determined after the taxpayer's PTC for the year of coverage has been calculated. Consequently, the potential to incur income tax liability for excess APTC is not limited to situations in which a consumer is enrolled in a policy for less than a full coverage month and our proposed policy will not completely eliminate an applicable taxpayer's risk of incurring tax liability from excess APTC.

policy for 1 month of coverage divided by the number of days in the month, and (2) the number of days for which coverage is provided on that policy during the applicable month. This methodology would align with the prorated calculation of premium amounts under § 155.240(e). Furthermore, this proposed methodology would provide Exchanges with a consistent method of prorating applied APTC amounts that aligns with the calculation of PTC under 26 CFR 1.36B–3(d) while ensuring that the calculation of APTC in situations in which an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, does not cause the APTC to exceed the PTC for the month as calculated per 26 CFR 1.36B–3(d). This proposal would create consistency for issuers across all Exchanges, help the enrollee by keeping the enrollee's share of premiums stable, and reduce the instances in which a taxpayer would have to repay excess APTC during tax filing per section 36B(f)(2) of the Code and 26 CFR 1.36B–4. If the proposal results in an excess of PTC over the amount of APTC paid for an enrollee's coverage (net PTC), the applicable taxpayer would claim the net PTC as a refundable tax credit.

These proposals are intended to protect consumers. State Exchanges are not currently required to prorate APTC for mid-month policy changes and, as a result, HHS may overpay APTC amounts to issuers in State Exchanges not currently prorating in this manner. Income tax liability due to excess APTC could pose significant financial burden to applicable taxpayers, particularly low-income taxpayers, and creates confusion about the affordability of health care coverage offered by an Exchange.

Additionally, E.O. 14009 [270] calls for a review of policies or practices that may present unnecessary barriers to individuals and families attempting to access Medicaid or ACA coverage, or that may reduce the affordability of coverage or financial assistance for coverage. Low-income populations are more likely to qualify for many federal and state health and human services programs, including APTC.[271] The proposed methodology aligns with the goals of E.O. 14009, as it would promote consumer protection, encourage continuity of coverage for individuals, and ensure consistent application of APTC which makes Exchange coverage more affordable.

Establishing a proration methodology that would apply universally across all Exchange types—FFEs, SBE–FPs, and State Exchanges—would ensure all Exchanges and issuers report and pay APTC similarly when enrollees are enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. HHS notes that this proposal would codify a methodology that the FFEs, SBE–FPs, and some State Exchanges already utilize to prorate APTC.

We are proposing to require this proposed proration methodology for all Exchanges to implement beginning with the PY 2024 benefit, as HHS acknowledges that implementing this proposed methodology will require implementation and operational costs and time on the part of most State Exchanges. HHS seeks comment on this proposal. HHS also seeks comment on whether PY 2023 benefit implementation is feasible.

10. Special Enrollment Periods—Special Enrollment Period Verification (§ 155.420)

In 2017, the HHS Market Stabilization Rule preamble explained that HHS would implement pre-enrollment verification of eligibility for certain special enrollment periods in all Exchanges on the Federal platform.[272] HHS also clarified its intention to not establish a regulatory requirement that all Exchanges conduct special enrollment period verifications in order to allow State Exchanges additional time and flexibility to adopt policies that fit the needs of their state.[273] However, all State Exchanges conduct verification of at least one special enrollment period type, and most State Exchanges have implemented a process to verify the vast majority of special enrollment periods requested by consumers.

We are now proposing to amend § 155.420 to add new paragraph (g) to state that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, and that Exchanges may provide an exception to pre-enrollment special enrollment period verification for special circumstances, which could include natural disasters or public health emergencies that impact consumers or the Exchange. This is in order to encourage State Exchanges to conduct special enrollment period verification but also allow the FFEs, SBE–FPs, and State Exchanges to maintain flexibility in implementing and operating special enrollment period verification.

Since 2017, Exchanges on the Federal platform implemented pre-enrollment special enrollment period verification for certain special enrollment period types commonly used by consumers to enroll in coverage. New consumers, meaning consumers who are not currently enrolled in coverage through the Exchange, who apply for coverage through a special enrollment period type that requires pre-enrollment verification by the Exchanges on the Federal platform must have their eligibility electronically verified using available data sources or submit supporting documentation to verify their eligibility for the special enrollment period before their enrollment can become effective. As stated in the HHS Marketplace Stabilization Rule, pre-enrollment special enrollment period verification is only conducted for consumers newly enrolling due to the potential for additional burden on issuers and confusion for consumers if required for existing enrollees.[274]

While pre-enrollment special enrollment period verification can decrease the risk for adverse selection and improve program integrity, it can also deter eligible consumers from enrolling in coverage through a special enrollment period because of the barrier of document verification. Younger, often healthier consumers submit acceptable documentation to verify their special enrollment period eligibility at much lower rates than older consumers, which can negatively impact the risk pool. Additionally, our experience operating the FFEs and the Federal platform shows that pre-enrollment special enrollment period verification disproportionately negatively impacts Black and African American consumers who submit acceptable documentation to verify their special enrollment period eligibility at much lower rates than White consumers.

To support program integrity and streamline the consumer experience, we are also proposing that the Exchanges on the Federal platform would only continue to conduct pre-enrollment verification of eligibility for one type of special enrollment period: The special

[270] Executive Order 14009; 86 FR 7793 (Feb. 2, 2021).

[271] See *https://familiesusa.org/wp-content/uploads/2021/04/2021-79_ARP-Coverage-Summary_Analysis_03_2021.pdf.*

[272] 82 FR at 18355 through 18358.

[273] Ibid.

[274] 82 FR at 18355 through 18360.

enrollment period for new consumers who attest to losing minimum essential coverage.[275] The loss of minimum essential coverage special enrollment period type comprises the majority, about 58 percent, of all special enrollment period enrollments on the Exchanges on the Federal platform and has electronic data sources that can be leveraged for auto-verification. By verifying eligibility for this special enrollment period type and not for other special enrollment periods, the Exchanges on the Federal platform could limit the negative impacts of special enrollment period verification and decrease overall consumer burden without substantially sacrificing program integrity.

We seek comment on these proposals.

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

The Payment Integrity Information Act of 2019 (PIIA) [276] requires federal agencies to annually identify, review, measure, and report on the programs they administer that are considered susceptible to significant improper payments. Pursuant to the PIIA, HHS is in the planning phase of establishing a State Exchange Improper Payment Measurement (SEIPM) program, as HHS has determined that APTC payments may be susceptible to significant improper payments and are subject to additional oversight. Therefore, we announced that we would be implementing the SEIPM program and establishing requirements, which are laid out in proposed provisions in a new subpart P.[277]

The SEIPM program would allow for the accurate calculation of an improper payment rate through the development of annual improper payment estimates and subsequent reporting of improper payments. To ensure improper payments can be calculated accurately, the SEIPM program would require State Exchanges to provide HHS with access to certain State Exchange data, including eligibility determinations and enrollment information. State Exchanges with significant improper payments may also be required to develop corrective action plans (CAP) to correct the causes of the identified improper payments.

Currently, HHS approves or conditionally approves a state's Blueprint Application to establish a State Exchange based on an assessment of a state's attested compliance with relevant Exchange statutory and regulatory requirements at section 1311 of the ACA and 45 CFR part 155. Thereafter, State Exchanges must meet specific program integrity and oversight requirements specified at section 1313(a) of the ACA, as well as §§ 155.1200 and 155.1210. These requirements provide HHS with the authority to oversee the Exchanges after their establishment. There are various annual reporting requirements for State Exchanges at § 155.1200(b) including the annual submission of: (1) A financial statement presented in accordance with generally accepted accounting principles (GAAP); (2) an annual report showing compliance with Exchange requirements; (3) performance monitoring data; and (4) the annual submission of a report on instances in which the State Exchange did not reduce an enrollee's premium by the amount of the APTC in accordance to § 155.340(g)(1) and (2).

Additionally, under § 155.1200(c), each State Exchange is required to engage or contract with an independent qualified auditing entity that follows generally accepted government auditing standards (GAGAS) to perform annual independent external financial and programmatic audits. State Exchanges are required to provide HHS with the results of the audits, to inform HHS of any material weakness or significant deficiency identified in the audit, to develop and inform HHS of any CAPs for such material weakness or significant deficiency, and to make a public summary of the results of the external audit. The CAPs are monitored by HHS until the findings are resolved. Specifically, for the annual programmatic audit requirement, State Exchanges must ensure that auditors address compliance with subparts D and E under 45 CFR part 155, and other requirements under part 155, as specified by HHS. This allows HHS to oversee compliance with eligibility and enrollment standards to ensure that State Exchanges are conducting accurate eligibility determinations and enrollment transactions.

We propose to add new § 155.1200(e) to permit a State Exchange to meet the requirement to conduct an annual independent external programmatic audit, as described at § 155.1200(c), by completing the required annual SEIPM program process. Therefore, HHS would generally accept a State Exchange's completion of the SEIPM process for a given benefit year as acceptable to meet the annual programmatic audit requirement for that benefit year. We also propose to amend § 155.1200(c) to cross-reference proposed § 155.1200(e) to ensure the coordination of these two requirements. We believe that these proposed changes would ensure HHS retains necessary oversight authority of the State Exchanges, particularly in the event that there are changes to the SEIPM program in future benefit years. However, we would strive to provide ample advance notice of any potential changes to the SEIPM program, or to potentially allow for flexibility to satisfy requirements at paragraph (c) in the event the SEIPM program is unexpectedly suspended. These proposed changes would eliminate duplicate efforts specific to the annual programmatic audit requirement and reduce burden on the State Exchanges. They would also allow HHS to continue to require programmatic audits of other subparts beyond eligibility and enrollment, should HHS deem it necessary in future years to ensure programmatic oversight and program integrity.

As described in new proposed subpart P, section 14, HHS intends to implement the SEIPM program beginning with the 2023 benefit year. Thus, measurement of improper payments for the 2023 benefit year would take place in benefit year 2024, and reporting of the improper payment rate would not occur until November 2025, at the earliest. Thereafter, State Exchanges that HHS determines must submit CAPs would do so no sooner than 2026. We would continue to closely coordinate with State Exchanges as these timeframes are finalized and provide as much advance notice as possible of relevant deadlines as they come due.

We seek comment on these proposals.

12. State Exchange Improper Payment Measurement Program (§§ 155.1500 Through 155.1540)

In 2016, HHS completed a risk assessment of the APTC program. Similar to other public-facing benefit programs, HHS determined that the APTC program is susceptible to significant improper payments, and as a result, HHS announced plans to increase the oversight of the APTC program through the development and reporting of annual improper payment estimates, and facilitating corrective actions.[278] At that time, we also announced that we would undertake rulemaking before implementing the improper payment measurement methodology.

[275] See 45 CFR 155.420(d)(1)(i).

[276] Public Law 116–117 (Mar. 2, 2020).

[277] Presentation and materials provided to the then operational State Exchanges as part of ''All States'' meeting held on February 21, 2019.

[278] Ibid.

In line with our prior announcement[279] HHS is establishing a pilot program and, as mentioned in section 12, is proposing regulations governing HHS' SEIPM program. The SEIPM program would address all HHS and State Exchange responsibilities so that HHS can accurately calculate the SEIPM improper payment rate. Specifically, these proposed regulations would pertain to State Exchanges that operate their own eligibility and enrollment platform. These proposed regulations would not pertain to State Exchanges that use the Federal platform to conduct eligibility determinations and enrollment transactions. Additionally, the proposed regulations would contain key SEIPM program definitions and specify the manner in which HHS would collect information from State Exchanges in order to estimate the SEIPM improper payment rate. The proposed regulations would also account for the State Exchanges' obligation to provide the required information and the manner in which State Exchanges can contest HHS' findings regarding errors. Also, the proposed regulations would convey State Exchange responsibilities regarding CAPs that State Exchanges must submit to HHS for approval in order to correct improper payments.

We would calculate the SEIPM improper payment rate for each benefit year and expect the first calculation beginning with the 2023 benefit year. Since the rate cannot be calculated until all SEIPM appeals are resolved, we anticipate that the improper payment rate for the 2023 benefit year would be published in approximately November 2025. The proposed regulations are necessary for HHS to properly oversee the State Exchanges and ensure that errors resulting in improper payments are corrected.

Current regulations found at 45 CFR 155.1200 and 155.1210 require that a State Exchange have financial and operational safeguards in place to avoid making inaccurate eligibility determinations, including those related to APTC, CSR, and enrollments. However, as we stated in our 2013 regulation, §§ 155.1200 and 155.1210 were not intended to be a part of any measurement program that may have been required under the Improper Payments Elimination and Recovery Act of 2010,[280] as updated by PIIA.[281] Current program integrity audits, especially as they relate to subparts D (eligibility) and E (enrollment) of part 155, focus on the processes and procedures that a State Exchange has established to verify that a qualified individual meets eligibility requirements. Current regulations at § 155.1200(c) require State Exchanges to hire an independent qualified auditing entity and submit the external audit results to HHS. These programmatic audits do not review, estimate, or report on the amounts or rates of improper payments as the result of eligibility determination errors made by State Exchanges. To meet the requirements of PIIA, to reduce burden on State Exchanges, and to ensure consistency across State Exchanges in terms of our review methodology, we propose to update programmatic auditing requirements such that the completion of the annual SEIPM program, as required by this subpart P, would satisfy the current auditing requirements prescribed in § 155.1200(c). As we transition, we would coordinate our efforts with the CMS Center for Consumer Information and Insurance Oversight and the CMS Office of Financial Management. The goal of this coordination is to gain efficiencies and avoid duplicative requirements that would unnecessarily increase State Exchanges' workload, as well as the requirement and burden of hiring independent qualified auditing entities. Doing so would enable HHS and its Federal contractors to obtain consistent information across all State Exchanges and to meet our statutory mandate under PIIA. Therefore, we propose to establish a new subpart P under 45 CFR part 155 (containing §§ 155.1500 through 155.1540) to codify the SEIPM program requirements.

We propose that the proposed regulations at subpart P would be applicable in 2023 when the SEIPM program is proposed to begin its operations.

a. Purpose and Definitions (§ 155.1500)

We are proposing to add new subpart P to part 155, which would address various State Exchange and HHS responsibilities. HHS may use Federal contractors as needed to support the performance of statistical, review, or other activities.

We are proposing to add new § 155.1500 to convey the purpose of subpart P and definitions that are relevant to the SEIPM program.

- At paragraph (a), we are proposing the purpose of subpart P as setting forth the requirements of the SEIPM program for State Exchanges.
- At paragraph (b), we are proposing to codify the definitions that are specific to the SEIPM program and key to understanding the process requirements.
- We are proposing the definition of ''Appeal of redetermination decision (or appeal decision)'' to mean HHS' appeal decision resulting from a State Exchange's appeal of a redetermination decision.
- We are proposing the definition of ''Corrective action plan (CAP)'' to mean the plan a State Exchange develops in order to correct errors resulting in improper payments.
- We are proposing the definition of ''Error'' to mean a finding by HHS that a State Exchange did not correctly apply a requirement in subparts D and E of part 155 regarding eligibility for and enrollment in a qualified health plan; APTC, including the calculation of APTC; redeterminations of eligibility determinations during a benefit year; or annual eligibility redeterminations.
- We are proposing the definition of ''Error findings decision'' to mean HHS' enumeration of errors made by a State Exchange, including a determination of how the enumerated errors inform improper payment estimation and reporting requirements.
- We are proposing the definition of ''Redetermination of an error findings decision (or redetermination decision)'' to mean HHS' decision resulting from a State Exchange's request for a redetermination of HHS' error findings decision.
- We are proposing the definition of ''Review'' to mean the process of analyzing and assessing data submitted by a State Exchange to HHS in order for HHS to determine a State Exchange's compliance with subparts D and E of part 155 as it relates to improper payments.
- We are proposing the definition of ''State Exchange improper payment measurement (SEIPM) program'' to mean the process for determining

[279] Ibid.

[280] Public Law 111–204, 124 Stat. 2224 (July 22, 2010). The original Improper Payment Information Act, Public Law 107–300 (2002) has been updated by it successors, which include the Improper Payment Elimination and Recovery Act, Public Law 111–204 (2010), the Improper Payment Elimination and Recovery Improvement Act, Public Law 112–248 (2012), and the Payment Integrity Information Act, Public Law 116–117 (2020).

[281] Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards, Proposed Rule, 78 FR 37032 at 37053 (Jun. 19, 2013).

estimated improper payments and other information required under the PIIA, and implementing guidance, for APTC, which includes a review of a State Exchange's determinations regarding eligibility for and enrollment in a QHP; the calculation of APTC; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations.

b. Program Notification and Planning Process (§ 155.1505)

We are proposing to add new § 155.1505 to outline the annual program notification requirements related to the SEIPM program.

• At paragraph (a), we are proposing the requirements associated with HHS' responsibility to notify the State Exchanges prior to the start of the measurement year regarding information pertinent to the SEIPM program and the program's upcoming measurement cycle, which may include but would not be limited to review criteria; key changes from prior measurement cycles, where applicable; or other modifications regarding specific SEIPM activities. This notification would occur during the benefit year (that is, the year under review for which data would be collected), which immediately precedes the measurement year (that is, the year in which the measurement will be completed). The measurement cycle would conclude with the reporting year during which all data issues would be resolved and the improper payment rate would be calculated and published.

• At paragraph (b), we are proposing the requirements associated with HHS' responsibility to notify the State Exchanges prior to the measurement year regarding SEIPM schedules, which will include relevant timelines. For example, among other things, the SEIPM annual program schedule would detail the time period during which HHS would provide the SEIPM data request form to State Exchanges with instructions regarding how to complete each part of the form. The SEIPM annual program schedule would also provide the deadlines prescribed for State Exchanges to complete each part of the form.

• At paragraph (c), we are proposing the requirements associated with information to be provided by State Exchanges to HHS regarding the operations and policies of the State Exchange, and changes that have been made by the State Exchange which could impact the SEIPM review process such as changes to business rules, business practices, policies, and information systems (for example, data elements and table relationships), which are used to review the State Exchange's execution of consumer verifications, verification inconsistency resolutions, eligibility determinations, enrollment management, and APTC calculations. HHS anticipates that State Exchanges may make changes periodically that could affect a State Exchange's eligibility determinations or other decisions relating to the SEIPM program. For example, HHS would need to be made aware of changes to the State Exchange's technical platform or modifications to its policies or procedures as these changes may impact specific review criteria, the data to be reviewed and ultimately a State Exchange's eligibility determinations. Other decisions or changes by a State Exchange could affect the SEIPM program, including any changes regarding items such as naming conventions or definitions of specific data elements used in the SEIPM program, since any lack of clarity in how determinations and payment calculations are being made could impact HHS' decisions regarding errors made by the State Exchanges.

c. Data Collection (§ 155.1510)

We are proposing to add new § 155.1510 to address the data collection requirements to support the SEIPM process. Consistent with this, we are establishing an SEIPM data request form that would incorporate two basic parts: (1) The pre-sampling data request; and (2) the sampled unit data request. We would use this form to compile information from each State Exchange in an ongoing manner.

• At paragraph (a)(1), we are proposing the requirement that the State Exchange annually provide pre-sampling data to HHS by the deadline provided in the annual program schedule. The pre-sampling data request would provide HHS with essential information about the composition of the State Exchange's application population in order to appropriately stratify and sample the population. In the pre-sampling data request, HHS would provide each State Exchange with a list of policy identifications (that is, policy ID, which is a unique identifier for a policy) that would have been analyzed to produce an aggregate applied APTC greater than $0. HHS would request each State Exchange to map the given policy IDs for their State Exchange to a tax household identifier (or a proxy if the State Exchange does not have an equivalent identifier) and provide characteristics of the population, which include counts of (or an indication of the presence in) different verification inconsistency types and the number of tax household members. HHS would then analyze these characteristics and select a statistically valid sample according to OMB requirements for estimating improper payments. For these sampled units, HHS would also request associated application and enrollment data and supporting consumer documentation, which will be used to conduct its review. HHS has submitted a PRA package to OMB for approval as detailed in ICR sections IV.G.1. and 2 of this proposed rule.

As explained below in section IV, Collection of Information Requirements, the SEIPM data request form has been submitted to the OMB for review and approval. The pre-sampling data are a building block for the development of the sampled unit data, which associate consumer attestation documentation to each sampled unit. As such, the timely receipt of the completed pre-sampling data from the State Exchange is imperative.

The cumulative sample size across all State Exchanges and the associated State Exchange-specific sample size would be determined using a statistically valid sampling and estimation methodology, in a manner that is consistent with Appendix C of OMB Circular A–123 and that would be designed to produce an aggregate estimated improper payment rate across all State Exchanges with a 3 percent margin of error and a 95 percent confidence interval.[282] HHS researched various sampling methodologies, for example, simple random sampling, stratified random sampling, and probability proportional to size sampling, taking into account level of burden, (for example, time and resources), on State Exchanges as well as enabling meaningful reviews for each State Exchange. Based on information currently available, we expect that a sample size of approximately 100 tax households for each State Exchange will be necessary to achieve this precision level. HHS will provide State Exchanges with an annual program notification that may include sampling methodology and sample size. Burden estimates contained within this document have been created using that sample size estimate. There are a variety of factors that we may consider each review cycle to determine the sample size and

[282] While OMB Memorandum M–21–19, dated March 5, 2021 at *https://www.whitehouse.gov/wp-content/uploads/2021/03/M-21-19.pdf* no longer includes the requirements of a 95 percent confidence interval or a 3% margin of error, we are using those measures that were included in Appendix C to the OMB circular prior to the 2021 changes.

methodology. Such factors may include the size of the State Exchange measured either by the number of payments or by the total dollar amount, specific factors that drive the improper payment rate, the number of State Exchanges under measurement for a given review cycle, or improper payment rates and margins of error from previous benefit years. Regardless of potential variations from one review cycle to the next, we would continue to use a methodology that supports statistically valid sampling and estimation.

• As stated previously, we would provide to each State Exchange an SEIPM data request form that includes the sampled unit data request. At paragraph (a)(2) we are proposing the requirement that annually the State Exchange provide to HHS, in a manner and within a deadline specified by HHS in the annual program schedule, sampled unit data. To meet this requirement, a State Exchange can submit consumer-submitted documentation in one or more batches so long as all of the batches are provided to HHS within the deadline specified in the annual program schedule. The sampled unit data request would include the list of sampled units and the associated information specific to each unit. The information required for the sampled units would include data and supporting documentation regarding various State Exchange functions, for example, electronic verifications, manual reviews of data matching inconsistencies, special enrollment period verifications, eligibility determinations, redeterminations, enrollment reconciliation, and plan management.

• At paragraph (b), we are proposing language regarding requests for extension which may be submitted by State Exchanges. Given the importance of the time frames associated with the measurement process, we do not anticipate granting extensions in most situations. The approval of extension requests would be reserved for extreme circumstances that directly impact operations of the particular State Exchange. This includes situations such as natural disasters, interruptions in business operations such as major system failures, or other extenuating circumstances.

• At paragraph (c), we are proposing language regarding potential consequences as a result of a State Exchange's failure to timely provide the information in accordance with the schedule and deadlines detailed in the annual program schedule, or in response to a request for extension in paragraph (b). As a result of not timely providing required data, we may cite errors due to lack of documentation to support the state's eligibility or payment decisions, inadvertently resulting in an increase in the State Exchange's improper payment rate.

d. Review Process and Improper Payment Rate Determination (§ 155.1515)

We are proposing to add new § 155.1515 to address the review process and the determination of the improper payment rate.

• At paragraph (a), we are proposing that HHS would keep a record of the status of receipt for information requested from each State Exchange for a minimum of 10 years.

• At paragraph (b), we are proposing to review the following for compliance with subparts D and E of part 155: A State Exchange's determinations regarding eligibility for and enrollment in a QHP; APTC, including the calculation of APTC; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations. As part of the review process, HHS would issue error findings decisions and render redeterminations of error findings decisions within the timeframe specified in the annual program schedule.

• At paragraph (c), we are proposing to notify each State Exchange of HHS' error findings decisions for that State Exchange and HHS' calculation of that State Exchange's improper payment rate.

e. Error Findings Decisions (§ 155.1520)

We are proposing to add new § 155.1520 to address the issuance of error findings decisions and the content of error findings decisions.

• At paragraph (a), we are proposing that HHS will issue error findings decisions to each State Exchange. While we anticipate that error findings decisions would be issued at regular and recurring points of time within the measurement year during each review cycle, we recognize that certain events could result in necessary delays, for example, public health emergencies, natural disasters, interruptions in business practices, or other extenuating circumstances. Thus, should these types of events warrant additional time, we would notify State Exchanges of the delay via the CMS website. In the situation where no errors are found during the course of the review, HHS will still issue an error findings decision to the State Exchange indicating that no errors were identified. The error findings decisions are intended to be communicated to each respective State Exchange only and would not be published publicly.

• At paragraph (b), we are proposing language regarding the specific information that would be included in error findings decisions. We propose that, at a minimum, error findings decisions will include HHS' findings regarding errors made by the State Exchange and information about the State Exchange's right to request a redetermination of the error findings decision in accordance with proposed § 155.1525. We anticipate that these are the key items to be conveyed through the error findings decision. However, should we determine that other information is warranted, the language of proposed § 155.1520 does not prohibit additional information from being included within the error findings decision.

f. Redetermination of Error Findings Decisions (§ 155.1525)

We are proposing to add new § 155.1525 to address a State Exchange's request for a redetermination as well as HHS' issuance of the redetermination decision and the content of that decision.

• At paragraph (a), we are proposing language indicating a State Exchange's ability to request a redetermination of the error findings decision within the deadline prescribed in the annual program schedule. During the period for a State Exchange to request a redetermination of the error findings decision, HHS would consider a request for an extension in extreme circumstances, which includes but is not limited to situations such as natural disasters, interruptions in business operations such as major system failures, or other extreme circumstances. While we recognize that each State Exchange has a multitude of responsibilities, HHS would not otherwise accept any request for a redetermination received after the expiration of the deadline prescribed by the annual program schedule, which is designed to enable HHS to meet deadlines for publication of the improper payment rate.

• At paragraph (a)(1), we are proposing language requiring that the State Exchange identify the specific error(s) for which the State Exchange is requesting a redetermination. This identification may pertain to a single individual's application or to a type of error affecting a class of applications. Since this redetermination constitutes a review of the initial decision and not a de novo investigation, the State Exchange must base its request on documentation and other information

already submitted to HHS (for example, if the application lacked income information, the State Exchange may not retrospectively seek this documentation and add it to the record). Any issues that do not relate to an error identified by HHS in the initial error findings decision would not be addressed.

• At paragraph (a)(2), we are proposing language that the State Exchange must include all data and information that support the State Exchange's request for a redetermination. Note that while State Exchanges are able to submit data and information in requesting a redetermination, new information submitted as part of the request for redetermination should supplement data previously submitted as part of the SEIPM data request form for the benefit year under review and would be accepted at HHS' discretion. State Exchanges may not use the redetermination process as a means to circumvent prior deadlines for submitting data or information to HHS.

• At paragraph (a)(3), we are proposing language that would require a State Exchange to provide an explanation of how the data and information submitted under paragraph (a)(2) pertains to the error(s) identified in the error findings decision. The State Exchange should clearly articulate how the data and information is related to HHS' findings, and also how it impacts HHS findings. If a State Exchange does not provide this explanation, HHS would not anticipate or assume a State Exchange's reasoning in requesting a redetermination on a particular error.

• At paragraph (b), we are proposing language regarding the issuance of redetermination decision. The redetermination of an error findings decision would be issued within the deadline prescribed in the annual program schedule. Our goal is to ensure that each State Exchange has ample time to assess the error findings decision, give HHS adequate time to thoroughly evaluate a State Exchange's request for a redetermination, and calculate an improper payment rate in adequate time to publish aggregate findings across all State Exchanges in the Agency Financial Report. As with the error findings decision, we anticipate HHS' redetermination decisions would be issued at regular and recurring points of time within the measurement year during each review cycle and in accordance with the annual program schedule. However, we also recognize that certain circumstances could result in necessary delays, for example, public health emergencies, natural disasters, interruptions in business operations, or other extenuating circumstances. Thus, we are proposing that if these types of circumstances result in HHS needing additional time to render the redetermination decisions, a state Exchange would be notified of the delay.

• At paragraph (c), we are proposing language conveying the minimum content requirements for HHS' redetermination decision.

• At paragraph (c)(1), we are proposing language specifying that HHS' decision must address its findings regarding the impact of any additional data and information provided by the State Exchange on the error(s) for which the State Exchange requested a redetermination.

• At paragraph (c)(2), we are proposing language that would establish HHS' responsibility to give a State Exchange information about the right to request an appeal of the redetermination of error findings decision in accordance with proposed § 155.1530.

g. Appeal of Redetermination Decision (§ 155.1530)

We are proposing to add new § 155.1530 to address a State Exchange's ability to request an appeal of the redetermination decision. Appeals will be administered by HHS.

• At paragraph (a), we are proposing language regarding a State Exchange's right to request an appeal of a redetermination within the deadline prescribed in the annual program schedule. Moreover, we are proposing that, in the request for an appeal, the State Exchange must indicate the specific error(s) identified in the redetermination decision for which the State Exchange is requesting an appeal. In accordance with proposed § 155.1530(d), which specifies that findings would be restricted to those errors for which a redetermination was sought, this proposed language also indicates that a State Exchange is prohibited from requesting an appeal of any error(s) that were not specified in a State Exchange's redetermination request.

• At paragraph (b), we are proposing language that conveys the appeal entity's review would be an on-the-record review, meaning that the appeal entity would only review data and information provided at the time of a State Exchange's redetermination request. No additional new data or information submitted in support of the request for appeal would be considered.

• At paragraph (c), we are proposing language that the appeal decision would be issued within the deadline prescribed in the annual program schedule. Again, as with the earlier time frames set in the annual program schedule, the time frame for appeal allows HHS adequate time to review information provided by the State Exchange, assess errors, and calculate an improper payment rate in adequate time to publish findings in the Agency Financial Report. We also acknowledge that unforeseen circumstances could result in necessary delays in the issuance of the appeal decision for example, public health emergencies, natural disasters, interruptions in business practices, or other extenuating circumstances. Thus, we are proposing that if these types of circumstances necessitate the appeals entity's need for additional time in rendering an appeal decision, the State Exchange would be notified about the delay.

• At paragraph (d), we are proposing the content of the appeal decision.

• At paragraph (d)(1), we are proposing that the appeal decision would include the final disposition of the on-the-record review and that findings would be restricted to those error(s) for which an appeal was sought.

• At paragraph (d)(2), we are proposing that the appeal decision would include the estimated improper payment rate for the State Exchange.

• At paragraph (e), we are proposing that upon completion of the review and the closure of all appeals, HHS would issue to each individual State Exchange, a report containing the error findings and the estimated improper payment rate for their respective program. That report will not be made public. The estimated improper payment rates for each State Exchange will be used to estimate an aggregate improper payment rate across all State Exchanges. That aggregate rate will be published in the agency's Annual Financial Report.

h. Corrective Action Plan (§ 155.1535)

We propose to add new § 155.1535 to address the scenario in which a State Exchange's improper payment rate for a given benefit year, in HHS's reasonable discretion, necessitates a CAP to correct the causes of any payment errors. Our goal is to lay out a set of minimum requirements in future rulemaking, using the standards provided under Appendix C to OMB Circular No. A–123, to support State Exchanges in satisfying the requirement of developing, implementing, and monitoring a CAP. Otherwise, State Exchanges should have the flexibility to conduct these activities in a manner that is tailored to their specific needs, including any standard practices, policies and procedures, or business needs. We also anticipate that there

would be collaboration required between HHS and the State Exchange to ensure the effectiveness of any CAP, and we underscore the importance of maintaining open lines of communication on significant CAP-related updates. As needed, a State Exchange should be prepared to consult with HHS and provide timely responses to any requests for clarification or additional information regarding the CAP.

As we gather additional information and data, and observe trends based on experience with implementing the SEIPM program, we will detail CAP parameters or requirements in future rulemaking. We note, as well, that the first improper payment report would not be released until November 2025 at the earliest, and so the first SEIPM program CAP likely would not be due until early 2026.

- At paragraph (a), we propose that, depending on a State Exchange's error rate for a given benefit year, we may require the State Exchange to develop and submit a CAP to HHS to correct errors resulting in improper payments. In future rulemaking, we may define a threshold error rate, dollar amount, or other scenarios that could necessitate a CAP. We do not, however, anticipate that these standards would deviate significantly from the standards of other improper payment measurement programs, such as the standards under the Medicaid and CHIP Payment Error Rate Measurement (PERM) program.
- At paragraph (b), we propose that Appendix C to OMB Circular No. A–123 would serve as a minimum set of guidelines to any State Exchange that is developing a CAP. The State Exchange otherwise has broad discretion to utilize a format tailored to its specific needs, so long as it can demonstrate that the CAP is effectively and timely correcting error causes.
- At paragraph (c), we propose that a State Exchange would be required to develop an implementation schedule to accompany its CAP, and implement any CAP initiatives in accordance with that schedule. In conjunction with completing CAP initiatives timely, a State Exchange would be required to regularly evaluate whether those initiatives are effective at correcting errors identified. It is critical that the State Exchange maintains regular communications with HHS of any evaluation findings, particularly for any CAP initiatives that are not correcting errors. In this situation a State Exchange may need to revise or discontinue these initiatives, or develop new ones.
- At paragraph (d), we propose the recourse HHS has in the event that a State Exchange that is required to submit a CAP fails to timely do so by stating that HHS may take actions consistent with § 155.1540.

i. Failure To Comply (§ 155.1540)

We propose to add new § 155.1540 that would address failures to comply with SEIPM requirements. At paragraph (a), we propose that HHS would have discretion to address failures of compliance with audit data submission and CAP requirements contained in subpart P, consistent with authorities HHS possesses under title I of the ACA or any other Federal law.

Based on experiences with other audit programs, HHS is of the view that without measures to ensure State Exchanges' compliance with SEIPM requirements, the audit program could easily become frustrated and inefficient, needlessly burdensome to the government and wasteful of government funds and resources, as well as ineffective to detect and prevent improper payments of APTC in State Exchanges. HHS finds that such failures would undermine or prohibit HHS's efficient administration of Exchange activities, including the administration of APTC. For this reason, we propose that if a State Exchange fails to substantially comply with the data collection requirements or the CAP provisions contained in subpart P, HHS may implement measures or procedures in relation to the State Exchange that HHS determines are appropriate to secure compliance with data collection and CAP provisions contained in subpart P of this part, and to detect, prevent, or reduce abuses in the administration of APTC under title I of the ACA, so long as such actions are within HHS's authorities under title I of the ACA or any other Federal law.

The ACA grants HHS broad discretion to ensure the effective and efficient administration of Exchange activities through audits and other authorized means, such as those HHS proposes in this rule to support its compliance with the PIIA.[283] Section 1313(a)(5) of the ACA authorizes HHS to implement any measure or procedure it determines appropriate to reduce fraud and abuse in the administration of title I of the ACA, which includes the conduct of APTC eligibility determinations and the administration of APTCs. HHS is considering exercising this authority to ensure State Exchange compliance with SEIPM program data collection and CAP requirements. For instance, upon a State Exchange's failure to substantially comply with data collection requirements, HHS could require the State Exchange to provide on-site access to required data and Exchange personnel capable of displaying requested data directly to HHS personnel or contractors.[284] If a State Exchange failed to substantially comply with requirements under an existing CAP, HHS could require the State Exchange to revise the CAP and its related implementation plan to contain revised or additional requirements specifically designed to address the State Exchange's compliance failures and ensure the State Exchange's future compliance with CAP requirements. We seek comment on these measures and invite suggestions for other measures HHS might undertake in relation to State Exchanges to incentivize compliance with data collection and CAP requirements (or cure non-compliance) and to ensure the efficient administration of APTCs.

We note that if the proposed SEIPM program requirements are finalized, HHS does not anticipate broad or willful noncompliance with data collection and CAP requirements by State Exchanges. Rather, we expect that HHS and State Exchanges would continue to work collaboratively to ensure the accuracy and integrity of APTC eligibility determinations and payments during SEIPM audits. Where a State Exchange's compliance failure is due to impediments outside of the Exchange's control or due to its need for technical assistance, HHS would provide such technical assistance and, when appropriate, could grant reasonable accommodations (such as additional time to submit data or implement elements of a CAP), in order to provide the State Exchange the resources and support it needs to meet SEIPM audit requirements. Considering the extremely close working relationships between HHS and State Exchanges and their combined interests in ensuring the integrity of APTC eligibility determinations, HHS does not anticipate that it would need to exercise its authority under title I of the ACA to impose financial penalties for substantial noncompliance resulting from serious or willful noncompliance with SEIPM requirements. Rather, we

[283] Although proposed § 155.1540 and other rules we propose to codify in part 155, subpart P, are specifically intended to support compliance with requirements under the PIIA, section 1313(a)(3) also authorizes HHS to subject State Exchanges to annual financial audits.

[284] See, for example, section 1313(a)(2) of the ACA (HHS may investigate the affairs of an Exchange, may examine the properties and records of an Exchange, and may require periodic reports in relation to activities undertaken by an Exchange, and an Exchange must fully cooperate in any investigation conducted under this paragraph).

expect that such penalties would be necessary to address only the most egregious situations that would amount to serious misconduct in relation to a State Exchange's administration of APTCs and its failure to comply with audit requirements.[285]

We invite comment on these proposals.

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

1. FFE and SBE–FP User Fee Rates for the 2023 Benefit Year (§ 156.50)

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 specified that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP.

OMB Circular No. A–25 established federal policy regarding user fees; it specifies 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 2023 Benefit Year

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. As in benefit years 2014 through 2022, issuers seeking to participate in an FFE in the 2023 benefit year will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. For the 2023 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).

To provide additional transparency into HHS' user fee calculation, we set forth below the costs, premium, and enrollment projections that went into calculating the proposed 2023 FFE user fee rates based on the best available data at the time of this proposed rulemaking, to the extent that none of this information is considered proprietary for issuers or confidential for the federal government. For the 2023 benefit year, we anticipate that spending on consumer outreach and education, eligibility determinations, and enrollment process activities will increase by approximately $140 million above the 2022 benefit year level. We anticipate spending on consumer assistance tools, management of a Navigator program, regulation of agents and brokers, and certification of QHPs activities will be similar to what was estimated for the 2022 benefit year. We do not anticipate any new services or contracts will fall under the FFE user fees for the 2023 benefit year.

Additionally, we considered a range of premium and enrollment projections in setting the proposed 2023 benefit year FFE user fee rates.[286] The weighted average premium projections that we considered ranged from $618 to $625 per month. The annual enrollment percentage change projections that we considered ranged from −1 percent to 2 percent. We took a number of factors into consideration in choosing which premium and enrollment projections should inform the proposed 2023 FFE user fee rates. The assumption that the enhanced premium tax credit subsidies in section 9661 of the ARP will expire after the 2022 benefit year significantly influenced our development of the 2023 enrollment and premium projections.[287] We expect the expiration of this provision of the ARP to revert enrollment and premium projections to the pre-ARP level observed in the 2020 benefit year. Our 2023 enrollment estimates also account for the 2021 benefit year transition (and projected transitions through the 2023 benefit year) of states from FFEs or SBE–FPs to State Exchanges, as well as the enrollment impacts of section 1332 state innovation waivers. We project that 2023 benefit year premiums will generally increase at the rate of medical inflation after expiration of the enhanced premium tax credit subsidies in section 9661 of the ARP. After considering the range of costs, premium and enrollment projections, we propose a 2023 user fee rate that will not result in a substantial increase to consumer premiums from prior years, and that also ensures adequate funding for federal Exchange operations.

As such, based on estimated costs, enrollment, and premiums for the 2023 benefit year, we propose a 2023 benefit year user fee rate for all participating FFE issuers of 2.75 percent of total monthly premiums. This is the same user fee rate that we established for the 2022 benefit year.[288] We seek comment on this proposal.

b. SBE–FP User Fee Rates for the 2023 Benefit Year

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

The benefits provided to issuers in SBE–FPs by the federal government include use of the federal Exchange

[285] See, for example, section 1313(a)(4) of the ACA (in such cases, the Secretary may rescind from payments due to the State an amount not to exceed one percent of such payments until corrective actions are taken by the State and determined to be adequate by the Secretary).

