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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

[CMS-9911-F]

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: Final rule.

SUMMARY: This final rule includes payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs, as well as 2023 user fee rates for issuers offering qualified health plans (QHPs) through Federally-facilitated Exchanges (FfEs) and State-based Exchanges on the Federal platform (SBE-FPs). This final rule also includes requirements related to guaranteed availability; the offering of QHP standardized plan options through Exchanges on the Federal platform; requirements for agents, brokers, and web-brokers; 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; and re-enrollment. This final rule also responds to comments on how the Department of Health and Human Services (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: These regulations are effective July 1, 2022.

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Background?

In the proposed rule, “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023” (87 FR 584), published in the January 5, 2022 edition of the **Federal Register** (2023 Payment Notice proposed rule), HHS proposed amendments to certain regulations prohibiting discrimination in health insurance coverage, including discrimination in the design and implementation of health plans, under §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) under title 45 of the Code of Federal Regulations (CFR). HHS proposed to amend these regulations to explicitly identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex consistent with the Supreme Court’s decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), and HHS nondiscrimination policy that existed prior to the 2020 regulatory amendments HHS made in conformance with the “Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority” final rule (85 FR 37160),

published in the June 19, 2020 edition of the **Federal Register**.¹ In connection with discriminatory benefit designs prohibited under § 156.125, HHS also included in the proposed rule an example related to gender-affirming care that was intended to illustrate a health plan design that presumptively discriminates against enrollees based on gender identity.

Currently, HHS is developing a proposed rule² that also will address prohibited discrimination based on sex in health coverage under section 1557 of the Patient Protection and Affordable Care Act (ACA)³ (42 U.S.C. 18116). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in 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 its amendments. Because HHS' proposed rule implementing section 1557 of the ACA will also address issues related to prohibited discrimination based on sex, HHS is of the view that it would be most prudent to address the nondiscrimination proposals related to sexual orientation and gender identity in the 2023 Payment Notice proposed rule at a later time, to ensure that they are consistent with the policies and requirements that will be included in the section 1557 rulemaking. Therefore, HHS will not address in this final rule the nondiscrimination proposals related to sexual orientation and gender identity included in the 2023 Payment Notice proposed rule or the comments submitted in response to those proposals.

HHS is committed to robust civil rights protections in health care for all consumers, including protections to combat discrimination on the basis of gender identity or sexual

¹ See also 85 FR 37160, 37218 through 21 (the 2020 final rule implementing section 1557 of the ACA revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

² HHS submitted a draft notice of proposed rulemaking addressing section 1557 of the Patient Protection and Affordable Care Act and its implementing regulations to the Office of Management and Budget on or around March, 22, 2022. See <https://www.reginfo.gov/public/do/eoDetails?rrid=234566>.

³ 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."

orientation.⁴ Moreover, to the extent that entities subject to the relevant regulations prohibiting discrimination in health insurance coverage are also covered by section 1557, they are already under the statutory obligation not to discriminate on the basis of sex.⁵ Consistent with the Supreme Court’s decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), and the HHS Notice of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 (86 FR 27984), published in the May 25, 2021 edition of the **Federal Register**, HHS will continue to interpret and enforce section 1557 of the ACA and its protections against sex discrimination to prohibit discrimination on the basis of sexual orientation and gender identity in all aspects of health insurance coverage governed by section 1557.⁶ Thus, notwithstanding that the Department will address in future rulemaking the proposals related to sexual orientation and gender identity and the example related to gender-affirming care, HHS will continue to scrutinize the activities of covered health plans to root out practices that unlawfully discriminate on the basis of sexual orientation or gender identity. HHS’ interpretation of section 1557 will guide HHS in processing complaints and conducting investigations, but does not itself determine the outcome in any particular case or set of facts. In enforcing Section 1557, HHS will comply with the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.*, and all other legal requirements.⁷

I. Executive Summary

⁴ HHS’ proposals related to sexual orientation and gender identity in the 2023 Payment Notice proposed rule resulted, in part, from reviews HHS conducted as directed in President Biden’s January 20, 2021, Executive Order 13988 (86 FR 7023), which stated the Administration’s policy on preventing and combating discrimination on the basis of gender identity and sexual orientation and the President’s conclusion that “[u]nder *Bostock*’s reasoning, laws that prohibit sex discrimination . . . , along with their respective implementing regulations — prohibit discrimination on the basis of gender identity or sexual orientation, so long as the laws do not contain sufficient indications to the contrary.” 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 construction of the laws, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with that policy and construction.

⁵ See 85 FR 37219 (explaining that section 1557 governs entities established under Title I of the ACA, including Exchanges).

⁶ See also *Hammons v. Univ. of Maryland Med. Sys. Corp.*, No. 20-cv-2009, 2021WL 3190492, at *17 (D. Md. July 28, 2021) (stating *Bostock* “made clear that the position stated in HHS’s [Bostock Notice] was already binding law”).

⁷ 86 FR 27985.

American Health Benefit Exchanges, or “Exchanges,” are entities established under the ACA 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 final rule, we amend some of these provisions and parameters, with a focus on maintaining a stable regulatory environment. These changes are intended to provide issuers with greater predictability for upcoming plan years (PYs), while simultaneously enhancing the role of States in these programs. They will also provide States with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability.

Risk adjustment continues to be a core program in the individual, small group, and merged markets both on and off Exchanges. We published a technical paper, the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes⁸ in October 2021 (2021 RA Technical Paper), and sought comment on three potential updates to the risk adjustment models. We are finalizing two of the three proposed updates to the HHS risk adjustment models beginning with the 2023 benefit year. Specifically, beginning with the 2023 benefit year, we are finalizing the removal of the current severity illness factors from the adult models and the addition of an interacted hierarchical condition category (HCC) count model specification to the

⁸ *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

adult and child models. We also are finalizing the replacement of the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors. We are not finalizing the proposed model specification change to add a two-stage weighted approach to the adult and child models. We are finalizing the use of the 2017, 2018, and 2019 enrollee-level External Data Gathering Environment (EDGE) data to recalibrate the 2023 benefit year risk adjustment models. For 2023, we are also finalizing the continued application of 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.

In addition, we are finalizing 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.⁹ We are also finalizing, for the 2024 benefit year and beyond, the proposal 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 will 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 will 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 are finalizing the proposal to repeal the ability of States, other than prior participants, to request a reduction in risk adjustment State transfers starting with the 2024 benefit year. We are also finalizing the changes that limit a prior participant's ability to request a reduction in risk adjustment transfers under § 153.320(d) to only those that meet the *de minimis* threshold criteria. In future rulemaking, HHS intends to propose to eliminate the prior participant exception starting with the 2025 benefit year. For the 2023 benefit year, we are announcing

⁹ 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.

approval of Alabama’s request to reduce risk adjustment State transfers for its individual and small group markets, but at lower percentages than requested. We approve a 25 percent reduction in Alabama’s individual market transfers (including the catastrophic and non-catastrophic risk pools) and a 10 percent reduction in Alabama’s small group market transfers for the 2023 benefit year.

We are finalizing the 2023 benefit year risk adjustment user fee for States where HHS operates the risk adjustment program of \$0.22 per member per month (PMPM). We are also finalizing the proposal to collect and extract five new data elements as part of the enrollee-level EDGE data beginning with the 2023 benefit year. We are also finalizing the proposal to extract three data elements issuers already report to their EDGE servers – plan ID, rating area, and subscriber indicator – as part of the required risk adjustment data. Plan ID and rating area will be extracted beginning with the 2021 benefit year, and subscriber indicator will be extracted beginning with the 2022 benefit year.

Finally, we are finalizing 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 will 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 are finalizing as proposed the refinements to the HHS risk adjustment data validation (HHS-RADV) error estimation methodology beginning with the 2021 benefit year to: (1) extend the application of Super HCCs¹⁰ (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

¹⁰ As finalized in this rule, beginning with the 2021 benefit year of HHS-RADV, a Super HCC will be defined as the aggregate de-duplicated frequencies of EDGE HCCs that share an HCC coefficient estimation group determined based on the enrollees’ risk adjustment model.

on the CCIIO website¹¹) 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, except when the child and adult coefficient estimation groups have identical definitions; 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 are finalizing updated parameters for the individual and small group markets. For the PY 2023, we are maintaining FFE and SBE-FP user fees at the current PY 2022 rates, 2.75 and 2.25 percent of total monthly premiums, respectively. On December 28, 2021, we released the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage for the 2023 Benefit Year guidance setting forth these parameters for PY 2023.¹²

We are not finalizing the proposal to require all Exchanges to prorate premiums and advance payments of the premium tax credit (APTC). After considering the comments received, we are finalizing the policy to clarify the APTC proration methodology which Exchanges on the Federal platform will be subject to under HHS' authority to administer APTC, but we are not finalizing the requirement for State Exchanges to prorate premium or APTC amounts as described in the proposed rule. Rather, beginning in PY 2024, State Exchanges must report to HHS through existing State Exchange oversight mechanisms the methodology the State Exchange will use that does not cause total monthly APTC amounts to exceed an enrollee's monthly PTC eligibility. This will ensure compliance with HHS and Internal Revenue Service (IRS) regulations particularly when an enrollee is enrolled in a policy for less than the full

¹¹ *Regulations and Guidance*. (2022). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance>. The January 7, 2022 version of the DIY software is available at *2021 Benefit Year Risk Adjustment Updated HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software*. (2022). CMS.

¹² *Premium Adjustment Percentage*. (2021, December 28). CMS. <https://www.cms.gov/files/document/2023-papi-parameters-guidance-v4-final-12-27-21-508.pdf>.

coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month.

We are finalizing 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 that did not. We also finalize 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 are finalizing 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 also finalize policies to address certain agent, broker, and web-broker practices. These policies will be added as part of the FFE standards of conduct codified at § 155.220(j)(2), improving CMS’ ability to enforce existing responsibilities and requirements applicable to agents, brokers, and web-brokers participating in the FFEs and SBE-FPs, while also providing more detail about specific business practices that are prohibited.

We are finalizing a revision to our interpretation of the guaranteed availability requirement to prohibit 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 are finalizing flexibility under which Exchanges may conduct risk-based employer sponsored coverage verification in connection with eligibility determinations for APTC. This policy will help States more effectively balance the need to prevent improper APTC payments with the costs of verification.

We are finalizing amendments to implementing regulations to codify existing MLR policy 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 are also updating the MLR regulations to 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, we are finalizing a technical amendment to the MLR provisions 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 rescinded the provision in a final rule published in the **Federal Register** on May 5, 2021 (86 FR 24140) (part 2 of the 2022 Payment Notice final rule).

With regard to the EHBs, we are finalizing a permanent annual deadline in early-May for EHB-benchmark plan applications by States, as well as the repeal of the ability for States to permit issuers to substitute benefits between EHB categories. In addition, we are finalizing changes to the *de minimis* thresholds for the 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 finalize the proposal to remove the State annual reporting requirement to report State-required benefits in addition to the EHB to HHS.

We are finalizing 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. We will begin implementation of appointment wait time standards in PY 2024. We are also finalizing the requirement for issuers to submit information about whether providers offer telehealth services. For plans with tiered networks, we are finalizing that, to count toward the issuer's satisfaction of the essential community provider (ECP) standards, providers must be contracted within the network tier that results in the lowest

cost-sharing obligation. This rule finalizes that the ECP threshold will increase from 20 percent to 35 percent.

We are finalizing the proposed amendments to the current HHS regulation that establishes standards for QHP issuer downstream and delegated entities. These changes will 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 solicited 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 finalize the proposal 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 proposed and are finalizing policies related to requirements that issuers of QHPs in FFEs and SBE-FPs offer standardized QHP options through the Exchange beginning in PY 2023.

Finally, we solicited 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 and provide responses to the public comments received.

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.¹³

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”.

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.

¹³ 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 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) of the ACA establishes 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.¹⁴

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 QHPs offered through Exchanges and (2) assist individuals in applying for PTC and CSRs for QHPs 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

¹⁴ 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.

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 Revised¹⁵ 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.

¹⁵ Office of Management and Budget. (2004). *Circular A-25 Revised*. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>.

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

Section 1411(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.¹⁶ 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, 2018.¹⁷ 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

The premium stabilization programs refer to the risk adjustment, risk corridors, and reinsurance programs established by the ACA.¹⁸ For past rulemaking, we refer readers to the following rules:

- In the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule), we implemented the premium stabilization programs.

- In the March 11, 2013 **Federal Register** (78 FR 15409) (2014 Payment Notice), we finalized the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs.

- In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the modification to the HHS-operated methodology related to community rating States.

¹⁶ 42 U.S.C. 18116.

¹⁷ Pub. L. 115-97, 131 Stat. 2054 (2017).

¹⁸ See 42 U.S.C. 18061, 18062, and 18063.

- In the November 6, 2013 **Federal Register** (78 FR 66653), we published a correcting amendment to the 2014 Payment Notice final rule to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

- In the March 11, 2014 **Federal Register** (79 FR 13743) (2015 Payment Notice), we finalized the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions and established payment parameters in those programs.

- In the May 27, 2014 **Federal Register** (79 FR 30240), we announced the 2015 fiscal year sequestration rate for the risk adjustment program.

- In the February 27, 2015 **Federal Register** (80 FR 10749) (2016 Payment Notice), we finalized the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and established the payment parameters in those programs.

- In the March 8, 2016 **Federal Register** (81 FR 12203) (2017 Payment Notice), we finalized the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions and established the payment parameters in those programs.

- In the December 22, 2016 **Federal Register** (81 FR 94058) (2018 Payment Notice), we finalized the benefit and payment parameters for the 2018 benefit year, added the high-cost risk pool parameters to the HHS risk adjustment methodology, incorporated prescription drug factors in the adult models, established enrollment duration factors for the adult models, and finalized policies related to the collection and use of enrollee-level EDGE data.

- In the April 17, 2018 **Federal Register** (83 FR 16930) (2019 Payment Notice), we finalized the benefit and payment parameters for 2019 benefit year, created the State flexibility framework permitting States to request a reduction in risk adjustment State transfers calculated by HHS, and adopted a new methodology for HHS-RADV adjustments to transfers.

- In the May 11, 2018 **Federal Register** (83 FR 21925), we published a correction to the 2019 risk adjustment coefficients in the 2019 Payment Notice final rule.
- On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level EDGE dataset.¹⁹
- In the July 30, 2018 **Federal Register** (83 FR 36456), we 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). The final rule set forth an additional explanation of the rationale supporting the 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. The 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 the publication of the final rule.²⁰
- In the December 10, 2018 **Federal Register** (83 FR 63419), we adopted 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**. In the rule, we set forth an additional explanation of the rationale supporting the 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.

¹⁹ *Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients*. (2018, July 27). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf>.

²⁰ *Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year*. (2018, July 27). <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf>.

- In the April 25, 2019 **Federal Register** (84 FR 17454) (2020 Payment Notice), we finalized the benefit and payment parameters for 2020 benefit year, as well as the policies related to making the enrollee-level EDGE data available as a limited data set for research purposes and expanding the HHS uses of the enrollee-level EDGE data, approval of the request from Alabama to reduce risk adjustment transfers by 50 percent in the small group market for the 2020 benefit year, and updates to HHS-RADV program requirements.

- On May 12, 2020, consistent with 153.320(b)(1)(i), we released 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients to the CCIIO website.²¹

- In the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice), we finalized the benefit and payment parameters for 2021 benefit year, as well as adopted updates to the risk adjustment models' HCCs to transition to ICD-10 codes, approved the request from Alabama to reduce risk adjustment transfers by 50 percent in small group market for the 2021 benefit year, and modified the outlier identification process under the HHS-RADV program.

- In the December 1, 2020 **Federal Register** (85 FR 76979) (Amendments to the HHS-Operated Risk Adjustment Data Validation Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program (2020 HHS-RADV Amendments Rule)), we adopted the creation and application of Super HCCs in the sorting step that assigns HCCs to failure rate groups , finalized a sliding scale adjustment in HHS-RADV error rate calculation, and added a constraint for negative error rate outliers with a negative error rate. We also established a transition from the prospective application of HHS-RADV adjustments to apply HHS-RADV results to risk scores from the same benefit year as that being audited.

- In the September 2, 2020 **Federal Register** (85 FR 54820), we issued an interim final rule containing certain policy and regulatory revisions in response to the COVID–19 public

²¹ *Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients*. (2020, May 12). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>.

health emergency (PHE), wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year.

- In the May 5, 2021 **Federal Register** (86 FR 24140), we issued part 2 of the 2022 Payment Notice final rule containing policy and regulatory revisions related to the risk adjustment program, including finalization of the benefit and payment parameters for the 2022 benefit year and 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. In addition, this final rule established a revised schedule of collections for HHS-RADV and updated the provisions regulating second validation audit (SVA) and initial validation audit (IVA) entities.

- On July 19, 2021, consistent with § 153.320(b)(1)(i), we released Updated 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website, announcing some minor revisions to the 2022 benefit year final risk adjustment adult model coefficients.²²

2. Program Integrity

We have finalized program integrity standards related to the Exchanges and premium stabilization programs in two rules: the “first Program Integrity Rule” 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). We also refer readers to the 2019 Patient Protection and Affordable Care Act; Exchange Program Integrity rule published in the December 27, 2019 **Federal Register** (84 FR 71674).

3. Market Rules

For past rulemaking related to the market rules, we refer readers to the following rules:

- In the April 8, 1997 **Federal Register** (62 FR 16894), HHS, with the Department of Labor and Department of the Treasury, published an interim final rule relating to the HIPAA

²² *Updated 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients*. (2021, July 19). CMS <https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf>.

health insurance reforms. In the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules), we published the health insurance market rules.

- In the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule), we published the Exchange and Insurance Market Standards for 2015 and Beyond.

- In the December 22, 2016 **Federal Register** (81 FR 94058), we provided additional guidance on guaranteed availability and guaranteed renewability.

- In the April 18, 2017 **Federal Register** (82 FR 18346) (Market Stabilization final rule), we further interpreted the guaranteed availability provision.

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

- In the June 19, 2020 **Federal Register** (85 FR 37160) (2020 section 1557 final rule), in which HHS discussed section 1557 of the ACA, HHS removed nondiscrimination protections based on 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 September 27, 2021 **Federal Register** (86 FR 53412) (part 3 of the 2022 Payment Notice final rule), which was published by HHS and the Department of the Treasury, we 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. In the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule), we implemented components of the Exchanges and set forth standards for eligibility for Exchanges, as well as network adequacy and ECP certification standards.

In the 2014 Payment Notice and 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.

We published the final rule in the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice).

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

In the January 5, 2022 **Federal Register** (87 FR 584), we published a proposed rule that outlined proposals to maintain the user fee rate for issuers offering plans through the FFEs and maintain the user fee rate for issuers offering plans through the SBE-FPs. We also proposed various policies to address certain agent, broker, and web broker practices and conduct. We also proposed updates to the requirement that all Exchanges conduct special enrollment period verifications.

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.²³ 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

²³ *Essential Health Benefits Bulletin*. (2011, December 16). CMS. https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

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), an interim final rule that was published in the September 2, 2020 **Federal Register** (85 FR 54820), and the May 5, 2021 **Federal Register** (86 FR 24140).

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 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 regulations at § 156.1130 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 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHB and AV requirements. In the February 25, 2013 **Federal Register** (78 FR 12834), HHS published the “Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation” final rule, which included nondiscrimination protections.

In the 2020 section 1557 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 consulted with stakeholders on policies related to the PHS Act and ACA Federal market reform requirements, including the operation of Exchanges and the risk adjustment program (including HHS-RADV). For example, related to risk adjustment, HHS released the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes²⁴ and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations.²⁵ We also held a number of meetings with consumers, providers, employers, health plans, advocacy groups, and the actuarial community to gather public input. We 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 and

²⁴ *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

²⁵ *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations*. (2021, December 28). CMS. <https://www.cms.gov/files/document/report-summary-results-transfer-simulations.pdf>.

written comments we received in response to the proposed rulemaking as we developed the policies in this final rule.

C. Structure of Final Rule

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

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

The changes to 45 CFR part 147 will ensure that issuers cannot refuse to effectuate new coverage based on the failure of an individual or employer to pay premiums owed for prior coverage.

The policies relating to 45 CFR part 153 involve recalibration of the 2023 benefit year risk adjustment models using the 2017, 2018, and 2019 enrollee-level EDGE data. We also finalize updates to the adult and child risk adjustment models for 2023 and beyond to better predict plan liability for certain subpopulations. Specifically, beginning with the 2023 benefit year, we will 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 will add an interacted HCC count model specification for 2023 and beyond to the adult and child models. We are not finalizing the proposal to add a two-stage weighted approach to model recalibrations.

We are finalizing 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 are finalizing 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.²⁶

²⁶ The same concern was not present for the 2017 enrollee-level EDGE data because hydroxychloroquine sulfate was not included in the RXC crosswalk until 2018.

For the 2024 benefit year and beyond, we will 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 are finalizing 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 will 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 are finalizing the proposal to collect and extract five new data elements as part of the enrollee-level EDGE data. Beginning with the 2023 benefit year, issuers will be required to populate the ZIP Code and subsidy indicator fields as part of their EDGE data submissions. Issuers will also be required to populate the race, ethnicity, and Individual Coverage Health Reimbursement Arrangement (ICHRA) indicator fields. For the 2023 and 2024 benefit years, we are adopting a transitional period for the race, ethnicity, and ICHRA indicator fields during which time issuers will be required to populate these fields using available data sources. Then, beginning with the 2025 benefit year, issuers that do not have an existing source to populate these fields for particular enrollees will also be required to make a good faith effort to collect and submit race, ethnicity, and ICHRA indicator data elements for these enrollees. We are also finalizing the proposal to extract three data elements – plan ID, rating area, and subscriber indicator – issuers already report to their EDGE servers as part of the required risk adjustment data. We are finalizing the extraction of plan ID and rating area beginning with the 2021 benefit year, and subscriber indicator will be extracted beginning with the 2022 benefit year.

Additionally, we finalize the proposal to amend § 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.

In part 153, we are finalizing policies related to risk adjustment State flexibility requests. We are finalizing the repeal of the ability of States to request a reduction in risk adjustment State

transfers starting with the 2024 benefit year, with an exception for prior participants. We further limit a prior participant's ability to request a reduction in risk adjustment transfers starting with the 2024 benefit year to only those that meet the *de minimis* threshold criteria. In future rulemaking, HHS intends to propose to eliminate the prior participant exception starting with the 2025 benefit year. For the 2023 benefit year, we approve Alabama's requests to reduce risk adjustment State transfers, but at lower percentages, than the State requested. We approve for the 2023 benefit year a 25 percent reduction in Alabama's individual market (including the catastrophic and non-catastrophic risk pools) transfers and a 10 percent reduction in Alabama's small group market transfers.