[286] We used the most recent projections from the Congressional Budget Office, the Office of Management and Budget, the Office of the Actuary, and the Office of Financial Management.

[287] Public Law 117–2.

[288] Part 3 of the 2022 Payment Notice (86 FR 53412).

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 user fee eligible FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs. To calculate the proposed SBE–FP rates for the 2023 benefit year, we used the same assumptions on contract costs, enrollment, and premiums as the proposed FFE user fee rates. We calculated the SBE–FP user fee rate based on the proportion of all FFE functions that are also conducted for SBE–FPs. The final SBE–FP user fee rate for the 2022 benefit year of 2.25 percent of premiums was based on HHS' calculation of the percent of costs of the total FFE functions utilized by SBE–FPs—the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, which we estimate to be approximately 80 percent. Based on this methodology, we propose to charge issuers offering QHPs through an SBE–FP a user fee rate of 2.25 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP for the 2023 benefit year. This is the same user fee rate that we established for the 2022 benefit year. We seek comment on this proposal.

2. User Fees for FFE–DE and SBE–FP–DE States

Consistent with the removal of § 155.221(j) and the repeal of the Exchange DE option in part 3 of the 2022 Payment Notice,[289] we propose a technical correction to remove from § 156.50 all references to the Exchange DE option and cross-references to § 155.221(j). In that rule, we also finalized the repeal of the accompanying user fee rate for FFE–DE and SBE–FP–DE states for 2023; however, HHS inadvertently did not amend the accompanying regulatory text in § 156.50 related to the Exchange DE option user fees.[290] As such, we propose to make conforming changes to § 156.50(c) and (d) to remove all references to the Exchange DE option and § 155.221(j). Specifically, we propose to remove § 156.50(c)(3), and amend §§ 156.50(d)(1); (d)(2)(i)(A) and (B); (d)(2)(ii); (d)(2)(iii)(B); (d)(3); (d)(4); (d)(6); and (d)(7) to remove the references to the Exchange DE option. We seek comment on these proposed technical amendments.

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

a. States' EHB-Benchmark Plan Options

At § 156.111(a), we allow a state to modify its EHB-benchmark plan by: (1) Selecting the EHB-benchmark plan that another state used for PY 2017; (2) replacing one or more EHB categories of benefits in its EHB-benchmark plan used for PY 2017 with the same categories of benefits from another state's EHB-benchmark plan used for PY 2017; or (3) otherwise selecting a set of benefits that would become the state's EHB-benchmark plan. In implementing this section, we stated in the 2019 Payment Notice that we would propose EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters.

Since we finalized that rule, we have set an early-May deadline for the submission of EHB-benchmark plans by states for each year from PY 2021–2024.[291] We believe that requiring these submissions in the first week of May that is two years before the effective date of the new EHB-benchmark plan has worked well. The feedback received from states that have submitted new EHB-benchmark plans indicates that this timeframe provides the states with enough time to prepare EHB-benchmark submissions. It also provides CMS with sufficient time to review and respond to these submissions in advance of issuers needing to make changes to plan design to conform with EHB changes.

Thus, we do not believe it is necessary to continue proposing deadlines for EHB-benchmark submissions under § 156.111 in each annual Notice of Benefit and Payment Parameters. We believe that it is in the interest of states and issuers that we formalize a consistent, permanent annual deadline in early-May for EHB-benchmark submissions. Accordingly, we propose that the first Wednesday in May that is two years before the effective date of the new EHB-benchmark plan to be the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for that PY. For example, under this proposal, the deadline for PY 2025 would be May 3, 2023, and the deadline for PY 2026 would be May 4, 2024. We propose corresponding edits to § 156.111(d) and (e) to reflect this proposed deadline.

If finalized, this proposed deadline would obviate the need to propose deadlines in future annual Notices of Benefit and Payment Parameters. We invite comment on this approach, including whether there are any unforeseen consequences to establishing this perpetual deadline.

We again emphasize that this would be a firm deadline, and that states should optimally have one of their points of contact who has been predesignated to use the EHB Plan Management Community reach out to us using the EHB Plan Management Community well in advance of the deadline with any questions. Although not a requirement, we recommend states submit applications at least 30 days prior to the submission deadline to ensure completion of their documents by the proposed deadline. We also remind states that they must complete the required public comment period and submit a complete application by the deadline. We seek comment on the proposed deadline.

b. Annual Reporting of State-Required Benefits

In the 2021 Payment Notice, we amended § 156.111(d) and added paragraph (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be ''in addition to EHB'' in accordance with § 155.170(a)(3) and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination.

Under this requirement, a state's submission must describe all benefits requirements under state mandates applicable to QHPs in the individual or small group market that were imposed on or before December 31, 2011, and that were not withdrawn or otherwise no longer effective before December 31, 2011, as well as all benefits requirements under state mandates that were imposed any time after December

[289] 86 FR 53412 at 53424–53429, 53445. We also clarified that the repeal of the Exchange DE option is specific to removing the Exchange DE option codified at § 155.221(j) and the accompanying FFE–DE and SBE–FP–DE user fees, and that the other federal requirements applicable to the FFE DE Pathways, as outlined in §§ 155.220, 155.221, and 156.1230, remain intact. See 86 FR at 53427.

[290] 86 FR at 53429.

[291] For PY 2021, the deadline was May 6, 2019 (see 84 FR at 17534); for PY 2022, it was May 8, 2020 (84 FR at 17534); for PY 2023, it was May 7, 2021 (85 FR at 29226); for PY 2024 it is May 6, 2022 (86 FR at 24232).

31, 2011, applicable to the individual or small group market. The state's report is also required to describe whether any of the state benefit requirements in the report were amended or repealed after December 31, 2011. Information in the state's report is required to be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

Pursuant to § 156.111(d)(2), if the state does not notify HHS of its required benefits considered to be in addition to EHB by the annual reporting submission deadline, or does not do so in the form and manner specified by HHS, HHS will identify which benefits are in addition to EHB for the state for the applicable PY.

In the 2021 Payment Notice, we finalized July 1, 2021 as the first deadline for states to submit annual reports to HHS. Additionally, in the 2022 Payment Notice, HHS finalized July 1, 2022 as the deadline for states to submit to HHS their annual reports for the second year of annual reporting. However, we simultaneously announced our intent to exercise enforcement discretion with regard to the first annual reporting submission deadline of July 1, 2021 due to delays in finalizing the reporting templates that states are required to use for their submissions, delays in issuing additional technical assistance on defrayal, and the added burden of the COVID–19 PHE on states. Pursuant to this enforcement posture, we explained that we would not take enforcement action against states that do not submit an annual report in 2021. Rather, we would begin enforcing the annual reporting requirement on July 1, 2022.

Since finalizing the annual reporting requirement in the 2021 Payment Notice, we have received consistent feedback from states and stakeholders restating the concerns raised by the majority of public comments on the annual reporting requirement in the 2021 and 2022 Payment Notices. Although we received some comments agreeing that this policy is important to ensure states are defraying state benefit requirements consistently, most commenters objected to the policy as unnecessary, burdensome on states, and without adequate justification. Several commenters explained that, contrary to HHS' concerns expressed in the 2021 and 2022 Payment Notices, states are already regularly making careful assessments about whether their state benefit requirements are in addition to EHB and are doing so in accordance with federal requirements. Commenters opposing the reporting policy as unnecessary also stated that existing regulations already establish robust requirements for states and issuers to follow when a state benefit requirement is in addition to EHB and requires defrayal, including performing actuarially sound analyses of costs associated with state benefit requirements in addition to EHB when calculating APTCs. Commenters noted that HHS already has existing authority to investigate states that are not complying with defrayal requirements and that, as such, imposing a reporting requirement on states is not necessary for federal oversight purposes. Other commenters expressed concern about the lack of transparency around the annual reporting and review process, requesting that HHS delay the reporting requirement until HHS provides further clarification and releases additional guidance clarifying its defrayal policies.

We have reassessed the value of the annual reporting policy in light of these comments and other stakeholder feedback and believe it is important to explore whether there may be ways to achieve compliance with the defrayal policy without imposing a requirement on states to submit detailed annual reports on state-required benefits. We therefore propose to eliminate the requirement at § 156.111(d) and (f) to require states to annually notify HHS of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be ''in addition to EHB'' and any benefits the state has identified as not in addition to EHB and not subject to defrayal. We also propose to revise the section heading to § 156.111 to reflect the proposed removal of the annual reporting requirements such that it would instead read, ''State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.''

Under this proposal, we would continue to engage in technical assistance with states to help ensure state understanding of when a state-benefit requirement is in addition to EHB and requires defrayal. We also intend to provide additional written technical assistance and outreach to clarify the defrayal policy more generally and to provide states with a more precise understanding of how HHS analyzes and expects states to analyze whether a state-required benefit is in addition to EHB pursuant to § 155.170. We believe this approach would still effectively promote state compliance with the defrayal requirement in the interim as we reassess whether or when an annual reporting policy may be warranted.

Although this proposal would relieve states of the annual reporting requirements, it would not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170. Under this proposal, states remain responsible for making payments to defray the cost of additional required benefits and issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the state. We also note that the obligation for a state to defray the cost of QHP coverage of state-required benefits in addition to EHB is an independent statutory requirement from the annual reporting policy finalized at § 156.111(d) and (f).

We solicit comment on this proposal, including on whether we should retain the reporting requirement or make it voluntary.

4. Provision of EHB (§ 156.115)

In the 2019 Payment Notice, we finalized flexibility through which states may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that this option would promote greater flexibility, consumer choice, and plan innovation through coverage and plan design options. Under this policy, a state must notify HHS if will permit issuers to substitute benefits between EHB categories by the deadlines specified by HHS in future Payment Notices.

To date, no state has ever notified HHS that it would permit issuers to substitute benefits between EHB categories. To our knowledge, no state has ever even approached HHS to discuss the merits of allowing this flexibility. In addition, we have received feedback from consumer advocates that the potential for between-category substitution could be particularly harmful to people living with chronic conditions and disabilities. Given that this policy has never been utilized, it has not promoted greater flexibility, consumer choice, or plan innovation through coverage and plan design options as intended. Rather, HHS is of the view that it may only create potential harm for consumers with chronic conditions and disabilities. Accordingly, whatever theoretical flexibility this policy could have afforded to states, such untapped flexibility is not justified given the potential negative effects on consumers. Thus, we propose to withdraw this flexibility by amending § 156.115 to no longer allow states to permit issuers to substitute benefits between EHB categories.

In the event we do not finalize this proposal to eliminate the state option

for between-category substitution, we propose to publish in guidance future deadlines for states to notify HHS that they wish to permit issuers to substitute benefits between EHB categories. We believe that it is in the interest of states and issuers that we establish a static, permanent annual deadline for such notifications. Accordingly, consistent with the deadline proposed for state submission of EHB-benchmark plans, we propose the first Wednesday in May to be the deadline for states to submit notifications to HHS that they wish to permit issuers to substitute benefits between EHB categories for the PY that is 2 years before the PY that the state wishes to permit. For example, under this alternate proposal, the deadline for issuers to notify HHS that they wish to permit issuers to substitute benefits between EHB categories for PY 2025 would be May 3, 2023; and the deadline for PY 2026 would be May 4, 2024. States wishing to make such an election must continue to do so via the EHB Plan Management Community. For additional discussion of this proposed deadline, see the preamble to § 156.111.

We seek comment on these proposals.

5. Prohibition on Discrimination (§ 156.125)

If the proposed nondiscrimination protections are finalized at § 156.200(e) that would explicitly prohibit discrimination based on sexual orientation and gender identity; § 156.125(b) would accordingly require issuers providing EHB to comply with such nondiscrimination requirements. Specifically, § 156.125(b) states that an issuer providing EHB must comply with the requirements of § 156.200(e), which currently states that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex. Elsewhere in this rule we propose to amend § 156.200(e) to prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 156.200(e), simultaneously requiring that issuers providing EHB comply with such requirements by virtue of the cross-reference in § 156.125(b) to § 156.200(e). However, amendments made in 2020 to § 156.200(e) removed any reference to sexual orientation and gender identity. If the proposals at § 156.200(e) are finalized, issuers providing EHB would again be required under § 156.125(b) to comply with nondiscrimination protections in § 156.200(e) that prohibit discrimination on the basis of sexual orientation and gender identity.

In the March 27, 2012 Exchange Standards final rule, we finalized § 156.200(e) to also prohibit discrimination based on sexual orientation and gender identity.[292] In the February 2013 ''Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule'' (EHB final rule), we finalized at § 156.125 that the nondiscrimination requirements in § 156.200 also apply to all issuers required to provide coverage of EHB, thereby prohibiting discrimination based on factors such as sexual orientation and gender identity.[293] In the 2020 section 1557 final rule, HHS revised certain CMS regulations, including § 156.200(e), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[294] As a result, § 156.200(e) currently prohibits a QHP issuer from discriminating on the basis of race, color, national origin, disability, age, or sex with respect to its QHP, but does not reference sexual orientation or gender identity.

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in the small group and individual markets pursuant to the authority to define EHB at section 1302(b) of the ACA.[295] The statute specifies that in defining EHB the Secretary must take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups. The EHB requirements apply to non-grandfathered health insurance coverage in the individual and small group markets under section 2707(a) of the PHS Act. CMS has the authority to interpret and implement these provisions under its general rulemaking authorities in sections 1321(a)(1)(B) and (D) of the ACA and section 2792 of the PHS Act. Pursuant to those authorities, HHS finalized in the EHB final rule that § 156.125 prohibits benefit discrimination on the grounds articulated by Congress in section 1302(b)(4) of the ACA, as well as those in § 156.200(e), which at the time included race, color, national origin, disability, age, sex, gender identity, and sexual orientation. It is under that same exercise of authority here that § 156.125 would again prohibit discrimination on the basis of sexual orientation and gender identity if the proposed changes to include such factors in the nondiscrimination protections at § 156.200(e) are finalized. Sections 1302(b) and 1321(a)(1)(B) and (D) of the ACA and section 2707(a) and 2792 of the PHS Act are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 156.125. Utilizing these same authorities to again prohibit discrimination based on sexual orientation and gender identity at § 156.125 by cross-reference to the nondiscrimination protections at § 156.200(e) would be consistent with the authority CMS relies upon for the existing protections at § 156.125 that prohibit discrimination on the basis of race, color, national origin, disability, age, or sex by cross-reference to § 156.200(e). We believe such protections are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer back to § 147.104 under section III.B.1.b. of the preamble rather than restating the issues here.

We seek comment on this proposal.

a. Refine EHB Nondiscrimination Policy for Health Plan Designs (§ 156.125)

We propose refining the EHB nondiscrimination policy and propose a clear regulatory framework for entities that are required to comply with EHB nondiscrimination policy. This proposed refinement would not only ensure consistent application of EHB nondiscrimination policy but would also better safeguard consumers who depend on nondiscrimination protections.

Under § 156.125(a) an issuer does not provide EHB ''if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.''[296] Section

[292] 77 FR 18310 (March 27, 2012).

[293] 78 FR 12834 (February 25, 2013).

[294] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[295] 85 FR 37218–21 (June 19, 2020).

[296] ACA section 1302(b)(4) prohibits discrimination based on ''age, disability, or expected length of life'' and requires that benefits not be subject to denial based on ''age or expected length of life, present or predicted disability, degree of medical dependency, or quality of life.''

156.125(b) provides that issuers must also comply with § 156.200(e) which states that ''a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex.'' [297] Section 156.110(d) states that an EHB benchmark plan may not include discriminatory benefit design that contravenes § 156.125. In the 2016 Payment Notice, we provided examples of potentially discriminatory practices, and in the 2017 Payment Notice we noted that we would consider providing further guidance regarding discriminatory benefit designs in the future.[298]

First, we propose revisions to § 156.125.The proposed revisions are intended to ensure that benefit designs, and particularly benefit limitations and plan coverage requirements are based on clinical evidence. Specifically, we propose that a nondiscriminatory benefit design that provides EHB is one that is clinically based, that incorporates evidence-based guidelines into coverage and programmatic decisions and relies on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources. Uniformity of applying this policy will ensure that enrollees are able to access covered benefits fairly, regardless of the coverage or issuer they choose. Although this proposal specifically applies to issuers that are required to provide EHB, we expect that states and other entities will also find this standard illustrative and helpful when, for example, conducting form review, issuing guidance, and drafting bills for mandated benefits. Furthermore, because providing a nondiscriminatory benefit design is a prerequisite to issuers fulfilling EHB requirements, we would expect that issuer questions and concerns regarding whether a particular benefit design may be discriminatory would be addressed the same way as other EHB issues—by issuers working primarily and cooperatively with states, where applicable. While states are generally the primary enforcers of EHB requirements, CMS will be available to assist states with their enforcement efforts by providing relevant technical assistance, available data, research, or other information. CMS will continue to monitor issuer compliance with EHB nondiscrimination requirements and states' oversight and enforcement activities to discern whether additional CMS assistance, policy changes, or rulemaking is necessary.

Under this proposal, unscientific [299] evidence, disreputable sources, and other bases or justifications that lack the support of relevant, clinically based evidence would be an unacceptable basis upon which to dispute a claim that an issuer's benefit design is discriminatory. Examples of peer-reviewed medical journals that we would generally consider reputable for purposes of disputing a discriminatory benefit design claim include the Journal of the American Medical Association (JAMA), published by the American Medical Association; Anesthesia, published by the Association of Anesthetists; Pediatrics, published by the American Academy of Pediatrics; Physical Therapy and Rehabilitation Journal, published by the American Physical Therapy Association; the New England Journal of Medicine (NEJM), published by the Massachusetts Medical Society; and the American Journal of Psychiatry, published by the American Psychiatric Association. We do not propose limiting the scope of acceptable peer-reviewed journal articles to those authored by persons who have earned the degree Doctor of Medicine (or M.D.). Rather, we would consider sufficient peer-reviewed articles authored by other relevant, licensed health professionals, including, for example, doctors of osteopathy, chiropractors, optometrists, nurses, occupational therapists, pharmacists, and dentists.

We would not consider to be acceptable articles that are not peer-reviewed or that are written primarily for a lay audience. For example, we would not find relevant or consider a WebMD article or blog acceptable, in and of itself, even where it cites and provides links to supporting peer-reviewed journal materials. We would also not consider sufficient a peer-reviewed journal article that has not been accepted for publication in a reputable medical publication. For example, Health Affairs would not provide sufficient and reliable support for this purpose because, although it is peer-reviewed, it is not a medical journal.

We also believe current evidence-based practice guidelines, sometimes called clinical guidelines, and recommendations from reputable governing bodies that are applicable to be a credible source. For example, we believe that practice guidelines from U.S. government bodies and government-created bodies, such as the HHS Agency for Healthcare Research and Quality (AHRQ) and the U.S. Preventive Services Task Force to be sufficient. Similarly, practice guidelines by health professional associations such as the American Academy of Family Physicians, American Academy of Pediatrics, American Society for Reproductive Medicine, and American Occupational Therapy Association would be relevant and credible. We also believe that any applicable source representing current thinking and subject to the previously discussed criteria would be relevant, since medicine is a constantly evolving field.

We seek comment on the types of clinically based justifications and level of clinical evidence that should be acceptable. Specifically, we seek comment on whether we should further define the types of acceptable clinical evidence.

Second, we are providing examples that illustrate presumptively discriminatory practices that HHS believes amount to prohibited discrimination. Individuals enrolled in health plans that have discriminatory benefit designs have been negatively impacted by the inherent design of such health plans. We are concerned that individuals with significant health needs have been discouraged from enrolling in such health insurance coverage altogether. Individuals may experience substantial improvements in health insurance coverage if the EHB nondiscrimination policy is refined.

In addition, we explain the rationale of why an example benefit design is presumptively discriminatory under § 156.125. HHS identified these examples as presumptively discriminatory practices based on clinical evidence related to each circumstance. We believe providing examples of presumptively discriminatory benefit designs will clarify EHB nondiscrimination policy and lead to greater protections for individuals seeking medically necessary treatment.

These presumptively discriminatory practice examples may point to a state's

[297] 45 CFR 156.200(e) states that a QHP issuer may not discriminate based on ''race, color, national origin, disability, age, or sex.''

[298] 80 FR 10750 (Feb. 27, 2015). The examples of potentially discriminatory practices were: (1) Attempting to circumvent coverage of medically necessary benefits by labeling the benefit as a ''pediatric service,'' thereby excluding adults; (2) refusing to cover a single-tablet drug regimen or extended release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal; and (3) placing most or all drugs that treat a specific condition on the highest cost tiers; 81 FR 12244.

[299] *See* Merriam-Webster.com Dictionary, s.v. ''unscientific,'' accessed November 5, 2021, *https://www.merriam-webster.com/dictionary/unscientific* (defining 'unscientific' as ''not based on or exhibiting scientific knowledge or scientific methodology: Not in accord with the principles and methods of science'').

benchmark plan, state law, or an issuer's application of a state's benchmark plan or law as being the source of the discriminatory benefit design. A benefit design that is discriminatory and inconsistent with § 156.125 must be cured regardless of how it originated. Thus, for example, if a state EHB-benchmark plan has a discriminatory benefit design, that state may issue guidance to issuers in the state explaining that to be compliant plans providing benefits that are substantially equal to the EHB-benchmark plan must not replicate this design. Similarly, if a state-mandated benefit has a discriminatory benefit design, the state may attempt to remedy this through revising the mandate or issuing guidance. Regardless, plans required to provide EHB would need to alter the benefit design or justify their approach with clinical evidence when designing plans that meet EHB standards. We seek comment on whether there are any unforeseen barriers in the ability to remedy inconsistencies with this refined EHB nondiscrimination policy.

In ensuring that benefit designs are not discriminatory, issuers should also consider the method that EHB are delivered and not inadvertently discriminate based on the service delivery model. Accessibility to EHB delivered virtually has significantly increased during the COVID–19 PHE as enrollees had limited options for in-person health care visits. We note that some issuers have designed health plans that deliver services virtually with no copay compared to in-person health care services with a copay. This type of health plan design could inadvertently incentivize enrollees to access EHB in a certain delivery method. Although this approach may not be a discriminatory practice pursuant to § 156.125, such a health plan design could influence whether an enrollee seeks medically-necessary in-person care due to the variation in the amount of copayment, potentially leading to adverse health outcomes. We intend to monitor the issue and remind issuers that while we encourage expanded use of EHB virtually, it should be done in a nondiscriminatory manner.

The following is a non-exhaustive list of examples of presumptively discriminatory benefit designs that address some of the issues that we have seen most frequently.

Examples: Discrimination Based on Age

1. Limitation on Hearing Aid Coverage Based on Age

a. *Background:* The National Institute on Deafness and Other Communication Disorders (NIDCD) defines a hearing aid as a small electronic device that you wear in or behind the ear. It makes some sounds louder so that a person with hearing loss can listen, communicate, and participate more fully in daily activities.[300] The FDA defines a hearing aid as ''any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.'' [301]

b. *Circumstance:* We note that some states have included age limits in their benefit mandates that require coverage for hearing aids by specifying in the mandate that such coverage applies only to enrollees in a certain age group. For example, a state has required hearing aid coverage for enrollees only up to age 21 with certain cost-sharing conditions.

c. *Rationale:* Individuals can experience hearing loss at any stage of life, and therefore the limitation in coverage would impact an individual in a different age group who has impaired hearing. Neither the FDA definition of hearing aid nor NIDCD specifies an age when individuals need hearing aids. However, the definitions explain that a hearing aid is for ''a person with hearing loss'' and as ''aiding persons with or compensating for, impaired hearing.'' Access to hearing aids can positively affect an individual's communication abilities, quality of life, social participation, and health.[302]

d. *Conclusion:* Age limits, when applied to services that have been found clinically indicated for all ages, are presumed to be discriminatory under § 156.125. Therefore, limiting coverage of hearing aids that are medically necessary to enrollees based on age presumptively conflicts with the prohibition under § 156.125 against discriminatory health plan design. For example, it would be arbitrary and discriminatory to limit a hearing aid to a subset of individuals such as enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary.[303]

2. Autism Spectrum Disorder (ASD) Coverage Limitations Based on Age

a. *Background:* According to the American Psychiatric Association, ''[p]eople with ASD may have communication deficits, such as responding inappropriately in conversations, misreading nonverbal interactions, or having difficulty building friendships appropriate to their age. In addition, people with ASD may be overly dependent on routines, highly sensitive to changes in their environment, or intensely focused on inappropriate items.'' [304]

b. *Circumstance:* We note that some states have mandated coverage for the diagnosis and treatment for ASD up to a certain age. For example, a state has required coverage for enrollees up to age 18 with certain cost-sharing conditions. Similarly, some states' benchmark plans that cover applied behavior analysis (ABA therapy) include age limits.

c. *Rationale:* The CDC recognizes the American Psychiatric Association's fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM–5) as standardized criteria to help diagnose ASD.[305] Under the DSM–5 criteria, individuals with ASD must show symptoms from early childhood, but may not be fully recognized until later in life.[306] We note that screening for ASD is usually done at a young age although an individual may not be diagnosed until later in life. The CDC estimates that 2.21 percent of adults in the U.S. have ASD.[307]

d. *Conclusion:* Limiting coverage of the diagnosis and treatment of ASD in a plan benefit design on the basis of the individual's age is presumed to be discriminatory under § 156.125. Limiting coverage that is medically necessary in a subset of individuals presumptively conflicts with the prohibition under § 156.125 against discriminatory benefit design.

3. Age Limits for Infertility Treatment Coverage When Treatment Is Clinically Effective for the Age Group

a. *Background:* The National Center for Health Statistics reported that 8.8 percent of couples in the U.S. have

[300] National Institute on Deafness and Other Communication Disorders FAQ on Hearing Aids: *https://www.nidcd.nih.gov/health/hearing-aids#hearingaid_01.*

[301] 21 CFR 801.420.

[302] National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/23446.*

[303] In the 2016 Payment Notice (which finalized as proposed), we cautioned ''both issuers and States that age limits are discriminatory when applied to services that have been found clinically effective at all ages. For example, it would be arbitrary to limit a hearing aid to enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary.''

[304] *https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/DSM/APA_DSM-5-Autism-Spectrum-Disorder.pdf.*

[305] *https://www.cdc.gov/ncbddd/autism/hcp-dsm.html.*

[306] American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013.

[307] *https://www.cdc.gov/ncbddd/autism/features/adults-living-with-autism-spectrum-disorder.html.*

experienced infertility issues while 9.5 percent have received infertility services (for example, medical assistance, counseling, testing for the woman and man, ovulation drugs, fallopian tube surgery, artificial insemination, assisted reproductive technology, and miscarriage preventive services).[308]

b. *Circumstance:* We note that some states have defined ''infertility'' in state law, which impacts insurance companies, hospitals, medical service corporations, and health care centers providing coverage for medically necessary expenses of the diagnosis and treatment of infertility. For example, a state restricted coverage for treatment of infertility to individuals who are ''presumably healthy,'' thus excluding from coverage of treatment for infertility those who are not presumably healthy.

c. *Rationale:* We note that an individual's age is an important factor for reproductive health and development. Fertility, especially in women, declines with age, which makes natural conception more unlikely as women get older.[309] However, we also note that the mean age for individuals experiencing their first childbirth has increased in recent years.[310] We also understand that not all individuals would be eligible for infertility treatment if they are not at the stage of development for reproduction or have certain medical conditions. Younger individuals, for example, who are not at the stage of reproductive development would reasonably not require treatment for infertility. Older adults as well would not need treatment for infertility, for example women who have reached post-menopause.

d. *Conclusion:* Age limits are presumptively discriminatory when applied to services that have been found clinically effective in certain age groups under § 156.125. Limiting coverage of the treatment of infertility in a plan benefit design based on age presumptively conflicts with the prohibition under § 156.125 against discriminatory benefit design unless clinical evidence acceptable under the proposed refinements to § 156.125 demonstrates that such a limitation is justifiable considering an individual's reproductive health and development. We would expect an issuer to be able to rebut a presumption that the plan's age limit on coverage for treatment of infertility is discriminatory by demonstrating clinical evidence that infertility treatments have low efficacy for the excluded age groups and/or are not clinically indicated for the excluded age groups.

Examples: Discrimination Based on Health Conditions

4. Limitation on Foot Care Coverage Based on Diagnosis (Whether Diabetes or Another Underlying Medical Condition)

a. *Background:* Routine foot care includes cutting or removing corns and calluses; trimming, cutting, or clipping or debriding of nails; and hygienic or other preventive maintenance care, such as using skin creams, cleaning and soaking the feet.[311] Although basic foot care is part of an individual's personal self-care, a health care provider in certain situations may perform routine foot care for a patient to the degree that is medically necessary to prevent perpetuation of chronic conditions.

b. *Circumstance:* We note that some issuers have restricted coverage for routine foot care to individuals diagnosed with diabetes. For example, several issuers have limited coverage for routine foot care to diabetes care only.

c. *Rationale:* The American Diabetes Association estimates that over 10 percent of the American population has diabetes, which costs $237 billon for direct medical costs.[312] The annual cost of diabetic foot ulcer treatment, for example, is significantly greater than non-diabetic foot ulcer treatment, estimated at $1.38 billion versus $0.13 billion.[313] Although diabetes is a vast medical expenditure in the United States, individuals may need routine foot care to treat other conditions associated with metabolic, neurologic, or peripheral vascular disease.[314]

d. *Conclusion:* Limiting coverage of routine foot care in a health plan based on an individual's diagnosis, whether for diabetes or another underlying medical condition, is presumed to be discriminatory under § 156.125. Limiting coverage of routine foot care that is medically necessary for a subset of individuals with other health conditions presumptively conflicts with the prohibition under § 156.125 against discriminatory benefit designs.

Examples: Discrimination Based on Sociodemographic Factors

5. Coverage of EHB for Gender-Affirming Care

a. *Background:* We refer to other nondiscrimination proposed provisions in § 156.200(e) of this rulemaking related to protecting individuals from discrimination based on sexual orientation and gender identity. If the proposed provisions in that section are finalized, the below example will be illustrative of a presumptively discriminatory benefit design that denies coverage of medically necessary gender-affirming care on the prohibited basis of gender identity. This example of presumptive discrimination also aligns with Executive Order 13988, which stated the Administration's policy on preventing and combating discrimination on the basis of gender identity and sexual orientation.[315]

b. *Circumstance:* The American Psychiatric Association describes ''gender dysphoria'' in transgender individuals as an experience of psychological distress that results from an incongruence between one's sex assigned at birth and one's gender identity.[316] *HeathCare.gov* notes that many health plans have unclear terms of coverage for transgender individuals.[317] Several states' EHB-benchmark plans contain either no language addressing coverage for gender dysphoria or limits coverage for specific gender-affirming services. Some states have updated their benchmark plan to add specific gender-affirming care benefits while other states prohibit discrimination based on sexual orientation and gender identity. We also note that issuers have published policies [318] related to specific coverage of gender affirming-care.

[308] *https://www.cdc.gov/nchs/nsfg/key_statistics/i_2015-2017.htm#infertility.*

[309] *https://www.acog.org/womens-health/faqs/having-a-baby-after-age-35-how-aging-affects-fertility-and-pregnancy.*

[310] Mean Age of Mothers is on the Rise: United States, 2000–2014, NCHS Data Brief No. 232, January 2016, *https://www.cdc.gov/nchs/products/databriefs/db232.htm.*

[311] Medicare Benefit Policy Manual. Routine Foot Care. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[312] *https://www.diabetes.org/resources/statistics/statistics-about-diabetes.*

[313] Hicks CW, Selvarajah S, et al. Burden of infected diabetic foot ulcers on hospital admissions and costs. *Ann Vasc Surg* 2016;33:149–58. 10.1016/j.avsg.2015.11.025.

[314] *https://wayback.archive-it.org/2744/20191012061156/https:/www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1113.pdf.*

[315] American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013; Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, January 20, 2021, *see* 86 FR 7023.

[316] *https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria.*

[317] *HealthCare.gov* states that ''many health plans are still using exclusions such as 'services related to sex change' or 'sex reassignment surgery' to deny coverage to transgender people for certain health care services. Coverage varies by state.'' ''These transgender health insurance exclusions may be unlawful sex discrimination.'' *https://www.HealthCare.gov/transgender-health-care/.*

[318] *See, for example,* Aetna Gender Affirming Surgery *http://www.aetna.com/cpb/medical/data/600_699/0615.html.*

c. *Rationale:* As discussed in more detail in the preamble to § 147.104(e), transgender individuals face health and health care disparities, and are at higher risk for many concomitant conditions.[319] Clinical evidence supports medically necessary gender affirming care and demonstrates that such coverage can significantly improve the health and well-being of individuals accessing medically necessary care. For example, for individuals diagnosed with gender dysphoria, the American Medical Association's Council on Science and Public Health supports the use of hormone therapy and supports health care providers that prescribe hormone therapy based on scientific evidence or sound medical opinion.[320] In addition, other professional societies have published criteria for guidelines in treating gender dysphoria and gender-affirming care for transgender people.[321]

d. *Conclusion:* Pursuant to §§ 156.125 and 156.200(e), as we have proposed to amend these provisions, benefit designs that restrict coverage of EHB due to gender identity are presumptively discriminatory. A health plan design, for example, is presumed to be discriminatory §§ 156.125 and 156.200(e) if it limits coverage of an EHB based on gender identity in treating gender dysphoria when clinical evidence demonstrates that such coverage is medically necessary to provide gender-affirming care. For example, excluding coverage of medically necessary hormone therapy for treatment of gender dysphoria where hormone therapy is otherwise a covered EHB is presumptively discriminatory.

6. Access to Prescription Drugs for Chronic Health Conditions: Adverse Tiering

Adverse tiering of prescription drugs presents unique issues different from presumptively discriminatory benefit designs in other categories of EHB. We acknowledge that cost is often an important factor in how plans and issuers, and their pharmacy benefit managers (PBMs) where applicable, tier their drugs and note that plans and issuers are permitted to use reasonable medical management practices and consider cost in structuring plan designs and cost sharing. However, we clarify that relying on cost alone is an insufficient basis to defend an otherwise discriminatory benefit design. An issuer providing EHB must not discriminate in its prescription drug tiering structure by discouraging enrollment of individuals with significant health needs. As proposed in § 156.125(a), in order to not discriminate, the issuer's EHB prescription drug benefit design must be clinically based. Factors that might be relevant to successfully demonstrating to CMS that the prescription drug tiering is not discriminatory would be demonstrating that neutral principles were used in assigning tiers to drugs and that those principles were consistently applied across types of drugs, particularly as related to other drugs in the same class (for example, demonstrating that the issuer or PBM weighed both cost and clinical guidelines in setting tiers).

a. *Background:* QHP issuers are allowed to structure and offer tiered prescription drug formularies. As a result, QHPs will have different tier structures depending on decisions, including on the basis of cost, that issuers make about their formulary structures. However, there is concern that formulary tiers may also be structured to discourage enrollment by consumers with certain chronic conditions. One approach to this, called adverse tiering, occurs when plans structure the formulary by assigning all or the majority of drugs for certain medical conditions to a high-cost prescription drug tier.[322]

b. *Circumstance:* Individuals with certain chronic health conditions, for example, have reported that the majority of their prescription drugs have been designated as specialty drugs and placed in the highest cost tier. Individuals have also seen most or all prescription drugs in the same therapeutic class, used to treat their chronic health condition, placed on the highest cost tiers.

c. *Rationale:* More than half of U.S. adults are diagnosed with a chronic condition. In 2018, prevalence of multiple chronic conditions was higher among women, non-Hispanic white adults, older adults, adults aged 18–64 enrolled in Medicaid, adults dually eligible for Medicare and Medicaid, and adults in rural areas.[323] Adults with certain high-cost chronic conditions require long-term treatment to manage their chronic health conditions. Health benefit designs with adverse tiering may discriminate based on an individual's present or predicted disability or other health conditions in a manner prohibited by § 156.125(a).

d. *Conclusion:* The 2016 Payment Notice provides that if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that such plan designs possibly discriminate against, individuals who have those chronic high cost conditions under § 156.125. We are clarifying that such instances of adverse tiering are presumptively discriminatory and that issuers and PBMs assigning tiers to drugs should weigh cost of drugs on their formulary with clinical guidelines for any such drugs used to treat high-cost chronic health conditions to avoid tiering such drugs in a manner that would discriminate based on an individual's present or predicted disability or other health conditions in a manner prohibited by § 156.125(a).

In addition, we indicated in the 2014 Letter to Issuers that we will notify an issuer when we see an indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices.[324] Issuers should expect to cover and provide sufficient access to treatment recommendations that have the highest degree of clinical consensus based on available data, such as professional clinical practice guidelines. Placing all drugs for a high cost chronic condition on the highest formulary tier is a presumed discriminatory benefit design, even when those drugs are costly. Plans and issuers that tier specialty drugs higher

[319] *See, for example,* Lesbian, Gay, Bisexual, and Transgender Health, Healthy People 2020, *https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health#:~:text=Research%20suggests%20that%20LGBT%20individuals,%2C%2C%203%20and%20suicide;* Hafeez, Hudaisa et al. ''Healthcare Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review.'' *Cureus* vol. 9,4 e1184. 20 Apr. 2017, doi:10.7759/cureus.1184 (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215/*); Fredriksen-Goldsen KI, Kim H–J, Barkan SE, Muraco A and Hoy-Ellis CP (2013) Health disparities among lesbian, gay, and bisexual older adults: Results from a population-based study. *American Journal of Public Health* 103, 1802–1809; Billy A. Caceres et al. ''A Systematic Review of Cardiovascular Disease in Sexual Minorities'', American Journal of Public Health 107, no. 4 (April 1, 2017): pp. e13–e21.

[320] Report of the Council on Science and Public Health, AMA. *Hormone Therapies: Off-Label Uses and unapproved Formulations (Resolution 512–A–15). https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/2016-interim-csaph-report-4.pdf.*

[321] World Professional Assn for Transgender Health, Standards of Care Version 7 (2018), available at *https://www.wpath.org/publications/.* J Clin Endocrinol Metab, November 2017, 102(11):3869–3903 *https://academic.oup.com/jcem.*

[322] Jacobs, Douglas B. and Sommers, Benjamin D. ''Using Drugs to Discriminate—Adverse Selection in the Insurance Marketplace.'' *New England Journal of Medicine.* 372:399–402. 29 Jan 2015. <*http://www.nejm.org/doi/citedby/10.1056/NEJMp1411376#t=citedby*>.

[323] Boersma P, Black LI, Ward BW. Prevalence of Multiple Chronic Conditions Among U.S. Adults, 2018. Prev Chronic Dis 2020;17:200130. DOI: *http://dx.doi.org/10.5888/pcd17.200130.*

[324] Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, page 15 and 2015 Letter to Issuers in the Federally facilitated Marketplaces, March 14, 2014, page 29.

for certain chronic conditions should expect to demonstrate that neutral principles were used in assigning tiers to such drugs and that those principles were consistently applied across types of drugs (for example, that the issuer weighed both cost and clinical guidelines in setting tiers).

For example, a generic drug requiring no special handling that is inexpensive to obtain might be rightly placed on a generic tier or the lowest tier whereas a specialty drug requiring special handling and counseling, and that is also very costly, might be rightly placed on specialty tier that has the highest cost sharing. However, a generic drug or common brand drug that does not require special handling, counseling, or medication management, and is not expensive, should not be placed on a specialty tier just because it is used to treat a condition that is a high-cost chronic condition. Furthermore, issuers and PBMs should pay close attention to any instances where all drugs to treat chronic conditions are placed on the highest-cost tiers.

In relation to the proposed refinement of the nondiscrimination standard under § 156.125, we propose that the policy become effective 60 days after publication of the final rule in the **Federal Register**. We seek comment on this proposed effective date.

In addition, we recognize that other nondiscrimination and civil rights law may apply. These laws are distinct from the nondiscrimination requirements in CMS regulations, and compliance with § 156.125 is not determinative of compliance with any other applicable requirements, nor is additional enforcement precluded. Section 156.125 does not apply to the Medicaid and CHIP programs, but a parallel provision applies to EHB furnished by Medicaid Alternative Benefit Plans.[325] We intend to provide additional examples and illustrative fact patterns of benefit designs that are discriminatory pursuant to § 156.125 in the future, as warranted. We seek comment on the nondiscrimination examples in this proposal and whether the proposed effective date is sufficient to implement the refined policy.