In part 153, we also finalize the risk adjustment user fee for the 2023 benefit year at \$0.22 PMPM. We also finalize the proposed update to 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. We further specify that Super HCCs will be defined separately according to the model (infant, child, adult) to which an enrollee is subject, except for where child and adult coefficient estimation groups have identical definitions. We also finalize the proposal 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. These refinements to the HHS-RADV error rate methodology and processes will apply beginning with the 2021 benefit year. Finally, we adopt the policy 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, we are finalizing the part 153 proposals related to MLR reporting requirements and how issuers should report certain ACA program amounts that could be subject

to reconsideration. More specifically, we add references to HHS-RADV adjustments to § 153.710(h) 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.

We finalize changes to 45 CFR part 155 to allow Exchanges to implement a verification process for enrollment in or eligibility for an eligible employer sponsored plan based on the Exchange's assessment of risk for inappropriate payments of APTC/CSR. We are codifying the proposed APTC proration methodology as the methodology Exchanges on the Federal platform will continue to use, but we are not finalizing the requirement for State Exchanges to prorate premium or APTC amounts using the methodology described in the proposed rule. Rather, we are finalizing that beginning in PY 2024, State Exchanges will be required to report to HHS their methodology that ensures the amount of APTC applied to an enrollee's monthly premium does not exceed their total monthly APTC.

We are also finalizing 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 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. After consideration and review of the comments, we will not finalize § 155.220(j)(2)(ii)(A)(1), which would prohibit agents from entering consumer email addresses with domains that remove email from an inbox after a set period of time. We encourage agents, brokers, and web-broker entities to remain aware of, and avoid using, such temporary email accounts when assisting consumers in obtaining coverage as a best practice and will likely issue future guidance on the matter. Otherwise, we are generally

finalizing the changes to the remainder of § 155.220(j)(2)(ii) to clarify the FFE standards of conduct for agents, brokers, and web-brokers, and what it means to provide the Exchange with correct information under section 1411(b) of the ACA. We also finalize the changes to § 155.220(j)(2)(vi) through (viii) to expand the FFE standards of conduct and codify more detail about specific business practices that are prohibited.

In 45 CFR part 156, we are finalizing the user fee rates for the 2023 benefit year for all issuers participating on Exchanges that use the Federal platform. We also finalize technical amendments to § 156.50 to conform with the repeal of the Exchange Direct Enrollment (DE) option finalized in part 3 of the 2022 Payment Notice (86 FR 53412 at 53424 through 53429 and 53445). Also, we finalize 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 an appropriation to make CSR payments and voluntary for other issuers.

In part 156, we are also finalizing a refinement to the EHB nondiscrimination policy to provide that a nondiscriminatory health plan design that provides EHB is one that is clinically based; a permanent annual deadline in early May for EHB-benchmark plan applications by States, a repeal of States' ability to permit issuers to substitute benefits between EHB categories; changes to the *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 a repeal of the annual requirement for States to report to HHS State-required benefits in addition to the EHB.

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

The changes to 45 CFR part 158 codify 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 changes to part 158 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, we finalize 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*,²⁷ and thus deleted in part 2 of the 2022 Payment Notice final rule.

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

A. Part 144 - Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 594), we proposed to remove the phrase “unless otherwise provided under State law” from the definition of large group market at § 144.103. As discussed in the proposed rule, the phrase has no meaning or application and does not appear in the statutory definition of large group market 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.²⁸ However, in the 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 section 2791(e) of the PHS Act, 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 proposed to do so in the proposed rule, to

²⁷ *City of Columbus, et al. v. Cochran*, 523 F. Supp. 3d 731 (D. Md. 2021).

²⁸ 62 FR 16894 and 69 FR 78720.

align these definitions and make the regulatory definition for large group market consistent with the definition under the ACA.

We sought comment on this proposal.

After reviewing public comments, we are finalizing this provision as proposed. The removal of the phrase “unless otherwise provided under State law,” will add clarity to the regulatory definition of “large group market,” and align with the current definition under section 2791(e) of the PHS Act.

We summarize and respond to public comments received on the definition of large group market below.

Comment: We received two comments related to the definition of a large group market. One commenter did not see any adverse consequences to the revision. Another expressed concern that State law definitions of “large group” would be adversely affected by the change in Federal law because each State passes laws tailored to the market in their respective State.

Response: As discussed in the proposed rule, we proposed this change to align the regulation with the underlying statutory definition of “large group market,” which does not include the phrase “unless otherwise provided under State law.” In addition, removing this language will not affect State law definitions of large group market to the extent that they do not prevent the application of Federal law.

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

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 594 through 595), we proposed 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 when the individual or employer

owes past-due premiums for coverage from the same issuer or another issuer in the same controlled group. Under the current interpretation of the guaranteed availability requirement, to the extent permitted by applicable State law, an issuer does not violate the guaranteed availability requirements under § 147.104 when 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.²⁹

On January 28, 2021, President Biden issued Executive Order 14009, “Strengthening Medicaid and the Affordable Care Act” (EO 14009).³⁰ Section 3 of EO 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 EO 14009, to include protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals. On April 5, 2022, President Biden issued Executive Order 14070, “Continuing to Strengthen Americans’ Access to Affordable, Quality Health Coverage” (EO 14070).³¹ Section 2 of EO 14070 directs agencies with responsibilities related to Americans’ access to health coverage, in addition to taking the actions directed pursuant to EO 14009, to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. Consistent with section 3(iv) of EO 14009 and section 2(a) of EO 14070, the re-interpretation of the guaranteed availability requirement is intended to remove an unnecessary barrier and make it easier for consumers to enroll in coverage.

²⁹ 82 FR 18346, 18349 through 18353.

³⁰ Executive Order 14009 on Strengthening Medicaid and the Affordable Care Act. (2021, February 2). See 86 FR 7793.

³¹ Executive Order 14070 on Continuing to Strengthen Americans’ Access to Affordable, Quality Health Coverage, April 5, 2022; see 87 FR 20689.

In the proposed rule (87 FR 594), we proposed to re-designate § 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). Based on our experience, we believe that the currently effective interpretation of guaranteed availability has the unintended consequence of creating barriers to health coverage that disproportionately affect low-income individuals.

After reviewing the public comments, we are finalizing this provision as proposed. We summarize and respond to public comments received on the proposed re-interpretation of guaranteed availability requirements for the group and individual health insurance markets below.

Comment: Many commenters supported the proposal, stating that the current interpretation of the guaranteed availability requirement is inconsistent with the ACA and creates barriers to accessing health care that disproportionately harm persons with low incomes and those experiencing economic hardship. Other commenters in favor of the proposal stated that the current interpretation of the guaranteed availability requirement is a barrier to enrollment that disproportionately impacts people of color, especially women of color, persons with disabilities, lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+) people, and immigrants.

Some commenters stated that non-payment of past-due premiums is typically not an intentional decision to avoid financial responsibility, and may be the result of a mistake or catastrophic events such as financial hardship, environmental disaster, hospitalization, or lack of awareness of past-due premium debt. Some commenters expressed concern that the current interpretation of the guaranteed availability requirement permits issuers to adopt punitive measures against consumers who, without malice, are unable to satisfy past-due premium debt.

Some commenters stated that the current interpretation of the guaranteed availability requirement compounds barriers to enrollment by requiring consumers with past-due premium debt to pay multiple months of premiums on top of a binder payment in order to effectuate coverage. A commenter noted that there is no evidence that individuals are attempting to “game the system” by enrolling in coverage and paying premiums only when care is needed. Other commenters stated that the current interpretation poses a steep barrier to enrollment for consumers responding to catastrophic life events, particularly given that the amount of past-due premiums owed to payors is nominal compared to issuer profits.

Other commenters opposed the proposed policy and stated that more research is necessary to determine why individuals and employers fail to pay past-due premiums and questioned whether other coverage options could be made more accessible.

Response: We believe finalizing the proposed re-interpretation of the guaranteed availability requirement will alleviate a barrier to enrollment for individuals struggling to access health coverage, which disproportionately affects historically marginalized populations and individuals facing financial hardship. The current interpretation of this policy disincentivizes enrollment by conditioning coverage on the repayment of the past-due premium debt, which may deter individuals who have accrued past-due premium debt from seeking coverage altogether. Conversely, permitting individuals to enroll in coverage, regardless of past-due premium debt, will help ensure continuous access to health care, especially for individuals facing dire economic circumstances. We agree with commenters that enrollees fail to pay premiums for numerous, valid reasons that have nothing to do with exploiting grace periods or special enrollment periods to avoid paying for health coverage. Additionally, many consumers and small businesses face financial challenges. As such, we believe it is prudent to remove barriers to accessing health coverage to ease the enrollment process.

While the exact cause of premium non-payment and past-due premium accrual may not be clear in all cases, we are of the view that this should not be a reason to deny individuals

coverage. We agree with commenters suggesting that more research is needed to determine why individuals and employers fail to pay past-due premiums, and believe that such research could inform future policies to better support consumers in staying enrolled in coverage.³²

Comment: Some commenters recommended limiting the re-interpretation of the guaranteed availability requirement to the individual market and not making it applicable to the group market. One commenter stated that the proposed change could have significant impacts on issuer management of enrollment and billing for group market accounts.

Response: Under section 2702 of the PHS Act and § 147.104, the guaranteed availability requirement applies to both the individual and group markets. We believe the same principles underlying this policy should apply equally to both markets, and therefore, decline to adopt this recommendation.

Comment: Commenters stated that this proposal restricts issuers' ability to collect past-due premiums or requires them to forgive such debt. Some commenters expressed concern that finalizing the proposal will remove a disincentive that guards against enrollees ceasing to pay premiums during the last 3 months of the plan year, and will leave issuers without adequate redress when faced with non-payment. Some commenters stated that permitting individuals with past-due premium debt to enroll in coverage before repaying past-due premiums will ultimately result in fewer choices and higher premiums, harming consumers with low incomes. One commenter requested that HHS specify other options for issuers besides collections.

In contrast, another commenter noted that issuers have largely chosen not to use the flexibility provided under the current interpretation of the guaranteed availability requirement because the implementation of a policy that attributes payments made for new coverage to past-due premiums before effectuating new enrollment would cost more than the past-due premiums the issuer would recoup through such a policy. Other commenters agreed that issuers have other

³² Cunningham, P.J., Green, T. L., & Braun, R. T. (2018, February 26). Income Disparities in the Prevalence, Severity, and Costs of Co-Occurring Chronic and Behavioral Health Conditions. *Medical Care*.

tools for recouping unpaid premiums. Some commenters suggested that issuers should be prohibited from acting to collect past-due premiums.

Response: We disagree that this proposal restricts issuers from collecting past-due premiums. Issuers are generally not permitted to forgive the past-due premium debt and have alternative methods to collect past-due premiums (such as pursuing debt collection). We believe this mitigates the risk that some enrollees may take advantage of the guaranteed availability rules. We also believe that the low adoption among issuers of policies that rely on the current interpretation of guaranteed availability demonstrates that there are sufficient avenues for issuers to collect past-due premium debt without having to condition enrollment into new coverage on the payment of past-due premium debt. However, we acknowledge that issuers that implemented a policy of attributing payment made for new coverage to past-due premiums before effectuating enrollment will need to make operational changes as a result of this re-interpretation of the guaranteed availability requirement. Finally, in response to the commenter's suggestion that issuers should be prohibited from acting to collect on debt for past-due premiums, we reiterate that an issuer's forgiveness of premium debt is generally not permissible under our rules.

b. Nondiscrimination based on sexual orientation and gender identity

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 595 through 597), we proposed to amend 45 CFR 147.104(e) to explicitly prohibit discrimination based on sexual orientation and gender identity. As we explain in the Supplemental Information section earlier in the preamble, HHS will address this policy, as well as the public comments submitted in response to this proposal, in a future rulemaking.

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. 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.³³ 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.³⁴ 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 amended, and the underlying authority for the risk adjustment program, the funds that are sequestered in the fiscal year 2022 from the risk adjustment program will become available for payment to issuers in the 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 the fiscal year 2030 at a rate of 5.7 percent per fiscal year.³⁵

We received no comments on the FY2022 sequestration rate for risk adjustment.

2. HHS Risk Adjustment (§ 153.320)

³³ See also 42 U.S.C. 18041(c)(1).

³⁴ *OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2022*. (2021, May 28). White House. https://www.whitehouse.gov/wp-content/uploads/2021/05/BBEDCA_251A_Sequestration_Report_FY2022.pdf.

³⁵ CARES Act, S.3548. (2020).

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 diagnosis is added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXC) beginning with the 2018 benefit year.³⁶ 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 or PLRS) 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

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 598), we proposed to recalibrate the 2023 benefit year risk adjustment models with 2017, 2018, and 2019 enrollee-level EDGE data. We sought comment on this proposal.

In the proposed rule, we also sought 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

³⁶ 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.

data would be used in the 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 years models.³⁷ Although HHS has not analyzed the 2020 enrollee-level EDGE data yet, we solicited comment on the future use of the 2020 enrollee-level EDGE data for the annual recalibration of the HHS risk adjustment models.

After reviewing the public comments, we are finalizing, as proposed, the use of the 2017, 2018, and 2019 enrollee-level EDGE data to recalibrate the 2023 benefit year risk adjustment models. We were unable to finalize coefficients in time to publish them in this final rule. Therefore, consistent with § 153.320(b)(1)(i), we will publish the final coefficients for the 2023 benefit year in guidance soon after the publication of this final rule.

Additionally, we appreciate comments on the future use of the 2020 enrollee-level EDGE data due to the COVID-19 PHE. We continue to consider how to handle 2020 enrollee-level EDGE data for recalibration of the 2024, 2025, and 2026 benefit year models and will work with stakeholders as we analyze the data. Changes to the established policies for recalibration of the risk adjustment models, including proposals related to the use of 2020 enrollee-level EDGE data for such purposes, would be pursued through notice-and-comment rulemaking.

We summarize and respond to public comments received on data for risk adjustment model recalibration for the 2023 benefit year and beyond below.

Comment: Many commenters supported the use of the 2017, 2018, and 2019 enrollee-level EDGE data to recalibrate the 2023 risk adjustment models. One commenter noted that the 2017, 2018, and 2019 enrollee-level EDGE data reflect the most recently available health outcomes and recent treatment patterns in the enrollee population. Another commenter supported using the most recent 3 years of EDGE data available in time for publication of the draft

³⁷ 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.

coefficients in the proposed rule in order to give the industry the earliest opportunity to model premium rates for the next benefit year.

Response: We are finalizing the use of the 2017, 2018, and 2019 enrollee-level EDGE data to recalibrate the 2023 risk adjustment models as proposed. The 2017, 2018, and 2019 enrollee-level EDGE data were the 3 most recent consecutive years of enrollee-level EDGE data that were available at the time we incorporated the data in the draft recalibrated coefficients published in the proposed rule. As discussed in the 2022 Payment Notice, the purpose of using the 3 most recent consecutive years of enrollee-level EDGE data that were available at the time we incorporated the data in the draft recalibrated coefficients published in the proposed rule was to respond to stakeholders' request to provide the draft coefficients in the proposed rule (86 FR 24152). We believe that this approach promotes stability and avoids the delays in publication of the coefficients while continuing to develop blended, or averaged, coefficients from the 3 years of separately solved models for model recalibration.

Comment: We received several comments on the use of 2020 enrollee-level EDGE data for recalibration of the 2024, 2025, and 2026 benefit years. Some of these commenters supported the inclusion of 2020 enrollee-level EDGE data in these future benefit year model recalibrations, stating that 2020 data would accurately reflect utilization patterns that can be expected in 2021 and beyond and that the inclusion of 3 years of enrollee-level EDGE data in recalibration would dampen the impact of 2020 data. Another commenter noted that failure to include 2020 data would result in an outdated picture of medical spending.

One commenter opposed the inclusion of 2020 enrollee-level EDGE data in model recalibration altogether. Another commenter noted that not relying on 2020 experience to develop risk adjustment coefficients is consistent with industry practice, asserting that the majority of Medicare Advantage and ACA issuers used 2019 data in lieu of 2020 data for 2022 pricing.

Several commenters requested HHS develop a technical paper on using 2020 enrollee-level EDGE data in future model recalibrations, with several commenters suggesting that HHS do a comparison of coefficients with and without the 2020 enrollee-level EDGE data to review relative changes in coefficients, and evaluate changes for clinical reasonability and consistency with 2018 and 2019 enrollee-level EDGE data. One commenter requested that HHS release 2020-related statistics and solicit further comment on how to best proceed with 2020 data, including whether to instead use 2017, 2018, and 2019 EGDE data for the 2024 benefit year recalibration of the HHS risk adjustment models.

One commenter recommended either assigning 2020 enrollee-level EDGE data lower weight if used to recalibrate the models in the 2024, 2025, and 2026 benefit years, or using four years of enrollee-level EDGE data in the annual model recalibration until 2020 data is no longer included in recalibration. Another commenter recommended that HHS evaluate if it would be better to use 1 or 2 years of data for recalibration of the models in the 2024, 2025, and 2026 benefit years on a transitional basis until only post-2020 data would be used.

Response: We appreciate comments on the future use of the 2020 enrollee-level EDGE data for risk adjustment model recalibration and will consider this feedback as we analyze the 2020 enrollee-level EDGE data and consider options for its use for recalibration of the risk adjustment models.

b. Risk Adjustment Model Updates

In the proposed rule (87 FR 598 through 605), we proposed three modeling updates to the risk adjustment models beginning with the 2023 benefit year. Consistent with the potential model updates discussed in the 2021 RA Technical Paper, we proposed the following model updates, which are the same as those proposed but not finalized in the 2022 Payment Notice:³⁸ (1) adding

³⁸ In the 2022 Payment Notice Proposed Rule, we proposed three model specification changes, see 85 FR 78572 at 78583 through 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 through 24162. See also HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf> and HHS-

a two-stage weighted model specification to the adult and child models; (2) removing the severity illness factors in the adult models and 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.

After a review of public comments, we are finalizing two of the three proposed model specification updates. We are not finalizing the proposed addition of a two-stage weighted model specification to the adult and child models. We are finalizing, as proposed, removing the current severity illness factors in the adult models and replacing them with new severity and transplant indicators that interacted with HCC count factors in the adult and child models. We are also finalizing, as proposed, replacing the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors in the adult models. In the following sections, we describe the proposed model specification changes, as well as summarize and respond to the comments received on each of these proposals.

i. Two-Stage Weighted Model Specification

We proposed 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 HCCs³⁹). For a full description of the proposed two-stage weighted model specification see the proposed rule (87 FR 599 through 601). We sought comment on the two-stage weighted model specification proposal.

After reviewing the public comments, we are not finalizing the adoption of the two-stage weighted model specification.

Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations. (2021, December 28). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

³⁹ When we refer to the enrollees without HCCs, we are referring to enrollees without payment HCCs.

We summarize and respond to public comments received on the proposed two-stage model specification below.

Comment: Several commenters supported the implementation of the proposed two-stage weighted model specification. Some of these commenters generally supported all of the proposed model specification changes, while others specifically noted that the proposed two-stage model improved prediction for the lowest-risk enrollees.

Conversely, several other commenters opposed the implementation of the proposed two-stage weighted model specification. Several commenters were concerned that the proposed two-stage weighted model specification would have anti-competitive effects, leading to fewer choices for consumers. These commenters stated that the two-stage weighted model specification would increase premiums on more generous health insurance coverage, incentivize issuers to adopt narrow networks and lower-quality plans, encourage issuers to avoid enrolling consumers with chronic illnesses, and contribute to the creation and use of discriminatory benefit designs.

Other commenters did not support a model change that improved risk predictions for certain subpopulations at the expense of the risk adjustment program's ability to mitigate adverse selection for high-cost enrollees. Some commenters stated that the proposed two-stage weighted model specification ignores current market dynamics in which plans are already incentivized to attract the healthiest enrollees. Additionally, some commenters recommended additional analysis of the two-stage weighted model specification, specifically geographic and market-specific considerations, before its adoption. One commenter suggested that if HHS finalizes the two-stage weighted model specification, HHS should pilot or phase-in the implementation based on an analysis of localized market conditions.

Response: After consideration of the comments on this proposal, we are not finalizing the proposed two-stage weighted model specification. We pursued the proposed model specification updates to improve the prediction of certain subpopulations in response to feedback from stakeholders and internal analysis where we had observed underprediction in the current models.

As we previously reported in the 2018 Payment Notice, our initial analysis found that, based on the commercial MarketScan® data, the HHS risk adjustment models slightly underpredicted risk for the lowest-risk enrollees (81 FR 61472 through 61473 and 81 FR 94082 through 94083). Our subsequent analysis of enrollee-level EDGE data confirmed this preliminary finding.⁴⁰ In addition, stakeholders have consistently encouraged HHS to adjust the models to address this underprediction of risk, which affects the PLRSs of plans that enroll more healthy individuals. HHS has therefore been examining these issues, considering different options, and soliciting comments on ways to modify the risk adjustment models to improve prediction for certain subpopulations, including the lowest-risk enrollees, over several years (81 FR 61473 and 85 FR 7101 through 7104). Throughout this process, we consistently emphasized the need to carefully evaluate the impact on and consider the trade-offs that would need to be made in model predictive power among subgroups of enrollees.

The proposed two-stage weighted model specification was targeted at improving model prediction for lowest-risk enrollees. As previously explained, we believed that by addressing the underprediction of costs associated with lowest-risk enrollees in the adult and child models, we could encourage the offering and retention of plans that enroll a higher proportion of this subpopulation of enrollees.⁴¹ We also recognized that issuers offering these types of plans were at greater risk of exiting the market if transfers calculated under the State payment transfer formula under-compensated for the true plan liability of the lowest-risk enrollees. These concerns, along with stakeholder comments on these issues, prompted the design of the two-stage weighted model specification two years ago. However, we acknowledged that there are trade-offs associated with the adoption of the proposed two-stage weighted model, including that while it would improve prediction for the lowest-risk enrollees it would worsen model prediction

⁴⁰ Section 2. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁴¹ Section 2.1. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

along other dimensions, such as reduced R-squared values, less accurate prediction of plan liability by age-sex factor (especially for younger and older women), as well as a less accurate prediction of costs for certain HCCs.⁴² Additionally, since developing the proposed two-stage weighted model specification, there have been key shifts in the individual market, including increased enrollment and increased availability of subsidies,⁴³ that have made the market more attractive to issuers. However, these market shifts have also shown the pressing need to update the adult model enrollment duration factors, which we are also finalizing as part of this rule.