7. Publication of the 2023 Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing and Required Contribution Percentage in Guidance (§ 156.130)

As established in part 2 of the 2022 Payment Notice, HHS will publish the premium adjustment percentage, the required contribution percentage, and maximum annual limitations on cost sharing and reduced maximum annual limitation on cost sharing, in guidance annually starting with the 2023 benefit year. We note that these parameters are not included in this rulemaking, as HHS does not propose to change the methodology for these parameters for the 2023 benefit year and therefore, HHS is required to publish these parameters in guidance no later than January 2022.

8. Levels of Coverage (Actuarial Value) (§§ 156.140, 156.200, 156.400)

HHS proposes to change the de minimis ranges at § 156.140(c) beginning in PY 2023 to +2/−2 percentage points for all individual and small group market plans subject to the AV requirements under the EHB package, other than for expanded bronze plans,[326] for which HHS proposes a de minimis range of +5/−2. Under § 156.200, HHS proposes, as a condition of QHP certification, to limit the de minimis range to +2/0 percentage points for individual market silver QHPs; HHS also proposes under § 156.400 to specify a de minimis range of +1/0 percentage points for income-based silver CSR plan variations.

Section 2707(a) of the PHS Act and section 1302 of the ACA direct issuers of non-grandfathered individual and small group health insurance plans (including QHPs) to ensure that these plans adhere to the levels of coverage specified in section 1302(d)(1) of the ACA. A plan's level of coverage, or actuarial value (AV), is determined based on its coverage of the EHB for a standard population. Section 1302(d)(1) of the ACA requires a bronze plan to have an AV of 60 percent, a silver plan to have an AV of 70 percent, a gold plan to have an AV of 80 percent, and a platinum plan to have an AV of 90 percent. Section 1302(d)(2) of the ACA directs the Secretary of HHS to issue regulations on the calculation of AV and its application to the levels of coverage. Section 1302(d)(3) of the ACA authorizes the Secretary to develop guidelines to provide for a de minimis variation in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates.

In the EHB Rule at § 156.140(c), we established that the allowable de minimis variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan was +2/−2 percentage points. In the 2018 Payment Notice, we revised § 156.140(c) to permit a de minimis variation of +5/−2 percentage points for bronze plans that either cover and pay for at least one major service other than preventive services before the deductible or meet the requirements to be a high deductible health plans (HDHP) within the meaning of section 223(c)(2) of the Code. In the 2017 Market Stabilization final rule, effective for PY 2018, we expanded the de minimis range for standard bronze, silver, gold, and platinum plans to +2/−4.[327] In that final rule, we stated that we believed that flexibility was needed for the AV de minimis range for metal levels to help issuers design new plans for future PYs, thereby promoting competition in the market.[328] In addition, we noted that changing the de minimis range would allow more plans to keep their cost sharing the same as well as provide additional flexibility for issuers to make adjustments to their plans within the same metal level. We stated our view that a de minimis range of +2/−4 percentage points provided the flexibility necessary for issuers to design new plans while ensuring comparability of plans within each metal level.

Since we finalized these de minimis ranges in the 2018 Payment Notice and the 2017 Market Stabilization final rule, we have observed an increasing percentage of bronze plans offered on *HealthCare.gov* with AVs in the upper end of the current de minimis range. In PY 2018, 8.45 percent of all bronze plans offered on *HealthCare.gov* had an AV between 64 and 65 percent. In PYs 2019 and 2020, this number grew to 14.29 percent and 24.44 percent, respectively. For PY 2021, 67.55 percent of bronze plans offered on *HealthCare.gov* had an AV between 64 and 65 percent. As the cost of health care services continues to increase, we

[325] 42 CFR 440.347(e).

[326] Expanded bronze plans are bronze plans currently referenced in § 156.140(c) that cover and pay for at least one major service, other than preventive services, before the deductible or meet the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Code.

[327] We did not in that rule modify the de minimis range for the income-based silver CSR plan variations (the plans with an AV of 73, 87 and 94 percent) under §§ 156.400 and 156.420. The de minimis variation for an income-based silver CSR plan variation is a single percentage point. In the Actuarial Value and Cost-Sharing Reductions Bulletin (2012 Bulletin) issued on February 24, 2012, we explained why we did not intend to require issuers to offer a silver CSR plan variation with an AV of 70 percent; to align with this change, we also modified the de minimis range for expanded bronze plans from +5/−2 to +5/−4.

[328] 82 FR at 18369.

expect more bronze plans to have an AV of at least 64 percent in future PYs.

TABLE 10: Distribution of Bronze Plans by Actuarial Value Percentage, PY 2018-2021

PY	< 60%	60.00 to 61.99%	62.00 to 63.99%	64.00 to 65.00%
2018	19.41%	61.50%	10.64%	8.45%
2019	26.64%	43.20%	15.87%	14.29%
2020	16.98%	22.64%	35.93%	24.44%
2021	0.00%	20.41%	12.04%	67.55%

During PYs 2018 through 2021, as the percentage of bronze plans within the upper limit of the +5/−4 percentage point range increases, the percentage of silver plans offered on *HealthCare.gov* within the lower end of the current +2/−4 percentage point range has remained consistent, with less than a third of silver plans having an AV between 66 and 68 percent.

TABLE 11: Distribution of Silver Plans by Actuarial Value Percentage, PY 2018-2021

PY	66.00 to 67.99%	68.00 to 69.99%	70.00 to 71.99%
2018	25.65%	29.47%	44.88%
2019	30.59%	17.59%	51.82%
2020	26.27%	23.44%	50.28%
2021	28.43%	34.20%	37.37%

Despite the consistency of silver plan distribution by AV percentage, the number of enrollees in silver plans on *HealthCare.gov* within the lower end of the current +2/−4 percentage point range has decreased each year since 2018, while the number of enrollees in bronze plans within the upper end of the current +5/−4 percentage point range has increased each year since 2018.

TABLE 12: Number of HealthCare.gov Enrollees in Plans by AV Percentage, PY 2018-2021

PY	62.00 to 63.99%	64.00 to 64.99%	66.00 to 67.99%	68.00 to 69.99%
2018	481,209	335,164	289,230	275,767
2019	511,823	514,874	197,918	160,841
2020	1,037,700	827,694	132,939	173,399
2021	395,175	2,184,483	102,878	144,818

As the availability of and enrollment in bronze plans within the upper end of the current de minimis range increases and the enrollment in silver plans within the lower end of the current de minimis range decreases, we believe that it is increasingly important for consumers to be able to distinguish the levels of coverage between bronze plans and silver plans and be assured that the level of coverage of their plan corresponds to the relevant metal tier. We are not confident that consumers can reliably distinguish plans that have similar AV percentages, but significantly different cost sharing. Despite their similar AVs, there is generally a 10 percentage point difference in median coinsurance per EHB between expanded bronze and base silver plans offered on *HealthCare.gov*. The difference between copayment amounts for expanded bronze plan and base silver plan is also apparent.

TABLE 13: Median Pre-Deductible Copays for Standard Silver and Expanded Bronze Plans on HealthCare.gov, PY 2021

Service	Expanded Bronze (56 to 65% AV)	Standard Silver (66 to 72% AV)
Primary Care Visit	$40	$30
Specialist Visit	$90	$65
Mental Health/ Substance Use Disorder Outpatient Office Visit	$50	$35
Generic Drugs	$25	$20
Preferred Brand Drugs	$165	$60
Non-Preferred Brand Drugs	$250	$150

Thus, we are no longer of the view that a silver de minimis range of +2/−4 percentage points ensures the meaningful comparison of plans between the silver and bronze levels of coverage. However, we continue to recognize the importance of permitting issuers to offer expanded bronze plans because the rationale for expanding the upper limit of the de minimis range for these plans to +5 still applies to the current market: Issuers continue to require greater flexibility for bronze plan design to assist with innovation, premium impact, and future impacts to the AV Calculator methodology, to ensure that bronze plans can continue to be more generous than catastrophic plans, and to ensure that HDHPs can be offered at the bronze level. At the same time, the 2017 Market Stabilization final rule also noted the narrow difference in bronze and silver QHPs and therefore, to improve a consumer's ability to meaningfully compare the bronze and silver levels of coverage, pursuant to our authority under sections 1302(d)(3) and 1321(a)(1)(A) and (D) of the ACA, and sections 2707 and 2792 of the PHS Act, we propose changing the de minimis range for standard silver plans.

Additionally, as shown in Tables 14 and 15, we have observed a shift in enrollment for gold plans in 2021 and bronze plans since 2019 within the +2/−4 de minimis towards the center of the de minimis (+2/−2).

TABLE 14: Distribution of Gold Plan Enrollment by AV Percentage, PY 2018-2021

PY	76.00 to 77.99%	78.00 to 79.99%	80.00 to 81.99%
2018	155,725	237,202	135,160
2019	247,467	185,302	196,882
2020	273,623	68,308	271,174
2021	80,624	175,056	234,361

TABLE 15: Distribution of Bronze Plan Enrollment by AV Percentage, PY 2018-2021

PY	56.00 to 57.99%	58.00 to 59.99%	60.00 to 61.99%	62.00 to 63.99%	64.00 to 64.99%
2018	161,536	282,003	1,192,625	481,209	335,164
2019	159,121	410,260	952,680	511,823	514,874
2020	110,689	193,673	568,351	1,037,700	827,694
2021	0	0	450,022	395,175	2,184,483

Because of this shift, and for consistency across the metal levels, which would help reduce potential consumer confusion, we believe it is appropriate to propose, starting with PYs beginning in 2023, to change the de minimis ranges for the standard bronze, gold, and platinum levels of coverage from +2/−4 percentage points to +/−2 percentage points. Likewise, we have observed a similar shift in enrollment for expanded bronze plans that currently utilize a +5/−4 de minimis range. Because of this shift, and to align with the proposal above, we also propose, starting with PYs beginning in 2023, to change the de minimis range for expanded bronze plans from +5/−4 to +5/−2.

Further, states generally remain the primary enforcers of the requirement to meet AV requirements, including, to the extent required by § 156.135, the use of the federal AV Calculator or an AV Calculator that utilizes state-specific data under § 156.135(e). In the 2017 Market Stabilization rule, we stated that states are the primary enforcers of AV requirements and can apply stricter AV standards that are consistent with federal law.[329] We also stated that a state cannot require issuers to design plans that apply an AV range that is not consistent with our implementation of section 1302(d)(1) and (d)(3) of the ACA (which defines the metal levels and de minimis ranges). We reiterate those statements here. Under this proposal, a state cannot apply an AV range that exceeds +2/−2 percentage points, except for under the proposed expanded bronze range originally provided for in § 156.140(c).

In addition to the proposal applicable to non-grandfathered individual and small group market health insurance coverage market-wide, we also propose to amend § 156.200(b)(3) to state that, beginning with year PY 2023, as a requirement for certification, the allowable variation in AV for individual market silver QHPs would be + 2/0 percentage points. Through the authority granted to HHS in sections 1311(c) and 1321(a) of the ACA to establish minimum requirements for QHP certification, we propose this narrower de minimis range for individual market silver QHPs in order to maximize PTC and APTC for subsidized enrollees. Narrowing the de minimis range of individual market silver QHPs would influence the generosity of the SLCSP, the benchmark plan used to determine an individual's PTC. A subsidized enrollee who has a SLCSP that is currently below 70 percent AV would see the generosity of their current SLCSP increase, likely accompanied by a corresponding increase in premium, resulting in an increase in PTC. As shown in Table 12, since 2018, enrollment in 66.00 to 69.99 percent AV silver plans has decreased and enrollment in 62 to 64.99 percent AV bronze plans has increased; enrollees in such bronze plans now outnumber enrollees in such silver plans by more than 10 to 1. In addition, after implementation of the ARP enhanced financial subsidies, there are even fewer enrollees remaining in silver QHPs with AVs between 66.00 and 69.99 percent offered through Exchanges that use the Federal platform. Approximately 248,000 enrollees remain, of which about 91,000 are unsubsidized. By comparison, enrollment for the income-based silver CSR variations corresponding to the above silver QHPs has increased to about 4.2 million. This proposal would reduce the cost of insurance coverage for an increasing population of subsidized enrollees. It would also mitigate the net burden of the additional cost to a decreasing population of unsubsidized enrollees by incentivizing healthier, subsidy-eligible enrollees to participate in the Marketplaces.

Thus, we believe maximizing PTC for all subsidized enrollees justifies a narrower de minimis range on

[329] 82 FR at 18369.

individual market silver QHPs that have fewer enrollments each year. We solicit comment on other cost implications the proposal might have.

Finally, we propose changing the de minimis variation for individual market income-based silver CSR plan variations from +1/−1 to +1/0 with a proposed revision to the definition of ''De minimis variation for a silver plan variation'' at § 156.400. Similar to the +2/0 de minimis proposal for individual market silver QHPs, this proposal would deliver further subsidization of premiums via increased APTC and PTC for subsidized enrollees in the income-based silver CSR plan variations and increase the generosity of these plans. While there would be an expected increase to the premium for the CSR plan variations as a result of the increased generosity, it would be substantially offset by increases to the APTC and PTC. We do not propose edits to the minimum AV differential in § 156.420(f) for silver QHPs and 73 percent income-based plan variations, where the AVs must differ by at least 2 percentage points. We would note for issuers that, similar to the current de minimis ranges, standard silver QHPs with plan AVs between 71 and 72 percent would require the corresponding 73 percent income-based plan variation AV to be at least 2 percentage points above the standard plan's AV.

We seek comment on this proposal.

9. QHP Issuer Participation Standards (§ 156.200)

We propose to amend 45 CFR 156.200(e) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 156.200(e), but amendments made in 2020 to § 156.200(e) removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 156.200(e) to the pre-2020 nondiscrimination protections.

Section 156.200(e) states that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex. Previously, in the March 27, 2012 Exchange Standards final rule, we finalized § 156.200(e) to also prohibit discrimination based on sexual orientation and gender identity.[330] However, in the 2020 final rule related to section 1557, HHS revised certain CMS regulations, including § 156.200(e), by removing sexual orientation and gender identity in § 156.200(e) as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[331]

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination by issuers of QHPs. Pursuant to section 1311(c)(1)(A) of the ACA, QHP issuers are required to comply with applicable state laws and regulations regarding marketing by health insurance issuers and not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs. CMS is authorized to interpret and implement this requirement, and to set additional requirements for QHPs under its authority to establish requirements with respect to the offering of QHPs through the Exchanges in section 1321(a)(1)(B) of the ACA.[332] Pursuant to this authority to set QHP standards in section 1321(a)(1)(B) of the ACA, HHS finalized in the 2012 Exchange Standards final rule requirements at § 156.200(e) intended to protect enrollees and potential enrollees from discriminatory practices, including on the basis of sexual orientation and gender identity. CMS proposes to exercise that same authority here to amend § 156.200(e) to again prohibit QHPs from discriminating based on sexual orientation and gender identity. Section 1321(a)(1)(B) of the ACA is the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 156.200(e). Utilizing this same authority to again prohibit discrimination based on sexual orientation and gender identity at § 156.200(e) would be consistent with the authority CMS relies upon for the existing protections at § 156.200(e) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex. We believe such amendments are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer readers back to § 147.104 under section III.B.1.b. of the preamble, rather than restating the issues here.

We seek comment on this proposal.

10. Standardized Options (§ 156.201)

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 with respect to, among other things, the offering of QHPs through such Exchanges. HHS proposes to exercise these authorities to require issuers of QHPs in FFEs and SBE–FPs, for PY 2023 and beyond, to offer through the Exchange standardized QHP options at every product network type, as described in the definition of ''product'' at § 144.103, metal level, and throughout every service area that they offer non-standardized QHP options. For example, if an issuer offers a non-standardized gold health maintenance organization (HMO) plan in a particular service area, that issuer must also offer a standardized gold HMO plan in that same service area. HHS does not propose to limit the number of non-standardized QHP options that issuers of QHPs in FFEs and SBE–FPs can offer through the Exchange in PY 2023. As discussed later, HHS is considering whether for future years it would be appropriate to limit the number of non-standardized QHP options that issuers of QHPs in FFEs and SBE–FPs can offer through the Exchange.

Standardized options were first introduced in the 2017 Payment Notice. In the first iteration of standardized options, HHS proposed one set of standardized options designed to be similar to the most popular QHPs in the 2015 individual market FFEs at the bronze, silver, and gold metal levels. Issuers were not required to offer standardized options. To facilitate plan shopping and to educate consumers about the distinctive cost sharing features of standardized options, standardized options were differentially displayed on *HealthCare.gov* per the authority at § 155.205(b)(1). Specifically, consumers had the ability to filter plan options to view only standardized options and received an accompanying message explaining how standardized options differed from non-standardized options.

In the 2018 Payment Notice, HHS proposed three new sets of standardized options. The original standardized options from the 2017 Payment Notice were updated to reflect changes in QHP enrollment data in 2016, to include

[330] 77 FR 18310 (March 27, 2012).

[331] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[332] 85 FR 37218–37221 (June 19, 2020).

SBE–FP data, and to account for state cost sharing laws. Standardized options were once more differentially displayed, but this time, they were also labeled ''Simple Choice'' plans to make them more easily distinguishable from non-standardized options. HHS also established display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. [333] [334] Per these requirements, these entities were required to differentially display standardized options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized options were displayed on *HealthCare.gov*, unless HHS approved a deviation.

Standardized options were then discontinued in the 2019 Payment Notice, but 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.[335] 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's practice of designating some plans in the FFEs as ''standardized options,'' a policy that the 2019 Payment Notice stated was seeking to maximize innovation by issuers in designing and offering a wide range of plans to consumers.[336] As such, HHS announced its intent to engage in rulemaking under which it would propose to resume standardized options in time for PY 2023.[337] More recently, President Biden's Executive Order on Promoting Competition in the American Economy directed HHS to implement standardized options in order to facilitate the plan selection process for consumers on the Exchanges.[338]

The standardized options that we are proposing are as follows: 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 do not propose to require FFE and SBE–FP issuers to offer standardized options for the Indian CSR plan variations given that the cost sharing parameters for these variations are already largely standard. Further, we do not propose to require State Exchange issuers to offer the standardized options in this proposal. We also propose that FFE and SBE–FP issuers that are already required to offer standardized options under state action taking place on or before January 1, 2020, such as issuers in the state of Oregon,[339] be exempt from the standardized options requirements in this proposal.

Additionally, in an approach similar to that taken in the 2018 Payment Notice, we propose two sets of standardized options to accommodate different states' cost sharing laws. Specifically, we propose that the first set of standardized options apply to all FFE and SBE–FP issuers, excluding Delaware and Louisiana, and we propose that the second set of standardized options apply to issuers in Delaware and Louisiana in order to accommodate these two states' specialty tier prescription drug cost sharing laws.

In conjunction with our standardized options proposal, we are considering exercising the existing authority under § 155.205(b)(1) to differentially display standardized options on *HealthCare.gov*. Similarly, we are considering resuming enforcement of the standardized options display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. If we were to resume enforcement of these requirements, these entities would be required to differentially display standardized options beginning with the PY 2023 open enrollment period [340] in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized options are displayed on *HealthCare.gov*, unless HHS approves a deviation. Any requests from web-brokers and QHP issuers seeking approval for an alternate differentiation format would be reviewed based on whether the same or similar level of differentiation and clarity is being provided under the requested deviation as is provided on *HealthCare.gov*.

We continue to believe that the differential display of standardized options will not require significant modification of web-broker and QHP issuer platforms, but that such display would provide an important service and information for consumers seeking to enroll in Exchange coverage. However, consistent with the approach finalized in the 2018 Payment Notice,[341] we also continue to recognize that system constraints may prevent some web-brokers and QHP issuers from precisely mirroring the *HealthCare.gov* display, which is why we would continue to allow these entities to submit a request to deviate from the manner in which standardized options are differentially displayed on *HealthCare.gov.*

If we were to resume enforcement of these requirements, we reaffirm that a QHP issuer using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—would only need to differentially display those standardized options it offers.[342] Additionally, we intend to provide access to information on standardized options to web-brokers and QHP issuers through the Health Insurance Marketplace Public Use Files (PUFs) and QHP Landscape file to further minimize burden on these entities. We seek comment on this potential approach to display requirements.

We are proposing this approach for several reasons. The 2019 Payment Notice eliminated standardized options with the intention of maximizing innovation and variety at a time when the individual market was considered to be at risk of destabilization. We believe that current market conditions differ significantly from the market conditions that defined the individual market when standardized options were eliminated. For example, the number of issuers offering plans on the Exchanges has increased considerably, the number of counties with a single issuer offering plans through the Exchange has decreased significantly, and the number of plan options that consumers have access to on the Exchanges has increased substantially since standardized options were discontinued in the 2019 Payment Notice. With

[333] See 81 FR at 94117—94118, 94148.

[334] See 45 CFR 155.220(l) and 155.221(i).

[335] 523 F. Supp. 3d 731 (D. Md. 2021).

[336] 83 FR 16974—16975.

[337] In part 3 of the 2022 Payment Notice final rule, we explained that we would not be able to fully implement those aspects of the court's decision regarding standardized options in time for issuers to design plans and for Exchanges to be prepared to certify such plans as QHPs for PY 2022, and therefore intended to address these issues in time for plan design and certification for PY 2023. See 86 FR 24140, 24264.

[338] Executive Order 14036 on Promoting Competition in the American Economy, July 9, 2021, *see* 86 FR 36987.

[339] See Or. Admin. R. 836–053–0009.

[340] The PY 2023 OEP is scheduled from November 1, 2022 to January 15, 2023. See 45 CFR 155.410(e)(3).

[341] See 81 FR at 94118.

[342] Ibid.

increased enrollment, increased issuer participation, decreased single issuer counties, and increased plan options available to consumers, we believe that resuming standardized options at this time can play a constructive role in enhancing consumer experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs that disproportionately impact disadvantaged populations, and advancing health equity.

We are proposing to require issuers offering QHPs through FFEs and SBE–FPs to offer standardized options, as opposed to allowing them to choose to offer these standardized options, as was done in the past, due in large part to the enhanced stability of the market as well as the consumer benefits derived from the ability to compare the same plans across different issuers. For example, in the FFEs and SBE–FPs in PY 2019, there was an enrollee-weighted average of 1.2 catastrophic plans, 7.9 bronze plans, 12.3 silver plans, 4.6 gold plans, and 1.1 platinum plans available per enrollee, amounting to a total of 25.9 plans available per enrollee. In the FFEs and SBE–FPs in PY 2022, based on current filing data, it is expected that there will be an enrollee-weighted average of 2.7 catastrophic plans, 40.4 bronze plans, 45.3 silver plans, 19.2 gold plans, and 1.6 platinum plans available per enrollee, amounting to a total of 106.5 plans available per enrollee. The proliferation of choices available to consumers on the Exchanges that makes it more difficult to meaningfully assess all available plan options.

The significant increase of plan offerings available on the Exchanges over the last several PYs highlights the need to facilitate the plan selection process for consumers. This is because when consumers are faced with an overwhelming amount of plan choices, each with slightly different cost sharing structures, these consumers can experience choice paralysis. Along with plan standardization, there are additional ways to facilitate more meaningful consumer choice, for example though directly limiting the number of allowable offerings by metal level or the imposition of strong meaningful difference standards. For example, six states limit the number of plans that issuers can offer through the Exchanges. We believe that requiring issuers to offer these standardized options will play a constructive role in facilitating the plan selection process, and we believe it will enable consumers to make more meaningful comparisons between plan offerings, thus optimizing the plan selection process. We also believe that given the large number of plan offerings on the Exchanges, a sufficiently diverse range of plan offerings exists for consumers to continue to select innovative plans that meet their unique health needs. We thus do not believe that requiring issuers to offer standardized options will hamper innovative plan designs, as we noted in the preamble to the 2017 Payment Notice.

We are proposing to require issuers in FFEs and SBE–FPs, but not issuers in State Exchanges to offer standardized options for several reasons. Eight State Exchanges already require or will require issuers to offer standardized options by PY 2023. Imposing duplicative federal standardized options requirements on issuers in State Exchanges that already have existing state standardized options requirements runs counter to the aforementioned goals of enhancing the consumer experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs, and advancing health equity.

Second, we believe State Exchanges are uniquely positioned to best understand the nature of their respective markets as well as the consumers in these markets. The eight State Exchanges that require or will require issuers to offer standardized options by PY 2023 have conducted extensive stakeholder engagement in designing standardized options that meet the unique needs of their respective consumers and stakeholders. As such, we believe State Exchanges are best positioned to design standardized options for their respective markets. We further believe that states that have invested the necessary time and resources to become State Exchanges have done so in order to implement innovative policies that differ from those on the FFEs. We do not wish to impede this innovation, so long as these innovations comply with existing legal requirements. However, because we propose to impose this requirement in the FFEs, and because the SBE–FPs use the same platform as the FFEs, we propose to apply the requirements equally on FFEs and SBE–FPs. Changing the platform to permit distinction on this proposal between FFEs and SBE–FPs would require a very substantial financial and operational burden that we believe outweighs the benefit of permitting such a distinction.

We propose one exemption to the above requirement for FFE and SBE–FP issuers to offer the specific standardized options that we propose in this rule. Specifically, we propose that FFE and SBE–FP issuers that are subject to existing state standardized options requirements under state action taking place on or before January 1, 2020, such as issuers in the state of Oregon, be exempt from being required to offer the specific standardized options that we propose in this rule. We do not wish to impose duplicative requirements that could conflict with these existing state standardized options requirements and the QHP plan designs applicable in such states. Regardless, HHS intends to differentially display these existing state standardized options on the Federal platform in the same manner as it displays the specific standardized options that we propose in this rule.

We also believe that requiring FFE and SBE–FP issuers to offer standardized options at every product network type, metal level, and throughout every service area that they also offer non-standardized options will ensure consumers have access to plans that have greater pre-deductible coverage, as the standardized options included in this proposal have greater pre-deductible coverage than most of the most popular QHPs in the FFEs and SBE–FPs in PY 2021. Additionally, the fact that these plans have standardized cost sharing parameters will enable consumers to more meaningfully compare other meaningful plan attributes, such as networks, formularies, and quality ratings during the plan selection process, optimizing the plan selection process.

We are not proposing standardized options for the Indian CSR plan variations at §§ 156.420(b)(1) and (2) for several reasons. First, the cost sharing parameters for the zero cost-sharing Indian CSR plan variations are already designated. Specifically, in the zero cost-sharing Indian CSR plan variations, eligible consumers do not have to pay for any out-of-pocket costs for EHB. Second, in the limited cost-sharing Indian CSR plan variations, eligible consumers also pay no out-of-pocket costs for EHB, but only when they receive them from an Indian health care provider or from another provider with a referral from an Indian health care provider.

Similar to how we have not specified the cost-sharing parameters for more than one tier of in-network providers or for out-of-network providers for the standardized option plan designs that we are proposing, we are proposing to not specify the cost-sharing parameters for EHBs received from non-Indian health care providers for limited cost-sharing Indian CSR plan variations. This is because eligible consumers will also pay no costs for EHBs provided by

Indian health care providers or from another provider with a referral from an Indian health care provider, obviating the need to specify the cost-sharing parameters for this type of plans. Altogether, we believe that proposing standardized options for the two Indian CSR plan variations, as well as applying the aforementioned requirements to the two Indian CSR plan variations, would impose duplicative requirements with little potential benefit since the cost sharing parameters for these plans are already specified.

We believe that not limiting the number of non-standardized QHPs that issuers can offer through the FFEs and SBE–FPs in PY 2023 will ensure that consumers continue to have access to a range of plans that meet their unique health needs. Furthermore, we do not wish to cause an excessive amount of disruption, particularly in too condensed a timeframe, and we do not wish to cause an excessive number of consumers to have their coverage under their current plan discontinued for a future plan year due to limits on the number of non-standardized options. Therefore, to address choice overload and enhance consumer choice-making ability, we are considering whether to limit the number of non-standardized QHPs that issuers can offer through the FFEs and SBE–FPs in future PYs, particularly in light of the significant growth in the number of plan choices offered.

We also believe concurrently resuming differential display of standardized options on *HealthCare.gov* per the authority at § 155.205(b)(1) as well as resuming enforcement of the accompanying display requirements applicable to approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively, is important considering that a steadily increasing number of consumers are enrolling in Exchange plans via these pathways. In addition, it will further streamline the plan selection and enrollment process for Exchange consumers, aid consumers in distinguishing standardized options from non-standardized options, and enhance consumer understanding of the benefits of standardized options, such as having more pre-deductible coverage, regardless of whether the consumer uses *HealthCare.gov* or a non-Exchange website.

We also note that the comments we received in response to part 3 of the 2022 Payment Notice informed our decision to resume the designation of standardized options as well as our specific approach for doing so. We received substantial comment from diverse stakeholders and carefully considered these comments. Many commenters recommended requiring issuers to offer standardized options and differentially or preferentially displaying standardized options. Commenters explained the importance of simplifying the complex process of purchasing insurance and the role that standardized options could play in that simplification.

Specifically, commenters explained that there is significant variation in the cost sharing structures of non-standardized options, much of which cannot be identified without a detailed analysis of benefit designs. Commenters explained that many individuals do not have the time, resources, or health literacy necessary for this level of analysis. Commenters explained that enrollees instead typically choose plans based on more readily available comparison points, like premiums, rather than factors that would be illuminated by a more detailed examination of plan designs, like expected out-of-pocket costs. Commenters further explained that selecting a plan solely based on its premium without taking into consideration other attributes of its design, such as its cost sharing structure, deductible, or expected out-of-pocket costs, can result in unexpected costs and financial harm for consumers.

Commenters also explained that barriers to conducting a detailed analysis of plan designs are particularly pronounced for those whose resources are already severely constrained, including those with limited English proficiency, those with inadequate internet access, and those with complex health needs. Commenters explained that facilitating consumer understanding and streamlining decision-making in the plan selection process would benefit these populations as well as populations with disproportionately high rates of chronic diseases.

Commenters also explained that standardized options could help individuals more easily identify plans that may have potentially discriminatory benefit designs. These commenters explained that discriminatory benefit designs target individuals with particular disabilities or health conditions by leaving them with substantial out-of-pocket costs. Commenters explained that conditions that are typically targeted, including HIV, diabetes, cancer, and mental health conditions, disproportionately affect individuals of color. Commenters explained that discriminatory benefit designs continue to violate the PPACA's protections for people with preexisting conditions and its prohibition on discrimination based on race, sex, and disability.

All of these considerations informed our decision to resume the designation of standardized options as well as our specific approach for designing and implementing standardized options requirements.

Regarding the methodology employed in designing these standardized options, similar to the approach taken in past iterations of standardized options in the 2017 and 2018 Payment Notices, we designed these plans to be similar to the most popular QHPs in FFEs and SBE–FPs in PY 2021.Several comments we received in response to part 3 of the 2022 Payment Notice proposed rule expressed support for continuing to use this methodology in our approach to standardized options. Commenters explained that continuing to use this methodology and designing plans to be similar to the most popular QHPs in FFEs and SBE–FPs would minimize the degree of disruption when these requirements are implemented.

We designed the proposed standardized options to be similar to the most popular QHPs based on an examination of the proportion of consumers enrolled in plans with different cost sharing types (including copay exempt from the deductible, copay subject to the deductible, coinsurance exempt from the deductible, and coinsurance subject to the deductible) for every benefit category in the actuarial value calculator (AVC) at each metal level. We chose the cost sharing type with the majority or plurality of enrollees. We then chose the enrollee-weighted median values for this cost sharing type as the copay amount or coinsurance rate for each benefit category before modifying these plans to have an AV near the lower end of the de minimis range for each metal level to ensure the competitiveness of these plans. Nothing in the design of these standardized options supersedes the obligation to cover certain benefits, such as the preventive services required under § 147.130, without cost sharing, even if such benefits would also fall into a category for which cost sharing is specified for the standardized option.

We applied this same methodology in selecting the deductible MOOPs for the proposed plans at each metal level. Specifically, we selected the enrollee-weighted median values for deductibles

and MOOPs to ensure these plans would be similar to plans that the majority or plurality of consumers are already currently enrolled in.

In addition to designing the proposed standardized options to be similar to the enrollee-weighted medians for each benefit category, we designed two sets of standardized options to accommodate applicable state cost sharing laws in different sets of FFE and SBE–FP states. This is similar to the approach taken the last time standardized options were offered. Specifically, In the 2018 Payment Notice, we designed three sets of plans tailored to unique cost sharing laws in different states. The second and third sets of these standardized options differed from the first set only to the extent necessary to comply with state cost sharing laws. The second set of standardized options in the 2018 Payment Notice was designed to work in states that: (1) Require that cost sharing for physical therapy, occupational therapy, and speech therapy be no greater than the cost sharing for primary care visits; (2) limit the cost-sharing amount that can be charged for a 30-day supply of prescription drugs by tier; or (3) require that all drug tiers carry a copayment rather than coinsurance. The second set of standardized options applied to Arkansas, Delaware Iowa, Kentucky, Louisiana, Missouri, Montana, and New Hampshire. The third set was designed to work in a state with maximum deductible requirements and other cost sharing standards. The third set of standardized options was designed to work in the Exchange in New Jersey, which has since transitioned to become a State Exchange and is thus outside the intended scope of this rulemaking for reasons described above.

We included several of the defining features of the second set of standardized options from the 2018 Payment Notice in the first set of standardized options we are proposing in this rulemaking. As a result, in the first set of standardized options, there is cost sharing parity between the primary care visit, the speech therapy, and the occupational and physical therapy benefit categories. There are also copays for all prescription drug tiers, including the non-preferred brand and specialty tiers, instead of coinsurance rates. Finally, the copayment for the mental health/substance use disorder in-network outpatient office visit sub-classification is equal to the least restrictive level for copayments for medical/surgical benefits in the in-network, outpatient office visit sub-classification (and copayments apply to substantially all medical/surgical benefits in this sub-classification), to ensure issuers are able to design plans that comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and its implementing regulations.[343] We propose that this first set of standardized options apply to all FFE and SBE–FP issuers, excluding issuers in Delaware and Louisiana.

We included all of the defining features of the second set of standardized options from the 2018 Payment Notice in the second set of standardized option plan designs we are proposing in this rule. As a result, in this set of standardized options, similar to the first set of standardized options, there is cost sharing parity between the primary care visit, the speech therapy, and the occupational and physical therapy benefit categories, and there are copays for all prescription drug tiers, including the non-preferred brand and specialty tiers, instead of coinsurance rates. Finally, the copayment for the mental health/substance use disorder in-network outpatient office visit sub-classification is equal to the least restrictive level for copayments for medical/surgical benefits in the in-network, outpatient office visit sub-classification (and copayments apply to substantially all medical/surgical benefits in this sub-classification), to ensure issuers are able to design plans that comply with MHPAEA and its implementing regulations.

The feature that distinguishes the first set of standardized options from the second is that the second set of standardized options have copays of $150 or less for the specialty drug tiers of standardized options at all metal levels. This feature was included in the second set of standardized options to accommodate relevant specialty tier prescription drug cost sharing laws in Delaware and Louisiana. We therefore propose that this set of standardized options apply to issuers in these two specific states.

The list of states for which these sets of standardized options apply differs slightly from the list of states for which the sets applied in the 2018 Payment Notice. Specifically, in the 2018 Payment Notice, the second set of standardized options applied to Arkansas, Delaware, Iowa, Kentucky, Louisiana, Missouri, Montana, and New Hampshire (with the first set applying to the rest of the FFE and SBE–FP states), whereas in the current proposal, we propose that the second set of standardized options apply only to Delaware and Louisiana (with the first set applying to the rest of the FFE and SBE–FP states).

This is because we incorporated the other two defining features of the second set of standardized options in the 2018 Payment Notice (that is, cost sharing parity between the physical therapy, occupational therapy, and speech therapy AVC benefit categories with the primary care visit AVC benefit category, and all drug tiers carry a copayment rather than coinsurance) in both sets of standardized options in the current proposal. We made this decision primarily because incorporating these two design features into the plan designs had a negligible impact to these plans' AVs, and including these features in both sets of standardized options decreases operational complexity and allows plan designs targeted to these specific states. As a result, the first set of standardized options can now be used in Arkansas, Iowa, Kentucky, Missouri, Montana, and New Hampshire.

We seek comment on this proposal, including comment on (1) requiring FFE and SBE–FP issuers to offer standardized options at every product network type, metal level, and throughout every service area that they offer non-standardized options; (2) not limiting the number of non-standardized options that issuers can offer through the Exchanges; (3) the feasibility, advantages, and disadvantages of gradually limiting the number of plan options over the course of several PYs; (4) whether standardized options should be differentially displayed on *HealthCare.gov* as well as the best manner for doing so; (5) whether web-brokers and issuers using the Classic DE and EDE Pathways should remain subject to differential display requirements; (6) the continuation of an exceptions process that allows these entities to deviate from the display of standardized options on *HealthCare.Gov*; (7) exempting State Exchange issuers from these requirements; (8) whether these plan designs should apply to State Exchanges that do not use the Federal platform and that have not implemented their own standardized options; (9) exempting FFE and SBE–FP issuers that are subject to existing state standardized options requirements under state action taking place on or before January 1, 2020 from being required to offer the standardized options in this proposal; (10) the

[343] In general, MHPAEA requires that the financial requirements (such as coinsurance and copays) and treatment limitations (such as visit limits) imposed on mental health or substance use disorder benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a classification.

methodology used to design these standardized options; (11) if these standardized options are compliant with state cost sharing laws in FFE and SBE–FP states; (12) the cost sharing parameters and plan designs for these standardized options; (13) how these plans can be designed in a way that maximizes the likelihood that plans will be able to comply with MHPAEA; (14) the policy approach for PYs 2023 and beyond; and (15) having two sets of standardized options (that is, a separate set for Delaware and Louisiana).

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TABLE 16: 2023 Standardized Options Set One (For All FFE and SBE-FP States, Excluding Delaware and Louisiana)

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	59.86%	64.06%	70.04%	73.10%	87.04%	94.02%	78.00%	88.00%
Deductible	$9,100	$7,500	$5,800	$5,700	$800	$0	$2,000	$0
Annual Limitation on Cost Sharing	$9,100	$9,000	$8,900	$7,200	$3,000	$1,700	$8,700	$3,000
Emergency Room Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Urgent Care	No charge after deductible	$75*	$60*	$45*	$30*	$5*	$45*	$15*
Specialist Visit	No charge after deductible	$100*	$80*	$60*	$40*	$10*	$60*	$20*
Mental Health/Substance Use Disorder Outpatient Office Visit	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Laboratory Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
X-rays and Diagnostic Imaging	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician and Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Generic Drugs	No charge after deductible	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	No charge after deductible	$50	$40*	$40*	$20*	$15*	$30*	$10*
Non-Preferred Brand Drugs	No charge after deductible	$100	$80	$80	$60	$50*	$60*	$50*
Specialty Drugs	No charge after deductible	$500	$350	$350	$250	$150*	$250*	$150*

*Benefit category not subject to the deductible

TABLE 17: 2023 Standardized Options Set Two (For Delaware and Louisiana)

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	59.86%	64.07%	70.05%	73.01%	87.05%	94.02%	78.02%	88.01%
Deductible	$9,100	$7,500	$5,800	$4,100	$800	$0	$2,000	$0
Annual Limitation on Cost Sharing	$9,100	$9,000	$8,900	$7,200	$3,000	$1,800	$8,700	$3,000
Emergency Room Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	No charge after deductible	$75*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	No charge after deductible	$100*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health/ Substance Use Disorder Outpatient Office Visit	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
X-rays and Diagnostic Imaging	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*

Skilled Nursing Facility	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician and Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	No charge after deductible	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	No charge after deductible	$50	$40*	$40*	$20*	$5*	$30*	$10*
Non-Preferred Brand Drugs	No charge after deductible	$100	$80	$80	$60	$10*	$60*	$50*
Specialty Drugs	No charge after deductible	$150	$125	$125	$100	$20*	$100	$75*

*Benefit category not subject to the deductible

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11. Network Adequacy (§ 156.230)

We propose to adopt FFE QHP certification standards that would ensure that QHP enrollees would have sufficient access to providers. HHS is of the view that strong network adequacy standards are necessary to achieve greater equity in health care and enhance consumer access to quality, affordable care through the Exchanges. We have engaged and received feedback from numerous stakeholders representing diverse perspectives in developing these policy proposals.

a. Background of Network Adequacy Standards

Section 1311(c)(1)(B) of the ACA directs HHS to establish by regulation certification criteria for QHPs, including criteria that require QHPs to ensure a sufficient choice of providers (in a manner consistent with applicable provisions under section 2702(c) of the PHS Act), and provide information to current and prospective enrollees on the availability of in-network and out-of-network providers. Federal network adequacy standards were first detailed in the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers [344] and codified at § 156.230. HHS seeks to ensure that quantitative, prospective network adequacy reviews [345] occur for QHPs offered through the FFEs so that enrollees have reasonable, timely access to health care providers.