While the interacted HCC count model specification and the enrollment duration factor updates finalized in this rule do not improve predictive accuracy for the lowest-risk enrollees as much as they would have if they were combined with the proposed two-stage weighted model specification, we believe the finalized model specifications will still make significant gains in improved predictive accuracy for our target subpopulations, including the lowest-risk enrollees, highest-risk enrollees, and partial-year enrollees.⁴⁴ As demonstrated in Chapter 4 of the 2021 RA Technical Paper, our analysis found the proposed interacted HCC counts model specification and the proposed HCC-contingent enrollment duration factors improved prediction for the lowest-risk enrollees, compared with the current adult models, even without accounting for the proposed two-stage weighted model specification.⁴⁵ Using 2018 enrollee-level EDGE data, the proposed interacted HCC counts model specification combined with the proposed HCC-contingent enrollment duration factors improves the PR for adult silver-plan enrollees in risk decile 1 from 0.52 to 0.81.⁴⁶ This approach of incremental improvements in predictive accuracy aligns with our

⁴² Section 2.3. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>. See also 87 FR 600 through 601.

⁴³ *Biden-Harris Administration Announces 14.5 Million Americans Signed Up for Affordable Health Care During Historic Open Enrollment Period*. (2022, January 27). CMS. <https://www.hhs.gov/about/news/2022/01/27/biden-harris-administration-announces-14-5-million-americans-signed-affordable-health-care-during-historic-open-enrollment-period.html#:~:text=Today%2C%20the%20Biden%2DHarris%20Administration,people%20who%20have%20newly%20gained>.

⁴⁴ Figures 4.2, 4.3, and 4.4. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁴⁵ *Ibid*.

⁴⁶ Section 4. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

commitment to continuously analyze and refine the risk adjustment models. After consideration of comments and further evaluation of the trade-offs, we are finalizing the interacted HCC count model specification and enrollment duration factor updates but are not finalizing the proposed two-stage weighted model specification.

Since we are not finalizing the proposed two-stage weighted model specification, we do not intend to pursue or otherwise consider pilot or phase-in implementation strategies. Similarly, we do not intend to engage in additional analysis of alternative implementations of the two-stage weighted model specification, including but not limited to an analysis of implementation by geographic or market-specific conditions, at this time.

Comment: One commenter that supported the proposed two-stage weighted model specification also encouraged HHS to recalibrate the State payment transfer formula to further ensure that plans do not face excessive risk adjustment charges when enrolling a high proportion of young and healthy enrollees. Another commenter supported the finalization of the two-stage weighted model specification, but noted that it is unclear to what extent these model changes address situations in which risk adjustment charges for some issuers exceed the premium collected for some lower-risk enrollees.

Response: We did not propose and are not finalizing changes to the State payment transfer formula. However, we intend to continue analysis of the risk adjustment State payment transfer formula to consider whether changes are needed to it. For example, in Appendix A of the 2021 RA Technical Paper, we discussed options to potentially update the risk adjustment State payment transfer formula to improve prediction for CSR enrollees' plan liability. More specifically, we identified several potential options to update the risk term and one option to update the rating term to more precisely account for CSR plan liability in the State payment transfer formula.⁴⁷ We familiarized stakeholders with these options and accepted public

⁴⁷ Appendix A. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

comments on the considerations in the 2021 RA Technical Paper. We continue to conduct analyses of these options and will propose any changes in future notice-and-comment rulemaking.

As part of future analyses, we also intend to assess the impact of the State payment transfer formula on risk adjustment covered plans with lowest-risk enrollees to the extent that our data allows. However, in response to commenters' concerns that risk adjustment charges exceed premiums collected for some of the lowest-risk enrollees, we do not believe that this concern falls within the scope of the proposed two-stage weighted model specification, and we reiterate that we do not believe that adjusting the State payment transfer formula to limit charges to the level of premiums for enrollees is appropriate (86 FR 24140 at 24186). Also, as previously described, we proposed the two-stage weighted model specification to address the underprediction of the lowest risk enrollees, not to address the situation described by the commenter in which risk adjustment charges may exceed premiums collected for some enrollees. As described in the most recent "Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year," risk adjustment is working as intended to transfer payments from plans with lower than average actuarial risk to plans with higher than average actuarial risk.⁴⁸ Furthermore, we do not believe that limiting risk adjustment charges to the level of enrollee premiums is consistent with the framework set forth in section 1343 of the ACA, which requires the establishment of a risk adjustment program focused on risk differentials at the plan level, not the enrollee level.⁴⁹ Risk adjustment transfers under the State payment transfer formula are therefore calculated based on the PLRS and the Statewide average premium, not based on individual enrollees' premiums.

⁴⁸ *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year*. (2021, June 30). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf>.

⁴⁹ Compare 42 U.S.C. 18063 (establishing the permanent risk adjustment program, which involves an assessment and comparison of the actuarial risk in each issuer's plans in a State market risk pool with the average actuarial risk of all plans in the applicable State market risk pool) and 42 U.S.C. 18061 (establishing the transitional reinsurance program, which involves an assessment of actuarial risk of individual enrollees to identify those that qualify as "high risk.")

Comment: Some commenters requested that if HHS finalizes the proposed two-stage weighted model specification, then HHS should reassess the 14 percent administrative adjustment, which they argue may already address some of the underprediction seen in predictive ratios.

Response: We did not propose and are not finalizing changes to the 14 percent administrative cost reduction to the Statewide average premium used in the State payment transfer formula. While HHS is not finalizing the proposed two-stage weighted model specification, we reiterate that the proposed two-stage weighted model specification and administrative cost adjustment to Statewide average premium address separate considerations. Specifically, the 14 percent administrative cost reduction is used in the State payment transfer formula to adjust the Statewide average premium and does not address the predictive accuracy of the risk adjustment models, as described in the 2021 RA Technical Paper. As detailed in the 2018 Payment Notice, the purpose of the administrative cost adjustment to the Statewide average premium is to exclude fixed administrative costs that are not dependent on enrollee risk, such as taxes (81 FR 61488 through 61489 and 81 FR 94099 through 94100). In contrast, and as previously described elsewhere,⁵⁰ the proposed two-stage weighted model specification was a targeted refinement aimed at improving the current adult and child models' prediction for the lowest-risk enrollees. Therefore, we do not agree with commenters' assertions that the administrative cost adjustment addresses the same issue as the two-stage weighted model specification, specifically the underprediction of costs in the lowest-risk enrollee subpopulation.

Comment: Some commenters that opposed the proposed two-stage weighted model specification were concerned it may be resulting in overfitting of the models and may not predict future costs accurately. They also noted that the two-stage weighted model specification is not a

⁵⁰ Section 2.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>. See also 85 FR 78667 and 86 FR 24283.

standard procedure for risk adjustment and worsens fit in some areas, such as the reduced R-squared values,⁵¹ although the effect is small.

Response: As previously described, we acknowledged that there are trade-offs associated with adoption of the proposed two-stage weighted model, including that it would worsen model prediction along some dimensions, such as reduced R-squared values. We also recognize that the two-stage weighted model specification is not a standard procedure for risk adjustment. After consideration of comments and further evaluation of the trade-offs, we are not finalizing the proposed two-stage weighted model specification update to the adult and child models. In response to commenters' concerns about overfitting, we note that we do not have concerns with respect to overfitting the models for a variety of reasons. First, we estimate the models using 3 years of data and the final model parameters are an average of coefficients across the 3 years. By using 3 years of data, the potential for one unusual year to skew the coefficients is limited. Second, for each model year, the overall sample size is quite large in each adult model, particularly relative to the number of model predictors used in the risk adjustment models.⁵² For example, the 2019 recalibration sample alone has 18.7 million adult enrollees whose data are used to fit adult models consisting of 181 predictors for the 2023 benefit year. Additionally, we ensure sample sizes for each coefficient are reasonable through the application of hierarchies, constraints, and similar model design choices.⁵³ We also note that although the models perfectly predict past experience, this does not guarantee the models will perfectly predict when applied to

⁵¹ We acknowledge three areas where the two-stage weighed model specification worsens fit of the risk adjustment models along other dimensions in Section 2.3 in the *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁵² Kautter, J., Pope, G., Ingber, M. J., Freeman, S. E., Patterson, L. J., Cohen, M. A., & Keenan, D. P. (2014). The HHS-HCC risk adjustment model for individual and small group markets under the Affordable Care Act. *Medicare & Medicaid Research Review*, 4(3), E1–E46. doi:10.5600/mmrr.004.03.a03.

Kautter, J., Pope, G., & Keenan, D. P. (2014). Affordable Care Act risk adjustment: Overview, context, and challenges. *Medicare & Medicaid Research Review*, 4(3), E1–E11. doi:10.5600/mmrr.004.03.a02.

⁵³ For information on the use of hierarchies and constraints, see Sections 2.1, 3.7 and 3.8 of the March 2016 Risk Adjustment Methodology White Paper. (2016, March 24). <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>. See also the June 2019 *Potential Updates to HHS-HCCs for the HHS-operated Risk Adjustment Program* Technical Paper (2019, June 17). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf>

future payment years, as that will depend, in part, on what happens between the calibration and payment years. However, this does not reflect overfitting. To the extent the calibration years are representative of future payment years, the models are positioned to perform well when used for payment.⁵⁴ For all of these reasons, we are not concerned about the proposed two-stage weighted model specification change resulting in overfitting of the models; however, as previously described, we are not finalizing the proposed two-stage weighted model specification.

ii. Interacted HCC Counts Model Specification

In addition to the two-stage weighted model specification, we proposed 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 0.1 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.⁵⁵

Therefore, to address the underprediction of the highest-risk 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. 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 by accounting for the fact that costs of certain HCCs rise significantly when they occur with multiple other HCCs.

In developing this interacted HCC counts model specification, we tested different types of severity and transplant indicators interacted with HCC counts with the goal of improving prediction for enrollees with the highest costs and multiple HCCs to counterbalance the

⁵⁴ Section 1.4. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁵⁵ Section 4.1. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

reciprocal prediction weights that relatively underpredicted costs for these enrollees. For this approach, we assessed the HCCs for enrollees with extremely high costs, and HCCs that were being underpredicted in the current risk adjustment models. We found that many of the HCCs that were flagged as being underpredicted were those HCCs that indicated severe illness, such as the transplant HCCs, and other HCCs related to severity of disease; therefore, we proposed dropping the current severity illness indicators in the adult models and replacing them with severity and transplant indicators interacted with HCC counts factors in the adult and child models.

We proposed the inclusion of the factors in Tables 1 and 2 of the proposed rule as the severity and transplant interaction factors in the adult and child models starting with the 2023 benefit year. We separated out severity and transplant HCCs into two sets of interaction factors, as expressed in Tables 1 and 2 of the proposed rule, because we found that this approach improved prediction for the highest-risk enrollees better than an approach that included a single set of factors.

If an enrollee has at least one severity HCC in Table 3 of the proposed rule (shown in Table 1 of this rule as the Final HCCs Selected for the HCC Interacted Counts), the enrollee will receive an interacted HCC count factor toward their risk score, and the severity HCC count factor selected would be based on the enrollee's total payment HCC count.⁵⁶ If an adult or child enrollee has at least one transplant HCC in Table 1 of this rule, the enrollee will receive an interacted HCC count factor for both a severity HCC interacted factor and, if the enrollee has four or more HCCs, a transplant HCC interacted factor towards their risk score, and both of those count factors would be based on the enrollee's total payment HCC count.

To further explain, as seen in Table 2 of this rule, the severity-HCC-count-interaction factors were calculated as 10 separate factors for the adult models, and seven separate factors for

⁵⁶ For additional information on how the interacted HCC counts model specification works, see Section 4.3 of the *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>. See also 87 FR at 601 through 603.

the child models. In the adult models, the first nine factors specified the presence of (1) an HCC in the severity list in Table 1 of this rule 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 1 of this rule and (2) 10 or more payment HCCs in the enrollee's data. For the child models, the first five factors represent the presence of (1) an HCC in the severity list in Table 1 of this rule 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 1 and (2) six to seven payment HCCs, and the seventh factor represents the presence of (1) an HCC in the severity list in Table 1 and (2) eight or more payment HCCs in the enrollee's data.

TABLE 1: Final HCCs Selected for the 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 Status	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 2: Structure of the Severity HCC Count Indicators

	Severity HCC Count Indicators
Adult Model Factors	1, 2, 3, 4, 5, 6, 7, 8, 9, 10+
Child Model Factors	1, 2, 3, 4, 5, 6 or 7, 8+

As seen in Table 3 of this rule, the transplant-HCC-count-interaction factors are calculated similarly. However, the transplant factors are 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 1 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 1 of this rule and (2) a total of four or more payment HCCs in the enrollee’s data. Using only one transplant-HCC-count-interaction factor stabilized the child model estimates by increasing the sample size used to estimate the factor coefficients.⁵⁷

TABLE 3: Structure of the Transplant HCC Count Indicators

	Transplant HCC Count Indicators
Adult Model Factors	4, 5, 6, 7, 8+
Child Model Factors	4+

To implement the severity- and transplant-HCC-count-interaction factors in the regression model and estimate the value of their factor coefficients, we proposed 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.

We sought comment on this proposal.

We are finalizing the removal of the current adult model severity illness factors and adding an interacted HCC count model specification to the adult and child risk adjustment models starting with the 2023 benefit year, as proposed.

We summarize and respond to public comments received on the interacted HCC counts model specification updates below.

Comment: Several commenters supported the proposal to add an interacted HCC counts model specification to the adult and child risk adjustment models noting that the interacted HCC counts model specification will improve model prediction and more accurately quantify risk. Some commenters expressed general agreement with HHS that the current models may be

⁵⁷ For an illustration of how the proposed severity- (or transplant-) HCC-count-interaction factors would be assigned to an enrollee, see 87 FR 601 through 602.

underpredicting plan liability of the highest-risk enrollees, but did not otherwise comment on the interacted HCC count model specification proposals. One commenter suggested that the proposed refinement will mitigate issuers' concerns about adverse selection and lead to a more competitive market, while another agreed that it would address the current models' underestimate of plan liability for the very highest-risk enrollees.

However, several other commenters opposed the proposed interacted HCC counts model policy, stating that this change would add undue complexity to the models and would increase coding and issuer gaming. Some commenters requested clarification on how the interacted HCC counts variable would be accommodated in the HHS-RADV process. These commenters requested that HHS increase program integrity measures and adopt additional safeguards against upcoding, such as targeted sampling to test for upcoding in the HHS-RADV process, as an additional measure to protect against gaming if this model specification change is finalized. One commenter generally noted they only supported the interacted HCC counts model specification if the two-stage weighted model specification was also finalized.

Response: We agree with the commenters that the interacted HCC counts model specification will improve model prediction, more accurately quantify risk, and address the underprediction of plan liability of the highest-risk enrollees that we have observed in the current adult and child models. The current adult models incorporate a severe illness adjustment that accounts for combinations of selected HCCs. However, the total count of an enrollee's HCCs does not currently independently affect the risk score and, while the current severity illness indicator helps predict costs accurately among most adult enrollees with qualifying severe illnesses, it does not fully address the underprediction for the very highest-risk enrollees. The current severity of illness indicators also do not extend to the child models. The proposed interacted HCC counts model specification was targeted at addressing these concerns and more accurately predicting risks and capturing costs for the highest-risk enrollees.

We understand that there are concerns about the increased complexity that the interacted HCC counts model specification may introduce. However, we see the interacted HCC counts model specification as an advancement of our current severe illness indicators, which have been in place since the beginning of the risk adjustment models, so we believe the interacted HCC counts model specification change only slightly increases complexity. As described in our analysis of 2018 enrollee-level EDGE data in the 2021 RA Technical Paper, the interacted HCC counts model specification, along with the HCC-contingent enrollment duration factors, significantly improved prediction for the very highest-risk enrollees, which we believe outweighs the disadvantages of slightly increasing model complexity.⁵⁸

Additionally, we acknowledge concerns over the potential for upcoding and issuer gaming and further note that incorporating safeguards to protect against the potential for gaming was a major consideration in our investigation of various interacted HCC counts model specifications. When developing the proposed interacted HCC counts model specification we were specifically concerned that the presence of counts across all HCCs, without requiring a severe illness or transplant HCC, would further incentivize issuers to code for more HCCs, thus increasing their payment or reducing their charge under the State payment transfer formula. This would be inconsistent with the risk adjustment principle not to encourage coding proliferation.⁵⁹ However, we believe that implementing the interacted HCC counts model specification updates, as proposed, which restricts the incremental risk score adjustment to enrollees with at least one severe illness or transplant HCC, reduces concerns of issuers inflating HCC counts to increase their transfers under the State payment transfer formula. More specifically, our analysis of 2016, 2017, and 2018 enrollee-level EDGE data revealed that severe illness HCCs are relatively uncommon; less than 2 percent of the adult enrollee-level EDGE data population across these 3

⁵⁸ Section 4.4. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁵⁹ For information on the principles that guide the HHS risk adjustment models' diagnostic classification system, see Section 1.1.2 of the *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf> (see, in particular, Principle 6: The diagnostic classification should not reward coding proliferation.)

benefit years had at least one severe illness HCC, as opposed to about 20 percent of adult enrollees with any payment HCC. Therefore, opportunities to inflate HCC counts would be limited to a small fraction of total enrollees.

Although we believe this approach appropriately balances the different trade-offs by improving prediction for highest-risk enrollees while mitigating the potential for gaming or upcoding, we generally intend to monitor implementation of the model specification updates finalized in this rule. Specifically, we will look for any notable changes in HCC failure rates for the interacted severity and transplant HCCs in HHS-RADV beginning with the 2023 benefit year that could be the result of implementation of the interacted HCC counts model specification updates.

Lastly, we note the interacted HCC counts model specification update finalized in this rule is effective beginning with 2023 risk adjustment. The HHS-RADV process for the 2023 benefit year would not begin until spring 2024. Therefore, we intend to consider whether changes are needed beginning with the 2023 benefit year HHS-RADV error estimation methodology or processes in recognition of the interacted HCC counts model specification and would propose any such changes in future notice-and-comment rulemaking. HHS will also consider whether targeted sampling, or other approaches, in HHS-RADV are necessary to detect and address upcoding or coding proliferation as a result of the implementation of the interacted HCC counts model specification.

Comment: Some commenters questioned whether the exclusion of capitated claims biases the analysis of the proposed interacted HCC counts model specification change.

Response: As previously explained,⁶⁰ 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 reliable data for

⁶⁰ March 2016 Risk Adjustment Methodology White Paper. (2016, March 24). <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>. See also 87 FR 602 through 603.

recalibration or analysis.⁶¹ However, in response to comments submitted to the 2021 RA Technical Paper and the proposed rule, we conducted additional analyses to investigate how enrollees with capitated claims could have impacted our assessment of the underpredicted subpopulations described in the 2021 RA Technical Paper. This additional analysis did not show that the exclusion of enrollees with capitated claims biased the analysis or results in the 2021 RA Technical Paper.

To conduct this additional analysis, we compared the recalibration sample, which excluded enrollees with any capitated claims,⁶² with the capitation sample, which included only enrollees with capitated claims. Overall, for the 2023 risk adjustment models, the capitation exclusion resulted in 15-17 percent of enrollees being dropped from the recalibration sample. As described in the 2021 RA Technical Paper, where we utilized the recalibration sample to analyze the proposed model changes, we observed underpredicted plan liability for the lowest-risk enrollees (enrollees in low-risk deciles and without HCCs) and underpredicted plan liability for the highest-risk enrollees (enrollees in the top 0.1 percent decile and with many HCCs).⁶³ In our additional analysis of the capitation sample, we also observed the same general trends of underprediction of the lowest-risk and highest-risk enrollees. Further, we evaluated whether the proposed 2023 model specification changes produced similar improvements in addressing the underprediction of these subpopulations in the capitation sample as the recalibration sample and found that the proposed 2023 model specification changes resulted in similar prediction improvements for both samples. Therefore, we do not believe that the exclusion of enrollees with

⁶¹ Enrollees with at least one capitated claim in EDGE are excluded from recalibration, as the risk adjustment models are used to evaluate enrollees' expenditures, and capitated claims do not provide meaningful and comparable cost (allowed charges) data in comparison to non-capitated claims. We are also concerned that methods for computing and reporting derived amounts from capitated claims could be inconsistent across issuers and would not provide reliable or comparable data.

⁶² The calibration sample is the same sample used for the analysis in the 2021 RA Technical Paper, which excludes capitated enrollees.

⁶³ Figures 1.2 and 1.3. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

capitated claims biased the analysis or results, and we do not believe that their inclusion would have meaningfully impacted our findings.

Comment: Some commenters recommended additional information and analysis on the proposed interacted HCC counts model change specification, such as its effect on calculations under the State payment transfer formula for issuers that tend to attract healthier enrollees, whether small sample sizes were an issue, and an evaluation of whether removing the interacted severity HCCs would improve PLRS PRs more than attaching counts to those HCCs. One of the commenters suggested that it is difficult to assess the net effect of the interacted HCC count proposals on risk adjustment State transfers selection incentives. This commenter further noted they would oppose the proposal if this proposed change reduced State transfers paid by issuers with lower than average risk scores.

Response: We provided extensive information on the interacted HCC counts model specification changes and the estimated impact on State transfers in rulemakings,⁶⁴ the 2021 RA Technical Paper,⁶⁵ and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations.⁶⁶ In the transfer simulation report, we provided summary-level information on the estimated combined impact of the proposed model specification changes on the calculation of plan-level risk scores and State transfers. Issuers that participated in the simulation also received detailed issuer-specific data, including risk score and transfer estimates for the simulated results.

While we acknowledge stakeholders' requests for additional analysis, such as the effect of the interacted HCC counts model specification updates on transfer calculations for issuers who tend to attract healthier enrollees, operational and technological limitations within both HHS and the issuer community limited capacity to conduct additional simulations. Despite these

⁶⁴ 85 FR 78583 through 78586 and 87 FR 598 through 605.

⁶⁵ *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁶⁶ *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations*. (December 28, 2021). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

limitations in being able to conduct additional simulations, we were able to produce and share evidence and detailed analyses in support of the proposed interacted HCC counts model specification.⁶⁷ For example, as described in the 2021 RA Technical Paper, the interacted HCC counts model specification improved prediction for the highest-risk enrollees.⁶⁸

We also acknowledge the request to evaluate the impact of removing the current severity and transplant indicators against the proposed interacted HCC counts model specification. However, we do not believe this approach warrants further evaluation because we did not propose to entirely remove the indicators without replacing them. Additionally, the current severity illness indicators improve the current adult models' prediction of high-risk enrollees, so we do not believe we should consider completely removing the severity illness terms from the models. We reiterate that the proposed interacted HCC counts model specification further improves the adult and child models' predictive power beyond the adult models' current severity illness indicators. Therefore, we do not believe that we should further consider removing the severity illness indicators and not replacing them.