The FFEs conducted network adequacy reviews of time and distance standards for QHPs for PYs 2015–2017. The Market Stabilization [346] final rule deferred reviews of network adequacy for QHPs to states that HHS determined to have a sufficient network adequacy review process, an approach that was extended by the 2019 Payment Notice.[347] Specifically, CMS deferred to states that possessed sufficient authority to enforce standards that were at least equal to the reasonable access standard defined in § 156.230 and that had the means to assess the adequacy of plans' provider networks. For PYs 2018–2022, HHS determined that all states had sufficient legal authority and means to assess the adequacy of plans' provider networks. On March 4, 2021, as noted previously, the United States District Court for the District of Maryland decided City of Columbus, *et al.* v. Cochran.[348] One of the policies the court vacated was the 2019 Payment Notice's elimination of the Federal Government's reviews of the network adequacy of QHPs and plans seeking QHP certification to be offered through the FFEs.

As such, we announced in Parts 2 and 3 of the 2022 Payment Notice final rules our intent to undertake rulemaking to establish network adequacy standards, beginning in this proposed rule for PY 2023.

b. FFE Network Adequacy Reviews

For the QHP certification cycle for PYs beginning in 2023, HHS proposes to evaluate the adequacy of provider networks of QHPs offered through the FFEs, or of plans seeking certification as FFE QHPs, except for FFEs in certain states. HHS would not evaluate QHP network adequacy in FFE states performing plan management functions that elect to perform their own reviews of plans seeking QHP certification in their state, so long as the state applies and enforces quantitative network adequacy standards that are at least as stringent as the federal network adequacy standards established for QHPs under § 156.230, and that network adequacy reviews are conducted prior to QHP certification. States performing plan management functions are states served by an FFE where the state has agreed to assume primary responsibility

[344] *https://www.federalregister.gov/documents/2012/03/27/2012-6125/patient-protection-and-affordable-care-act-establishment-of-exchanges-and-qualified-health-plans.*

[345] Prospective network adequacy reviews would occur during the QHP certification process.

[346] *https://www.federalregister.gov/documents/2017/04/18/2017-07712/patient-protection-and-affordable-care-act-market-stabilization.*

[347] *https://www.federalregister.gov/documents/2018/04/17/2018-07355/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2019.*

[348] 523 F. Supp. 3d 731 (D. Md. 2021).

for reviewing issuer-submitted QHP certification material and making certification recommendations to HHS.

We seek comment on this proposal.

c. FFE Network Adequacy Standards Beginning With PY 2023

i. Network Adequacy Standards Applicable to Plans That Use a Provider Network

Section 1311(c)(1)(B) of the ACA directs HHS to establish criteria for the certification of health plan as QHPs, which includes the requirement that QHPs must ''ensure a sufficient choice of providers.'' HHS codified QHP network adequacy requirements under § 156.230(a)(2). In the 2012 Exchange final rule, we established the minimum network adequacy criteria that health and dental plans must meet to be certified as QHPs at § 156.230. This regulation provided that an issuer of a QHP that uses a provider network must maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to ensure that all services will be accessible to enrollees without unreasonable delay. In the 2016 Payment Notice, we modified § 156.230(a) in part to specify that network adequacy requirements only apply to QHPs that use a provider network, and that a provider network includes only providers that are contracted as in-network.

Later in this section of the preamble, we propose to refine the FFE's QHP certification standards regarding the adequacy of plans' provider networks by imposing time and distance standards, appointment wait time standards, and standards related to tiered networks.

ii. Time and Distance Standards

For the certification cycle for PYs beginning in 2023, HHS proposes to adopt for QHPs offered through the FFEs time and distance standards that HHS would use to assess whether FFE QHPs (or QHP candidates) fulfill network adequacy standards applicable to plans that use provider networks.

The proposed provider specialty lists for time and distance standards for PY 2023 are informed by prior HHS network adequacy requirements, consultation with stakeholders, and other federal and state health care programs, such as Medicare Advantage and Medicaid. The provider specialty lists cover more provider types than previously evaluated under FFE standards so that QHP networks will be more robust, comprehensive, and responsive to QHP enrollees' needs. The proposed provider specialty lists are generally consistent with standards used for plans in the Medicare Advantage program. For brevity purposes, when discussing provider types for network adequacy, we will use the term ''behavioral health'' to encompass mental health and substance use disorders.

HHS proposes reviewing additional specialties for time and distance, beyond those included by Medicare Advantage, that are necessary to meet the health care needs of QHP enrollees since Medicare Advantage and the FFEs serve different enrollee populations. The additional specialties proposed are: Emergency medicine, outpatient clinical behavioral health, pediatric primary care, and urgent care. Individual market health insurance has typically provided coverage of these specialties, as well.

We are aware of issues faced by consumers where in-network emergency physicians are in limited supply or not available at in-network hospitals. To provide proactive consumer protections, and, similar to the No Surprises Act, incentivize contracting between emergency medicine physicians and issuers to increase enrollee access to in-network providers, we propose adding emergency medicine physicians to our provider specialty list for time and distance standards. Behavioral health services are similarly critical to meeting QHP enrollees' health needs, so we also propose to add outpatient clinical behavioral health to our provider specialty list for time and distance standards. Since QHP enrollees include dependents under the age of 18, we propose adding pediatric primary care as a specialty. We further propose to include urgent care facilities in our time and distance standards because they help meet QHP enrollees time-sensitive health care needs when primary care is unavailable and the issues do not require emergency intervention. We seek to ensure the QHP enrollees have access to a variety of behavioral health facilities at the residential and inpatient levels of care. Consequently, we are also proposing to broaden the inpatient psychiatry facility specialty to be inpatient or residential behavioral health facility.

HHS proposes that time and distance standards would be calculated at the county level and vary by county designation. CMS would use a county type designation method that is based upon the population size and density parameters of individual counties, in alignment with Medicare Advantage. The time and distance standards would apply to the provider specialty lists contained in Tables 18 and 19. To count towards meeting the time and distance standards, individual and facility providers listed on Tables 18 and 19 would have to be appropriately licensed, accredited, or certified to provide services in their state, as applicable, and would need to have in-person services available.

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TABLE 18: Proposed Individual Provider Specialty List for Time and Distance Standards

Individual Provider Specialty Types
Allergy and Immunology
Cardiology
Cardiothoracic Surgery
Chiropractor
Dental
Dermatology
Emergency Medicine
Endocrinology
ENT/Otolaryngology
Gastroenterology
General Surgery
Gynecology, OB/GYN
Infectious Diseases
Nephrology
Neurology
Neurosurgery
Occupational Therapy
Oncology – Medical, Surgical
Oncology – Radiation
Ophthalmology
Orthopedic Surgery
Outpatient Clinical Behavioral Health (Licensed, accredited, or certified professionals)
Physical Medicine and Rehabilitation
Physical Therapy
Plastic Surgery
Podiatry
Primary Care – Adult
Primary Care – Pediatric
Psychiatry
Pulmonology
Rheumatology
Speech Therapy
Urology
Vascular Surgery

TABLE 19: Proposed Facility Specialty List for Time and Distance Standards

Facility Specialty Types
Acute Inpatient Hospitals (Must have Emergency services available 24/7)
Cardiac Catheterization Services
Cardiac Surgery Program
Critical Care Services - Intensive Care Units (ICU)
Diagnostic Radiology (Free-standing; hospital outpatient; ambulatory health facilities with Diagnostic Radiology)
Inpatient or Residential Behavioral Health Facility Services
Mammography
Outpatient Infusion/Chemotherapy
Skilled Nursing Facilities
Surgical Services (Outpatient or ASC)
Urgent Care

The county-specific time and distance parameters that plans would be required to meet would be detailed in future guidance. These parameters would be informed by industry standards.

Issuers that are unable to meet the specified standards would be able to submit a justification to account for variances. HHS would review such justifications to determine whether the variance(s) is/are reasonable based on circumstances, such as the local availability of providers and variables reflected in local patterns of care, and whether offering the plan through the FFE would be in the interest of qualified individuals and employers. We propose to codify the network adequacy justification process in regulation at § 156.230.

HHS seeks comment on this proposal, including on the specific parameters for time and distance standards, and flexibilities that may be needed in rural areas when there are provider or plan shortages. In particular, HHS seeks comment on the parameters that should apply with respect to behavioral health providers in order to ensure adequate access to these services. HHS also seeks comment on the specialty list to which time and distance standards would apply and whether HHS should establish time and distance standards for additional specialties in future PYs.

iii. Appointment Wait Times

For the certification cycle for PYs beginning in 2023, HHS proposes to adopt appointment wait time standards to assess whether QHPs offered through the FFEs fulfill network adequacy standards applicable to plans that use a provider network. We are proposing a short list of critical service categories for which appointment wait time standards would be assessed. The proposed provider specialty list for appointment wait time standards for PY 2023 is included below and is informed by prior federal network adequacy requirements and consultation with stakeholders, including issuers and other federal and state health care programs, such as Medicare Advantage and Medicaid.

The appointment wait time standards would apply to medical QHPs. For stand-alone dental plans (SADPs), only the dental provider specialty within the Specialty Care (Non-Urgent) category of appointment wait time standards would apply. To count towards meeting appointment wait time standards, providers listed in Table 20 must be appropriately licensed, accredited, or certified to practice in their state, as applicable, and must have in-person services available.

TABLE 20: Proposed Provider Specialty List for Appointment Wait Time Standards

Provider/Facility Type
Behavioral Health Services
Primary Care (Routine)
Specialty Care (Non-Urgent)

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The specific appointment wait time parameters that plans would be required to meet, including specifications for individual provider and facility types, would be detailed in future guidance. These parameters would be informed by industry standards. Issuers applying for FFE QHP certification would need to attest that they meet these standards as part of the certification process. HHS proposes to conduct post-certification reviews to monitor compliance with these standards. These compliance reviews would occur in response to access to care complaints or through random sampling.

Similar to the proposed justification process for time and distance standards, issuers that are unable to meet the appointment wait time standards would be able to submit a justification to account for variances. HHS would review such justifications to determine whether the variance(s) is/are reasonable based on circumstances,

such as the local availability of providers and variables reflected in local patterns of care, and whether offering the plan through the FFE would be in the interest of qualified individuals and employers. We propose to codify the network adequacy justification process in regulation at § 156.230.

HHS seeks comment on this proposal, including on the specialty list to which appointment wait time standards would apply, specific parameters for appointment wait time standards, and other ideas to strengthen network adequacy policy in future years, such as provider-enrollee ratios, provider demographics, and accessibility of services and facilities. We also seek comment on possible methods to collect and analyze claims data to inform future network adequacy standards and other aspects of QHP certification that impact health equity.

iv. Tiered Networks

HHS proposes that, for plans that use tiered networks, to count toward the issuer's satisfaction of the network adequacy standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For example, a QHP issuer cannot use providers contracted with their PPO network when certifying a plan using their HMO network, if use of PPO network providers would result in higher cost-sharing obligations for HMO plan enrollees. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards network adequacy standards. We propose to codify the network tiering requirement for network adequacy in regulation at § 156.230.

Network adequacy standards are tailored to ensure QHP enrollees have reasonable access to a sufficient number and type of providers to meet their health care needs. HHS is aware of instances in which issuers have attempted to satisfy QHP certification requirements related to networks, such as ECP standards, using providers that would require enrollees to pay higher cost sharing. We seek to ensure that QHP enrollees have access to networks with sufficient numbers and types of providers without the imposition of a higher cost-sharing requirement.

HHS seeks comment on this proposal.

v. Telehealth Services

HHS proposes to require all issuers seeking certification of plans to be offered as QHPs through the FFEs to submit information about whether network providers offer telehealth services. HHS proposes that this requirement would be applicable beginning with the QHP certification cycle for PY 2023. We believe this information could be relevant to HHS' analysis of whether a QHP meets network adequacy standards. For PY 2023, this data would be for informational purposes; it would be intended to help inform future development of telehealth standards and would not be displayed to consumers. Issuers should not construe this proposal to mean that telehealth services could be counted in place of in-person service access for the purpose of network adequacy standards.

As further explained in the ICRs and Regulatory Impact Analysis sections for network adequacy, we believe the telehealth data collection would create some additional burden for issuers who do not already have this data. The estimated burden for the telehealth data collection is included as part of the total burden for completing and submitting the ECP/NA template and is detailed in the ICRs and Regulatory Impact Analysis sections for network adequacy. We believe that the potential benefits of obtaining this information and using it to inform future network adequacy standards are in the best interests of both QHP enrollees and QHP issuers. As such, we anticipate that the additional burden would be mitigated by the expected benefits.

HHS seeks comment on this proposal, including comments on how HHS might incorporate telehealth availability into network adequacy standards in future PYs. We specifically seek comment on whether HHS should consider aligning the FFE network adequacy standards with Medicare Advantage's telehealth approach in which issuers are offered a credit towards meeting time and distance standards.

vi. Solicitation of Comments—Unintended Impacts of Stronger Network Adequacy Standards

HHS is of the view that the network adequacy standards we propose in this rule are reasonable, necessary, and appropriate to ensure that QHPs enrollees have the access to the in-network providers the ACA requires. We acknowledge, however, that there is some risk that stronger network adequacy standards could be leveraged to create an uneven playing field in network agreement negotiations that could result in higher health care costs for consumers. We are also interested in exploring rules and policies that would promote competition, taking into consideration the interests of issuers, providers, and consumers by limiting the potential that network adequacy standards may be used by parties to network agreements as leverage to obtain more favorable contract terms, leading to higher health care costs for consumers.

Strengthening network adequacy standards may increase the market power of some providers and inadvertently increase the cost of health care—for issuers, and, consequently, for enrollees. Some issuers seek to counteract these costs by incentivizing enrollees to seek care from lower-cost providers. However, some providers impose contractual steering restrictions in contracts with issuers. For example, where only one hospital is available to an issuer to meet the network adequacy standard, that hospital could charge higher prices without the threat of being excluded from the issuer's network. Such a price increase may be avoided if the issuer can include the hospital in its network, while giving incentives to its enrollees to use a more cost-effective alternative. This procompetitive option to ''steer'' patients away from high-cost providers can be precluded by the provider imposing contractual steering restrictions on issuers. A rule that circumscribes such steering restrictions may prevent providers from exploiting network adequacy standards to charge higher prices. We seek comment on the feasibility and parameters of such a rule and other solutions that would balance bargaining power between issuers and providers in a way that protects the interests of consumers.

The risk that a network adequacy standard may inadvertently empower a provider to charge higher prices is particularly problematic when the provider is part of a multi-provider hospital system and that system contracts on an all-or-nothing basis with issuers. An all-or-nothing contract is one that requires that an issuer contract with all facilities in a health system if the issuer wants to include any of the health system's facilities in its plan networks. When a multi-provider hospital system requires an all-or-nothing provision in its network agreements with issuers, issuers may be required to contract with the entire system in order to meet the network adequacy standard, and this may compel issuers to pay higher prices across the system, or else fail to meet the network adequacy standard. For this reason, we are interested in exploring how limiting ''all-or-nothing'' contracting provisions in payer contracts might counteract the potential for stronger network adequacy standards

to increase health care costs and seek comment on this topic. We understand that provider organizations typically use all-or-nothing provisions to leverage the status of their facilities that plan networks must have to satisfy network adequacy standards. These circumstances may compel the issuer to pay higher prices across the system. We are interested in understanding how this practice affects enrollees' use of and access to in-network care and how it may contribute to the cost of care. We seek comment on these issues, including comments on ways that HHS could help stem the use of all-or-nothing contracts that may drive up health care costs for consumers; how issuers can use provider networks to drive costs down; and what impact all-or-nothing contracting has on enrollees, plans, providers, and the market.

vii. Solicitation of Comments—Network Adequacy in State Exchanges

HHS is interested in learning more about network adequacy in states with State Exchanges. HHS understands that State Exchanges have a mix of network adequacy policies in place, and that about 75 percent of those states have at least one quantitative standard for time and distance, appointment wait times, or both. While the new proposed network adequacy standards for QHP issuers in FFEs differ from those in State Exchanges, HHS has not been inclined to propose additional regulations that specifically target network adequacy reviews for QHP issuers in State Exchanges, and we are not inclined to propose regulating network adequacy for State Exchanges at this time. However, we are considering whether there is a need for greater alignment in FFE and State Exchange network adequacy standards.

Starting in PY 2022, there will be 21 State Exchanges. We are concerned that there is no preferred network adequacy model that is shared among states, which indicates that there is no general agreement among states or Exchanges regarding what exactly constitutes an adequate network. Moreover, the proliferation of narrower networks in recent years presents a number of potential consumer protection concerns, including whether a narrow network has sufficient capacity to serve plan enrollees, or whether providers may be too geographically dispersed to be reasonably accessible. We are aware of the NAIC Health Benefit Plan Network Access and Adequacy Model Act,[349] which includes recommendations for network adequacy standards to which states could hold their issuers accountable, and requires submission of access plans. Since there has been limited uptake of the full Model Act by states, there remains a lack of consistency in network adequacy standards among states and Exchanges.

HHS seeks comment on whether these conditions necessitate a more coordinated, national approach to network adequacy rules across all Exchanges that is suited to address contemporary conditions in the health care markets. For example, we seek comment on whether in future PYs, HHS should consider imposing network adequacy rules in FFEs and State Exchanges that would be intended to increase the standardization of network adequacy across the Exchanges. Moreover, we seek comment on specific measures to support such standardization to ensure that all Exchange enrollees can access the benefits and services under their plans as required by the ACA. We further seek comments that identify specific gaps in provider accessibility that exist under disparate State Exchange network adequacy standards that might be addressed through greater federal regulation of network adequacy standards across all Exchanges.

12. Essential Community Providers (§ 156.235)

Essential community providers (ECPs) include providers that serve predominantly low-income and medically underserved individuals, and specifically include providers described in section 340B(a)(4) of the PHS Act and section 1927(c)(1)(D)(i)(IV) of the Social Security Act. The ECP categories include: Family planning providers, Indian health care providers, Federally Qualified Health Centers, hospitals, Ryan White providers, and other ECP providers. QHP issuers must include a sufficient number and geographic distribution of ECPs in their networks, where available. Section 156.235 establishes the requirements for inclusion of ECPs in QHP provider networks and provides an alternate standard for issuers that provide a majority of covered services through physicians employed directly by the issuer or a single contracted medical group.

In assessing the appropriate PY 2023 ECP standard for medical QHP and SADP QHP certification, HHS has considered multiple options for strengthening our ECP policy. After careful consideration, HHS proposes the approaches described below. States performing plan management functions in the FFEs would be permitted to use a similar approach.

Section 156.235(a)(2)(i) provides that a plan has a sufficient number and geographic distribution of ECPs if it demonstrates, among other criteria, that the network includes as participating practitioners at least a minimum percentage, as specified by HHS. HHS proposes that for PY 2023 and beyond, the required ECP provider participation standard be raised from 20 percent to 35 percent of available ECPs based on the applicable PY HHS ECP list, including approved ECP write-ins that would also count toward a QHP issuer's satisfaction of the 35 percent threshold. HHS would consider a plan to have satisfied the regulatory standard if the issuer contracts with at least 35 percent of available ECPs in each plan's service area to participate in the plan's provider network. The calculation methodology outlined in the 2018 Letter to Issuers in the federally-facilitated Marketplaces and 2018 Payment Notice would remain unchanged for issuers offering plans with a provider network.

The PY 2023 HHS ECP list will be based on data maintained by HHS as well as provider data that HHS receives directly from providers through the ECP petition process for PY 2023. HHS will include on the PY 2023 HHS ECP list those providers that submitted an ECP petition during the ECP petition window that closed on August 18, 2021, and that meet the definition of an ECP under § 156.235.

In developing this proposal, HHS considered that when the ECP threshold was 30 percent in PYs 2015–2017, all QHP issuers satisfied the 30 percent threshold with minimal reliance on ECP write-ins and justifications. In PYs 2018–2021, when the ECP threshold was 20 percent, all QHP issuers satisfied the lower threshold with ease and very little reliance on ECP write-ins and justifications. Beginning in 2019, HHS began publication of the ''Rolling Draft ECP list'', which significantly eased issuer burden for satisfying a higher threshold by allowing issuers to preview changes (that is, additions and removals) to the ECP list year-round in preparation for upcoming plan year contracting. Finally, in PY 2021, the percentage of medical and dental FFE issuers that could have satisfied a 35 percent ECP threshold was 80 percent and 74 percent, respectively; while the mean and median ECP score across all FFE issuers was 55 percent and 54 percent, respectively.

HHS anticipates that any QHP issuers falling short of the 35 percent threshold for PY 2023 could satisfy the standard by using ECP write-ins and

[349] *https://content.naic.org/sites/default/files/inline-files/MDL-074.pdf.*

justifications. As in previous years, if an issuer's application does not satisfy the ECP standard, the issuer would be required to include as part of its application for QHP certification a satisfactory justification describing how the issuer's provider networks, as presently constituted, provides an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer's provider network(s) in future years. At a minimum, such justification must include the number of contracts offered to ECPs for PY 2023, the number of additional contracts an issuer expects to offer and the timeframe of those planned negotiations, the names of the specific ECPs to which the issuer has offered contracts that are still pending, and contingency plans for how the issuer's provider network, as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECP types that are missing from the issuer's provider network.

HHS also proposes that, for plans that use tiered networks, to count toward the issuer's satisfaction of the ECP standard, ECPs must be contracted within the network tier that results in the lowest cost sharing obligation. For example, a QHP issuer cannot use the number of ECPs contracted with their PPO network when certifying a plan using their HMO network, if use of PPO network providers would result in higher cost sharing obligations for HMO plan enrollees. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only the preferred network would be counted towards ECP standards. We propose to codify the network tiering requirement for ECP in regulation at § 156.235.

Additionally, for PY 2023 and beyond, HHS proposes that issuers could comply with the requirement at § 156.235(a)(2)(ii)(B) to offers contracts to at least one ECP in the category of 'other ECP providers'' by offering a contract to a Substance Use Disorder Treatment Center. These facilities are critical to HHS' efforts to ensure that low-income, medically underserved individuals have sufficient access to this EHB. We are also considering making non-substantive revisions to § 156.235, which requires QHPs to offer contracts to at least one ECP in each of the ECP categories, to improve readability and clarity, and to more closely reflect how Exchanges may operationalize this requirement. For example, the regulation text presently does not include language that specifically identifies which providers may fit the category of 'Other ECP Providers.' We solicit comments on whether clarifying revisions are necessary and on how best to clarify this requirement in the regulation text.

In addition to these proposed changes, HHS seeks comment on whether and how QHP issuers should increase the use of telehealth services as part of their contingency planning to ensure access to adequate care for enrollees who might otherwise be cared for by relevant ECP types that may be missing from the issuer's provider network. We also seek comment on if we should consider adding newly Medicare-certified Rural Emergency Hospitals to our Hospitals ECP category.

These proposed changes are consistent with the directive from E.O. 13985. HHS anticipates positive health equity impact as we believe these changes will increase access to quality, relevant health care for low-income and medically underserved individuals. HHS seeks comment on these proposals, including from ECPs and issuers serving low-income and medically underserved populations. HHS also seeks comment on ideas for further strengthening ECP policy.

14. Standards for Downstream and Delegated Entities (§ 156.340)

We propose to amend and add language to § 156.340 to extend the existing downstream and delegated standards to QHP issuers on all Exchange models, including State Exchanges and State Exchange SHOPs, and Exchange models that use the Federal platform, including, FFEs, SBE–FPs, FF–SHOPs; and HHS also proposes to add a requirement that all agreements between QHP issuers and their downstream and delegated entities include language stating that the relevant Exchange authority, including State Exchanges, may demand and receive the downstream or delegated entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period. These changes would hold QHP issuers in all models of Exchange responsible for their downstream and delegated entities' adherence to applicable federal standards related to Exchanges, and to make their oversight obligations, and the obligations of their downstream and delegated entities, explicit in regulation and in the QHP issuers' agreements with their downstream and delegated entities. We also propose to amend the title of subpart D of 45 CFR part 156 from ''Standards for Qualified Health Plan Issuers on Federally Facilitated Exchanges and State-Based Exchanges on the Federal platform'' to ''Standards for Qualified Health Plan Issuers on Specific Types of Exchanges'' to align with the proposed changes to extend the applicability of the § 156.340 to all Exchange models.

Section 156.340 was originally adopted in 2013 as part of the first Program Integrity Rule and is similar to existing standards for downstream and delegated entity that contract with Medicare Advantage Organizations.[350] It currently provides that, notwithstanding any relationship(s) that a QHP issuer may have with delegated or downstream entities, the QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities, with all applicable federal standards related to Exchanges, including those at § 156.340(a)(1) through (4). Specifically, these paragraphs reference obligations set forth under: Subpart C of part 156, which governs QHP minimum certifications standards for all types of Exchange, with several provisions specific to FFEs or to Exchanges that use the Federal platform; subpart K of part 155, which governs Exchange functions pertaining to QHP certification for all types of Exchange, with several provisions specific to FFEs; subpart H of part 155, which governs the Exchange functions of the SHOP, including State Exchange SHOPs, SBE–FP–SHOPs and FF–SHOPs; standards in § 155.220 with respect to agents, brokers, and web-brokers assisting with enrollment in QHPs offered through FFEs, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs; and standards in §§ 156.705 and 156.715 for maintenance of records and compliance reviews for QHP issuers operating in an FFE and an FF–SHOP. In the 2019 Payment Notice, we amended § 156.340(a)(2) to include language incorporating cross-references to SHOP provisions, to ensure consumers on the FF–SHOPs received the protections the provision intended for them to receive.[351]

In this rule, we propose to amend paragraph (a) by adding language stating that the applicable standards for which the QHP issuers and their downstream and delegated entities are responsible depend on the Exchange model in which the issuer provides coverage. We propose to remove existing paragraphs

[350] 78 FR at 54120.

[351] 83 FR at 17028.

(a)(1) through (a)(4) that currently identify the key applicable standards as examples of the requirements with which QHP issuers must ensure their downstream and delegated entities comply, and create a new paragraph (a)(1) that outlines the standards applicable to QHP issuers participating in State Exchanges. In proposed new paragraph (a)(1), QHP issuers participating in State Exchanges, including State Exchange SHOPs, would be responsible for ensuring their downstream and delegated entities comply with the standards of subpart C of part 156 with respect to each of its QHPs on an ongoing basis and the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155, including §§ 155.705 and 155.706 for the small group market, unless the standard is specifically identified as applicable to only the FFE or FF–SHOP. This new proposed paragraph (a)(1) would generally extend applicability of the current downstream and delegated standards captured in existing paragraphs (a)(1)–(a)(2) of § 156.340 to QHP issuers participating in State Exchanges, including State Exchange SHOPs, if the standard is otherwise applicable to the Exchange type in which the QHP issuer is operating.

We further propose to create a new paragraph (a)(2) to outline the standards applicable to QHP issuers providing coverage on Exchange models that use the Federal platform. In proposed new paragraph (a)(2), QHP issuers participating in FFEs, FF–SHOPs, SBE–FPs, or SBE–FP–SHOPs would be responsible for ensuring their downstream and delegated entities comply with the standards of subpart C of part 156 with respect to each of its QHPs on an ongoing basis; the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155, including §§ 155.705 and 155.706 for the small group market; the standards of § 155.220 with respect to agents, brokers and web-brokers assisting with enrollment in QHPs; and the standards of §§ 156.705 and 156.715 for maintenance of records and compliance reviews if applicable to the Exchange type in which the QHP issuer is operating. This new proposed paragraph (a)(2) would apply the current downstream and delegated standards in existing paragraphs (a)(1) through (a)(4) of § 156.340 to QHP issuers participating in FFEs, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs if the standard is otherwise applicable to the Exchange type in which the QHP issuer is operating.

We also propose to add a new paragraph (b)(5), pertaining to record retention, incorporating the requirement that contracts between QHP issuers and their downstream and delegated entities include language that the relevant Exchange authority, including State Exchanges, may demand and receive the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period. This amendment would ensure the relevant Exchange authority—whether the FFE, SBE–FP or State Exchange—has access to the records and information from delegated and downstream entities that are necessary to ensure compliance with applicable minimum Federal standards related to Exchanges.

These proposed amendments to § 156.340 will better align the regulation with its intent and prevent confusion on the part of regulated entities and their downstream and delegated entities.

We propose this amendment be applicable as of the effective date of the final rule. We seek comment on these proposed amendments.

15. Payment for Cost-Sharing Reductions—Clarification of CSR Payment and Data Collection Processes (§ 156.430)

HHS proposes to amend § 156.430 to clarify when CSR data submission is mandatory or voluntary. Section 156.430 establishes parameters for the advance payment for CSRs, the associated data submission standards, and how final CSR payment and charges are reconciled. On October 11, 2017, the Attorney General issued a legal opinion that HHS did not have a valid Congressional appropriation with which to make CSR payments to issuers.[352] As a result, CSR payments ceased as of October 12, 2017.[353] Because issuers were not receiving CSR payments from HHS, beginning with the 2018 benefit year CSR Reconciliation Data Submission process, HHS made the CSR data submission process voluntary. To clarify the data submission requirements, we propose to amend § 156.430 to clarify that this data submission is mandatory for those issuers that receive CSR payments from HHS for any part of the benefit year and voluntary for other issuers.

To do this, we are proposing several modifications to § 156.430. First, we propose to amend § 156.430(b)(1) to clarify that when there is an HHS appropriation to make CSR payments to issuers, an issuer will receive periodic advance payments to the extent permitted by the appropriation and based on the advance payment amounts established in guidance. We believe that this proposed change clarifies that the data submission requirements are mandatory for those issuers that receive CSR payments from HHS for any part of the benefit year. Further, and in line with the current practice, HHS will continue to provide those issuers that do not receive CSR payments from HHS the option to submit CSR data.

Second, we propose to amend § 156.430(d) to reflect a change of focus from reconciliation of CSR amounts to the timing and nature of CSR data submissions, specifically when CSR payments are made. We propose to amend § 156.430(d) to state that HHS will periodically provide a submission window for issuers to submit CSR data documenting CSR amounts issuers paid, as specified in § 156.430(d)(1) and (2), in a form and manner specified by HHS in guidance, and calculated in accordance with § 156.430(c). When an appropriation is available for HHS to make CSR payments to QHP issuers, HHS will notify QHP issuers that the submission of the CSR data is mandatory for those issuers that received CSR payments from HHS for any part of the benefit year, and will use the data to reconcile advance CSR payments to issuers against the actual amounts of CSRs issuers provided, as determined by HHS based on amounts specified in § 156.430(d)(1) and (2), and calculated in accordance with § 156.430(c).

When CSR payments are not made, HHS will notify those QHP issuers that did not receive CSR payments from HHS for any part of the benefit year that the submission of the CSR data is voluntary. The CSR data that must be submitted in either a voluntary or mandatory submission includes the data elements listed in § 156.430(d)(1) and (2). The purpose of this change is to clarify when HHS will use CSR data to reconcile CSR payments. Specifically, we are proposing that to the extent that CSR payments from HHS are made to issuers, the CSR data submission process would be mandatory for those issuers having received CSR payments for any part of the benefit year from HHS, and would be voluntary for issuers that did not receive CSR

[352] Acting Secretary's memorandum enclosing Attorney General's opinion regarding CSR payments (2017), available at *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.*

[353] Ibid.

payments from HHS for any part of the benefit year. This approach is consistent with how HHS has conducted these data submission processes since the 2018 benefit year CSR data submission process.

Third, we propose to amend the title of § 156.430(e) from ''Payment of discrepancies'' to ''Cost-sharing Reductions Payments and Charges'' to reflect that this section governs both payments to issuers for CSR and charges levied against issuers for CSR.

Lastly, we propose to amend § 156.430(e)(1) to clarify that HHS will collect data regarding the CSRs actually provided by issuers to their enrollees as opposed to collecting data on the dollar value of CSRs HHS provided to the issuer, and to further clarify that HHS only pays reconciled CSR amounts when there is an appropriation to make CSR payments and to the extent permitted by such appropriation. We believe these proposed changes would provide issuers with further clarity regarding the intention of CSR data submission requirements.

We note that, regardless of whether HHS makes CSR payments, issuers are required to provide CSRs to enrollees as specified at § 155.1030. We solicit comment on these proposals.

16. Quality Standards: Quality Improvement Strategy (§ 156.1130)

In accordance with section 1311(c)(1)(E) of the ACA, quality improvement strategies described in section 1311(g)(1) of the ACA must be implemented across Exchanges as a QHP certification requirement. Section 1311(g)(1) of the ACA defines a QIS as a payment structure that provides increased reimbursement or other incentives for implementing activities related to the five health care topic areas defined in statute: Improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, promoting wellness and health, and reducing health and health care disparities. Under § 156.1130(a), a QHP issuer participating in an Exchange for 2 or more consecutive years must implement and report on a QIS, including a payment structure that provides increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of the ACA, for each QHP offered in an Exchange, consistent with the guidelines developed by HHS under section 1311(g) of the ACA. In the 2016 Payment Notice, HHS established a phase-in approach for QIS implementation standards and reporting requirements to provide QHP issuers the necessary time to understand the populations enrolling in a QHP offered through the Exchange and to build quality performance data on their respective QHP enrollees.[354] HHS noted that implementation of a QIS should be a continuous improvement process for which QHP issuers define the health outcome needs of their enrollees, set goals for improvement, and provide increased reimbursement to their providers or other market-based incentives to reward achievement of those goals.[355] In line with this approach and pursuant to the authority granted under § 156.1130(a) and section 1311(g) of the ACA, HHS proposes to update the QIS standards and enter the next phase of implementation by adopting a new guideline that would apply to QHP issuers beginning in 2023. Specifically, we propose a new guideline under which QHP issuers would be required to address health and health care disparities as a specific topic area within their QIS, in addition to at least one other topic area described in section 1311(g)(1) of the ACA beginning in 2023. We propose this expansion of the QIS standards, which aligns with health equity efforts across federal government policies and programs; however, we are not proposing amendments to the regulatory text outlined in § 156.1130.

Persistent inequities in health care outcomes exist in the United States, including among populations enrolling in QHPs across Exchanges. Belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQI+) community, having limited English proficiency, living in a rural area, or being near or below the poverty level, is often associated with worse health outcomes.[356] Such disparities in health outcomes are the result of a number of factors and exist irrespective of health insurance coverage type. Although not the sole determinant, poor health care access and provision of lower quality health care contribute to health disparities. In fact, research has shown that the expansion of health insurance coverage, for example through Medicaid expansion under the ACA, and the resulting increased access to health care, is linked to reductions in disparities in health insurance coverage as well as reductions in disparities in health outcomes.[357]

We are specifically committed to achieving equity in health care outcomes for QHP enrollees by supporting QHP issuers in quality improvement activities to reduce health and health care disparities, and promoting issuer accountability for improving equity in the health and health care of their enrollee populations. For the purposes of this proposed rule, we are using the definition of ''equity'' established in Executive Order 13985, issued on January 20, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities who have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQI+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [358] In light of the COVID–19 PHE, which is having a disproportionate and severe impact on underserved populations, and in line with the goals of Executive Order 13985, CMS is strengthening efforts across all programs to address disparities and advance health equity. This is a topic area that QHP issuers across the Exchanges have increasingly been focusing on in their QIS submissions.

Upon CMS evaluation of QHP issuer QIS submissions in the FFEs, an estimated 60 percent of QIS submissions in PY 2020 did address health care disparities. Building on the phase-in

[354] 80 FR 10750 at 10844 (Feb. 27, 2015).

[355] Ibid.

[356] See Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346; Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308; Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316; Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018; *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf; www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm;* Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[357] Guth M, Garfield R, Rudowitz R. The Effects of Medicaid Expansion Under the ACA: Studies from Jan 2014 to Jan 2020.

[358] 86 FR 7009 (Jan. 25, 2021), available at *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

approach established in the 2016 Payment Notice and our experiences evaluating QIS submissions over the years and during the COVID–19 PHE, we now propose to update the QIS standards. We propose to require QHP issuers to address health and health care disparities as one topic area of their QIS in addition to at least one other topic area described in section 1311(g)(1) of the ACA beginning in 2023. As previously noted, we are proposing this expansion of the QIS standards, which aligns with health equity efforts across federal government policies and programs; however, we are not proposing amendments to the regulatory text outlined in § 156.1130. We seek comment on this proposal.

17. Disbursement of Recouped High-Cost Risk Pool Funds—Administrative Appeals of Issuers of Risk Adjustment Covered Plans (§ 156.1220)

HHS proposes that any funds recouped as a result of a successful high-cost risk pool administrative appeal under § 156.1220(a)(1)(ii) would be used to reduce high cost-risk pool charges for that national high-cost risk pool for the current benefit year, if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for that benefit year, we propose to use any funds recouped as a result of a successful high-cost risk pool administrative appeal to reduce high-cost risk pool charges for that national high-cost risk pool for the next benefit year. As discussed earlier in this rule, we also proposed similar treatment of high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii) and as a result of actionable discrepancies under § 153.710(d). We propose to treat high-cost risk pool funds recouped as a result of a successful appeal the same way, that is, the recouped funds would be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next benefit year for which high-cost risk pool payments have not already been calculated.

We also clarify that when HHS recoups high-cost risk pool funds as a result of a successful administrative appeal, the issuer that filed the appeal would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in 45 CFR 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of high-cost risk pool funds recouped as a result of an actionable discrepancy, issuers whose charge amounts are reduced would report the high-cost risk pool charges paid for that benefit year net of recouped audit funds in the next MLR reporting cycle consistent with 45 CFR 153.710(h).

We seek comment on this proposal.

18. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

We propose to amend § 156.1230 such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 156.1230, but amendments made in 2020 to § 156.1230 removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 156.1230 to the pre-2020 nondiscrimination protections.

Section 156.1230(b)(2) states that the QHP issuer must provide consumers with correct information, without omission of material fact, regarding the FFE, QHPs offered through the FFE, and insurance affordability programs, and refrain from marketing or conduct that is misleading a consumer into believing they are visiting *HealthCare.gov*, coercive, or discriminates based on race, color, national origin, disability, age, or sex. Previously, in the 2017 Payment Notice final rule, HHS finalized at § 155.220(j)(2)(i) standards that prohibited agents, brokers and web-brokers from discriminating on the basis of sexual orientation and gender identity, among other factors.[359] In the 2018 Payment Notice final rule, we added this nondiscrimination standard from § 155.220(j) to § 156.1230(b) so that the nondiscrimination protections on the basis of sexual orientation and gender identity also applied to issuers using direct enrollment on an FFE.[360] However, in the 2020 final rule related to section 1557, HHS revised certain CMS regulations, including § 156.1230(b)(2), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[361]

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in enrollment through the Exchanges by issuers of QHPs on the Exchanges under the authority to establish requirements with respect to the operation of Exchanges, the offering of QHPs through such Exchanges, and other requirements as the Secretary determines appropriate in sections 1321(a)(1)(A), (B), and (D) of the ACA. Pursuant to this authority, in the 2018 Payment Notice final rule, HHS finalized at § 156.1230(b)(2) standards applicable to issuers using direct enrollment on an FFE to require that issuers refrain from marketing or conduct that is misleading, coercive, or discriminatory, including on the basis of sexual orientation or gender identity. HHS explained it was adding this nondiscrimination standard from § 155.220(j) to § 156.1230(b) so that the nondiscrimination protections on the basis of sexual orientation and gender identity also applied to issuers using direct enrollment on an FFE. HHS proposes to exercise that same authority here to amend § 156.1230(b) to again prohibit issuers using direct enrollment on an FFE from discriminating based on sexual orientation and gender identity. Sections 1321(a)(1)(A), (B), and (D) of the ACA are the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 156.200(e). Utilizing this same authority to again prohibit discrimination based on sexual orientation and gender identity at § 156.1230(b) would be consistent with the authority CMS relies upon for the existing protections at § 156.1230(b) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex. We believe such amendments are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing these amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer back to that section of the preamble rather than restating the issues here.