We recognized that one potential concern with this model specification change was that the severity- and transplant-HCC-count-interaction factor coefficients might be based on small sample sizes. Therefore, 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 individually 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

⁶⁷ Figures 4.2, 4.3, and 4.4 in the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes demonstrate the improvements in PRs of the interacted HCC counts and HCC-contingent EDFs. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁶⁸ Section 4.4. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

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+ 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 are comparable to the sample sizes used for individual HCCs in the adult and child risk adjustment models.

iii. Changes to the Adult Model Enrollment Duration Factors⁶⁹

In the proposed rule, we proposed to change the enrollment duration factors in the adult risk adjustment models to improve prediction for partial-year adult enrollees with and without HCCs (87 FR 603 through 604). Although the values 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 in the 2018 Payment Notice (81 FR 94071 through 94074).

As described in prior rules and the 2021 RA Technical Paper, we found that the current adult model enrollment duration factors underpredicted plan liability for partial-year adult

⁶⁹ 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 through 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. Therefore, we proposed to continue to apply enrollment duration factors to the adult models only.

enrollees with HCCs and overpredicted plan liability for partial-year adult enrollees without HCCs.^{70, 71}

Therefore, beginning with the 2023 benefit year, we proposed 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. We explained that under this proposal 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.

We solicited comments on the proposed changes to the enrollment duration factors for the adult models.

After reviewing the public comments, we are finalizing the proposal to replace the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors as proposed. As such, beginning with the 2023 benefit year, there will no longer be enrollment duration factors for adult enrollees without HCCs starting with the 2023 benefit year, nor will there be enrollment duration factors for adult enrollees with HCCs and more than 6 months of enrollment.

We summarize and respond to public comments received on proposed changes to the adult model enrollment duration factors below.

Comment: Most commenters supported the proposed changes to the enrollment duration factors for the adult models. Many of these commenters asserted that the proposed changes would improve model prediction. One commenter noted that the HCC-contingent enrollment duration factors would solve the majority of model prediction issues even in the absence of the

⁷⁰ 85 FR 29164 at 29188 through 29190.; 86 FR 24140 at 24151 through 24162; and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁷¹ When we refer to the enrollees with and without HCCs, we are referring to enrollees without payment HCCs.

adoption of the proposed two-stage weighted model and interacted HCC counts model specification updates. Several commenters also stated that the proposed HCC-contingent enrollment duration factors would reduce issuers' incentives for risk selection.

Response: We are finalizing the replacement of the current monthly enrollment duration factors of up to 11 months for all enrollees in the adult models with new monthly enrollment duration factors of up to 6 months that would apply only to enrollees in the adult models with HCCs. As previously explained, our analysis of the current adult model enrollment duration factors found that plan liability was underpredicted for partial-year adult enrollees with HCCs and overpredicted for partial-year adult enrollees without HCCs.⁷² This targeted refinement was developed in response to this finding and will improve prediction for partial-year adult enrollees with and without HCCs. Additionally, HHS agrees that the enrollment duration factor changes will reduce issuers' incentives for risk selection by improving model prediction.

Comment: Several commenters focused on the intersection of special enrollment periods (SEP) and these proposed changes. Some commenters suggested that the proposed enrollment duration factor updates would mitigate the impact of the recent access to SEPs enhanced during the 2020 and 2021 benefit years due to the COVID-19 PHE and ARP,⁷³ which changed the SEP enrollee pool and increased opportunities for adverse selection. One of these commenters noted the importance of predictive accuracy for 1 to 6-month enrollees as Exchanges on the Federal platform and State Exchanges expand plan selection options during SEP enrollments. Another commenter noted HHS' analysis of the proposed HCC-contingent duration factors is not representative of the current SEP landscape and recommended additional analysis before the proposed enrollment duration factor updates are implemented.

⁷² HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁷³ See, for example, HHS Announces Marketplace Special Enrollment Period for COVID-19 Public Health Emergency. (2021, January 28). CMS. <https://www.hhs.gov/about/news/2021/01/28/hhs-announces-marketplace-special-enrollment-period-for-covid-19-public-health-emergency.html>.

Response: We appreciate the comments on the intersection of SEP opportunities and the proposed updates to the adult model enrollment duration factors. We agree with commenters that the proposed updates would mitigate the impact of the recent SEPs enhanced during the 2020 and 2021 benefit years due to the COVID-19 PHE and ARP on potential opportunities for adverse selection, but note that these updates to the enrollment duration factors will not be implemented until the 2023 benefit year. We also agree with the commenter on the importance of predictive accuracy for partial-year enrollees and believe that these changes will improve the current models' predictive accuracy for partial-year adult enrollees with and without HCCs.

As noted above, we are finalizing the changes to the adult model enrollment duration factors as proposed and will implement the new factors beginning with the 2023 benefit year adult models. To develop the 2023 benefit year risk adjustment models, we used the 2017, 2018, and 2019 enrollee-level EDGE data, as these datasets were the 3 most recent consecutive years of enrollee-level EDGE data that were available at the time we incorporated the data in the draft recalibrated coefficients published in the proposed rule. Therefore, we believe that the data years that we used to develop the HCC-contingent enrollment duration factors are the most appropriate data years available at this time for purposes of analyzing the proposal to adopt these changes beginning with the 2023 benefit year and that further analysis is not required at this time. As discussed elsewhere in this rule, we are still assessing whether to use the 2020 enrollee-level EDGE for model recalibration in the future, and we do not have 2021 benefit year enrollee-level EDGE yet.⁷⁴ As such, we have not yet been able to analyze the impact of the most recent SEP changes. However, HHS remains committed to ongoing analysis of these issues and intends to study the impact of the new factors once implemented.

Comment: A few commenters expressed concerns that the proposed HCC-contingent enrollment duration factors would negatively impact the small group market or that the changes

⁷⁴ See 45 CFR 153.730. Since April 30, 2022, falls on a weekend, CMS will exercise enforcement discretion to shift the deadline for submission of final 2021 benefit year risk adjustment data to May 2, 2022.

would not align with small group market enrollment renewal patterns (for example, non-calendar year coverage). One commenter that opposed the adoption of the proposed changes stated that eliminating enrollment duration factors for non-HCC enrollees would disincentivize issuers from taking on new small group employers in the fourth quarter. Other commenters that supported the proposed enrollment duration factors changes noted general concerns that the proposed updates to the enrollment duration factors may negatively impact the small group market.

Response: We explored partial-year enrollment patterns between the individual⁷⁵ and small group markets as part of the consideration of updates to the enrollment duration factors for the risk adjustment adult models. In the 2021 Payment Notice (85 FR 29189), we shared our preliminary analysis of the 2017 enrollee-level EDGE dataset found separate enrollment duration factors by market in the adult models could be warranted; therefore, we continued to study these issues as additional enrollee-level EDGE data became available. Our analysis of partial-year enrollment using the 2018 enrollee-level EDGE dataset, which occurred alongside our development of the proposed HCC-contingent enrollment duration factors in the proposed 2022 Payment Notice, did not find a meaningful distinction in relative costs between markets on average once the proposed enrollment duration factors of up to 6 months for adult enrollees with HCCs were implemented.⁷⁶ Even though reasons for and patterns of partial-year enrollment differ by market, we concluded that the patterns most relevant for predicting cost (for example, how enrollment duration relates to cost conditional on the presence of HCCs) were the same for both markets.⁷⁷ Therefore, we determined it would not be necessary to introduce market-specific factors if the proposed HCC-contingent enrollment duration factors were adopted in place of the existing enrollment duration factors. We also explained that if the HCC-contingent factors were to vary by market, the factors for both markets would generally be very similar, which would add

⁷⁵ Section 3. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>. In the enrollee-level EDGE dataset, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

⁷⁶ Section 3.3.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>. See also 86 FR 24161.

⁷⁷ Ibid.

little value to the models while adding additional complexity.⁷⁸ Therefore, we proposed the adoption of the same HCC-contingent factors for both markets.

In response to comments, we again considered whether the HCC-contingent enrollment duration factors could have negative impacts on small group market issuers, such as on those that offer non-calendar year coverage and take on new business later in the year. Our continued consideration of these issues did not find evidence of such negative impacts.⁷⁹ More specifically, while we recognize there are likely some cases where a partial-year enrollee only receives risk adjustment ineligible services, our analysis found no evidence that it is associated with meaningful underpayment in either the individual or small group market. In other words, on average, costs are sufficiently low for partial-year enrollees with no HCCs that even a risk score based only on demographic factors would generally overpredict plan liability.⁸⁰ Commenters did not provide data or other information in support of the general assertions or concerns about potential impacts on the small group market and have not otherwise refuted the conclusions drawn from our analysis of available enrollee-level EDGE data. Therefore, we continue to believe it is appropriate to finalize and apply the proposed changes to the adult model enrollment duration factors to both the individual and small group (including merged) markets and to not pursue factors that vary by market. For the reasons outlined above, we also believe that the presumed negative impact on new business in the small group market would be limited, and the guaranteed availability provisions, which require health insurance issuers offering non-grandfathered coverage in the individual or small group market to accept every individual and employer in the State that applies for such coverage unless an exception applies, further protects against issuers declining to take on new small group employers.

⁷⁸ Section 3.3.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁷⁹ Section 3.4. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>

⁸⁰ Ibid.

Comment: One commenter stated that they were against limiting enrollment duration factors to up to 6-month enrollees and would support the proposed changes if the upper limit for the factors was extended to 9 months. The commenter noted this change to the upper limit would better account for renewal patterns in the small group market.

Response: While we considered other enrollment duration factor structures, we proposed and are finalizing a 6-month limit to the enrollment duration factors because we found that the monthly average cost variation by the 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 prediction for the adult models.⁸¹ Specifically, we found that these coefficients would have been close to 0 (and in some cases negative), which means they would not have contributed much to the overall risk score for enrollees or would have had to be constrained to 0 in the risk adjustment adult models. Given this analysis and in an effort to limit the number of factors in the models, we are finalizing the HCC-contingent enrollment duration factors for up to 6 months as proposed.

Additionally, as explained above, we continue to believe it is appropriate to finalize and apply the proposed changes to the adult model enrollment duration factors to the small group market and to not pursue factors that vary by market.

iv. Combined Impact of the Model Changes

As discussed in detail above, after reviewing the public comments on the proposed risk adjustment model changes, we are finalizing the addition of the interacted HCC counts factors in the adult and child models, the removal of the current adult model severity illness factors, and the replacement of the existing enrollment duration factors with the HCC-contingent enrollment duration factors in the adult models, as proposed. Our analysis of the proposed interacted HCC counts factors combined with the proposed HCC-contingent enrollment duration factors in the

⁸¹ Section 3.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

adult models significantly improves predictions across most deciles and HCC counts for the very highest-risk enrollees, as well as the lowest-risk enrollees without HCCs.⁸² However, we are not finalizing the proposal to add a two-stage weighted model specification to model recalibrations.

We summarized and responded to public comments received on proposed model specifications updates in the above sections.

c. Pricing Adjustment for the Hepatitis C Drugs

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 605), for the 2023 benefit year, we proposed to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models.⁸³

We sought comment on this proposal.

After reviewing the public comments, we are finalizing this proposal 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 summarize and respond to public comments received on the pricing adjustment for Hepatitis C drugs below.

Comment: Most commenters supported the Hepatitis C pricing adjustment. One commenter noted that the pricing adjustment ensures HHS is applying the most accurate data, while protecting against issuers that might seek to influence provider prescribing patterns to the issuers' benefit. Another commenter noted that without the Hepatitis C pricing adjustment, issuers would be incentivized to focus on only a subset of enrollees needing treatment if they can trigger an increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim.