19. Solicitation of Comments—Choice Architecture and Preventing Plan Choice Overload

One of the primary goals of the ACA is to provide consumers access to quality, comprehensive health coverage options, as well as the information and assistance they need to make coverage choices that are right for them. For this reason, both Federal and State Exchanges invest significant time and resources to building Exchanges that

[359] 81 FR 12204 (March 8, 2016).

[360] 81 FR 94058 (December 22, 2016).

[361] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

support consumer access to competitive health plan options that offer sufficiently diverse benefit options that give consumers a meaningful choice between Exchange coverage options. Exchanges also work to ensure that QHP information is presented to consumers in a manner that is clear and easy to understand, and allows consumers to accurately recognize the material differences between plan options.

Although HHS continues to prioritize competition and choice on the Exchanges, we are concerned about plan choice overload which can result when consumers have too many choices in plan options on an Exchange. A 2016 report by the RAND Corporation reviewing over 100 studies concluded that having too many health plan choices can lead to poor enrollment decisions due to the difficulty consumers face in processing complex health insurance information.[362]

Earlier under this section E. of the preamble, we introduced a proposal to require that FFE and SBE–FP issuers offer certain standardized options to be designed by HHS. Standardized options offer a solution to the problems of choice overload through simplifying cost sharing structures and increasing plan comparability by allowing consumers to focus on premium price, provider network, and plan quality.[363] In light of the proliferation of seemingly similar plans offered through the Exchanges over the last several years, HHS wishes to explore whether it should limit the total number of plans issuers may offer through the FFEs and SBE–FPs in future PYs in order to further streamline and optimize the plan selection process for consumers on the Exchanges.

HHS's desire to limit the number of plans that issuers can offer through the Exchanges arises following the sharp increase in plan offerings in recent years. For example, in the FFEs and SBE–FPs in PY 2019, there was an enrollee-weighted average of 1.2 catastrophic plans, 7.9 bronze plans, 12.3 silver plans, 4.6 gold plans, and 1.1 platinum plans available per enrollee, amounting to a total of 27.1 plans available per enrollee. In the FFEs and SBE–FPs in PY 2022, based on current filing data, it is expected that there will be an enrollee-weighted average of 2.7 catastrophic plans, 40.4 bronze plans, 45.3 silver plans, 19.2 gold plans, and 1.6 platinum plans available per enrollee, amounting to a total of 109.2 plans available per enrollee.

In PY 2022, it is expected that several rating areas will have more than 50 silver plans, excluding CSR variations, available to consumers—a number we expect will make it difficult for consumers to make reasonably informed decisions. This proliferation of plans is only partially attributable to new market entrants, since in PY 2019, consumers could select QHPs from an enrollee-weighted average of 2.8 issuers per enrollee, while in PY 2022, it is expected consumers will be able to select QHPs from an enrollee-weighted average of 6.3 issuers per enrollee. The fact that the enrollee-weighted average number of plan offerings increased by a factor of four while the enrollee-weighted average number of issuers only increased by a factor of just over two between PYs 2019 and 2022 suggests consideration of the need to limit the proliferation of seemingly similar plans in order to further streamline and optimize the plan selection process for consumers on the Exchanges.

HHS is concerned that having an excessive number of health plan options may make consumers less likely to complete any plan selection and more likely to select a plan that does not match their health needs. In studies of consumer behavior in Medicare Part D, Medicare Advantage, and Medigap, a choice of 15 or fewer plans was associated with higher enrollment rates, while a choice of 30 or more plans led to a decline in enrollment rates.[364] These conclusions are supported by the comments received during prior rulemaking in which a significant number of commenters raised concerns that removing tools that facilitate the plan selection process causes consumers to face choice paralysis and leads to a reduction in overall enrollment in QHPs, undermining the purpose of Exchanges—to allow people to compare and purchase QHPs.

HHS's experience during its annual open enrollment period also suggests that ''many consumers, particularly those with a high number of health plan options, find the large variety of cost-sharing structures available on the Exchanges difficult to navigate.'' [365] Thus, in order to streamline and optimize the plan selection process for consumers on the Exchanges, HHS is interested in exploring possible methods of improving choice architecture. Several proposals within this rulemaking complement this goal, including the standardized options proposal at § 156.201 and the proposals to change the applicable AV de minimis range at §§ 156.140, 156.200, and 156.400.

Specifically, the standardized options proposal at § 156.201 proposes to require FFE and SBE–FP issuers to offer plans with standardized cost-sharing parameters at every product network type, metal level, and throughout every service area that they offer non-standardized options. Though this proposal does not limit the number of non-standardized options, HHS intends to consider and propose future rulemaking, as appropriate, to determine whether to limit the number of non-standard plans that FFE and SBE–FP issuers may offer through the Exchanges in PYs beginning on or after January 1, 2024.

Additionally, the proposals at §§ 156.140, 156.200, and 156.400 propose to modify the AV de minimis ranges. HHS proposes to modify the de minimis ranges at § 156.140(c) beginning in PY 2023 to +2/−2 percentage points for all individual and small group market plans subject to the AV requirements under the EHB package, other than for expanded bronze plans, for which HHS proposes a de minimis range of +5/−2. Under § 156.200, HHS proposes, as a condition of certification as a QHP, to limit the de minimis range to +2/0 percentage points for individual market silver QHPs. HHS also proposes under § 156.400 to specify de minimis ranges of +1/0 percentage points for income-based silver CSR plan variations. HHS anticipates that these proposals will have the effect of decreasing the number of plan offerings due to more restricted AV de minimis ranges.

HHS is also considering resuming the meaningful difference standard that was previously codified at 45 CFR 156.298. The meaningful difference standard was first finalized in the 2015 Payment Notice, revised in the 2017 Payment Notice, and discontinued and removed from regulation in the 2019 Payment Notice. The meaningful difference standard was originally intended to enhance consumer understanding of the differences between plans and enable optimal consumer choice. It was then considered to be no longer necessary given the decreased number of issuers and plans offered through the FFEs and SBE–FPs in PY 2019. Given that the

[362] Taylor EA, Carman KG, Lopez A, Muchow AN, Roshan P, and Eibner C. Consumer Decisionmaking in the Health Care Marketplace. RAND Corporation. 2016.

[363] ''Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces.'' Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. December 2021. Available at *https://aspe.hhs.gov/*.

[364] Chao Zhou and Yuting Zhang, ''The Vast Majority of Medicare Part D Beneficiaries Still Don't Choose the Cheapest Plans That Meet Their Medication Needs.'' *Health Affairs,* 31, no.10 (2012): 2259–2265.

[365] 80 FR 75,488, 75,542 (Dec. 2, 2015).

number of plans offered through the Exchanges has increased sharply over the last several years, HHS believes that resuming the meaningful difference standard could play a constructive role in limiting the proliferation of seemingly similar plans on the Exchanges, thus further streamlining and optimizing the plan selection process for consumers on the Exchanges.

HHS also acknowledges that a number of State Exchanges have successfully employed an active purchaser model in which these Exchanges selectively negotiate contracts with issuers, limit the total number of issuers that can offer QHPs through the Exchange, require issuers to offer standardized options exclusively, and exclude plans that have not demonstrated the administrative capability, prices, networks or product designs that improve consumer value. HHS intends to consider whether such a model would be appropriate in future PYs to achieve the aforementioned goals of streamlining the plan selection process for consumers on the Exchanges.

We seek comment on the utility of limiting the number of plans that FFE and SBE–FP issuers can offer through the Exchanges in future PYs in order to avoid plan choice overload and to further streamline and optimize the plan selection process for consumers on the Exchanges. We also seek comment on the impact of limiting the number of plans that issuers can offer through the Exchanges and on effective methods to achieve this goal, the advantages and disadvantages of these methods, and if there are alternative methods we have not considered.

We also seek comment on other evidence-based approaches to improve choice architecture within the Exchanges.

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

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

We propose to amend § 158.140(b)(2)(iii) to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes.

Section 2718(a) of the PHS Act requires health insurance issuers offering group or individual health insurance coverage (including a grandfathered health plan) to, for MLR purposes, separately report the percentage of total premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage, for activities that improve health care quality, and on all other non-claims (administrative) costs. Section 2718(b) of the PHS Act requires a health insurance issuer to provide an annual rebate to each enrollee if the issuer's MLR falls below the applicable MLR standard established in section 2718(b)(1)(A)(i) and (ii). Section 158.140 sets forth the MLR reporting requirements related to the reimbursement for clinical services provided to enrollees, including a requirement in § 158.140(b)(2)(iii) that issuers must include in incurred claims the amount of incentive and bonus payments made to providers. Incentive and bonus payments made to providers were originally required to be included in incurred claims to reflect certain claim liability accounting practices of HMOs,[366] but due to the lack of clarity and specificity in the regulations, have resulted in inclusion of a variety of incentive and bonus payments to providers. However, inclusion of many types of provider incentives and bonuses in incurred claims is appropriate and consistent with the purpose of the statute to the extent such bonuses reward or incentivize providers to deliver higher-quality care to consumers and thus lead to higher value for consumers' premium payments.

In the course of conducting MLR examinations pursuant to §§ 158.401 and 158.402, we have observed some issuers reporting incentive or bonus payments to providers that are not based on quality or performance metrics, but rather, involve transferring excess premium revenue to providers to circumvent MLR rebate requirements and avoid paying MLR rebates when issuers do not meet the applicable MLR standard.

Most provider incentive and bonus agreements we encounter during MLR examinations tend to have clinical metrics that must be met by the provider, rather than the issuer, in order for payment to occur. However, we have observed arrangements where the issuer's failure to meet the MLR standard is itself the metric that triggers the payment of a bonus to the provider. Under such arrangements, any time an issuer's MLR falls below a specified threshold, including below the applicable MLR standard (or, similarly, a metric tied to the issuer's profitability or surplus exceeds a specified threshold), the issuer must pay the excess profits to a provider group or hospital system. If such payments are labeled as a provider ''incentive'' or ''bonus'' and are included in the issuer's incurred claims, the issuer's MLR is artificially raised so that it is close to or meets the applicable MLR standard. This artificial inflation of MLR often eliminates most, or in some cases even all, of the rebate owed to enrollees, regardless of how low enrollees' claims costs are relative to premiums those enrollees pay. Such artificial inflation of MLR denies consumers the protection of receiving premium rebates guaranteed by the statute for the years when claims costs are low due to low utilization of health care services, such as the years when numerous medical procedures are deferred due to a pandemic. In some cases, when such payments to providers are inappropriately labeled as ''incentives'' or ''bonuses,'' they inflate paid claims by as much as 30 percent to 40 percent. The incentive for such arrangements is particularly high for integrated medical systems where the issuer is the subsidiary, owner, or affiliate of a provider group or a hospital system. Further, in some cases these ''incentives'' or ''bonuses'' are not even paid to the clinical providers, but rather to the non-clinical parent holding company of the hospital or provider group and the issuer.

Although we consider inclusion of the provider ''incentives'' and ''bonuses'' described above in incurred claims inappropriate under existing regulations because the described approach directly contravenes the statute, in order to increase compliance and improve program integrity, we propose to amend § 158.140(b)(2)(iii) to clarify that only those provider incentives and bonuses made to providers that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We seek comment on this proposal.

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

We propose to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes.

Section 2718(a) of the PHS Act requires health insurance issuers offering group or individual health insurance coverage (including a

[366] *See* 75 FR 74874 *and https://www.govinfo.gov/content/pkg/FR-2010-12-01/pdf/2010-29596.pdf.*

grandfathered health plan) to, for MLR purposes, report the percentage of total premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage, for activities that improve health care quality, and on all other non-claims costs. Section 158.221 defines the numerator of an issuer's MLR to include the issuer's incurred claims plus the issuer's expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151. Section 158.150 describes the types of activities that qualify as QIA, but does not specify the types of expenses that may be included as QIA expenses, or the extent to which such expenses must relate to the activity. The lack of clarity in existing regulations has caused wide discrepancies in the types of expenses that issuers include in QIA expenses and creates an unequal playing field among issuers. Some issuers appropriately include only direct expenses, such as the salaries of the staff performing actual QIA functions in QIA expenses. However, other issuers additionally allocate indirect expenses such as overhead, marketing, lobbying, corporate or holding group overhead, and vendor profits in QIA expenses. To the extent they can be quantified, such indirect expenses often inflate QIA amounts by 33 percent to 50 percent, potentially reducing rebates provided to enrollees while providing no value for consumers' premium dollars. In many other cases, the amounts of indirect expenses included in QIA expenses appear to be arbitrary because there is no reasonable method to allocate them to QIA as the expenses have no direct or quantifiable relationship to health care quality.

A significant portion of QIA expenses is attributable to salaries of employees actually performing the QIA. However, issuers' employees often perform QIA only part of the time, while performing cost containment and other strictly administrative and profit-generating functions (such as negotiating provider rates, or claims adjustment and appeals) the rest of the time. As a result, numerous fixed costs that some issuers allocate to QIA simply because some of their staff spend some of their time performing QIA would, for the most part, exist even if the issuer did not engage in any QIA. Examples of such indirect expenses include: Office space (including rent or depreciation, facility maintenance, janitorial, utilities, property taxes, insurance, wall art), human resources, salaries of general counsel and executives, computer and telephone usage, and company parties and retreats, including catering and travel.

Some issuers additionally allocate a fixed percentage of their entire IT cost centers to QIA, even though the IT infrastructure disproportionately supports regular business functions such as billing, claims processing, financial analysis, and cost containment, and for the most part would exist even if the issuer did not engage in any QIA. Examples of such expenses include: Salaries of IT staff and call center or help desk staff, data centers and warehouses, mainframe equipment, network system applications and equipment, enterprise data management, as well as depreciation, maintenance, and utilities associated with IT equipment.

Some issuers include in QIA expenses amounts exceeding the cost of providing the actual QIA service. For example, some issuers make a profit when providing wellness incentives to enrollees, but structure cost reporting in a manner that includes such profits in QIA expenses. In addition, some issuers include the promotion or marketing of their QIA services to group policyholders or enrollees as QIA expenses. Some issuers also include the cost of developing the prices of QIA services sold to group policyholders, or costs associated with calculating and reporting QIA expenses.

Section 2718 of the PHS Act created the first national MLR reporting and rebating program with the goal of putting downward pressure on issuers' administrative expenses and encouraging issuers to devote more of the premium dollars to medical spending and enrollee health. Section 2718 of the PHS Act recognizes that investing in QIA may improve enrollee health, thereby increasing the value of their premium dollars. However, facility maintenance, utilities, human resources, salaries of counsel and executives, computers, travel and entertainment, IT systems, and marketing of issuers' products provide no benefit to an enrollee's health. By including such costs in the MLR numerator, the value of the enrollee's premium dollars is actually reduced. Thus, indirect expenses such as those are described here are classified as non-claims, administrative costs for purposes of reporting incurred claims under § 158.140. Allowing issuers to report these same excluded expenses as expenditures on QIA is inappropriate and would undermine the very purpose and intent of section 2718 of the PHS Act. It would allow issuers to inflate QIA costs by including expenses that do not actually improve health care quality, particularly since these expenses are often fixed costs that would occur regardless of whether the issuer engages in QIA. Further, some issuers are not able to precisely determine what portion of indirect costs is tied to QIA, as many issuers do not have an accurate method to quantify the actual cost of each expense category as it relates to each QIA, and thus issuers are often arbitrarily determining or apportioning indirect expenses without adequate documentation to support their determinations. The lack of clarity in § 158.150 as to what expenses may be included in QIA expenses has created an uneven playing field that is unfairly boosting the MLRs of issuers that include indirect or overhead expenses in QIA expenses as compared to those that are not reporting these expenses in QIA expenses, thus driving up health care spending and depriving consumers of value for their premium dollars.

In order to ensure reporting consistency among issuers and ensure that QIA expenses included in the MLR numerator represent actual value provided for consumers' premium dollars, we propose to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses.

We seek comment on this proposal.

3. Allocation of Expenses (§ 158.170)

As noted in part 2 of the 2022 Payment Notice final rule, on March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus, et al.* v. *Cochran*, 523 F. Supp. 3d 731 (D. Md. 2021). Among other things, the court vacated § 158.221(b)(8), which provided that beginning with the 2017 MLR reporting year, an issuer had the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151.[367] Accordingly, in part 2 of the 2022 Payment Notice final rule, we finalized the deletion of § 158.221(b)(8) and removed the option allowing issuers to report the fixed, standardized amount of QIA and reverted to requiring issuers to itemize QIA expenditures, beginning with the 2020 MLR reporting year (MLR reports that were due by July 31, 2021). However, we inadvertently failed to make a conforming amendment to

[367] 86 FR 24140.

§ 158.170(b). Section 158.170 addresses allocation of expenses in relation to MLR reporting in general. Section 158.170(b) requires issuers to describe the methods used to allocate expenses. Specifically, § 158.170(b) requires the report required in § 158.110 to include a detailed description of the methods used to allocate, among other things, ''quality improvement expenses (unless the report utilizes the percentage of premium option described in § 158.221(b)(8), in which case the allocation method description should state so),'' to each health insurance market in each State. Given the deletion of § 158.221(b)(8) in part 2 of the 2022 Payment Notice final rule, the reference in § 158.170(b) to the percentage of premium QIA reporting option described in § 158.221(b)(8) is no longer applicable. Accordingly, we propose make a technical amendment to § 158.170(b) to correct this oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8).

G. Solicitation of Comments on Health Equity, Climate Health, and Qualified Health Plans

On January 20, 2021, President Biden issued Executive Order 13985, titled ''Advancing Racial Equity and Support for Underserved Communities through the Federal Government,'' which established a government-wide approach to advancing equity and addressing disparities for historically marginalized communities in the United States. The order defines equity as ''the consistent and systematic fair, just and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment.'' [368]

CMS' Office of Minority Health (CMS OMH) aligns with Healthy People 2030 that defines health disparities as ''a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.'' [369]

In alignment with the objectives set forth by the President's Executive Order and CMS OMH, CMS aims to proactively advance health equity and improve the health of all Americans, including racial and ethnic minorities, sexual and gender minorities, people with disabilities, individuals with limited English proficiency, rural populations, and historically underserved communities.

Section 1311(e)(1)(B) of the ACA states an Exchange may certify a health plan as a QHP if the Exchange determines that making available such health plan through such Exchange is in the interests of qualified individuals and qualified employers. Section 1321(a)(1) of the ACA provides the Secretary with general rulemaking authority, including with respect to setting standards for meeting the requirements for offering QHPs through Exchanges and such other requirements as the Secretary determines appropriate. In addition to the proposals in this rule,[370] CMS is considering other ways to incorporate health equity standards by using the Secretary's authority to enhance criteria for the certification of QHPs and/or leverage existing QHP requirements, such as the Network Adequacy Standards at 45 CFR 156.230 and Accreditation of QHP Issuers at 45 CFR 156.275. Furthermore, CMS seeks input on additional ways to incentivize QHP issuers to improve health equity and improve conditions in enrollees' environments, as well as to address other SDOH outside of the QHP certification process.

CMS seeks comment from stakeholders on advancing health equity through QHP certification standards; advancing CMS's understanding of the existing landscape of issuer collection of health equity data; and assessing data sources that focus on population-level factors made available by governments, quasi-governmental entities, data vendors and other organizations, both generally and with respect to the following specifics:

- CMS seeks input on:

++ Requiring QHP issuers to obtain the National Committee for Quality Assurance (NCQA) Health Equity Accreditation in addition to their existing accreditation requirements,

++ Other health equity assessment tools that achieve this goal, and (3) the challenges QHP issuers could face implementing a new accreditation product on health equity.[371]

- What demographic and/or SDOH data do QHP issuers currently collect from enrollees? Should QHP issuers be required to collect demographic and other SDOH data to help issuers gain a better understanding of the populations they serve, and thereby develop more equity-focused QHPs? Which data elements should be considered to advance health equity within QHPs? What are some of the challenges and barriers to collect this data?
- What datasets related to population factors could CMS leverage to analyze whether QHP networks are providing adequate access to health care services for members within specific geographic areas?
- What ability do QHP issuers have to tailor provider networks based on the health needs of enrollees in specific geographic areas?
- What health conditions or outcome variables should CMS analyze to identify gaps in the health care services? What are some of the ways that CMS could measure QHP issuers' progress toward advancing health equity?
- Should CMS encourage QHP issuers to be accountable for improving health outcomes across all populations equitably, while acknowledging variations in SDOH?
- Are there ways that CMS could incentivize QHP issuers to advance health equity outside of the QHP certification requirement, such as through other federal reporting requirements, including MLR reporting?
- What are the challenges QHP issuers face in promoting and advancing health equity? What are some strategies that could overcome those challenges?
- What other health equity tools made available by organizations should CMS consider to address health disparities within QHPs?

HHS further seeks to explore how Exchanges and their constituent organizations can more fully prepare for the harmful impacts of climate change on their enrollees. Since we know that climate change causes great and growing harm to Americans (through both catastrophic events and chronic disease) and since we know that it will disproportionately harm vulnerable populations, including those groups subject to health disparities described

[368] Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Executive Office of the President. 2021, *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[369] *https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/questions-answers.*

[370] See, for example, the proposed updated quality standards under 45 CFR 156.1130 for QHP issuer quality improvement strategies and interoperability requirements under 45 CFR 156.221 for QHP issuers in the FFE to implement and maintain a patient access application programming interface.

[371] *https://store.ncqa.org/accreditation/health-equity-he.html.*

above, HHS and CMS believe that it is critical to study and prepare for these dire impacts. Generally, HHS seeks input on how Qualified Health Plans can more effectively: (1) Determine likely climate impacts on their enrollees and particularly the most vulnerable enrollees; (2) determine potential costs of these impacts; (3) develop plans to mitigate catastrophic and chronic impacts for these populations (that is, plans for resilience); and (4) take responsibility for greenhouse gas emission reduction across the networks of organizations that make up their exchanges. Specific questions include:

- Do Exchanges and issuers have a plan to assess, reduce or mitigate its emissions in its operations or organizations?
- What data do Exchanges and issuers currently collect with respect to the climate threats faced by their enrollees and particularly their most vulnerable enrollees? Do they complete risk assessments or surveys that have a geographic or population focus?
- What types of utilization reviews could issuers perform of medical or prescription data to better understand the impact of climate change events on their enrollees?
- Do National Committee for Quality Assurance (NCQA) health equity requirements include reviews of climate resilience?
- What would incentivize Exchanges and issuers participating in those Exchanges to more fully prepare for climate change's impacts on vulnerable populations? What would incentivize them to take action on decarbonization? How can issuers strengthen the overall health of their enrollees to be more resilient to harmful climate change events?
- Do issuers currently use, or could they use, apps and/or AI to alert enrollees of severe climate events and steps to mitigate related harmful effects (for example, extreme heat or wildfire events)?
- What measures would be appropriate for assessing QHP performance on climate change and health equity?

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. This proposed rule contains information collection requirements that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 22. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[372] Table 21 in this proposed rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage. As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 21: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Management Analyst	13-1111	$46.91	$46.91	$93.82
Business Operations Specialist	13-1199	$37.66	$37.66	$75.32
Operations Manager	11-1021	$60.45	$60.45	$120.90
Computer and Information Systems Manager	11-3021	$77.76	$77.76	$155.52
Eligibility Interviewers, Government Programs	43-4061	$23.07	$23.07	$46.14
Computer System Analyst	15-1121	$47.61	$47.61	$95.22
Computer Programmer	15-1251	$45.98	$45.98	$91.96
Computer & Information Systems Manager	11-3021	$77.76	$77.76	$155.52
Compliance Officer	13-1041	$36.35	$36.35	$72.70
Web Developer and Digital Interface Designer	15-1257	$41.10	$41.10	$82.20

[372] See May 2020 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at *https://www.bls.gov/oes/current/oes_stru.htm.*

B. ICRs Regarding State Flexibility for Risk Adjustment (§ 153.320)

We are proposing to generally repeal the ability of states to request a reduction in risk adjustment state transfers in any state market risk pool starting with the 2024 benefit year, with an exception for states that previously participated in risk adjustment state flexibility. We propose to provide an exception for states that previously submitted state flexibility requests under § 153.320(d) so that only those states would be able to continue to request this flexibility in 2024 and future benefit years. We further propose to remove as an option for a prior participant justification and HHS approval of a state flexibility request the demonstration of state-specific circumstances that warrant an adjustment to more precisely account for relative risk differences in the state individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, and to retain as the only option for state justification and HHS approval the demonstration that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments. This change would also apply beginning with 2024 prior participant benefit year requests from prior participant states. As such, we propose various amendments to the risk adjustment state flexibility regulations at § 153.320(d) to reflect the general repeal of this flexibility, with the exception for states that previously participated, and to remove one of the criteria for state justification and HHS approval beginning with benefit year 2024 requests. The burden associated with this requirement is the time and effort for the state regulator to submit its request and supporting evidence and analysis to HHS. We estimate that submitting the request and supporting evidence and analysis will take a business operations specialist 40 hours (at a rate of $75.32 per hour) to prepare the request and 20 hours for a senior operations manager (at a rate of $120.90 per hour) to review the request and transmit it electronically to HHS. We estimate that each state seeking a reduction will incur a burden of 60 hours at a cost of approximately $5,430.80 per state to comply with this reporting requirement (40 hours for the insurance operations analyst and 20 hours for the senior manager). The estimated burden related to submission of these requests would be reduced as a result of these proposed changes, since only one state, Alabama, previously participated and would still be able to request this flexibility. In the 2019 Payment Notice,[373] we estimated that 25 states would submit requests and provided a total burden of approximately 1,500 hours across all states, which would total $135,770 based on current wage estimates. Since there is only one prior participating state, we estimate that this burden will be reduced by $130,339.20 to a total annual cost of $5,430.80, reflecting the burden associated with one state's submission. This information collection is approved under OMB control number 0938–115, and if this proposal is finalized, HHS would revise the information collection under OMB control number 0938–1155 accordingly and provide the applicable comment periods.

C. ICRs Regarding Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610 and 153.710)

Pursuant to section 1343(b) of the ACA, 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 risk adjustment program in any state that fails to do so. As described in § 153.610, health insurance issuers are required to maintain risk adjustment data in order for HHS to operate risk adjustment on behalf of a state. HHS employs a distributed data approach when running risk adjustment on behalf of a state and uses the same data for the purpose of determining the risk adjustment user fee for each issuer. In this proposed rule, we propose to collect five new data elements from issuers' EDGE servers through issuers' Edge Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files: ZIP code, race, ethnicity, ICHRA indicator and subsidy indicator. We also propose to extract these new data elements as part of the enrollee-level EDGE data beginning with the 2023 benefit year. In addition, we propose to begin extracting three data elements issuers already report to their EDGE servers—plan ID, rating area and subscriber indicator—as part of the enrollee-level EDGE data beginning with the 2022 benefit year.

Section 153.700(a), requires an issuer of a risk adjustment covered plan in a state where HHS is operating the risk adjustment program to provide HHS, through its dedicated distributed data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by plan ID, rating area, and subscriber indicator. Thus, the proposals to extract these data elements will not pose additional operational burden to issuers, since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. Therefore, we are not proposing to change the existing burden for the proposal to extract plan ID, rating area, and subscriber indicator.

For the five new data elements we propose to collect beginning with the 2023 benefit year, we estimate that approximately 600 issuers would be subject to this new data collection. We propose to collect these new data elements via issuers' ESES files and risk adjustment recalibration enrollment files. We estimate a cost of approximately $375.28 in total labor costs for each issuer, which reflects 4 hours of work by a management analyst per issuer at an average hourly rate of $93.82 per hour. The cumulative additional cost estimate as a result of this proposal is $225,168 for 600 issuers (2,400 total hours per year for all issuers). The proposals to extract these data elements will not pose additional operational burden to issuers, since the creation and storage of the extract is mainly handled by HHS. If the proposed collection of ZIP code, race, ethnicity, the ICHRA indicator, and the subsidy indicator are finalized, we would revise the information collection under OMB control number 0938–1155 accordingly and provide the applicable comment periods.

D. ICRs Regarding 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)

We propose to revise § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(1) through (5) a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We also propose to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website.

[373] 82 FR at 51118.

This proposal should result in very limited new burden for web-brokers. The proposed new standardized disclaimer would require web-brokers to make minor updates to their non-Exchange websites in cases where they do not support enrollment in all available QHPs. However, in those cases, web-brokers would be displaying a disclaimer much like the plan detail disclaimer that they have historically been required to display.

We estimate this proposal will affect approximately 20 web-brokers based on the number of web-brokers currently approved by CMS and our internal knowledge of entities that have expressed interest in becoming web-brokers. Given the minor modifications necessary to implement the revised disclaimer in this proposal, we estimate a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this proposal is $8,220 for 20 web-brokers in the 2022 benefit year. If this proposal is finalized, we would revise the information collection under OMB control number 0938–1349 accordingly and provide the applicable comment periods.

We propose to amend § 155.220 to add a proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on plan name, from lowest to highest premium, etc.). We believe this proposed new requirement would provide consumers with a better understanding of the information being presented to them on web-broker websites, thereby enabling them to make better informed decisions and shop for and select QHPs that best fit their needs.

We support web-broker websites' use of innovative decision-support tools for consumers to help them shop for and select QHPs that best fit their needs. However, web-broker websites that explicitly recommend or rank QHPs do not always provide an explanation for their recommendations or rankings. Similarly, web-broker websites may not include an explanation of the methodology used for their default displays of QHPs, and it may not otherwise be apparent what methodologies are used. The absence of such explanations may cause some consumers to misunderstand the bases for the recommendations displayed to them on web-broker websites (whether explicit or implicit), or may prevent them from assessing the value of the recommendations (for example, whether a recommendation is based on the factors most important to them). In addition, the lack of explanations for QHP recommendations on web-broker websites may obscure that the web-broker is recommending QHPs based on compensation the web-broker receives from QHP issuers in violation of § 155.220(c)(3)(i)(L). For these reasons, we propose to amend § 155.220 to add proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for QHP recommendations and the methodology for their default display of QHPs.

This proposal should result in very limited new costs for web-brokers, since the information it would require they display on their websites would only require text-based changes that are relatively easy to implement. Furthermore, the extent of those textual updates should be relatively minor in most cases. For example, if a web-broker is recommending a QHP based on the fact that it has the lowest monthly premiums for a consumer, that can likely be communicated in one or two sentences of informational text, or possibly even in a single phrase or set of short bullet points. Some web-brokers are already providing the information that would be required by this proposal, and therefore would not have to make any website updates. Other web-broker websites do not explicitly recommend QHPs, and therefore the impact of this proposal would be limited to providing similar information about the methodology for their default display of QHPs (for example, explaining QHPs are sorted from lowest to highest premium, etc.), assuming they do not already provide that information.

We estimate this proposal will affect approximately 20 web-brokers. Given the minor text-based changes necessary to implement the informational text detailing the rationale for QHP recommendations and the methodology for a default display of QHPs, we estimate a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this proposal is $8,220 for 20 web-brokers in the 2022 benefit year. If this proposal is finalized, we would revise the information collection under OMB control number 0938–1349 accordingly and provide the applicable comment periods.

E. ICRs Regarding Verification of Eligibility for Special Enrollment Periods (§ 155.420)

Since 2017, the Exchanges on the Federal platform have implemented pre-enrollment special enrollment period verification for special enrollment period types commonly used by consumers to enroll in coverage. We propose to amend § 155.420 to add new paragraph (g) to state that Exchanges may conduct pre-enrollment eligibility verification for special enrollment periods at the option of the Exchange. The Exchanges on the Federal platform would verify special enrollment period eligibility for the most common special enrollment period type, loss of minimum essential coverage. This special enrollment period type comprises the majority of all special enrollment period enrollments on the Exchanges on the Federal platform.

Since consumers on Exchanges on the Federal platform currently must provide eligibility verification documentation for more special enrollment period types, the provision would decrease burden on consumers applying for special enrollment period types that no longer require pre-enrollment verification. We expect that it takes an individual, on average, about 1 hour to gather and submit the relevant documentation needed for pre-enrollment special enrollment period eligibility verification. This estimate is based on the assumption that each individual required to submit documentation will submit, on average, two documents for review. It could take significantly less time if an individual already has the documents on hand, or more time if the individual needs to procure documentation from a government agency or other source.

Based on enrollment data for Exchanges on the Federal platform, we estimate that HHS eligibility support staff members would conduct pre-enrollment verification for 194,000 fewer individuals. We estimate that Once individuals have submitted the required verification documents, it would take an Eligibility Interviewer approximately 12 minutes (at an hourly cost of $46.14) to review and verify submitted verification documents. In 2017, the Exchanges on the Federal platform expanded pre-enrollment special enrollment period verification to include five special enrollment period types and estimated an annual additional administrative burden of

130,000 hours at a cost of $5,306,600.[374] Limiting pre-enrollment verification to one special enrollment period type would decrease the annual administrative burden of special enrollment period verification. The proposed change would result in a decrease in annual burden for the federal government of 38,800 hours at a cost of $1,790,232. It would also result in a decrease in annual burden for consumers attesting to special enrollment period types that no longer require document verification of 194,000 hours.

The proposed information collection requirements and the related burden decrease discussed in this section will be submitted for OMB review and approval as part of a revision of the information collection currently approved under OMB control number 0938–1207 (Expiration date: February 29, 2024).[375]

F. ICRs Regarding General Program Integrity and Oversight Requirements (§ 155.1200)

We propose to add § 155.1200(e) to permit a State Exchange to meet the requirement to conduct an annual independent external programmatic audit, as described at § 155.1200(c), by completing an audit that year under the SEIPM audit process we propose under Part 155, subpart P. We estimate that there would be a burden reduction for State Exchanges related to the programmatic audit requirement under § 155.1200(c). In particular, the 18 State Exchanges that manage their own eligibility and enrollment platforms would no longer be required to dedicate resources to procure and reimburse auditing entities for services rendered to complete the annual independent external programmatic audits, assuming the State Exchanges were instead completing the required SEIPM program process that year. Based on industry estimates of the average cost of contracting an auditor to conduct an independent external programmatic audit, HHS estimates that the cessation of contracting such audit entities would result in an annual cost reduction of approximately $90,000 for each State Exchange, which is described in detail in the RIA section of this rule.

Additionally, staff resources would no longer be needed to submit the results of the programmatic audit as a component of the State-based Marketplace Annual Reporting Tool (SMART). This would result in a reduction in cost and staff resources for each State Exchange. We anticipate a reduction in cost associated with compiling data, summarizing the programmatic audit results, and submitting to CMS. State Exchanges are required to provide the results of the programmatic audit in a public summary. This proposal would remove the burden associated with reporting requirements, which includes the burden for a management analyst taking 3 hours (at $93.82 an hour) to pull data into a report, the time and effort necessary for a policy analyst taking 2 hours (at $93.82) to prepare the report of the audit results, and the time for a senior manager taking 1 hour (at $155.52 an hour) to review and submit to CMS. We estimate the burden of 6 hours at a cost of $624.62 for each State Exchange. Therefore, the aggregate burden for the 18 State Exchanges that manage their own eligibility and enrollment platforms is 108 hours at a cost of $11,243.16.

Based on these estimates we expect the cost reduction associated with compiling and reporting audit data to total $11,243.16 across all 18 State Exchanges beginning in the 2024 benefit year. The information collection associated with the burden being reduced is covered under OMB Control Number 0938–1244. If this rule is finalized as proposed, we would revise the burden estimates covered under 0938–1244 before the implementation of the SEIPM program.

We estimate this impact to take effect in June 2024 at the earliest, which is when the State Exchanges would otherwise be providing completed independent external audits as a component of their PY 2023 SMART submissions. There would, however, be a corresponding new burden created to complete the SEIPM process. For an estimate of the burden created under SEIPM, please refer to section 14.

We request comment on the reduction in burden proposed, and specifically seek feedback from State Exchanges regarding the annual cost of the programmatic audit process.

G. ICRs Regarding State Exchange Improper Payment Measurement Program (§§ 155.1500–155.1540)

1. Data Collection (§ 155.1510)

In the preamble to § 155.1510, we explain the sampling process for each SEIPM review cycle. In § 155.1510(a)(1), we propose that HHS will provide State Exchanges with the pre-sampling data request, which State Exchanges will complete and return to HHS. Both the pre-sampling data request and the requested source data are in an electronic format. The burden associated with completion and return of the pre-sampling data request would be the time it would take each State Exchange to interpret the requirements, analyze and design the database queries based on the data elements identified in the SEIPM data request form, develop the database queries, test the data, perform verification and validation of the data, and return the form to HHS.

Once the pre-sampling data request is returned to HHS, HHS will draw the sample for each State Exchange. In § 155.1510(a)(2), we propose that HHS will provide the sampled unit data request to the State Exchange for completion and return to HHS. The sampled unit data request will include the sampled units specific to each State Exchange. Both the sampled unit data request and the requested source data are in an electronic format. The burden associated with completion and return of the sampled unit data request would be the time it would take each State Exchange to interpret the requirements, analyze and design the database queries based on the data elements identified in the SEIPM data request form, develop the database queries, test the data, perform verification and validation of the data, and return the form to HHS.

We expect respondent costs will not substantially vary since the data being collected is largely in a digitized format and that each State Exchange will be providing information for approximately 100 sampled units. We do not expect reporting costs to vary considerably based on sample size. We seek comment on these assumptions.

We estimate completion of the pre-sampling data request would take 12 hours per respondent at an estimated $1,364 per respondent. We estimate completion of the sampled unit data request would take 707 hours per respondent at an estimated cost of $73,054 per respondent. To compile our estimates, we referenced our experience in collecting data in our FFE pilot initiative. We identified specific personnel and the number of hours that would be involved in collecting the sampled unit data broken down by specific area (for example, eligibility verification, auto re-enrollment, periodic data matching, enrollment reconciliation, plan management, and manual reviews including document retrieval). Additionally, to account for the time needed for any State Exchanges to convert hard copies to a digitized format, we added 20 hours for each

[374] 82 FR 18346.

[375] Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment (CMS–10468).

State Exchange into the burden estimates.

Hourly wage rates are based on May 2020 Bureau of Labor Statistics Occupational Codes and vary from $45.98 (adjusted to $91.96 to account for overhead) to $77.76 (adjusted to $155.52 to account for overhead) depending on occupation code and function. With a mean hourly rate of $103.50 for the respective occupation codes, the burden across the 18 State Exchanges equals 12,942 hours for a total cost of up to $1,339,523. The burden related to this information collection is being submitted to OMB for approval with this proposed regulation.

2. Determination of Error Findings Decision and Appeal Redetermination (§§ 155.1525 and 155.1530)

As described in the preamble to § 155.1525, Redetermination of Error Findings Decision, a State Exchange may file a request with HHS to resolve issues with HHS' findings within the deadline prescribed in the annual program schedule.

The burden associated with the information collection requirements contained in §§ 155.1525 and 155.1530 is the time and effort necessary to draft and submit a request for a redetermination of an error findings decision and, if requested, an appeal of a redetermination decision. In accordance with 5 CFR 1320.4, information collected during the conduct of an administrative action is not subject to the PRA. As a result, we believe the burden associated with these requirements is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

3. Corrective Action Plan (§ 155.1535)

As described in the preamble to § 155.1535, we are proposing that State Exchanges may be required to develop and implement corrective action plans following a completed SEIPM measurement designed to reduce improper payments as a result of eligibility determination errors. The burden associated with this requirement is the time and effort put forth by State Exchanges to develop and submit a corrective action plan to HHS. We estimate that it would take each selected State Exchange up to 1,000 hours to develop a CAP. We estimate that the total annual burden associated with this requirement for up to 18 State Exchange respondents would be up to 18,000 hours. Assuming the management analyst average hourly rate of $93.82 per hour, we estimate that the cost of a corrective action plan per State Exchange could be up to $93,820, and for all 18 State Exchanges, up to $1,688,760. The burden related to this information collection will be submitted to OMB for approval after future rulemaking has been completed regarding the CAP process and requirements.

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

We are proposing to eliminate the requirement at § 156.111(d) and (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be in addition to EHB in accordance with § 155.170(a)(3) and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination.

Under this proposal, states would no longer be required to submit an annual report that complies with each requirement listed at § 156.111(f)(1) through (6), nor would HHS identify which benefits are in addition to EHB for the applicable PY in the state if a state does not submit an annual reporting package.

As states are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of QHP coverage of those benefits, the 2021 Payment Notice estimated that a majority of states, approximately 41, would submit annual reports and that 10 states would not submit annual reports.[376]

The 2021 Payment Notice estimated that the burden for each state to meet this reporting requirement in the first year would be 30 hours, with an equivalent cost of approximately $2,459, with a total first year burden for all 41 states of 1,230 hours and an associated total first year cost of approximately $100,829. Because the first year of annual reporting was intended to set the baseline list of state-required benefits which states would update as necessary in future annual reporting cycles, the 2021 Payment Notice explained that the burden associated with each annual reporting thereafter would be lower than the first year. The 2021 Payment Notice therefore estimated that for each annual reporting cycle after the first year the burden for each state to meet the annual reporting requirement would be 13 hours with an equivalent cost of approximately $1,117, with a total annual burden for all 41 states of 533 hours and an associated total annual cost of approximately $45,817. The average annual burden over 3 years was estimated at approximately 765 hours with an equivalent average annual cost of approximately $64,154.

Given that we did not require states to submit annual reports in 2021 pursuant to our enforcement posture in part 2 of the 2022 Payment Notice final rule, if finalized as proposed, repealing the annual reporting requirement would also remove the associated ICRs and the anticipated burden on states submitting such reports. Thus, if finalized as proposed, we will request discontinuation of the ICRs associated with the repealed annual reporting requirement (OMB control number: 0938–1174 Essential Health Benefits Benchmark Plans (CMS–10448)/ Expiration date: February 29, 2024).

I . ICR Regarding Differential Display of Standardized Options on the Websites of Web-Brokers (§ 155.220) and QHP Issuers (§ 156.265)

In the current rulemaking, we consider resuming the differential display of standardized options per the existing authority at § 155.205(b)(1). We also consider resuming enforcement of the standardized options differential display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively.

We estimate that a total of 110 web-brokers and QHP issuers participating in the FFEs and SBE–FPs would be required to comply with these requirements. We estimate that it would take a web developer/digital interface designer (OES occupational code 15–1257) 2 hours annually, at an average hourly cost of $82.20 per hour, to implement these changes, at a total annual cost of $164.40 per entity. We therefore estimate a total annual burden of 220 hours at a cost of $18,804 for all applicable web-brokers and QHP issuers.

Consistent with the approach finalized in the 2018 Payment Notice,[377] we continue to recognize that system constraints may prevent web-broker and QHP issuers from mirroring the *HealthCare.gov* display. We would therefore continue to permit web-brokers and QHP issuers that use a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP to submit a request to deviate from the display on *HealthCare.gov*, with approval from HHS. Any requests from

[376] 85 FR 29164, 29244.

[377] See 81 FR at 94118.

web-brokers and QHP issuers seeking approval for an alternate differentiation format would be reviewed based on whether the same level of differentiation and clarity is being provided under the requested deviation as is provided on *HealthCare.gov*.

We estimate that 55 of the above web-brokers and QHP issuers would submit a request to deviate from the manner in which standardized options are differentially displayed on *HealthCare.gov*. We estimate it would take a compliance officer (OES occupational code 13–1041) approximately 1 hour annually, at a rate of $72.70 per hour, to complete the request to deviate from the display on *HealthCare.gov* as well as the justification for the request. We therefore estimate a total annual burden for all web-brokers and issuers subject to the differential display requirements submitting a request to deviate of approximately $3,998.50 beginning in 2023.

To account for the burden associated with this ICR, HHS will submit a revised version of the existing PRA package for Non-Exchange Entities (under OMB control number: 0938–1329 (CMS–10633)) which was previously discontinued on March 4, 2020. This proposed rule serves as the initial notice for the revised PRA package.

J. ICRs Regarding Network Adequacy and Essential Community Providers (§§ 156.230 and 156.235)

In this rule, HHS is proposing amendments to § 156.230, including adoption of standards related to time and distance and appointment wait time to assess QHP issuers' fulfillment of the reasonable access network adequacy standard. HHS is proposing to raise the ECP threshold from 20 percent to 35 percent. Issuers will continue to submit provider facility information and geographic location of participating ECPs participating in an issuer's provider network or other documentation necessary to demonstrate that an issuer has a sufficient number and geographic distribution of ECPs for the intended service areas. This is done to ensure QHP enrollees have reasonable and timely access to providers that serve predominantly low-income, medically underserved individuals in accordance with ECP inclusion requirements found at § 156.235.

Additionally, issuers must collect and submit provider information necessary to demonstrate satisfaction of time and distance standards and appointment wait time standards to ensure that an issuer's network has fulfilled the network adequacy reasonable access standard found at § 156.230. Lastly, an issuer must report the offering of telehealth services for each provider to help inform future development of telehealth standards. We would provide the definition of telehealth and ask issuers to respond yes or no as to whether each network provider offers telehealth. As described in the preamble, issuers who do not have the information available by the time of the QHP certification process would be able to respond that they have requested the information from the provider and are awaiting the response.

HHS anticipates burden for completing the ECP/NA template will increase based on the changes in this proposed rule to an estimated 20 hours in total for each medical QHP submitted by issuers and 4 hours in total for each SADP submitted by issuers. This estimate is inclusive of the requirement to report provider facility information and geographic location of ECPs in an issuer's provider network. Since we propose to raise the ECP threshold from 20 percent to 35 percent, QHP issuers will need to submit information on a sufficient number of their contracted ECPs to meet the higher threshold.[378] Some issuers have previously only included enough contracted ECPs on the template in order to meet the current threshold for that year's certification process. For those issuers, the proposed increase in the ECP threshold would somewhat increase burden in completing the ECP/NA template as they would need to include more contracted ECPs on the template to meet the standard. Notwithstanding, HHS estimates that the burden associated with showing compliance with the increased ECP threshold will account for 3 hours of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs and 1 hour of the total 4 hours we estimate for SADPs.

The 20-hour burden estimate for the ECP/NA template also includes burden resulting from the requirement that QHP issuers report information relevant to compliance with time and distance standards and appointment wait time standards. For PYs 2018–2022, HHS deferred reviews of network adequacy for QHPs to states that HHS determined to have a sufficient network adequacy review process, which was all FFE states for that time period. As HHS resumes network adequacy reviews, we are proposing to include a broader provider specialty list for time and distance standards than was evaluated for PYs 2015–2017, and to add appointment wait time standards. HHS estimates that the burden associated with the requirement that QHPs report information sufficient to show compliance with the proposed network adequacy standards would account for 12 of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs, and 1 hour of the total 4 hours we estimate for SADPs.

The 20-hour estimate also includes the burden associated with the requirement that issuers report whether network providers provide telehealth services. HHS believes that many QHP issuers already collect and maintain information on whether network providers furnish telehealth services. Approximately half of the parent companies of issuers on the FFEs also offer Medicare Advantage plans. Since Medicare Advantage offers a telehealth credit for network adequacy, we expect those issuers would already have telehealth information available for their providers. HHS further is of the view that those QHP issuers that do not currently collect this information may do so using the same means and methods by which they already collect information from their network providers relevant to time and distance standards and provider directory information. For these reasons, HHS estimates that any additional burden relative to the requirement that QHP issuers report whether each network provider is furnishing telehealth services would lead to a minimal increase in burden for many issuers. The requirement to report whether providers offer telehealth services would account for four of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs and 1 of the total 4 hours we estimate for SADPs. Finally, we estimate it will take 1 hour for issuers, including both medical QHPs and SADPs, to submit the ECP/NA template and complete the portions of the Issuer Module that are relevant to these reviews.

We estimate that the total annual burden associated with completing the additional requirements proposed in this rule within the ECP/NA template for medical QHPs for up to 215 issuers would be up to 4,300 hours. Assuming the compliance officer average hourly rate of $36.35 per hour, we estimate that the cost of completing the ECP/NA template for an individual medical QHP could be up to $1,454, and for all 215 issuers, up to $312,610. We estimate that the total annual burden associated

[378] The ECP/NA template requires QHP issuers to report only that number of providers sufficient to demonstrate compliance with relevant requirements.

with this requirement for SADPs for up to 270 issuers would be up to 1,080 hours. Assuming the compliance officer average hourly rate of $36.35 per hour, we estimate that the cost of completing the ECP/NA template for an individual SADP could be up to $290.80, and for all 270 issuers, up to $78,516. The total estimated cost for the annual burden associated with completing the ECP/NA template across both medical QHP and SADP issuers is $391,126.

HHS is submitting a new information collection package to OMB to cover data collection related to essential community provider and network adequacy requirements, which will include the changes proposed in this proposed rule. This proposed rule serves as the initial notice for the PRA package. The existing information collection package for QHP certification (under OMB control number: 0938–1187 (CMS–10433)/Expiration date: June 30, 2022) includes the data collection and burden information for the ECP/NA template, outside of what is proposed in this rule.

K. ICRs Regarding Payment for Cost-Sharing Reductions (§ 156.430)

In this rule, HHS is proposing several amendments to § 156.430 to clarify that CSR data submission is mandatory for those issuers that received CSR payments from HHS for any part of the benefit year, and voluntary for other issuers. The currently approved burden estimate is a total cost of $235,683 (2,362.50 hours) across 150 issuers ($1,571.22 per issuer), which accounts for 0.75 hours per issuer to complete and submit the Issuer Summary Report to HHS each year and 15 hours per issuer to complete and submit the Standard Methodology Plan and Policy Report to HHS each year.[379] We expect that these proposals will reduce the burden associated with the CSR data submission process when HHS is not making CSR payments to QHP issuers, as we expect that the number of issuers submitting CSR data each year will decrease due to these proposals. We have revised the information collection currently approved under OMB control number: 0938–1266 (Cost-Sharing Reduction Reconciliation (CMS–10526)/Expiration date: July 31, 2024) to account for this decreased burden when HHS is not making CSR payments to QHP issuers.

L. ICRs Regarding Quality Improvement Strategy (§ 156.1130)

We are not proposing to amend regulatory text in 45 CFR 156.1130 which outlines QIS standards established in the 2016 Payment Notice. The information collections associated with QIS data collection and submission requirements are approved under OMB control number 0938–1286 (Quality Improvement Strategy Implementation Plan and Progress Report (CMS–10540)/Expiration date: February 25, 2024) and encompasses the estimated burden and costs associated with a QIS submission that may include several QIS topic areas. In this proposed rule, we propose that beginning in 2023, a QHP issuer would be required to address reducing health and health care disparities as one of their QIS topic areas in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA, including: Improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, and promoting wellness and health. We do not estimate additional burden to be accounted for since the QIS submission form currently approved under OMB control number: 0938–1286 (Quality Improvement Strategy Implementation Plan and Progress Report (CMS–10540)/Expiration date: February 25, 2024) already encompasses the estimated burden and costs associated with a QIS submission that may include several QIS topic areas.

M. ICRs Regarding Medical Loss Ratio (§§ 158.140, 158.150, 158.170)

We propose to amend § 158.140 to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We also propose to amend § 158.150 to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes. We further propose to make a technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), which was deleted in part 2 of the 2022 Payment Notice final rule. We anticipate that implementing these provisions would require minor changes to the MLR Annual Reporting Form Instructions, but would not significantly increase the associated reporting burden. The burden related to this information collection is currently approved under OMB control number: 0938–1164 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS–10418)). The control number is currently set to expire on July 31, 2024.

O. Summary of Annual Burden Estimates for Proposed Requirements

[379] OMB control number 0938–1266 (Cost-Sharing Reduction Reconciliation (CMS–10526)/Expiration date: July 31, 2024).

TABLE 22: Proposed Annual Recordkeeping and Reporting Requirements (New Burden)

Regulation Section(s)	OMB control number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)
§§ 153.610 and 153.710	0938-1155	600	600	4	2,400	$225,168	$225,168
§ 155.220	0938-1349	20	40	5	200	$16,440	$16,440
§ 155.1510	0938-NEW	18	18	719	12,942	$1,339,523	$1,339,523
§ 155.1535	0938-NEW	18	18	1,000	18,000	$1,688,760	$1,688,760
§§ 156.230 and 156.235	0938-NEW	485	485	20	5,380	$391,126	$391,126
§§ 155.220 and 156.265	0938-1329	55	55	1	55	$3,998.50	$3,998.50
§§ 155.220 and 156.265	0938-1329	110	110	2	220	$18,804	$18,804
Total				1,751	39,197	$3,683,819.50	$3,683,819.50

TABLE 23: Proposed Annual Recordkeeping and Reporting Requirements (Reduction)

Regulation Section(s)	OMB control number	Original Number of Respondents	Number of Respondents (if reduced)	Burden per Response (hours)	Reduced Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)
§ 153.320	0938-1155	25	1	60	-1,440	-$130,339.20	-$130,339.20
§ 155.1510*	0938-1207	n>10		.2	-38,800	-$1,790,232	-$1,790,232
§ 155.1200	0938-1244	18	0	6	-108	-$11,243.16	-$11,243.16
§156.111	0938-1174	41	0	13	-533	-$45,817	-$45,817
Total				79.2	-40,881	-$1,977,631.36	-$1,977,631.36

*This proposal estimates a decrease in annual burden for consumers attesting to special enrollment period types that no longer require document verification, because the number of consumers enrolling through a loss of minimum essential coverage is represented as n>10 since the number is undefined.

This proposed rule includes several proposals, including information collection requests for which we seek to use this rulemaking as the **Federal Register** notice through which to receive comment on their proposed revisions to or submissions of PRA packages. These proposals include Verification of Eligibility for Special Enrollment Periods (§ 155.420), Data Collection and Corrective Action Plans related to the SEIPM Program(§ 155.1510, 155.1535), and the proposals on Network Adequacy and Essential Community Providers (§§ 156.230 and 156.235) and the proposal regarding Differential Display of Standardized Options (§§ 155.220) and 156.265).

The following proposals with associated information collection requests, including the proposal regarding State Flexibility for Risk Adjustment (§ 153.320), the proposal regarding risk adjustment Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610 and 153.710), the proposal on General Program Integrity and Oversight Requirements (§ 155.1200), will be submitted for PRA approval outside of this rulemaking, through a separate **Federal Register** notice.

The proposals for Quality Improvement Strategy (§ 156.1130), Medical Loss Ratio (§§ 158.140, 158.150, 158.170), and Payment for Cost-Sharing Reductions (§ 156.430) contain information collections which are covered by existing PRA packages. One proposal, the State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111), proposes to discontinue the associated information collections and remove them from the PRA package, and the information collection in the Determination of Error Findings Decision and Appeal Redetermination (§§ 155.1525 and 155.1530) proposal is exempt from the PRA.

P. Submission of PRA-Related Comments

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

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

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

ADDRESSES section of this proposed rule and identify the rule (CMS–9911–P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due March 7, 2022.

V. Response to Comments

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

VI. Regulatory Impact Analysis

A. Statement of Need

This rule proposes standards related to the risk adjustment program for the 2023 benefit year and beyond, as well as standards for the HHS–RADV program beginning with the 2021 benefit year. This rule proposes additional standards related to eligibility redetermination, special enrollment periods, requirements for agents, brokers, web-brokers, and issuers assisting consumers with enrollment through Exchanges that use the Federal platform; state selection of EHB-benchmark plan and annual reporting of state-required benefits, termination of coverage, the MLR program, and 2023 FFE and SBE–FP user fees. This rule also proposes to remove the annual reporting requirement on states to report state-required benefits to HHS. In addition, it proposes to reinstate nondiscrimination provisions related to sexual orientation and gender identity. The rule also proposes to refine the EHB nondiscrimination framework by including examples of presumptively discriminatory cases. The rule also proposes to require issuers in FFEs and SBE–FPs to offer standardized options. This rule proposes to expand QIS standards and require QHP issuers to address health and health care disparities in their QIS submissions in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA. Finally, this proposed rule would implement the PIIA requirements for State Exchanges.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4) and 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any one year).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. An RIA must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of $100 million or more in at least 1 year. Based on HHS estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The provisions in this proposed rule aim to ensure that consumers continue to have access to affordable coverage and quality health care. Although there is still some uncertainty regarding the net effect on premiums, we anticipate that the provisions of this proposed rule would help further HHS' goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 24 depicts an accounting statement summarizing HHS' assessment of the benefits, costs, and transfers associated with this regulatory action.

This proposed rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this proposed rule. The effects in Table 24 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 24 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers and the potential increase in rebates from issuers to consumers due to proposed amendments to MLR requirements.

We are proposing the risk adjustment user fee of $0.22 PMPM for the 2023 benefit year to operate the risk adjustment program on behalf of states, which we estimate to cost approximately $60 million in benefit year 2023.[380] We expect risk adjustment user fee transfers from issuers to the federal government to remain steady at $60 million, the same as estimated for the 2022 benefit year; this is included in Table 24.

Additionally, for 2023, we are proposing maintaining the FFE and the SBE–FP user fee rates at current levels, 2.75 and 2.25 percent of premiums, respectively.

For our proposed implementation of the State Exchange Improper Payment Measurement program, we estimate record keeping costs for data collection and corrective action plan development and implementation to be approximately $3.0 million annually beginning in PY 2023.

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[380] As noted previously in this proposed rule, no state has elected to operate the risk adjustment program for the 2023 benefit year; therefore, HHS will operate the program for all 50 states and the District of Columbia.

TABLE 24: Accounting Table

Benefits:

Qualitative:

Increased access to health insurance coverage for individuals who are currently unable to enroll in coverage because of past-due premiums.

Greater market stability resulting from updates to the risk adjustment models.

Increased access to health insurance coverage due to the proposal to decrease the scope of special enrollment period verification.

Greater protection of individuals in the LGBTQI+ community from discrimination on the basis of their sexual orientation and gender identity.

Greater consistency in protections based on EHB nondiscrimination.

Potential direct benefit of reducing improper payments, with secondary effects including a boost of insurer confidence in State Exchanges through implementation of the proposed State Exchange Improper Payment Measurement program.

- Increased access to more comprehensive provider networks and enhanced health equity[381] due to the network adequacy and ECP proposals which would better ensure that individuals have reasonable, timely access to an adequate number, type, and distribution of providers and facilities to manage their health care needs.
- Enhanced access to behavioral health providers who provide key services for vulnerable populations via the network adequacy and ECP proposals

Greater access to primary care and OB/GYN providers in recognition of the importance of preventive care for underserved populations through the network adequacy and ECP proposals

Encourage continuous quality improvement among QHP issuers to help strengthen health care system-wide efforts to improve health outcomes, lower costs, and advance health equity.

Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	-$97.7 Million	2021	7 percent	2022-2026
	-$98.9 Million	2021	3 percent	2022-2026

Quantitative:

Recordkeeping costs incurred by State Exchanges as detailed in the Collection of Information Requirements section, related to SEIPM data collection and corrective action plan development and implementation estimated to be approximately $3.0 million annually beginning in 2023.

Reduction in costs for states related to annual reporting of state-required benefits, estimated to be one-time savings of $100,829 in 2022 and annual savings of $45,817 each year thereafter.

Reduction in potential costs to Exchanges since they would not be required to conduct random sampling as a verification process for enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data, estimated to be one-time savings of $49.5 million in 2022 and annual savings of $113 million in 2023 and onwards.

Increased costs to Exchanges to design a risk-based verification process for enrollment in or eligibility for employer sponsored coverage based on a risk assessment for inappropriate subsidy payments estimated to be about $4.7 million in one-time costs in 2022.

Annual cost savings of $5.2 million related to the proposal to decrease the scope of special enrollment period verification beginning in 2023.

- Reduction of $130,339.20 in reporting costs across states participating in risk adjustment associated with repealing the ability of states to request a reduction in risk adjustment state transfers in any state market risk pool starting with the 2024 benefit year.

Cumulative additional cost estimate for the collection of five new data elements for risk adjustment estimated to be approximately $225,168 for 600 issuers, or $375.28 per issuer annually, beginning in 2023.

Increased cost to 10 State Exchanges to implement system builds to prorate APTC and premium amounts, as proposed. Estimated $10,000,000in one-time costs for State Exchanges in the 2024 benefit year.

Increased cost to web-brokers to implement minor text-based changes to their websites to add or modify a disclaimer. Estimated $8,220 in one-time costs for 20 web-brokers in the 2022 benefit year.

- Increased cost to web-brokers to implement minor text-based changes to their websites to add text-based explanations for how they display QHPs. Estimated $8,220 in one-time costs for 20 web-brokers in the 2022 benefit year.

- Increased annual cost of $18,804 across all web- brokers and QHP issuers utilizing the Classic DE and EDE Pathways to comply with the standardized options differential display requirements in the 2023 benefit year.
- Increased annual cost of $3,998.50 across the subset of web-brokers and issuers subject to the differential display requirements submitting a request to deviate from the requirements beginning in the 2023 benefit year.
  - Increased cost to issuers for completing the updated ECP/NA template that includes a longer provider specialty list for network adequacy, appointment wait time standards, and a question on providers offering telehealth. The total estimated annual burden for medical QHP and SADP issuers to complete the updated ECP/NA template is $391,126 beginning in PY 2023.
  - Estimated Reduction in cost of $1,631,243.16 beginning in the 2024 benefit year to State Exchanges associated with new standards for completing external audits under 155.1200. This total reflects a reduction of roughly $11,000 for audit data collection and reporting, and a reduction of roughly $1.6 million for annual audit firm contracts across all State Exchanges.

Qualitative:
Potential reduction in costs and increased access to coverage to enrollees who are currently unable to enroll in coverage because of past-due premiums related to searching for a new plan from another issuer when seeking to enroll in health care coverage.
Potential increased costs of coverage of medical services for health insurance issuers (if health insurance enrollment increases).
Potential administrative burden on State Exchanges due to SEIPM program.
Potential administrative burden on states and regulated entities that would need to take action to come into compliance with the updated nondiscrimination policies (for example, regulated entities under § 156.125).
Potential administrative burden on states if they choose to align their network adequacy standards with the new federal standards (instead of having HHS complete the reviews).

Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$1.125 Billion	2021	7 percent	2022-2026
	$1.150 Billion	2021	3 percent	2022-2026

Quantitative:
- Federal Transfers to Consumers: Increase in PTC payments estimated to be approximately $1.32 billion in 2023, $1.41 billion in 2024, $1.43 billion in 2025, and $1.44 billion in 2026.

Other Transfers: Increase in rebate payments from issuers to consumers due to the clarification regarding the reporting of provider incentives and bonuses and the removal of indirect expenses from QIA in MLR and rebate calculations, estimated to be $61.8 million annually, beginning in 2023.

Qualitative:
Potential transfers from issuers who would have been able to recoup unpaid premiums from enrollees to those enrollees who would now be able to enroll in coverage from the same issuer or another issuer in the same controlled group without having to pay past-due premiums.
- Potential transfer from consumers to issuers: An estimated two percent premium increase for individuals not eligible for PTC due to the proposal to require individual market silver QHPs to provide an AV between 70-72 percent and associated income-based CSR plan variations to follow a de minimis range of +1/0 (impact on approximately 248,000 enrollees in HealthCare.gov silver plans below 70 percent AV, with approximately 4.2 million enrollees in corresponding CSR plan variations).

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This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the ACA's impact on federal spending, revenue collection, and insurance enrollment. Table 25 summarizes the effects of the risk adjustment program on the federal budget from fiscal years 2023 through 2027, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the

[381] Healthy People 2030 defines health equity as ''the attainment of the highest level of health for all people.'' *https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/questions-answers.*

provisions of this proposed rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 25.

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that, quantitatively, the effects of the provisions proposed in this rule are consistent with our previous estimates in the 2022 Payment Notice for the impacts associated with the APTCs, the premium stabilization programs, and FFE (including SBE–FP) user fee requirements.

TABLE 25: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2023-2027, in billions of dollars[382]

Year	2023	2024	2025	2026	2027	2023-2027
Risk Adjustment and Reinsurance Program Payments	6	6	6	7	7	32
Risk Adjustment and Reinsurance Program Collections	6	6	7	7	7	33

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: 2020 to 2030 Table A-2. September 29, 2020. Available at https://www.cbo.gov/system/files/2020-09/56571-federal-health-subsidies.pdf.https://www.cbo.gov/system/files/2020-09/56571-federal-health-subsidies.pdf.

1. Guaranteed Availability of Coverage (§ 147.104(i))

This proposed rule proposes amendments to § 147.104(i), which would reverse the policy allowing an issuer to attribute a premium payment made for new coverage to any past-due premiums owed for coverage from the same issuer or another issuer in the same controlled group within the prior 12-month period preceding the effective date of coverage before effectuating enrollment in new coverage. Under current rules, individuals may have to pay up to 3 months of past-due premiums plus a binder payment before enrolling in coverage.[383] CMS lacks information on the frequency with which consumers miss payments or the frequency with which binder payments are currently being made, and seeks data or information related to past-due premiums. CMS is also interested in learning more about the population and characteristics of individuals with past-due premiums.

Individuals often stop making premium payments or forgo health insurance because they are unable to afford the premium payments. In a 2019 survey, 42 percent of insured adults reported being worried about paying for their monthly health insurance premium, with 18 percent being ''very worried'' and 24 percent being ''somewhat worried''.[384] In addition, 28 percent of insured adults reported having a difficult time covering the cost of health insurance each month. In 2019, 73.7 percent of uninsured adults pointed to high cost of coverage as the reason for being uninsured.[385]

Based on internal analysis, we estimate that approximately 7.8 percent of enrollees in Exchanges using the Federal platform had their coverage terminated in 2020 for non-payment of premiums. That figure was 10.7 percent in 2019, 12.4 percent in 2018, and 17.3 percent in 2017.[386] Among those enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) had plans available the next year, we estimate that 16.9 percent enrolled with the same issuer (or a different issuer in the same controlled group) the following year. That figure was 16.5 percent in 2018 and 16.8 percent in 2017.[387] For those enrollees with household incomes below the federal poverty level, 15.3 percent of enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) was available the next year enrolled with the same issuer (or a different issuer in the same controlled group) the following year.[388] That figure was 13.5 percent in 2018 and 13.2 percent in 2017. Our analysis also suggests that those enrollees with lower household incomes (specifically, household incomes below the federal poverty level) were less likely to enroll in coverage from the same issuer or another issuer in the same controlled group the following year. In 2017, 2018, and 2019, those enrollees who were less than 35 years old were also less likely to enroll in coverage from the same issuer or another issuer in the same controlled group the following year than those aged 35 to 54.

Due to data limitations, we are unable to directly attribute any changes in enrollment behavior in the Exchanges using the Federal platform to the interpretation of the guaranteed availability requirement stated in the Market Stabilization final rule. However, this proposed rule would

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

[383] Section 156.270(d) requires issuers to observe a 3-consecutive month grace period before terminating coverage for those enrollees who upon failing to timely pay their premiums are receiving APTC. Section 155.430(d)(4) requires that when coverage is terminated following this grace period, the last day of enrollment in a QHP through the Exchange is the last day of the first month of the grace period. Therefore, individuals whose coverage is terminated at the conclusion of a grace period would owe at most 1 month of premiums, net of any APTC paid on their behalf to the issuer. Individuals who attempt to enroll in new coverage while in a grace period (and whose coverage has not yet been terminated) could owe up to 3 months of premiums, net of any APTC paid on their behalf to the issuer.

[384] Kirzinger, Ashley et al., Data Note: Americans' Challenges with Health Care Costs, KFF, June 11, 2019. *https://www.kff.org/health-costs/issue-brief/data-note-americans-challenges-health-care-costs/.*

[385] Tolbert, J. and Orgera, K., Key Facts about the Uninsured Population, KFF, November 6, 2020. *https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.*

[386] The annual figures presented in this section should not necessarily be interpreted as trends, as some states moved from Exchanges using the Federal platform to State Exchanges and the overall composition of the dataset may have changed.

[387] As we reported in the April 18, 2017 **Federal Register** (82 FR 18346), that figure was approximately 16 percent in 2016.

[388] Of the 936,637 enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) was available the next year, 24,784 (or 2.6 percent) had incomes below the federal poverty level. Many, but not all, of these enrollees lived in states that did not expand Medicaid eligibility following the implementation of the ACA.

increase access to health insurance coverage for individuals who stop paying premiums due to reasons such as financial hardship or affordability and who are currently unable to enroll in coverage because they cannot afford to pay past-due premiums. This increased access could lead to better health outcomes, if these individuals are able to maintain coverage.[389] This proposed rule would also increase the ability for enrollees to access coverage with the same issuer in the next year. This would be of particular benefit to those Exchange enrollees living in counties with only one or two participating issuers.[390] It could also reduce the costs and burden to enrollees related to searching for a new plan from another issuer when seeking to enroll in health care coverage. Being able to enroll with the same issuer would also allow individuals to have access to the same network of services and providers, which could improve continuity of care.

This policy could result in transfers from issuers who would have been able to recoup unpaid premiums from enrollees to those enrollees who would now be able to enroll in coverage from the same issuer or another issuer in the same controlled group without having to pay past-due premiums. However, we anticipate that these transfers would be minimal, as issuers are not permitted to waive past-due premiums and would be expected to pursue other means of collecting them.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

2. Nondiscrimination Based on Sexual Orientation and Gender Identity (§§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b)), and EHB Nondiscrimination Policy for Health Plan Designs (§ 156.125)

Many of the entities regulated by §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) may have previously incorporated the proposed nondiscrimination protections related to sexual orientation and gender identity into their operations in response to the inclusion of these protections in these regulations prior to the effective date of the June 19, 2020 rulemaking on section 1557 that eliminated the references to these protections from these regulations. These regulated entities may have incurred any administrative costs at that time. We do not anticipate coming into compliance with these proposed changes would substantially impose administrative costs on any regulated entities that did not subsequently revise nondiscrimination policies based on the 2020 section 1557 final rule. Although costs may be incurred by any regulated entities that did subsequently revise nondiscrimination policies in response to the removal of such protections from the affected regulations based on the 2020 section 1557 final rule, we believe such costs are justified in light of the potential significant benefits the proposed changes could provide to individuals in the LGBTQI+ community, by ensuring they are not subject to discrimination on the basis of their sexual orientation or gender identity.

The EHB nondiscrimination policy proposals in this rulemaking will most likely impact the vast majority of state EHB-benchmark plans. If the nondiscrimination policy proposals become final, issuers subject to § 156.125 and states subject to the standards under § 156.125 through the cross-reference at § 156.111(b)(2)(v) will most likely need to take action to come into compliance with the updated nondiscrimination policies, and states may choose to provide guidance to assist issuers in doing so. The actions necessary to come into compliance with the updated nondiscrimination policies will likely impact and minimally increase premiums (for example, Colorado 2023 EHB-benchmark plan[391] noted a minimal increase to premiums with the updated benefits). States have the flexibility to design their EHB-benchmark plans consistent with § 156.111, which provides more options in plan designs. We note that several states have already used this flexibility to update their EHB-benchmark plans. CMS provides states with greater flexibility to select their EHB-benchmark plans by providing three new options for selection in PY 2020 and beyond, including: (1) Selecting the EHB-benchmark plan that another state used for PY 2017, (2) replacing one or more categories of EHBs under its EHB-benchmark plan used for PY 2017 with the same category or categories of EHB from the EHB-benchmark plan that another state used for PY 2017, or (3) otherwise selecting a set of benefits that would become the state's EHB-benchmark plan. Under each of these three options, the new EHB-benchmark also must comply with additional requirements, including scope of benefits requirements, under § 156.111(b).[392]

We seek comment on the potential costs, benefits, and transfers associated with this provision.

3. Risk Adjustment (§§ 153.320, 153.610, 153.620, 153.700, 153.710, and 153.730)

Beginning with the 2023 benefit year, we propose the following model specification changes to the HHS risk adjustment models: (1) To add a two-stage weighted model specification to the adult and child risk adjustment models, (2) to remove the existing severity illness factors in the adult models and add interacted HCC counts factors to the adult and child risk adjustment models, and (3) to revise the enrollment duration factors for the adult models. By prioritizing simplicity and limiting the number of changes to the current model structure, we minimize administrative burden for HHS, and as HHS runs risk adjustment in all 50 states and the District of Columbia, we do not expect these policies to place additional burden on state governments. These proposed model specifications would 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 risk adjustment program.[393] To

[389] We request comment on whether there would be any impact on premiums, affordability, and access for the individuals who reliably pay. We are interested in comments regarding whether issuers who implemented policies requiring payment of past due premiums prior to reenrollment experienced declines in administrative costs related to the collection of past-due premiums.

[390] According to recent figures from KFF, in 2021, there were only two issuers participating in the ACA Exchanges in 44 percent of counties, and there was only one issuer participating in the ACA Exchanges in 10 percent of counties. Source: McDermott, Daniel and Cynthia Cox (2020). ''Insurer Participation on the ACA Marketplaces, 2014–2021.'' KFF, November 23. *https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021/*; This was noted by Sandy Ahn and JoAnn Volk in their analysis of the previous interpretation of the guaranteed availability requirement. Reference: Ahn, Sandy and JoAnn Volk (2017). ''Relaxing the Affordable Care Act's Guaranteed Issue Protection: Issues for Consumers and State Options.'' CHIRblog, June 2. *http://chirblog.org/relaxing-the-affordable-care-acts-guaranteed-issue-protection-issues-for-consumers-and-state-options/.*

[391] *See for example,* Colorado 2023 EHB Benchmark Plan Actuarial Report: Suite of Gender-affirming care benefits to treat gender dysphoria resulted cost estimate was 0.04% of the total allowed claims assuming utilization would be for adults. *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.*

[392] Section 156.111(b). *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-156.*

[393] See current burden estimates in the Supporting Statement of OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401)),

Continued

further assist issuers in understanding the potential impact of these changes on risk adjustment transfers, we released the 2021 RA Technical Paper and conducted an EDGE transfer simulation that estimated the impact on risk scores and transfers with and without these proposed changes using 2020 benefit year risk adjustment data.[394] Based on results from this simulation, we estimate the impact of these policies on risk adjustment transfers to be relatively minor.[395]

Additionally, we propose to recalibrate the HHS risk adjustment models for the 2023 benefit year using the 2017, 2018, and 2019 enrollee-level EDGE data. We believe that the approach of blending (or averaging) 3 years of separately solved coefficients will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2022 benefit year to the 2023 benefit year. We also propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models. For the 2023 benefit year, we propose to recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for the 2018 and 2019 benefit year, with the exception of the 2017 enrollee-level EDGE data year, for which we propose to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018) for consistency with prior model year recalibrations, as we did not include RXCs in the adult risk adjustment models until 2018.[396] For the 2024 benefit year and beyond, we propose to recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration. We also propose to continue to apply a pricing adjustment for Hepatitis C drugs for all three model types (adult, child, and infant), as well as outline our consideration for targeted removal of the mapping of hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions for the 2018 and 2019 benefit years' enrollee-level EDGE data used for model recalibration,[397] as well as our consideration for the targeted removal of the mapping of Descovy® to RXC 01 ((Anti-HIV Agents) from all three benefit year datasets used for model recalibration. For the 2023 benefit year, we are proposing to maintain the CSR adjustment factors finalized in the 2019–2022 Payment Notices. Overall, we do not estimate that these changes will impact issuer burden beyond the current burden for the HHS-operated risk adjustment program.

For the 2023 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS' operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. For the 2023 benefit year, we propose to use the same methodology that we finalized in the 2022 Payment Notice to estimate our administrative expenses to operate the program. Risk adjustment user fee costs for the 2023 benefit year are expected to remain steady from the prior 2022 benefit year estimates. However, we project a small increase in billable member months in the individual and small group markets overall in the 2023 benefit year based on the enrollment increases observed in the 2020 benefit year. We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states for 2023 will be approximately $60 million, and therefore, the proposed risk adjustment user fee would be $0.22 PMPM. Because overall risk adjustment costs estimated for the 2023 benefit year are similar to 2022 costs, we do not expect the proposed risk adjustment user fee for the 2023 benefit year to materially impact the transfer amounts collected or paid by issuers of risk adjustment covered plans.

We also propose to generally repeal the ability for states to request a reduction in risk adjustment state transfers of up to 50 percent in all state market risk pools beginning with the 2024 benefit year, with an exception for prior participants. We propose to provide an exception for states that have previously submitted risk adjustment state flexibility requests, so only such states may continue to request this flexibility beginning with the 2024 benefit year. We also propose to remove as a criterion for state justification and HHS approval of these requests the demonstration of state-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool. As proposed, we would retain as the sole requirement for state justification and criterion for HHS approval the demonstration that the requested reduction would have a de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments beginning with the 2024 benefit year.

We anticipate that the proposed changes to risk adjustment state flexibility requests would have a minimal impact on states and other interested parties. Only one state, Alabama, has requested a reduction in risk adjustment state transfers since this flexibility was first made available beginning in the 2020 benefit year, and under this proposal, Alabama would be considered a prior participant and could continue to request such reductions. We do not anticipate any new burden or costs as a result of this policy.

We also propose to collect and extract five new data elements from issuers' EDGE servers through issuers' Edge Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files: ZIP code, race, ethnicity, subsidy indicator, and ICHRA indicator beginning with the 2023 benefit year. In addition, we propose to begin extracting three data elements issuers already report to their EDGE servers—plan ID, rating area and subscriber indicator—as part of the enrollee-level EDGE data beginning with the 2022 benefit year. The proposal to extract plan ID, rating area, and subscriber indicator will pose minimal burden on issuers (only the burden associated with running of a command) since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. For the collection of the five new data elements we propose to collect and extract beginning with the 2023 benefit year, the cumulative additional cost estimate is $225,168 for 600 issuers. We estimate that the addition of these five new data elements to the risk adjustment data

which is currently being updated. The previous version of the Supporting Statement is available at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201712-0938-015.*

[394] See the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.* Issuers that participated in the simulation also received detailed issuer-specific data, including risk score and transfer estimates for the simulated results.

[395] We estimate that the impact of the model specification changes between the proposed and final 2022 benefit year risk adjustment models in total absolute value change in transfer over premium is –0.3 in the individual marker and –0.2 in the small group market.

[396] See 81 FR at 94075.

[397] The same concerns were not present for the 2017 enrollee-level EDGE data because hydroxychloroquine sulfate was not included in the RXC crosswalk until 2018.

submission requirements would be $375.28 per issuer. The proposal to extract these data elements will pose minimal burden on issuers (only the burden associated with running of a command) since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. We expect minimal costs to HHS as a result of these proposals.

We also propose to amend § 153.730 to clarify that in situations where the April 30 deadline for issuers to submit risk adjustment data to HHS in states where HHS is operating the risk adjustment program falls on a non-business day, the deadline for issuers to submit the required data would be the next applicable business day. We believe this proposal would not pose additional burden since it does not change any of the data submission requirements and only clarifies the deadline when April 30 falls on a non-business day.

We seek comment on estimated costs and transfers and potential benefits associated with these provisions.

4. Risk Adjustment Data Validation (§§ 153.350 and 153.630)

In this proposed rule, we propose updates to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year to (1) extend the application of Super HCCs from their current application only in the sorting step that assigns HCCs to failure rate groups to broader application throughout the HHS–RADV error rate calculation processes, (2) specify that Super HCCs will be defined separately according to the age group model to which an enrollee is subject, and (3) constrain to zero any negative failure rate outlier in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate. Although we anticipate the proposed changes will have a small impact on issuers' HHS–RADV risk adjustment transfer adjustments, risk adjustment is a budget neutral program and we expect these proposals to refine the HHS–RADV error rate calculation methodology will not have an impact on the administrative burden to issuers subject to the current HHS–RADV process because HHS is responsible for calculating error rates and applying error rates to adjust risk scores and state market risk pool transfers. Furthermore, we expect these changes will have minimal impacts on administrative costs to the federal government as the described changes do not impact the underlying HHS–RADV data, the amount of data HHS collects, or the SVA, which is conducted by an entity HHS retains.

We seek comment on these burden estimates.

5. Agents, Brokers, and Web-Brokers (§ 155.220)

a. Required QHP Comparative Information on Web-Broker Websites and Related Disclaimer

We propose to amend § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(1) through (c)(3)(i)(A)(5) a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We also propose to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website.

In the preamble of part 2 of the 2022 Payment Notice final rule, we announced our intention to enforce the requirement that web-brokers display the QHP comparative information described under § 155.205(b)(1) beginning with the PY 2022 open enrollment period.[398] Specifically, we propose to create proposed new §§ 155.220(c)(3)(i)(A)(1) through (5) to list premium and cost-sharing information, the summary of benefits and coverage established under section 2715 of the PHS Act, identification of the metal level of the QHP as defined by section 1302(d) of the ACA or whether it is a catastrophic plan as defined by section 1302(e) of the ACA, the results of the enrollee satisfaction survey as described in section 1311(c)(4) of the ACA, quality ratings assigned in accordance with section 1311(c)(3) of the ACA, and the provider directory made available to the Exchange in accordance with § 156.230 as the minimum QHP comparative information web-broker non-Exchange websites must display for all available QHPs. Including this information within § 155.220, instead of through a cross-reference to § 155.205(b)(1), would provide better clarity and ease of reference and establish a list of required QHP comparative information consistent with our current enforcement approach, which, as discussed above, does not require the display of MLR information and transparency of coverage measures.

We propose to revise § 155.220(c)(3)(i)(A) to state that web-broker websites must disclose and display the following QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c), and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a web link to the Exchange website.

These proposals should result in very limited new burden for web-brokers. As we explained in Section III of the preamble, given CMS's current enforcement policies relative to these requirements, the QHP comparative information we propose to require web-broker websites to display is consistent with current requirements. As a result, this proposed requirement would not present new burden to web-brokers.

The proposed new disclaimer would require web-brokers to make minor updates to their websites in cases when they do not support enrollment in all available QHPs. However, in those cases, they would be displaying a standardized disclaimer much like the plan detail disclaimer that they have historically been required to display.

We estimate this proposal will affect approximately 20 web-brokers. Given the minor modifications necessary to implement the revised disclaimer in this proposal, we estimate a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this proposal is $8,220 for 20 web-brokers in the 2022 benefit year.

We seek comment on the estimated burden associated with these proposals.

b. Prohibition of QHP Advertising on Web-Broker Websites

Section 155.220(c)(3)(i)(L) prohibits web-broker non-Exchange websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers. We propose to amend § 155.220(c)(3)(i)(L) to make clear that web-broker non-Exchange websites are also prohibited from displaying QHP advertisements, or otherwise providing

[398] See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Final Rule, 86 FR 24140 at 24206 (May 5, 2021).

favored or preferred placement in the display of QHPs, based on compensation agents, brokers, or web-brokers receive from QHP issuers.

This proposal should impose no new costs on web-brokers so long as they are not displaying QHP advertisements on their websites. We believe that very few web-brokers are currently doing so. However, for those few web-brokers that are displaying QHP advertisements on their websites, they would be required to update their websites to remove those advertisements and would lose any advertising revenue associated with such placements. Since advertisements on websites are inherently subject to change, even for those web-brokers that would be required to make updates to their websites if this proposal is finalized, the costs may be very limited, although we request comment on this assumption and acknowledge that there may be loss of advertising revenue. We also realize, to the extent advertising revenue is lost, web-brokers may seek to recoup the lost revenue from other sources resulting in a transfer of costs. For example, web-brokers may seek to increase fees received from agents and brokers using their websites or may pursue increased commissions from QHP issuers.

We seek comment on the potential costs, benefits, and transfers associated with this proposal.

c. Explanation of Rationale for QHP Recommendations on Web-Broker Websites

We propose to amend § 155.220 to add a proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on plan name, from lowest to highest premium, etc.). We believe this proposed new requirement would provide consumers with a better understanding of the information being presented to them on web-broker websites, thereby enabling them to make better informed decisions and shop for and select QHPs that best fit their needs.

We support web-broker websites' use of innovative decision-support tools for consumers to help them shop for and select QHPs that best fit their needs. However, web-broker websites that explicitly recommend or rank QHPs do not always provide an explanation for their recommendations or rankings. Similarly, web-broker websites may not include an explanation of the methodology used for their default displays of QHPs, and it may not otherwise be apparent what methodologies are used. The absence of such explanations may cause some consumers to misunderstand the bases for the recommendations displayed to them on web-broker websites (whether explicit or implicit), or may prevent them from assessing the value of the recommendations (for example, whether a recommendation is based on the factors most important to them). In addition, the lack of explanations for QHP recommendations on web-broker websites may obscure that the web-broker is recommending QHPs based on compensation the web-broker receives from QHP issuers in violation of § 155.220(c)(3)(i)(L). For these reasons, we propose to amend § 155.220 to add proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for QHP recommendations and the methodology for its default display of QHPs.

This proposal should result in very limited new costs for web-brokers, since the information it would require they display on their websites would only require text-based changes that are relatively easy to implement. Furthermore, the extent of those textual updates should be relatively minor in most cases. For example, if a web-broker is recommending a QHP based on the fact that it has the lowest monthly premiums for a consumer, that can likely be communicated in one or two sentences of informational text, or possibly even in a single phrase or set of short bullet points. Some web-brokers are already providing the information that would be required by this proposal, and therefore would not have to make any website updates. Other web-broker websites do not explicitly recommend QHPs, and therefore the impact of this proposal would be limited to providing similar information about the methodology for their default display of QHPs (for example, explaining QHPs are sorted from lowest to highest premium, etc.), assuming they do not already provide that information.

We estimate this proposal will affect approximately 20 web-brokers. Given the minor text-based changes necessary to implement the informational text detailing the rationale for QHP recommendations and the methodology for a default display of QHPs, we estimate a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this proposal is $8,220 for 20 web-brokers in the 2022 benefit year.

We seek comment on the potential costs and benefits associated with this proposal.

d. Providing Correct Information to the FFEs and Prohibited Business Practices

These proposed revisions to § 155.220(j)(2) are focused on addressing various areas where HHS has thus far identified a need for more direct and clear guidance, including ensuring that correct consumer information is entered onto Exchange applications. This includes contact information, such as the consumer's email address, telephone number, and mailing address, as well as information related to projected consumer household income. They also set forth prohibited business practices, such as using automation when interacting with CMS Systems or the DE Pathways without CMS' advance written approval and failing to properly identity proof Exchange applicants. These proposed changes will clarify HHS' expectations in these areas, and create clear, enforceable standards and bases for taking enforcement action for violations of these requirements.

HHS believes these proposals would not impose any burden on any of the parties the proposals would impact, including agents, brokers, and web-brokers. None of these proposals propose to impose new requirements. Rather, these proposals are intended to address common problems that HHS has observed, and provide clear, enforceable standards intended to protect consumers and support the efficient operation of Exchanges by substantially reducing the occurrence of those problems.

We seek comment on any potential costs or benefits associated with these proposals.

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

We propose to amend § 155.320(d)(4) to remove the requirement that Exchanges that do not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage conduct random sampling to verify whether an applicant is eligible for or enrolled in an eligible employer sponsored plan in favor of a verification process that is based on risk for inappropriate APTC/CSRs. We believe this proposal would benefit employers, employees, Exchanges using the Federal platform, and State Exchanges that operate their own eligibility and enrollment platform,

as this proposal would relieve them from the burden of investing resources to conduct and respond to random sampling, as applicable.

In the 2019 Payment Notice final rule, we discussed a study that HHS conducted in 2016 and the burden associated with sampling based in part on the alternative process used for the Exchanges.[399] HHS incurred approximately $750,000 in costs to design and operationalize this study, and the study indicated that $353,581 of APTC was potentially incorrectly granted to individuals in the sampled population who inaccurately attested to their enrollment in or eligibility for a qualifying eligible employer sponsored plan. We placed calls to employers to verify 15,125 cases but were only able to verify 1,948 cases. A large number of employers either could not be reached or were unable to verify a consumer's information, resulting in a verification rate of approximately 13 percent. The sample size involved in the 2016 study did not represent a random sample of the target population and did not fulfill all regulatory requirements for sampling under § 155.320(d)(4)(i).

Taking additional costs into account—namely, the cost of sending notices to employees as required under § 155.320(d)(4)(i)(A), the cost of building the infrastructure and implementing the first year of operationalizing this process, and the cost of expanding the number of cases to a random sample size of approximately 1 million cases—we estimate that the overall one-time cost of implementing sampling would have been approximately $8 million for the Exchanges using the Federal platform, and between $2 million and $7 million for other Exchanges, depending on their enrollment volume and existing infrastructure. Therefore, we estimate that the average per-Exchange cost of implementing sampling that resembles the approach taken by the Exchanges using the Federal platform would have been approximately $4.5 million for State Exchanges that operate their own eligibility and enrollment platform, for a total cost of $67.5 million for the 15 State Exchanges that operate their own eligibility and enrollment platform (operating in 14 states and the District of Columbia). However, we are aware that 4 State Exchanges that operate their own eligibility and enrollment platform have already incurred costs to implement sampling and estimate that they have incurred one-time costs of approximately $4.5 million per Exchange with a total of $18 million and will only experience savings related to recurring costs. Therefore, the one-time savings for Exchanges using the Federal platform and the remaining State Exchanges that operate their own eligibility and enrollment platform will be approximately $49.5 million.

We estimate the annual costs to conduct sampling on a random sample size of approximately 1 million cases to be approximately $8 million for the Exchanges using the Federal platform and $7 million on average for each State Exchange that operates its own eligibility and enrollment platform. This estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. The total annual cost to conduct sampling would have been $105 million for 15 State Exchanges. Therefore, the total annual cost for the Exchanges using the Federal platform and the 15 State Exchanges that operate their own eligibility and enrollment platform would have been $113 million in 2022 and onward.

Eliminating these estimated costs would be offset by the costs of designing and implementing an appropriate verification process. We estimate that the cost to conduct research for Exchanges using the Federal platform to be approximately $295,000 and for the 15 State Exchanges that operate their own eligibility and enrollment platform to be approximately $4.4 million. In addition to significant cost savings, this proposal would provide more flexibility for states to design and implement a verification process for employer sponsored coverage that is tailored to their unique populations, and would protect the integrity of states' respective individual markets. Furthermore, we believe that this proposal would reduce burden on employers and employees, as compliance with the current random sampling, notification, and information gathering processes require significant time and resources, which likely would be reduced if this proposal is finalized.

HHS requests comment on the estimated and potential costs and impacts of this proposal.

7. Proration of Advance Premium Tax Credit and Premium (§§ 155.240(e), 155.305(f)(5), and 155.340)

HHS is proposing amendments to part 155, specifically at §§ 155.240(e), 155.305(f)(5), and 155.340 to establish the requirement that all Exchanges prorate both premiums and APTCs for enrollees enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month using a specified methodology. In line with calculating PTC according to the provisions at 26 CFR 1.36B–3, this method of administering APTC would reduce instances of payments of APTC in excess of an applicable taxpayer's monthly PTC for a month in which an enrollee is enrolled for less than a full calendar month and thus would protect the applicable taxpayer from incurring income tax liability due to excess APTC.

This would benefit both issuers and enrollees by preventing APTC overpayment and eliminating wasted resources dedicated to resolving overpayment issues. While the FFEs and SBE–FPs already prorate APTC and premium amounts, State Exchanges do not currently prorate consistently the amount of applied APTC administered to issuers in their applicable states.

HHS acknowledges that those State Exchanges that do not currently prorate APTC or premium amounts will be financially impacted by the proposed requirement to implement this methodology, and this proposal will likely require operational systems builds to support this new proration requirement.

Based on historical cost data for SBEs to implement changes to their IT systems and operations related to premium processing functionality and similar functionality, such as functionality for processing consumer failures to reconcile APTC received for a previous plan year, HHS estimates that State Exchanges that currently do not implement proration of APTC or premium amounts according to the proposed methodology could expect to incur one-time implementation costs. HHS anticipates that each affected State Based Exchange that does not already prorate APTC or premium amounts according to the proposed methodology would expect an estimated $1 million one-time burden to account for the IT build to support the new calculation and reporting systems associated with this requirement.

HHS estimates that 8 State Exchanges currently prorate premium amounts but do not prorate APTC amounts. HHS anticipates that those State Exchanges which already prorate premium amounts will have the operational and systems capacity to calculate the prorated premium and APTC amounts as required in this proposed policy.

Currently, State Exchanges vary in their approaches to implementing the proposed APTC and premium proration. In order to provide the most conservative estimate of this proposal's

[399] See *https://www.govinfo.gov/content/pkg/FR-2017-11-02/pdf/2017-23599.pdf*, p. 51128.

burden, HHS assumes that 10 State Exchanges, including State Exchanges that newly transitioned to being State Exchanges by the time of this rulemaking, will incur the highest level of implementation cost detailed earlier in this proposed rule ($1 million in one-time implementation burden per State Exchange) for a total estimated impact of $10,000,000 in the 2024 benefit year across all State Exchanges. HHS seeks comment on the estimated costs and benefits described in this section.

10. Special Enrollment Periods—Special Enrollment Period Verification (§ 155.420)

We are proposing to amend § 155.420 to add new paragraph (g) to state that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, and that Exchanges may provide an exception to pre-enrollment special enrollment period verification for special circumstances. Exchanges on the Federal platform would conduct pre-enrollment special enrollment period eligibility verification for new consumers who attest to losing minimum essential coverage.

We do not anticipate that revisions to § 155.420 would impose regulatory burden or costs on the Exchanges on the Federal platform because these Exchanges will decrease the number of special enrollment period types that require pre-enrollment verification to only include special enrollment periods for new consumers who attest to losing minimum essential coverage. The provisions proposed in this rule would decrease the scope of pre-enrollment special enrollment period verification in all states with Exchanges served by the Federal platform. We anticipate that this would result in 194,000 fewer individuals having their enrollment delayed or ''pended'' annually until eligibility verification is completed, which would result in a $5,150,700 decrease in annual ongoing costs to the federal government.

There may be State Exchanges that also decide to reduce the scope of their current pre-enrollment special enrollment period verification, which would also decrease annual ongoing costs for State Exchanges. State Exchanges that are currently conducting pre-enrollment verification of eligibility for more special enrollment period types than those that the Exchanges on the Federal platform would be verifying under this proposal could experience a decrease in burden and costs if they choose to align their approaches with the Exchanges on the Federal platform. State Exchanges that are currently conducting pre-enrollment verification of eligibility for fewer types of special enrollment periods than the proposed special enrollment period that the Exchanges on the Federal platform would be verifying under this proposal could experience an increase in burden and costs if they choose to align with the Exchanges on the Federal platform, but State Exchanges will not be required to align with the Exchanges on the Federal platform.

We do not anticipate that this would increase administrative costs on QHP issuers. Additionally, our data suggests that SEP documentation deters younger, likely healthier individuals from enrolling, but there could be an increase in claims costs to QHP issuers since the Exchanges on the Federal platform will be requiring document submission prior to enrollment for fewer special enrollment period types.

We seek comment on the potential costs, benefits, and transfers associated with this proposal.

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

We propose to add new § 155.1200(e) to permit a State Exchange to meet the requirement to conduct an annual independent external programmatic audit, as described at § 155.1200(c), by completing the annual, required SEIPM program process. As a result, we estimate that there would be a general reduction in reporting and contracting costs to State Exchanges related to meeting auditing requirements under § 155.1200. We anticipate the combined cost in contracting and reporting would result in an average annual reduction of approximately $90,624.62 for each State Exchange beginning in benefit year 2024. The total cost annual reduction across 18 State Exchanges would be approximately $1,631,243.16. Any new costs, burdens, and benefits to State Exchanges of meeting requirements for the SEIPM program are described later in this proposed rule.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

12. State Exchange Improper Payment Measurement Program (§§ 155.1500 Through 155.1540)

The implementation of the SEIPM program could have the direct effect of reducing improper payments. Measuring the error rate of State Exchange Premium Tax Credit payments will reveal vulnerable processes to be corrected. Recordkeeping costs of $3.0 million annually will begin in 2023.

We seek comment on the estimated costs and benefits and potential transfers associated with this provision.

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

We are proposing an FFE user fee rate of 2.75 percent of monthly premiums for the 2023 benefit year, which is the same as the 2.75 percent FFE user fee rate finalized in part 3 of the 2022 Payment Notice.[400] We also propose an SBE–FP user fee rate of 2.25 percent for the 2023 benefit year, which is the same as the 2.25 percent SBE–FP user fee rate finalized in part 3 of the 2022 Payment Notice. Therefore, we do not believe that these proposed user fee rates will have any additional impact on premiums compared to the 2022 benefit year. We also propose to amend § 156.50 to conform the user fee regulations with the repeal of the Exchange DE option finalized in part 3 of the 2022 Payment Notice.[401] As this proposal does not alter existing policy, we do not expect that it will have any additional regulatory impact.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

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

We are proposing to eliminate the requirement at § 156.111(d) and (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be in addition to EHB in accordance with § 155.170(a)(3) and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination.

Under this proposal, states would no longer be required to submit an annual report that complies with each requirement listed at § 156.111(f)(1) through (6), nor would HHS identify which benefits are in addition to EHB for the applicable PY in the state if a state does not submit an annual reporting package.

The 2021 Payment Notice acknowledged that requiring states to annually report to HHS would require that states submit additional paperwork to HHS on an annual basis but noted that, as states are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of those benefits,

[400] 86 FR 53412 at 53445.

[401] 86 FR 53412.

any such burden experienced by states would be minimal.[402] The 2021 Payment Notice also stated that this reporting requirement would be complementary to the process the state should already have in place for tracking and analyzing state-required benefits. The 2021 Payment Notice further explained that states may opt not to report this information and instead let HHS make this determination for them. In the 2021 Payment Notice, we also discussed that any state burden associated with this policy would be limited to the completion of the HHS templates, validation of that information, and submission of the templates to HHS. Repealing the annual reporting requirement would remove the burden associated with that policy, detailed in 2021 Payment Notice and summarized previously in the Collection of Information Requirements section in this proposed rule.

Although this proposal would relieve states of the annual reporting requirements and any associated burden with submission and validation of the information on the annual reporting templates, it would not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170. Under this proposal, states remain responsible for making payments to defray the cost of additional required benefits and issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the state. We also note that the obligation for a state to defray the cost of QHP coverage of state-required benefits in addition to EHB is an independent statutory requirement from the annual reporting policy finalized at § 156.111(d) and (f).

We seek comment on the potential costs, benefits, and transfers associated with this provision.

15. Levels of Coverage (Actuarial Value) (§ 156.140, 156.200, 156.400)

We are proposing to change the de minimis range for levels of coverage at § 156.140(c) to a variation of +2/−2 percentage points for all standard bronze plans, gold plans, platinum plans, individual market off-Exchange silver plans, and all small group market silver plans (on- and off-Exchange), as well as proposing to change the de minimis for expanded bronze plans to +5/−2, that are required to comply with AV standards for PYs beginning in 2023. In addition, we are proposing to change the de minimis under § 156.200 to +2/0 percentage points for individual market silver QHPs and for the income-based silver CSR plan variations under § 156.400 to +1/0.

In the 2017 Market Stabilization rule,[403] we acknowledged that in the short run, expanding the standard de minimis range to +2/−4 would generate a transfer of costs from consumers to issuers in the form of decreased APTC and increased premiums, but stated our belief that the additional flexibility for issuers would have positive effects for consumers over the longer term as premiums stabilized, issuer participation increased, and coverage options at the silver level and above increased, which would attract more young and healthy enrollees into such plans. As discussed above, since we finalized the expanded de minimis ranges, we have observed decreased enrollment in silver plans (from 963,241 enrollees in PY 2018 to 424,345 enrollees in PY 2021), despite the number of standard silver plans available on *HealthCare.gov* steadily increasing from 811 silver plans in PY 2018 to 1,386 silver plans in PY 2021. Thus, we cannot justify the decreased APTC with evidence of increased enrollment of younger and healthier enrollees in silver plans.

Changing the de minimis ranges for standard metal level plans would generate a transfer of costs from the government and issuers to consumers in the form of increased APTC and decreased premiums, because narrowing the de minimis range for silver plans can affect the generosity of the SLCSP. The SLCSP is the benchmark plan used to determine an individual's PTC. A subsidized enrollee in any county that has a SLCSP that is currently below 70 percent AV would see the generosity of their current SLCSP increase, resulting in an increase in PTC. Not all counties would see the SLCSP change as a result of this proposal. In states using *HealthCare.gov,* approximately 87 percent of counties across 23 states have a SLCSP that is below 70 percent AV.

For this proposal, the CMS Office of the Actuary estimates a nationwide increase in PTCs through PY 2032, as shown in Table 26:

TABLE 26: PTC Impact of +2/0 Silver, +1/0 CSR De Minimis Plan AVs, 2023-2032

Calendar Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
PTC Impact ($ Billions)	0.73	0.77	0.77	0.76	0.77	0.78	0.82	0.83	0.87	0.92
Fiscal Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
PTC Impact ($ Billions)	0.55	0.76	0.77	0.76	0.77	0.78	0.81	0.83	0.86	0.91

This proposal would impact those consumers currently enrolled in standard silver plans that are currently in the −4 to −0.01 percent de minimis range that would be out of compliance under this proposal, as well as consumers currently enrolled in individual market silver QHPs that are currently in the −4 to −0.01 percent de minimis range and associated income-based CSR silver plan variations currently enrolled in the −1 to −0.01 percent de minimis range. Of the plans on *HealthCare.gov,* we estimate that there are approximately 150,000 enrollees in gold plans below 78 percent AV, and 3,500 enrollees in platinum plans below 88 percent AV.[404] Additionally, we estimate there are approximately 248,000 enrollees in *HealthCare.gov* silver QHPs below 70 percent AV, with approximately 4.2 million enrollees in corresponding income-based CSR plan variations. Under these proposals, those enrollees would need to select a different plan for PY 2023 if the issuer chooses to discontinue the plan rather than revise the plan's cost sharing. Additionally, these proposals would similarly affect enrollees in such plans that are not available on *HealthCare.gov,* such as plans sold on state Exchanges, for which

[402] 85 FR 29164, 29252.

[403] Patient Protection and Affordable Care Act; Market Stabilization, 82 FR 18346 (April 18, 2017). Available at *https://www.govinfo.gov/content/pkg/FR-2017-04-18/pdf/2017-07712.pdf.*

[404] There are no enrollees in bronze plans below 58% AV.

we do not have data to make an informed estimate.

We estimate the premiums for these plans would increase approximately 2 percent on average because of benefit changes required for plans to meet a +2/0 de minimis threshold. However, for Exchange enrollees, we expect this premium increase to be substantially offset by the corresponding increase in PTC because of the proposal's impact on the SLCSP. Similarly, the proposal to change the de minimis range for CSR variants to +1/0 would lead to improved cost-sharing due to the higher relative AV compared to the current +1/−1 range, along with increased gross premiums that would be substantially offset by increased PTC payments. After implementation of the ARP enhanced financial subsidies, subsidized enrollees make up the majority of *HealthCare.gov* silver QHP enrollees—only 91,000 of approximately 248,000 individual market silver QHP enrollees in plans with AV between 66.00 and 69.99 percent plan AV remain unsubsidized. By comparison, enrollment within the corresponding income-based silver CSR variations of the above silver QHPs has increased to approximately 4.2 million. We expect the increased PTC payments due to the premium increase to incentivize healthier subsidy-eligible enrollees to participate in the Marketplace, and that the improved risk pool as a result of increased healthier enrollees would mitigate the net cost burden of covering a decreasing population of unsubsidized enrollees.

In addition, changing the de minimis range for standard silver plans would impact ICHRAs, which use the Lowest Cost Silver Plan (LCSP) as the benchmark to determine whether an ICHRA is considered affordable to an employee. Under this proposal, as silver plans become more generous and premiums increase, an employer would have to contribute more to an ICHRA to have it be considered affordable. This change could discourage large employer use of ICHRAs because large employers need to offer affordable coverage to satisfy the employer shared responsibility provisions.[405] Additionally, if coverage is considered unaffordable to the employee, the employee can opt out of the ICHRA and instead purchase coverage on the Exchange with APTC, if otherwise eligible; and increasing the LCSP premiums could make employer-sponsored coverage unaffordable to more employees. We estimate silver plans with an AV below 70 percent will see premiums increase approximately 2 percent on average due to more generous benefits. We do not believe this will have a significant impact on the number of employers willing to offer ICHRAs or whether an ICHRA is considered affordable to most employees, but invite comment to refute or refine this understanding on these issues in particular.

We seek comment on the estimated costs, benefits, and transfers associated with this provision.

16. Standardized Options (§ 156.201)

Section 156.201 would require QHP issuers to offer standardized QHP options. Though these proposed requirements would necessitate the creation of new plans, HHS believes the burden imposed on issuers would be minimal because these new plans' benefits, networks, and formularies would not differ substantially from the benefits, networks, and formularies of plans that issuers currently offer and because HHS is specifying the cost sharing parameters, MOOPs, and deductibles for these new plans. Additionally, HHS would design these standardized options to resemble the most popular QHPs in the individual market FFEs and SBE–FPs in PY 2021, making these standardized options comparable to plans that the majority of issuers already offer. Furthermore, since HHS proposes to require QHP issuers to offer standardized options at every product network type, metal level, and throughout every service area that they also offer non-standardized QHPs (but not at different product network types, metal levels, and service areas that they do not also offer non-standardized QHPs), issuers would not be required to extend plan offerings beyond their existing service areas.

Additionally, since HHS does not propose to limit the number of non-standardized QHP options that issuers can offer in PY 2023, HHS believes the majority of enrollees will remain enrolled in their current non-standardized options. Moreover, since HHS does not propose to require issuers to offer a higher number of QHPs than what they currently offer, issuers would still be able to determine how many QHPs they wish to offer. As a result, HHS does not expect the total number of plans that issuers will offer to change substantially subsequent to the imposition of requirement. Thus, though these new plans would have to be submitted for approval, certification, and display, we expect that the overall burden for issuers and states alike would not substantially increase because we do not expect the number of overall plan offerings to substantially increase—due in part to issuers discontinuing some old plans.

As noted earlier in the preamble, HHS is considering resuming the differential display of standardized options per the existing authority at § 155.205(b)(1). HHS would assume burden for the differential display of standardized options on *HealthCare.gov,* meaning FFE and SBE–FP issuers would not be subject to this burden. In addition, as noted above in the preamble, HHS is considering resuming enforcement of the standardized options display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively.

HHS believes that resuming enforcement of these differential display requirements will not require significant modification of these entities' platforms and non-Exchange websites. Further, since HHS would continue to allow these entities to submit requests to deviate from the manner in which standardized options are differentially displayed on *HealthCare.gov,* potential burden for these for these entities would be further reduced. HHS also intends to provide access to information on standardized options to web-brokers through the Health Insurance Marketplace PUFs and QHP Landscape file to further minimize burden. The specific burden estimates for these requirements can be found in the corresponding ICR sections for §§ 155.220 and 156.265.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

17. Network Adequacy (§ 156.230)

Section 156.230(a)(2) currently requires a QHP issuer to maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorders, to ensure that all services will be accessible without unreasonable delay. In this proposed rule, HHS proposes for PY 2023 and future PYs that all QHPs or QHP candidates that use a provider network must comply with network adequacy standards.

HHS proposes to conduct prospective quantitative network adequacy reviews for all FFEs in all FFE states except in states performing plan management functions that adhere to a standard as stringent as the federal standard, conduct reviews prospectively, and choose to conduct their own reviews.

[405] See section 4980H of the Code; 26 CFR 54.4980H–1—26 CFR 54.4980H–6.

HHS proposes for PY 2023 and future PYs to adopt time and distance standards to assess whether FFE QHPs or QHP candidates fulfill network standards based on numbers and types of providers and providers' geographic locations. Time and distance standards would be calculated at the county level using information from the ECP/NA template. HHS also proposes to adopt appointment wait time standards to assess whether FFE QHPs or QHP candidates fulfill network adequacy standards. For PY 2023, issuers would attest to meeting the appointment wait time standards. Issuers that are unable to meet the specified standards for time and distance or appointment wait times must submit a justification to account for such variances.

HHS proposes that, for plans that use tiered networks to count toward the issuer's satisfaction of the network adequacy standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards network adequacy standards.

Finally, HHS proposes to collect information about providers who offer telehealth services via the ECP/NA template to inform network adequacy and provider access standards for future PYs. As discussed previously in the Collection of Information Requirements section, this may increase related administrative costs for issuers who do not already possess this data, though many issuers already collect and submit this information for network adequacy submissions in other markets. While we anticipate that increased burden related to telehealth data collection would be minimal for many issuers, the increased burden could ultimately lead to an increase in premiums for consumers. As noted previously, we believe that the potential benefits of obtaining telehealth information and using it to inform future network adequacy standards are in the best interests of both QHP enrollees and QHP issuers. As such, we anticipate that the additional burden would be mitigated by the expected benefits.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

18. Essential Community Providers (§ 156.235)

Section 156.235(a)(2)(i) provides that a plan has a sufficient number and geographic distribution of ECPs if the issuer demonstrates, among other things, that a QHP or QHP candidate provides access to a network of providers that includes at least a minimum percentage of ECPs, as specified by HHS.

For PY 2023 and future PYs, HHS proposes to raise the ECP threshold applicable to QHPs and QHP candidates from 20 percent to 35 percent. For this increased threshold, HHS would consider issuers to have satisfied the regulatory threshold requirement if the issuer contracts with at least 35 percent of available ECPs in each plan's service area to participate in the plan's provider network.

We note that in PYs 2015–2017, all FFE QHP issuers satisfied the 30 percent threshold with minimal reliance on ECP write-ins and justifications. In PYs 2018 through 2021, when the ECP threshold was 20 percent, all QHP issuers satisfied the lower threshold with ease and very little reliance on ECP write-ins and justifications.

Consequently, HHS anticipates that issuers can meet the proposed 35 percent threshold using ECP write-ins and justifications as needed. We believe that increasing the ECP threshold would lead to greater ECP access for low-income and medically underserved individuals. HHS anticipates that costs may not increase since HHS' data analysis shows most issuers could easily meet this standard or use the justification process. HHS expects that administrative cost changes would likely be minimal for most issuers.

HHS proposes that, for plans that use tiered networks to count toward the issuer's satisfaction of ECP standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards ECP standards.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

19. Standards for Delegated and Downstream Entities (§ 156.340)

We propose to amend and add language to § 156.340, to extend its applicability to QHP issuers on all Exchange models. The proposed changes capture the delegated and downstream entity standards that would apply to QHP issuers on State Exchanges and State Exchange SHOPs, as well as QHP issuers providing coverage on Exchange models that use the Federal platform, including, but not limited to, FFEs, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs. HHS also proposes to add a requirement that all agreements between QHP issuers and their downstream and delegated entities include language stating that the relevant Exchange authority, including State Exchanges, may demand and receive a delegated and downstream entity's records related to the QHP issuer's obligations in accordance with the minimum Federal standards related to Exchanges. These proposed amendments are intended to hold QHP issuers in all Exchange models responsible for their downstream and delegated entities' compliance with applicable Exchange standards, and to make their oversight obligations, and the obligations of their downstream and delegated entities, explicit. We also propose conforming amendments to the title of subpart D of 45 CFR part 156 from ''Standards for Qualified Health Plan Issuers on Federally Facilitated Exchanges and State-Based Exchanges on the Federal platform'' to ''Standards for Qualified Health Plan Issuers on Specific Types of Exchanges''.

We anticipate these proposals will impose a minimal burden on QHP issuers and Exchange authorities impacted by them. HHS expects some QHP issuers may need to make changes to existing record retention policies and their agreements with delegated and downstream entities. If finalized as proposed, the conforming amendments will become applicable to all books, contracts, computers, or other electronic systems, including medical records and documentation relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period, as of the effective date of the final rule. State Exchange authorities will retain primary enforcement authority and would be responsible for ensuring QHP issuers in State Exchanges and State Exchange SHOPs maintain oversight over downstream and delegated entities.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

20. Payment for Cost-Sharing Reductions (§ 156.430)

We propose to amend § 156.430 to clarify that the CSR data submission process is mandatory only for those issuers that received CSR payments from HHS for any part of the benefit year as a result of a valid appropriation to make CSR payments, and voluntary for other issuers. In the event HHS has not made CSR payments to issuers

because there is no appropriation to do so, HHS will continue to provide those issuers that have not received CSR payments from HHS for any part of the benefit year the option to submit CSR data, but issuers will not be required to do so. We do not expect any of these provisions to increase burden on issuers, as this amendment would codify existing practices.

We seek comment on any potential costs, benefits, and transfers associated with this provision.

21. Quality Improvement Strategy (§ 156.1130)

We propose that beginning in 2023, a QHP issuer would be required to address reducing health and health care disparities as one of their QIS topic areas in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA, including improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, and promoting wellness and health. We are not proposing any changes to regulatory text. We do not estimate additional costs or burdens as a result of this proposal.

We seek comment on any potential costs, benefits, and transfers associated with this proposal.

22. Medical Loss Ratio (§§ 158.140, 158.150, 158.170)

We propose to amend § 158.140(b)(2)(iii) to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. To the extent some issuers currently include in incurred claims payments to providers that significantly reduce or eliminate rebates while providing no value to consumers, the proposed clarification would result in transfers from such issuers to enrollees in the form of higher rebates or lower premiums. Although we do not know how many issuers currently engage in such reporting practices or the amounts improperly included in MLR calculations, we estimate the impact of the proposed clarification by assuming that provider incentive and bonus payments of 1.06 percent or more of paid claims (the top 5 percent of such observations) may represent incentives based on MLR or similar metrics. Based on this assumption and the MLR data for 2019, the proposed clarification would increase rebates paid by issuers to consumers or reduce premiums collected by issuers from consumers by approximately $ 12 million per year.

We also propose to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes. This proposed change would result in transfers from issuers that currently include indirect expenses in QIA to enrollees in the form of higher rebates or lower premiums. Although we do not know how many issuers include indirect expenses in QIA, we estimate the impact of the proposed change by assuming that indirect expenses inflate QIA by 41.5 percent (the midpoint of the 33 percent- to 50 percent range we have observed during MLR examinations) for half of the issuers that report QIA expenses (based on the frequency of QIA-related findings in MLR examinations). Based on these assumptions and the MLR data for 2020, the proposed clarification would increase rebates paid by issuers to consumers or reduce premiums collected by issuers from consumers by approximately $ 49.8 million per year.

We also propose to make a technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus, et al.* v. *Cochran,*[406] and thus deleted in part 2 of the 2022 Payment Notice final rule. We do not anticipate any impact on rebates or premiums as a result of this change. We seek comment on any potential costs, benefits, and transfers associated with these provisions.

D. Regulatory Alternatives Considered

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

As described in prior rulemakings and the 2021 RA Technical Paper, we considered a variety of alternatives to the proposed model specifications and updated enrollment duration factors for the HHS risk adjustment models.[407] For example, we considered adding a non-linear term or HCC counts terms for all enrollees in the adult and child risk adjustment models. As detailed in the proposed 2022 Payment Notice and the 2021 RA Technical Paper, we found that non-linear model specifications often failed to converge, preventing us from testing the impact of the non-linear model specifications on the magnitude of transfers.[408] In addition, the non-linear model specifications would significantly overhaul the current linear models, increasing the administrative burden on issuers and HHS. We also found that the HCC counts terms approach posed gaming concerns, which would violate principle six of the HHS-operated risk adjustment program by rewarding coding proliferation.

In addition to the non-linear and HCC counts model specifications, we also considered variations to the interacted HCC counts factors and the two-stage weighted model specifications. Specifically, we tested various alternative caps for the weights based on the distribution of costs, but found the proposed caps resulted in better prediction on average. For the prediction weights, we tested various alternative forms of weights, including reciprocals of the square root of prediction, log of prediction, and residuals from the first-step estimation, but the reciprocal of the capped predictions resulted in better PRs for low-cost enrollees compared to any of the other weights.

For the interacted HCC counts factors, we tested several HCCs and considered adding and removing certain HCCs from the proposed list in Table 3. We chose the list of HCCs in Table 3 because including these HCCs most improved prediction for enrollees with the highest costs, multiple HCCs, and with these specific HCCs. We also considered various alternatives to structure the interacted HCC counts, such as applying individual interacted HCC count factors (between 1–10 based on the number of HCCs an enrollee has) to each of the selected HCCs included in the models, instead of combining all of the selected HCCs into two severe and transplant indicator groups. We chose the proposed model specification because it would add fewer additional factors to the models, which minimizes the increased burden on issuers and HHS without sacrificing any significant predictive accuracy.

For the enrollment duration factors in the adult models, we propose to replace the enrollment duration factors with monthly duration factors of up to 6 months for enrollees with HCCs. The purpose of this proposed change is to

[406] 523 F. Supp. 3d 731 (D. Md. 2021).

[407] 85 FR 78572 at 78583–78586; See the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[408] Ibid.

address the underprediction of plan liability for partial-year adult enrollees with HCCs. As part of this assessment, we considered whether enrollment duration factors by type of partial-year enrollment (enrolling through a special enrollment period versus enrolling during the annual open enrollment period and dropping enrollment partway through the year), by market type (individual versus small group market), or by specific HCC (as well as by type of HCC—acute versus chronic) may be warranted. As previously noted, varying enrollment duration factors by partial-year enrollment type or by market produced factors that were generally very similar between partial- and full-year enrollees, which indicates they would add little value to the models while increasing complexity.[409] We chose the proposed enrollment duration factors, contingent on the presence of at least one HCC, because these factors improve predictive accuracy for partial-year enrollees and simplify the adult risk adjustment models compared to the current models.[410]

Relative to the other considered alternatives, our proposed model specification changes would improve the current models' predictive accuracy and minimize burden on issuers and HHS by avoiding unnecessary complexity.

With respect to the proposed changes to § 153.320(d), we considered repealing risk adjustment state flexibility for the individual catastrophic and non-catastrophic market risk pools, while retaining risk adjustment state flexibility for the small group market risk pool. Consistent with the directive in E.O. 14009[411] to prioritize protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals, we considered whether this approach is inconsistent with policies described in Sections 1 and 3 of E.O. 14009. In prior rulemakings, we received comments stating that risk adjustment state flexibility in any market may result in risk selection, market destabilization, increased premiums, smaller networks, and worse plan options. we believe that generally retaining state flexibility could introduce unnecessary risk of undermining the stated goals of the risk adjustment program.

We also considered whether to adopt an exception for states that previously requested reductions under § 153.320(d) to the risk adjustment transfers calculated by HHS under the state payment transfer formula. In the one state that has requested to reduce transfers under this policy, it has stabilized market participation and impacts issuers who receive risk adjustment payments by less than 1 percent of premiums.[412] Although allowing state flexibility may undermine the efficacy of risk adjustment by not fully compensating higher-risk plans for their enrollees, we believe the benefit of maintaining participation in markets that might otherwise only have a single issuer offering coverage outweighs the potential harm of not fully compensating the higher-risk plan for its enrollees when there is a *de minimis* (less than 1 percent) impact on premiums. Additionally, under the proposal in this rulemaking, if a prior participant seeks a future reduction to risk adjustment transfers in the 2024 benefit year or beyond, the state would need to demonstrate that it meets the de minimis regulatory criteria, meaning no issuer would need to increase its premiums by more than 1 percent as a result of the reduced risk adjustment payments.

With regard to the proposed changes to § 155.320, we considered taking no action to modify the requirement that when an Exchange does not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage, the Exchange must select a random sample of applicants and attempt to verify their attestation with the employer listed on their Exchange application. However, based on HHS' experience conducting sampling, this manual verification process requires significant resources for a low return on investment, as using this method HHS identified only a small population of applicants who received APTC/CSR payments inappropriately. We believe the proposed change discussed earlier in the preamble to design a process to verify enrollment in or eligibility for an employer sponsored plan, informed by a risk assessment, is reasonably designed to ensure the accuracy of data, and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data. We also believe the proposed change would protect the integrity of the individual market by allowing all Exchanges to proactively identify applicants with the greatest incentive to forego enrolling in an employer sponsored plan in favor of Exchange coverage with APTC/CSRs that they may not be eligible to receive, thereby potentially adding high health risk to the individual market risk pool that should be covered by the group health market, for example.

We considered several alternatives to specifying in § 155.420 that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, including requiring Exchanges to verify a certain percentage of special enrollment period enrollments and designating specific special enrollment period types for which eligibility must be verified by the Exchange. However, we believed that imposing any requirements for pre-enrollment special enrollment period verification would increase burden on consumers and Exchanges and decrease implementation flexibility to decide the best way to conduct special enrollment period verification based on Exchange type, population characteristics, and trends.

HHS considered multiple options for measuring the improper payment amounts and rates for State Exchanges to comply with its statutory mandate in the PIIA. HHS developed and pilot tested the proposed methodology with extensive collaboration from participating Exchanges during a multi-year research and demonstration period. HHS considered the following alternatives while developing this proposed rule:

1. Conducting No Reviews

HHS might take no preventive efforts to detect improper payments. We would wait passively until third-party investigators, private whistleblowers, qui tam relators, disgruntled relatives, or others report speculation through Inspector General channels. Advanced statistical analysis could estimate the odds of third-party prosecution and project the improper payment amount and rate for each State Exchange (with wide confidence intervals). This low intervention strategy may not fully comply with statutory intent.

2. Placing More Responsibility on State Exchanges To Conduct Reviews

HHS could require that each State Exchange determine its own improper payment rate with broad discretion on

[409] See, for example, 85 FR 78572 at 78585–78586 and Sections 3.3.1 and 3.3.2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[410] As detailed above, these new proposed factors would only apply to partial-year adult enrollees with up to 6 months of enrollment and at least one payment HCC.

[411] Executive Order 14009; 86 FR 7793 (Feb. 2, 2021).

[412] See, for example, the 2019, 2020, and 2021 Unified Rate Review Public Use Files, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/ratereview.*

the methodology. This option would maximize regulatory flexibility while still complying with PIIA 2019 requirements. However, diverse methodology would make the State Exchanges' results difficult to compare and of variable validity. In addition, the costs resulting from higher error rates are borne by the federal government in the form of increased APTC and CSRs, giving State Exchanges' minimal incentive to aggressively reduce improper payments.

3. Placing More Responsibility on State Exchanges To Engage Third-Party Reviewers

HHS could require that State Exchanges engage third-party reviewers to determine the improper payment rate. As with financial reporting, the State Exchange could select among competing vendors to obtain its preferred combination of methodology, service, quality, and price. However, this approach would require more work and resources from both State Exchanges and HHS than the proposed methodology would require. The third party would need to obtain personally identifiable information from both state and federal data systems. These processes suffer from potential record matching and data security issues. In addition, competing vendors might offer incompatible methodologies, producing non-comparable improper payment rates.

4. Conducting a Random Sample Across All State Exchanges

HHS could annually sample from the population of all State Exchange enrollees, rather than within each State Exchange. Thus, more cases would come from larger State Exchanges. This design would increase the efficiency and decrease the variance for the national estimate, but it would not provide an estimate for each State Exchange. It also would not reduce the burden on each State Exchange and may not comply with statutory intent.

With respect to standardized options, we considered a range of options for our proposed policy approach at § 156.201. On one end of this range, we considered resuming standardized options as reflected in the 2017 and 2018 Payment Notices. This approach would have allowed issuers to voluntarily offer standardized options and have the Exchanges on the Federal platform, web-brokers, and Classic DE and EDE Pathways differentially display these plans. We also considered gradually limiting the number of non-standardized options per issuer, product network type, metal level, and service area over the course of several PYs. We also considered preferentially displaying standardized options over non-standardized options. We also considered requiring issuers to offer exclusively standardized options in FFEs and SBE–FPs. We believe the approach we have chosen for standardized options in which we propose to require issuers to offer standardized options and do not propose to limit the number of non-standardized offerings in PY 2023 strikes the greatest balance between simplifying the plan selection process, combatting discriminatory benefit designs, and advancing health equity, all while promoting a smooth transition to the introduction of standardized options.

For our proposal in §§ 155.240(e), 155.305(f)(5), and 155.340 on prorating the calculation and administration of premium and APTC, HHS considered an alternative form of implementation in which HHS would perform the proration on behalf of each State Exchange which does not already implement proration according to the proposed methodology. This approach would lessen concern regarding the burden of implementing a new proration methodology among State Exchanges. HHS already has the structures in place to prorate APTC and premium amounts in accordance with the proposed methodology and has already implemented proration in the FFEs and SBE–FPs.[413] Under this alternative, HHS would assume responsibility for prorating the amount of APTC due to each State Exchange based on the methodology HHS proposes in § 155.340 which states that when an enrollee is enrolled in a particular policy for less than the full coverage month (including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month) the amount of APTC paid to the issuer of the policy will be calculated as the product of (1) the APTC applied on the policy for one month of coverage divided by the number of days in the month, and (2) the number of days for which coverage is provided during the applicable month. However, this alternative would require State Exchanges to agree to allow HHS to use the data on the monthly SBMI to calculate the prorated amount. This would require State Exchanges to review payment reports to ensure the correct calculation of APTC and premium is reflected on each applicable State Exchanges' 1095–A. HHS expects that this alternative would produce additional burden of $4,500 in contract labor to update each State Exchange's SBMI and would necessitate increased data sharing and coordination back and forth between HHS and the applicable State Exchanges. In order to streamline the process of proration and allow State Exchanges greater control in the administration of APTC, HHS determined that it would propose that each State Exchange would prorate their own APTC and premium amounts for the applicable enrollees in their state. HHS seeks comment on the alternative proposals considered.

Additionally, for the proposal to prorate APTC amounts with amendments to §§ 155.240, 155.305(f)(5) and 155.340, we considered proposing to implement this requirement for the 2023 benefit year. However, after analyzing the potential burden on State Exchanges to achieve operational readiness, we concluded that 2023 may not provide sufficient time. Therefore, we propose 2024 benefit year implementation and request comment on the feasibility of 2023 benefit year implementation.

E. Regulatory Flexibility Act

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

In this proposed rule, we propose standards for the risk adjustment and HHS–RADV programs, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not believe that an initial regulatory

[413] Under the SBE–FP agreement, the same method also applies in the SBE–FPs, as they rely on the Federal platform, which calculates applicable premiums in those Exchanges.

flexibility analysis is required for such firms.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35 million or less.[414] We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less.[415] This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 72 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 $41.5 million. Only 10 of these 90 potentially small entities, three of them part of larger holding groups, are estimated to experience a change in rebates under the proposed amendments to the MLR provisions of this proposed rule in part 158. Therefore, we do not expect the proposed MLR provisions of this rule to affect a substantial number of small entities.

The proposals related to SEIPM at §§ 155.1500–155.1540 will affect only State Exchanges. As state governments do not constitute small entities under the statutory definition, and as all State Exchanges have revenues exceeding $5 million, an impact analysis for these provisions is not required under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under title XVIII, title XIX, or part B of title 42 of the Social Security Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that This proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector 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 that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications.

In compliance with the requirement of E.O. 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 E.O. 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For states that elected previously to operate an Exchange, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. Current State Exchanges charge user fees to issuers.

In our view, while this proposed rule would not impose substantial direct requirement costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. For example, the repeal of the risk adjustment state flexibility policy may have federalism implications, but they are mitigated because states have the option to operate their own Exchange and risk adjustment program if they believe the HHS risk adjustment methodology does not account for state-specific factors unique to the state's markets.

In addition, we believe this proposed regulation has federalism implications due to our proposal for Exchanges to design a new risk-based verification process for enrollment in or eligibility for employer sponsored plan coverage that meets minimum value standards, that is based on the Exchange's assessment of risk for inappropriate APTC/CSR payments. However, the federalism implications are mitigated because the proposed requirement provides Exchanges with the flexibility to determine the best process to verify employer sponsored coverage and may choose not to implement such a risk-based verification process.

As previously noted, the proposals in this rule related to SEIPM would impose a minimal unfunded mandate on State Exchanges to supply data for the improper payment calculation. Accordingly, E.O. 13132 does not apply to this section of the proposed rule. In addition, statute requires HHS to determine the amount and rate of improper payments. Finally, states have the option to choose an FFE or SBE–FP, each of which place different federal burdens on the state. As the SEIPM section of the proposed rule should not conflict with state law, HHS does not anticipate any preemption of state law. We invite State Exchanges to submit comments on this section of the proposed rule if they believe it would conflict with state law.

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

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

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 15, 2021.

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, 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 administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended.

§ 144.103 [Amended]

■ 2. Amend § 144.103 in the definition of ''large group market'' by removing the phrase '', unless otherwise provided under State law.''

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 3. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 4. Amend § 147.104 by—
■ a. Revising paragraph (e);
■ b. Redesignating paragraph (i) as paragraph (j); and
■ c. Adding a new paragraph (i).

The revision and addition read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(e) *Marketing.* A health insurance issuer and its officials, employees, agents, and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, sexual orientation, gender identity, expected length of life, degree of medical dependency, quality of life, or other health conditions.

* * * * *

(i) *Coverage denials for failure to pay premiums for prior coverage.* A health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates paragraph (a) of this section.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 5. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 6. Amend § 153.320 by—
■ a. Revising paragraphs (d) introductory text and (d)(1)(iii);
■ b. Adding paragraph (d)((1)(iv);
■ c. Revising paragraphs (d)(4)(i)(A) and (B); and
■ d. Adding paragraph (d)(5).

The revisions and additions read as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(d) *State flexibility to request reductions to transfers.* For the 2020 through 2023 benefit years, States can request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged markets risk pools by up to 50 percent in States where HHS operates the risk adjustment program. Beginning with the 2024 benefit year, only prior participants, as defined in paragraph (d)(5) of this section, may request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged markets risk pools by up to 50 percent in States where HHS operates the risk adjustment program.

(1) * * *

(iii) For the 2020 through 2023 benefit years, a justification for the reduction requested demonstrating the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, or demonstrating the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments; or

(iv) Beginning with the 2024 benefit year, a justification for the reduction requested demonstrating the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers

that would receive reduced transfer payments.

* * * * *

(4) * * *

(i) * * *

(A) For the 2020 through 2023 benefit years, that State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and support the percentage reduction to risk adjustment transfers requested; or State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(B) Beginning with the 2024 benefit year that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

* * * * *

(5) *Exception for prior participants.* As used in paragraph (d) of this section, prior participants mean States that submitted a State reduction request in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool in the 2020, 2021, 2022, or 2023 benefit year.

■ 7. Amend § 153.710 by—

■ a. Revising paragraphs (h)(1) introductory text and (h)(1)(iii) and (iv);

■ b. Adding paragraph (h)(1)(v); and

■ c. Revising paragraphs (h)(2) and (3).

The revisions and addition read as follows:

§ 153.710 Data requirements.

* * * * *

(h) * * *

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) of this section, any discrepancy filed under § 153.630(d)(2), or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; reinsurance payment; cost-sharing reduction payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and MLR programs:

* * * * *

(iii) A cost-sharing reduction amount equal to the actual amount of cost-sharing reductions for the benefit year as calculated under § 156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service;

(iv) For medical loss ratio reporting only, the risk corridors payment to be made or charge assessed by HHS under § 153.510; and

(v) The risk adjustment data validation adjustment calculated by HHS in the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers.

(2) An issuer must report during the current MLR and risk corridors reporting year any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge before August 15, or the next applicable business day, of the current MLR and risk corridors reporting year unless instructed otherwise by HHS. An issuer must report any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge where such adjustment has not been accounted for in a prior MLR and Risk Corridor Annual Reporting Form, in the MLR and Risk Corridors Annual Reporting Form for the following reporting year.

(3) In cases where HHS reasonably determines that the reporting instructions in paragraph (h)(1) or (2) of this section would lead to unfair or misleading financial reporting, issuers must correct their data submissions in a form and manner to be specified by HHS.

■ 8. Revise § 153.730 to read as follows:

§ 153.730 Deadline for submission of data.

A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year or, if such date is not a business day, the next applicable business day.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 9. 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.

§ 155.120 [Amended]

■ 10. Amend § 155.120 in paragraph (c)(1)(ii) by removing the phrase ''age, or sex'' and adding in its place the phrase ''age, sex, sexual orientation, or gender identity''.

§ 155.206 [Amended]

■ 11. Amend § 155.206 in paragraph (i) by removing the phrase ''$100 for each day for each'' and adding in its place the phrase ''$100 for each day, as adjusted annually under 45 CFR part 102, for each''.

■ 12. Amend § 155.220 by—

■ a. Revising paragraphs (c)(3)(i)(A) and (L);

■ b. Adding paragraph (c)(3)(i)(M);

■ c. In paragraph (j)(2)(i) by removing the phrase ''age, or sex'' and adding in its place the phrase ''age, sex, sexual orientation, or gender identity'';

■ d. Revising paragraphs (j)(2)(ii);

■ e. In paragraph (j)(2)(iv), by removing the phrase ''described in § 155.260(b)(2); and'' and adding in its place the phrase ''described in § 155.260(b)(2);''; and

■ f. Adding paragraphs (j)(2)(vi) through (viii).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) Disclose and display the following QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c), and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a Web link to the Exchange website:

(*1*) Premium and cost-sharing information;

(*2*) The summary of benefits and coverage established under section 2715 of the PHS Act;

(*3*) Identification of whether the QHP is a bronze, silver, gold, or platinum

level plan as defined by section 1302(d) of the Affordable Care Act, or a catastrophic plan as defined by section 1302(e) of the Affordable Care Act;

(*4*) The results of the enrollee satisfaction survey, as described in section 1311(c)(4) of the Affordable Care Act;

(*5*) Quality ratings assigned in accordance with section 1311(c)(3) of the Affordable Care Act; and

(*6*) The provider directory made available to the Exchange in accordance with § 156.230 of this subchapter.

* * * * *

(L) Not display QHP advertisements or recommendations, or otherwise provide favored or preferred placement in the display of QHPs, based on compensation the agent, broker, or web-broker receives from QHP issuers; and

(M) Prominently display a clear explanation of the rationale for QHP recommendations and the methodology for its default display of QHPs.

* * * * *

(j) * * *

(2) * * *

(ii) Provide the federally-facilitated Exchanges with correct information under section 1411(b) of the Affordable Care Act, including, but not limited to:

(A) Only entering an email address on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost sharing reductions for QHPs that is secure, not disposable, and belongs to the consumer or the consumer's authorized representative designated in compliance with § 155.227. A consumer's email address may only be entered on an Exchange application with the consent of the consumer or the consumer's authorized representative. Properly entered email addresses must adhere to the following guidelines:

(*1*) The email address may not have domains that remove email from an inbox after a set period of time;

(*2*) The email address must be accessible by the consumer, or the consumer's authorized representative designated in compliance with § 155.227, and may not be accessible by the agent, broker, or web-broker assisting the consumer; and

(*3*) The email address may not have domains that belong to the agent, broker, or web-broker or their business or agency.

(B) Only entering a telephone number on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost sharing reductions for QHPs that belongs to the consumer or their authorized representative designated in compliance with § 155.227. Telephone numbers entered on Exchange applications may not be the personal number or business number of the agent, broker, or web-broker assisting the consumer, or their business or agency, unless the telephone number is actually that of the consumer or their authorized representative.

(C) Only entering a mailing address on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost sharing reductions for QHPs that belongs to, or is primarily accessible by, the consumer or their authorized representative designated in compliance with § 155.227, is not for the exclusive or convenient use of the agent, broker, or web-broker, and is an actual residence or a secure location where the consumer or their authorized representative may receive correspondence, such as a P.O. Box or homeless shelter. Mailing addresses entered on Exchange applications may not be that of the agent, broker, or web-broker assisting the consumer, or their business or agency, unless the address is the actual residence of the consumer or their authorized representative.

(D) When submitting household income projections used by the Exchange to determine a tax filer's eligibility for advance payments of the premium tax credit in accordance with § 155.305(f) or cost-sharing reductions in accordance with § 155.305(g), only entering a consumer's household income projection that the consumer or the consumer's authorized representative designated in compliance with § 155.227 has knowingly authorized and confirmed as accurate. Household income projections on Exchange applications must be calculated and attested to by the consumer. The agent, broker, or web-broker assisting the consumer may answer questions posed by the consumer related to household income projection, such as helping the consumer determine what qualifies as income.

* * * * *

(vi) Not engage in scripting and other automation of interactions with CMS Systems or the Direct Enrollment Pathways, unless approved in advance in writing by CMS.

(vii) Only use an identity that belongs to the consumer when identity proofing the consumer's account on *HealthCare.gov*.

(viii) When providing information to federally-facilitated Exchanges that may result in a determination of eligibility for a special enrollment period in accordance with § 155.420, obtain authorization from the consumer to submit the request for a determination of eligibility for a special enrollment period and make the consumer aware of the specific triggering event and special enrollment period for which the agent, broker, or web-broker will be submitting an eligibility determination request on the consumer's behalf.

* * * * *

■ 13. Amend § 155.240 by adding paragraph (e)(2) to read as follows:

§ 155.240 Payment of premiums.

* * * * *

(e) * * *

(2) For plan years 2024 and beyond, in each Exchange, the premium for a policy in which an enrollee is enrolled for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, must equal the product of:

(i) The premium for 1 month of coverage divided by the number of days in the month; and

(ii) The number of days for which coverage is being provided in the month described in paragraph (e)(1)(i) of this section.

■ 14. Amend § 155.305 by revising paragraph (f)(1)(i) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(1) * * *

(i) He or she is expected to have a household income that will qualify the tax filer as an applicable taxpayer according to 26 CFR 1.36B–2(b) for the benefit year for which coverage is requested; and

* * * * *

■ 15. Amend § 155.320 by—

■ a. Revising paragraphs (d)(4) introductory text, (d)(4)(i) introductory text, and (d)(4)(i)(A);

■ b. Removing paragraph (d)(4)(i)(D).

■ c. Redesignating paragraph (d)(4)(i)(E) as paragraph (d)(4)(i)(D).

■ d. Removing paragraph (d)(4)(i)(F);

■ e. Redesignating paragraph (d)(4)(i)(G) as paragraph (d)(4)(i)(E) and revising it; and

■ f. Removing and reserving paragraph (d)(4)(ii).

The revisions read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(d) * * *

(4) *Alternate procedures.* For any benefit year for which it does not reasonably expect to obtain sufficient

verification data as described in paragraphs (d)(2)(i) through (iii) of this section, the Exchange may follow the procedures specified in paragraph (d)(4)(i) of this section, or the Exchange may follow the procedures specified in paragraph (d)(4)(ii) of this section. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for any benefit year when, for the benefit year, the Exchange is able to obtain data about enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan from at least one electronic data source that is available to the Exchange and that has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described under paragraphs (d)(2)(i) of this section.

(i) Based on the Exchange's assessment of risk for inappropriate payment of advance payments of the premium tax credit or cost-sharing reductions, implement a verification process that is reasonably designed to ensure the accuracy of the data and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data, for enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan, as appropriate.

(A) If, as part of the verification process described under paragraph (d)(4)(i) of this section, the Exchange will be contacting any employer identified on the application for the applicant and the members of his or her family, as defined in 26 CFR 1.36B–1(d), to verify whether the applicant is enrolled in an eligible employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan for the benefit year for which coverage is requested, the Exchange must provide notice to the applicant;

* * * * *

(E) To carry out the process described in paragraph (d)(4)(iii) of this section, the Exchange must only disclose an individual's information to an employer to the extent necessary for the employer to identify the employee.

* * * * *

■ 16. Amend § 155.340 by adding paragraph (i) to read as follows:

§ 155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(i) *Calculation of advance payments of the premium tax credit when policy coverage lasts less than the full coverage month.* (1) For plan years beginning in 2024 and beyond, when the Exchange determines that an individual is eligible for advance payments of the premium tax credit and the enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, the amount of the advance payment of the premium tax credit paid to the issuer of the policy must equal the product of—

(i) The advance payments of the premium tax credit applied to the policy for one month of coverage divided by the number of days in the month; and

(ii) The number of days for which coverage is being provided in the month under the policy described in paragraph (i)(1)(i) of this section.

(2) [Reserved]

■ 17. Amend § 155.420 by adding paragraph (g) to read as follows:

§ 155.420 Special enrollment periods.

* * * * *

(g) *Pre-enrollment special enrollment period verification.* At the option of the Exchange, an Exchange may verify prior to processing a qualified individual's plan selection that the qualified individual is eligible for a special enrollment period under this section. In special circumstances where the Exchange determines that such pre-enrollment special enrollment period verification may cause undue burden on qualified individuals, the Exchange may provide an exception to the pre-enrollment special enrollment period verification process, provided it does so in a manner that is not based on a prohibited discriminatory basis. Exchanges on the Federal platform will conduct pre-enrollment special enrollment verification of eligibility only for special enrollment periods under paragraph (d)(1) of this section.

■ 18. Amend § 155.1200—

■ a. In paragraph (c) introductory text by removing the phrase ''HHS for review'' and adding in its place the phrase, ''HHS for review, unless a State Exchange is meeting its programmatic audit requirement for a given benefit year under paragraph (e) of this section''; and

■ b. By adding paragraph (e).

The addition reads as follows.

§ 155.1200 General program integrity and oversight requirements.

* * * * *

(e) *State Exchange Improper Payment Measurement (SEIPM) program.* For a given benefit year, a State Exchange may meet the independent external programmatic audit requirement outlined in paragraph (c) of this section by completing the required SEIPM program process, established through 45 CFR part 155, subpart P.

■ 19. Add subpart P to read as follows:

Subpart P—State Exchange Improper Payment Measurement Program

Sec.
155.1500 Purpose and definitions.
155.1505 Program notification and planning process.
155.1510 Data collection.
155.1515 Review process and improper payment rate determination.
155.1520 Error findings decisions.
155.1525 Redetermination of error findings decisions.
155.1530 Appeal of redetermination decision.
155.1535 Corrective action plan.
155.1540 Failure to comply.

Subpart P—State Exchange Improper Payment Measurement Program

§ 155.1500 Purpose and definitions.

(a) *Purpose.* This subpart sets forth the requirements of the State Exchange Improper Payment Measurement program.

(b) *Definition*s. As used in this subpart—

Appeal of redetermination decision (or appeal decision) means the HHS appeal decision resulting from a State Exchange's appeal of the HHS' redetermination decision.

Corrective action plan (CAP) means the plan a State Exchange develops in order to correct errors resulting in improper payments.

Error means a finding by HHS that a State Exchange did not correctly apply a requirement in subparts D and E of this part regarding eligibility for and enrollment in a qualified health plan; advance payments of the premium tax credit, including the calculation of advance payments of the premium tax credit; redeterminations of eligibility determinations during a benefit year; or annual eligibility redeterminations, which have a payment impact.

Error findings decision means the enumeration of errors made by a State Exchange, including a determination of how the enumerated errors inform improper payment estimation and reporting requirements.

Redetermination of an error findings decision (or redetermination decision) means HHS' decision resulting from a State Exchange's request for a redetermination of an error findings decision.

Review means the process of analyzing and assessing data submitted by a State Exchange to HHS in order to determine a State Exchange's

compliance with subparts D and E of this part as it relates to improper payments.

State Exchange Improper Payment Measurement (SEIPM) program means the process for determining estimated improper payments and other information required under the Payment Integrity Information Act of 2019, and implementing guidance, for advance payments of the premium tax credit, which includes a review of a State Exchange's determinations regarding eligibility for and enrollment in a qualified health plan; the calculation of advance payments of the premium tax credit; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations.

§ 155.1505 Program notification and planning process.

(a) *Annual program notification.* Beginning no earlier than in 2023, prior to the start of the measurement year, HHS will annually issue a notification to State Exchanges concerning information related to the SEIPM program and the program's upcoming measurement cycle, which may include but would not be limited to review criteria; key changes from prior measurement cycles, where applicable; or other modifications regarding specific SEIPM activities.

(b) *Issuance of annual program schedule.* Beginning no earlier than 2023, prior to the start of the measurement year, HHS will annually issue a schedule that prescribes the timeline for the data requests in accordance with § 155.1510.

(c) *Notification of changes.* In response to the annual program notification, the State Exchange must provide HHS with operational and policy information required to perform the SEIPM review process, as well as any operational, policy, or other changes that may impact the SEIPM review process within the deadline prescribed in the annual program schedule.

§ 155.1510 Data collection.

(a) *Requirements.* For purposes of the SEIPM program, a State Exchange must annually submit the following eligibility and enrollment information, in a manner specified by HHS.

(1) Pre-sampling data.

(2) Sampled unit data.

(b) *Timing.* The State Exchange must submit the data specified in paragraph (a) of this section within the timelines specified in the annual program schedule described in § 155.1505(c). HHS will consider requests for extension when extreme circumstances hinder the ability of a State Exchange to submit data in accordance with the requirements of this section.

(c) *Compliance.* Failure to timely provide the information in accordance with paragraph (a) or (b) of this section may result in one or more error findings during the review based upon insufficient data to support that the State was in compliance with subparts D and E of this part as it relates to advance payments of premium tax credits.

§ 155.1515 Review process and improper payment rate determination.

(a) *Receipt of data.* HHS will maintain a record of status of receipt for the information that is requested from each State Exchange for a minimum of 10 years.

(b) *Review of records.* For each sampled record, HHS will review the information provided by the State Exchange. The review will determine whether any errors were made in a State Exchange's determinations regarding eligibility for and enrollment in a qualified health plan; advance payments of the premium tax credit, including the calculation of advance payments of the premium tax credit; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations.

(c) *Improper payment rate.* HHS will notify each State Exchange of HHS' error findings decisions for that State Exchange and HHS' estimate of that State Exchange's improper payment rate.

§ 155.1520 Error findings decisions.

(a) *Issuance of error findings decisions.* Upon completion of the review, HHS will issue the error findings decision to the State Exchange.

(b) *Content of error findings decision.* The error findings decisions at a minimum will include:

(1) The review findings regarding any errors made by the State Exchange.

(2) Information regarding the State Exchange's right to request a redetermination of the error findings decision in accordance with § 155.1525.

§ 155.1525 Redetermination of error findings decisions.

(a) *Request for redetermination.* A State Exchange may request a redetermination of error findings decision within the deadline prescribed by the annual program schedule. During the period for a State Exchange to request a redetermination of the error findings decision, HHS will consider a request for an extension in extreme circumstances, which includes but is not limited to situations such as natural disasters, interruptions in business operations such as major system failures, or other extreme circumstances. At a minimum, the request for redetermination must include:

(1) The error(s) for which the State Exchange is requesting a redetermination;

(2) All data and information that supports the State Exchange's request for a redetermination; and

(3) An explanation of how the data and information pertains to the error(s) specified in (a)(1).

(b) *Issuance of redetermination decision.* The redetermination of an error findings decision will be issued within the deadline prescribed by the annual program schedule. A State Exchange will be notified of any delays in the issuance in the redetermination of an error findings decision.

(c) *Content of redetermination decision.* HHS' redetermination of an error findings decision, at a minimum, will include:

(1) HHS' findings regarding the impact of the additional data and information provided by the State Exchange on the error(s) for which the State Exchange requested a redetermination,

(2) Information regarding the State Exchange's right to request an appeal of the redetermination of the error findings decision in accordance with § 155.1530.

§ 155.1530 Appeal of redetermination decision.

(a) *Request for appeal.* A State Exchange may request an appeal of a redetermination decision within the deadline prescribed by the annual program schedule. The request for appeal must indicate the specific error(s) identified in the redetermination decision for which the State Exchange is requesting an appeal.

(b) *On-the-record review.* Additional data or information, beyond that submitted during the redetermination request, will not be considered in rendering the appeal decision.

(c) *Issuance of appeal decision.* The appeal decision will be issued within the deadline prescribed in the annual program schedule unless there is a delay. A State Exchange will be notified of any delays in the issuance of the appeal decision.

(d) *Content of appeal decision.* HHS' appeal decision will include:

(1) The findings regarding the error(s) for which an appeal was requested. The findings will be limited to those error(s) identified in the request for an appeal.

(2) The final disposition of the appeal request.

(e) *Final report.* Upon completion of the review and the closure of all appeals, HHS may issue a report containing the error findings and the estimated improper payment rate.

§ 155.1535 Corrective action plan.

(a) *Corrective action plan.* Based on a State Exchange's error rate for a given benefit year, HHS, in its reasonable discretion, may require the State Exchange to develop and submit a corrective action plan to correct errors resulting in improper payments.

(b) *Content of proposed corrective action plan.* A State Exchange's corrective action plan must be developed in accordance with Appendix C to Office of Management and Budget Circular No. A–123.

(c) *Implementation and evaluation of corrective action plan.* A State Exchange must develop an implementation schedule for its corrective action plan, implement the plan in accordance with that schedule, and regularly evaluate whether the initiatives are effective at reducing or eliminating error causes.

(d) *Failure to submit.* If a State Exchange does not submit a corrective action plan when required, HHS may take actions consistent with § 155.1540(a)(1) and (2).

§ 155.1540 Failure to comply.

(a) *Failure to comply.* If a State Exchange fails to substantially comply with the data collection requirements or the CAP provisions contained in this subpart, and HHS finds that such failures undermine or prohibit HHS's efficient administration of Exchange improper payment measurement activities, HHS may implement measures or procedures in relation to the State Exchange that:

(1) HHS determines are appropriate to secure the State Exchange's compliance with the data collection requirements or the CAP provisions contained in subpart P, and to detect, prevent or reduce abuses in the administration of advance payments of the premium tax credit under title I of the ACA; and

(2) the Secretary has authority to implement under title I of the Affordable Care Act or any other Federal law.

(b) [Reserved]

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 20. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 21. Amend § 156.50 by—

■ a. Removing paragraph (c)(3); and

■ b. Revising paragraphs (d)(1) introductory text, (d)(2)(i)(A) and (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3) introductory text, (d)(4) and (6), and (d)(7) introductory text.

The revisions read as follows:

§ 156.50 Financial support.

* * * * *

(d) * * *

(1) A participating issuer offering a plan through a federally-facilitated Exchange or State Exchange on the Federal platform may qualify for an adjustment of the federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section or the State Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, to the extent that the participating issuer—

* * * * *

(2) * * *

(i) * * *

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable; and

* * * * *

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the federally-facilitated Exchange user fee or the State-based Exchange on the Federal platform user fee based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4).

(iii) * * *

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable;

* * * * *

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, equal in value to the sum of the following:

* * * * *

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

* * * * *

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1) or (2) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

* * * * *

■ 22. Amend § 156.111 by—

■ a. Revising the section heading;

■ b. Revising paragraph (d) and paragraph (e) introductory text; and

■ c. Removing paragraph (f).

The revisions read as follows:

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

* * * * *

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by the first Wednesday in May that is 2 years before the effective date of the new EHB-benchmark plan.

(1) If the State does not make a selection by the first Wednesday in May that is 2 years before the effective date of the new EHB-benchmark plan, or its benchmark plan selection does not meet the requirements of this section and section 1302 of the ACA, the State's EHB-benchmark plan for the applicable plan year will be that State's EHB-benchmark plan applicable for the prior year.

(2) [Reserved]

* * * * *

(e) A State changing its EHB-benchmark plan under this section must submit documents in a format and manner specified by HHS by the first Wednesday in May that is 2 years before the effective date of the new EHB-benchmark plan. These must include:

* * * * *

■ 23. Amend § 156.115 by revising paragraph (b)(2) to read as follows:

§ 156.115 Provision of EHB.

* * * * *

(b) * * *

(2) An issuer may substitute a benefit within the same EHB category, unless prohibited by applicable State requirements. Substitution of benefits between EHB categories is not permitted.

* * * * *

■ 24. Amend § 156.125 by revising paragraph (a) to read as follows:

§ 156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefits design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. A non-discriminatory benefit design that provides EHB is one that is clinically-based, incorporates evidence-based guidelines into coverage and programmatic decisions, and relies on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources.

* * * * *

■ 25. Amend § 156.140 by revising paragraph (c) to read as follows:

§ 156.140 Levels of coverage.

* * * * *

(c) *De minimis variation.* (1) For plan years beginning on or after January 1, 2018 through December 31, 2022, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −4 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −4 percentage points and +5 percentage points.

(2) For plan years beginning on or after January 1, 2023, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −2 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −2 percentage points and +5 percentage points.

■ 26. Amend § 156.200—

■ a. By revising paragraph (b)(3); and

■ b. In paragraph (e) by removing the phrase ''age, or sex'' and adding in its place the phrase ''age, sex, sexual orientation, or gender identity''.

The revision read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(b) * * *

(3) Ensure that each QHP complies with benefit design standards, as defined in § 156.20, except that individual market silver QHPs must have an AV of 70 percent, with a de minimis allowable AV variation of −0 percentage points and +2 percentage points;

* * * * *

■ 27. Add § 156.201 to read as follows:

§ 156.201 Standardized options.

For plan year 2023 and subsequent plan years, a QHP issuer in a federally-facilitated Exchange or a State-based Exchange on the Federal platform, other than an issuer that is already required to offer standardized options under state action taking place on or before January 1, 2020, must offer at least one standardized QHP option, defined at § 155.20 of this subchapter, at every product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, metal level, and throughout every service area that it also offers non-standardized QHP options, including, for silver plans, for the income-based cost-sharing reduction plan variations, as provided for at § 156.420(a), but not for the zero and limited cost sharing plan variations, as provided for at § 156.420(b).

■ 28. Amend § 156.230 by—

■ a. Revising paragraphs (a)(1) through (3); and,

■ b. Removing paragraph (f).

The revisions read as follows:

§ 156.230 Network adequacy standards.

(a) * * *

(1) Each QHP issuer that uses a provider network must ensure that the provider network consisting of in-network providers, and, for plans with more than one tier of network, specifically the provider network consisting of in-network providers in the tier for which the plan imposes the lowest cost-sharing obligation, as available to all enrollees, meets the following standards:

(i) Includes essential community providers in accordance with § 156.235;

(ii) Maintains a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to ensure that all services will be accessible without unreasonable delay; and

(iii) Is consistent with the rules for network plans of section 2702(c) of the PHS Act.

(2)(i) *Standards.* For plan years beginning on or after January 1, 2023, a QHP issuer on a federally-facilitated Exchange must comply with the requirement in paragraph (a)(1)(ii) of this section by:

(A) Meeting time and distance standards established by the federally-facilitated Exchange. Such time and distance standards will be developed for consistency with industry standards and published in guidance.

(B) Meeting appointment wait time standards established by the federally-facilitated Exchange. Such appointment wait time standards will be developed for consistency with industry standards and published in guidance.

(ii) *Written justification.* If a plan applying for QHP certification to be offered through a federally-facilitated

Exchanges does not satisfy the network adequacy standards described in paragraphs (a)(2)(i)(A) and (B) of this section, the issuer must include as part of its QHP application a justification describing how the plan's provider network provides an adequate level of service for enrollees and how the plan's provider network will be strengthened and brought closer to compliance with the network adequacy standards prior to the start of the plan year. The issuer must provide information as requested by the FFE to support this justification.

(3) The federally-facilitated Exchange may grant an exception to the requirements in paragraph (a)(2)(i)(A) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates.

* * * * *

■ 29. Amend § 156.235 by revising paragraphs (a)(2)(i) and (b)(2)(i) to read as follows:

§ 156.235 Essential community providers.

(a) * * *

(2) * * *

(i) The network includes as participating providers at least a minimum percentage, as specified by HHS, of available essential community providers in each plan's service area. Multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the essential community provider standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers will be counted towards essential community provider standards; and

* * * * *

(b) * * *

(2 * * *

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal poverty level satisfies a minimum percentage, specified by HHS, of available essential community providers in the plan's service area. Multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the essential community provider standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards essential community provider standards; and

* * * * *

Subpart D—Standards for Qualified Health Plan Issuers for Specific Types of Exchanges

■ 30. Revise the subpart D heading to read as set forth above.

■ 31. Amend § 156.340 by revising paragraphs (a) and (b)(4) and (5) to read as follows:

§ 156.340 Standards for downstream and delegated entities.

(a) *General requirement.* Effective October 1, 2013, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities with all applicable Federal standards related to Exchanges. The applicable standards depend on the Exchange model type in which the QHP is offered, as described in paragraph (a)(1) and (2) of this section.

(1) QHP issuers participating in Exchange models that do not use the Federal platform, including State Exchanges and State Exchange SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with the Federal standards related to Exchanges, including the standards in of subpart C of this part with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, §§ 155.705 and 155.706 of this subchapter, unless the standard is specifically applicable to a federally-facilitated Exchange or FF–SHOP;

(2) QHP issuers participating in Exchanges that use the Federal platform, including federally-facilitated Exchanges, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with Federal standards related to Exchanges, including the standards in subpart C of part 156 with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 of this subchapter and, in the small group market, §§ 155.705 and 155.706 of this subchapter if applicable to the Exchange type in which the QHP issuer is operating. QHP issuers are also responsible for their downstream and delegated entities' compliance with the standards of § 155.220 of this subchapter with respect to assisting with enrollment in QHPs, and to the standards of §§ 156.705 and 156.715 of this subchapter for maintenance of records and compliance reviews if applicable to the Exchange type in which the QHP issuer is operating.

(b) * * *

(4) Specify that the delegated or downstream entity must permit access by the Secretary and the OIG or their designees in connection with their right to evaluate through audit, inspection, or other means, to the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period;

(5) All agreements between issuers offering QHPs through an Exchange and delegated or downstream entities the issuers engage to support the issuer's activities on an Exchange must include text under which the language stating that the relevant Exchange authority may demand and receive the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period.

■ 32. Amend § 156.400 by revising the definition of ''De minimis variation for a silver plan variation'' to read as follows:

§ 156.400 Definitions.

* * * * *

De minimis variation for a silver plan variation means a −0 percentage point

and +1 percentage point allowable AV variation.

* * * * *

■ 33. Amend § 156.430 by revising paragraphs (b)(1), (d) introductory text, (e) introductory text, and (e)(1) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

* * * * *

(b) * * *

(1) When there is an appropriation to make cost-sharing reduction payments to QHP issuers, a QHP issuer will receive periodic advance payments from HHS to the extent permitted by the appropriation and calculated in accordance with § 155.1030(b)(3) of this subchapter.

* * * * *

(d) *Cost-sharing reductions data submissions.* HHS will periodically provide a submission window for issuers to submit cost-sharing reduction data documenting cost-sharing reduction amounts issuers paid, as specified in paragraphs (d)(1) and (2) of this section, in a form and manner specified by HHS in guidance, calculated in accordance with paragraph (c) of this section. When HHS makes cost-sharing reduction payments to QHP issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is mandatory for those issuers having received cost-sharing reduction payments for any part of the benefit year and voluntary for other issuers, and HHS will use the data to reconcile advance cost-sharing reduction payments to issuers against the actual amounts of cost-sharing reductions QHP issuers provided, as determined by HHS based on amounts specified in paragraphs (d)(1) and (2) of this section, as calculated in accordance with paragraph (c) of this section. In the absence of an appropriation to make cost-sharing reduction payments to issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is voluntary. The cost-sharing data that must be submitted in either a voluntary or mandatory submission includes:

* * * * *

(e) *Cost-sharing reductions payments and charges.* If the actual amounts of cost-sharing reductions determined by HHS based on amounts described in paragraphs (d)(1) and (2) of this section are—

(1) More than the amount of advance payments HHS provided, and the QHP issuer has timely provided the data of actual amounts of cost-sharing reductions as required under paragraph (c) of this section, if an appropriation is available to make cost-sharing payments to QHP issuers, HHS will make a payment to the QHP issuer for the difference; or

* * * * *

§ 156.1230 [Amended]

■ 34. Amend § 156.1230 in paragraph (b)(2) by removing the phrase ''age, or sex'' and adding in its place the phrase ''age, sex, sexual orientation, or gender identity''.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 35. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 36. Amend § 158.140 by revising paragraph (b)(2)(iii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(2) * * *

(iii) The amount of incentive and bonus payments made to providers that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

* * * * *

■ 37. Amend § 158.150 by revising paragraph (a) to read as follows:

§ 158.150 Activities that improve health care quality.

(a) *General requirements.* The report required in § 158.110 must include expenditures directly related to activities that improve health care quality, as such activities are described in this section.

* * * * *

■ 38. Amend § 158.170 by revising paragraph (b) introductory text to read as follows:

§ 158.170 Allocation of expenses.

* * * * *

(b) *Description of the methods used to allocate expenses.* The report required in § 158.110 must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

* * * * *

Dated: December 23, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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