Conversely, a few commenters expressed concerns about the Hepatitis C drugs pricing adjustment. These commenters asserted that the professional independence and ethical standards

⁸² Figure 4.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>

⁸³ 84 FR 17463 through 17466.

of providers would prevent them from prescribing drugs that they did not believe were medically necessary and appropriate, reducing the potential for issuers to game the model. These commenters were concerned about undercompensating issuers for enrollees with serious chronic conditions, which would incentivize issuers to avoid these enrollees. They encouraged HHS to evaluate the models continually to ensure they fully capture the cost of the current standard of care for conditions in the models. Additionally, one commenter cautioned against reducing the coefficient more than the expected decrease, which the commenter explained would incentivize issuers to reduce the availability of the treatment. This commenter also recommended that HHS clarify the data source and approach it is using to constrain the Hepatitis C RXC coefficient. Finally, one commenter expressed concern that constraining the Hepatitis C RXC coefficient would undermine recent progress to treat Hepatitis C infections.

Response: We continue to believe that the Hepatitis C pricing adjustment is appropriate at this time, will help avoid perverse incentives, and will lead to Hepatitis C RXC coefficients that better reflect anticipated actual 2023 benefit year plan liability associated with Hepatitis C drugs. Specifically, the purpose of the Hepatitis C pricing adjustment is to address 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 that present a risk of creating perverse incentives by overcompensating issuers. We reassessed the pricing adjustment for the Hepatitis C RXC for the 2023 benefit year model recalibration and found that the data used for the 2023 benefit year risk adjustment model recalibration (that is, 2017, 2018, and 2019 enrollee-level EDGE data) still does not account for the significant pricing changes that we have observed for the Hepatitis C drugs due to the introduction of newer and cheaper Hepatitis C drugs. Therefore, the data that will be used to recalibrate the models needs to be adjusted because it does not precisely reflect the average cost of Hepatitis C treatments expected in the 2023 benefit year.

In making this determination, we consulted our clinical and actuarial experts, and analyzed the most recent enrollee-level EDGE data available to further assess the changing costs associated with Hepatitis C enrollees. Due to the high cost of these drugs reflected in the 2017, 2018, and 2019 enrollee-level EDGE data, without a pricing adjustment to plan liability, issuers would be overcompensated for the Hepatitis C RXC in the 2023 benefit year, and they could be incentivized to encourage overprescribing practices and game risk adjustment such that the issuer's risk adjustment payment is increased or risk adjustment charge is decreased. We also recognize concerns that applying a pricing adjustment that would reduce the coefficient for the Hepatitis C RXC by more than the expected decrease in costs could incentivize issuers to reduce the availability of the treatment. However, we believe that the Hepatitis C pricing adjustment accurately captures the costs of Hepatitis C drugs for the applicable risk adjustment benefit year using the most recently available data, balances the need to deter gaming practices with the need to ensure that issuers are adequately compensated, and does not undermine recent progress in the treatment of Hepatitis C.

Additionally, we recognize the important role that the ethical standards of providers play in preventing overprescribing of drugs that they do not believe are medically necessary and appropriate, but we believe that the Hepatitis C pricing adjustment is the most effective way to protect against perverse incentives that could affect prescribing patterns. Furthermore, while we appreciate commenters' concerns about undercompensating issuers for enrollees with serious chronic conditions, HHS is adopting several proposals in this rulemaking to address the adult and child models' underprediction for enrollees with many HCCs.⁸⁴ Specifically, we finalized the interacted HCC counts and HCC-contingent enrollment duration factors model specifications to improve model prediction for the higher risk enrollees and ensure that issuers are being

⁸⁴ Figure 1.3. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

accurately compensated for these enrollees.⁸⁵ We intend to continue to reassess this pricing adjustment as part of future benefit years' model recalibrations using additional years of available enrollee-level EDGE data.

- d. Risk adjustment RXC mapping for recalibration
- i. Inclusion and exclusion criteria for drugs in RXC mapping and recalibration

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 605), we provided an overview of the inclusion and exclusion criteria HHS uses to identify drugs for mapping to RXCs in the adult risk adjustment models, reviewed 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 outlined the criteria that warrant consideration for changes to the incorporation (or exclusion) of particular drugs from the RXC mappings in future benefit year recalibrations. We also proposed 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 information on the annual recalibration of the adult risk adjustment models' RXC coefficients using data from the applicable prior benefit years trended forward 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).⁸⁶ 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

⁸⁵ The Interacted HCC Counts and HCC-contingent enrollment duration factors also improve the models' predictive accuracy for the lower risk deciles. See, for example, Figure 4.2. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁸⁶ See, for example, 81 FR 94074 through 94080.

available in the market during the benefit year.⁸⁷ As explained in the proposed rule, we had been using the most recent RXC mappings (RXCUIs that map to RXCs) that were available when we first processed the enrollee-level EDGE data for a benefit year for recalibration of the adult risk adjustment models.⁸⁸ 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 2017⁸⁹ and the Q2 2019 mapping document for 2018 for recalibration of the adult risk adjustment models' RXC factors.

As noted in the 2022 Payment Notice (86 FR 26164), 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. 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 the pharmacological properties and prescribing patterns are consistent with treatment of a particular condition (also evaluated through clinical expert review), and (4) stakeholder

⁸⁷ See, for example, Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXC) Crosswalk Memorandum. (2017, September 18). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf>.

⁸⁸ RXCUIs differ by chemical (drug ingredient), strength, and dose form, but not by manufacturer or package size. This means that RXCUIs describe the same drugs year-over-year, even as the underlying NDCs and HCPCS change due to changes in labelers, which is why it is possible to apply different mappings to different years. For further information, see *RxNorm Overview*. (2022, January 3). NIH. <https://www.nlm.nih.gov/research/umls/rxnorm/overview.html>.

⁸⁹ 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.

feedback.⁹⁰ As a result of this ongoing assessment, we 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 “Do It Yourself” (DIY) software and EDGE reference data, to ensure drugs are appropriately mapped to RXCs. 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,⁹¹ 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).⁹²

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

In the proposed rule, we proposed 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 proposed to recalibrate the adult risk adjustment models using each 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 year enrollee-level EDGE data, we would use the Q4 RXC mapping document for each

⁹⁰ See, for example, Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXC) Crosswalk *Memorandum*. (2017, September 18). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf>.

⁹¹ The January 7, 2022 version of the DIY software is available at *2021 Benefit Year Risk Adjustment Updated HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software*. (2022). CMS.

⁹² Available at *Distributed Data Collection*. REGTAP.

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 appropriately mapped to RXCs.

We proposed 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 proposed 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 proposed 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 generally hold those mappings constant when using the 2018 and 2019 enrollee-level EDGE data years in future benefit year model recalibrations (except under the extenuating circumstances that are described in the next section that can result in targeted changes to RXC mappings) – 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.⁹³ The purpose of maintaining a specific version of the same RXC mapping document for future recalibrations 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 are likely to 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 proposed an exception for the 2017 benefit year enrollee-level EDGE data and would instead use the most recent RXC

⁹³ Consistent with the approach finalized in the 2022 Payment Notice, the 2018 and 2019 enrollee-level EDGE data would be used for the recalibration 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.

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 proposed this approach for the 2017 benefit year enrollee-level EDGE data because the RXCs were still under development in 2017, and were not included in the adult risk adjustment models until 2018;⁹⁴ therefore, no RXC mappings existed for the 2017 benefit year. Thus, we proposed to use the Q2 2018 RXC mapping document for the 2017 benefit year enrollee-level EDGE data for 2023 model recalibration, consistent with the mapping used for processing the 2017 data for recalibration of the 2021 and 2022 adult models. We sought comment on this proposal.

We summarize and respond to public comments received on the proposals related to the RXC mapping document used for the annual recalibration of the adult models, along with the comments and responses on the other risk adjustment RXC mapping proposals.

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 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.⁹⁵ However, in extenuating circumstances where HHS believes there will be a significant impact

⁹⁴ See 81 FR 94075.

⁹⁵ For example, in reviewing drugs removed in Q1 2020, the average effect of the removal of a single therapeutic drug ingredient was an approximate decrease of 0.14 percent in total pharmacy claims spending among RXC drugs. In reviewing drugs removed in Q1 2021, the average effect of the removal of a single non-hydroxychloroquine therapeutic drug ingredient was an approximate decrease of 0.68 percent in total pharmacy claims spending among RXC drugs.

from a change in an RXCUI to RXC mapping, such as: (1) evidence of significant off-label prescribing (as was the case with hydroxychloroquine sulfate⁹⁶); (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 proposed rule (87 FR 608 through 609), we illustrated cases where we believe extenuating circumstances existed and how we evaluated whether to make targeted changes to RXC mappings due to those extenuating circumstances as part of the annual recalibration process for the 2023 benefit year adult models. In particular, we considered the cases of RXCUI to RXC mapping of Descovy[®] and hydroxychloroquine sulfate. For Descovy[®], we did not propose to make an exception to remove Descovy[®] from mapping to RXC 01 in 2017, 2018 or 2019 benefit year enrollee-level EDGE datasets used for the 2023 benefit year recalibration of the adult models. For hydroxychloroquine sulfate, we proposed 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 the one used for the 2022 benefit year risk adjustment model recalibration and would instead 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 explained that 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.⁹⁷

⁹⁶ See, for example, 86 FR 24180.

⁹⁷ 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. See 85 FR 78582 through 78583.

For a full discussion of these examples, see the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 608 through 609).

After reviewing the public comments on the various risk adjustment RXC proposals, we are finalizing using the Q4 RXC mapping document for each benefit year of recalibration data, as proposed. Additionally, as proposed, we will remove hydroxychloroquine sulfate in the 2023 benefit year model recalibration and will not 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 summarize and respond to public comments received on all of the risk adjustment recalibration RXC mapping proposals below.

Comment: Several commenters supported our RXC mapping proposal to recalibrate the 2023 benefit year models and future model years using the final, Q4 RXC Crosswalk associated with the applicable EDGE data year, with the exception of the 2017 enrollee-level EDGE data year, for which we would use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (Q2 2018). Those supporting comments noted that the changes improve the risk adjustment models and will align condition identification experienced in the data year with concurrent relevance of particular drugs for each RXC. These commenters appreciated the increased transparency into the approach HHS takes to RXC mapping noting it would allow stakeholders to plan for downstream implications of changes to RXC mapping.

A few commenters requested that HHS provide a technical paper on the impact of the different approaches outlined in the RXC mapping proposal. One commenter requested that HHS provide a technical paper with analysis on the impact of the different approaches for identifying the RXC mapping document to use for the annual recalibration of the adult models, but stated that in lieu of that analysis, the commenter would support the adoption of the alternative

approach to use the latest RXC mapping available at the time of recalibration as it would most closely aligns costs between recalibration data and current benefit year data.

Response: We appreciate the support for the proposal to recalibrate the adult risk adjustment model using the final, Q4 RXC Crosswalk associated with the applicable EDGE data year. Recalibrating the adult risk adjustment models using the final, Q4 RXC mapping document that was applicable for each benefit year of data that is included in the applicable benefit year's model recalibration will ensure that we are capturing the utilization and costs observed for the underlying drugs in use in that year for the condition. We are finalizing, as proposed, implementation of this approach beginning with the 2023 benefit year recalibration of the adult models, with an exception for the 2017 enrollee-level EDGE data year, for which we will 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 will generally hold these mappings constant when using the 2018 and 2019 enrollee-level EDGE data years in future benefit year model recalibrations (except under the extenuating circumstances that are described previously in this section that can result in targeted changes to RXC mappings) – 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.

We also agree that this approach will improve issuers' ability to plan for downstream implications of changes to RXC mapping as it will provide 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. We believe that the benefits of limiting the volatility of some coefficients from year-to-year, ensuring that we are capturing the utilization and costs observed for the underlying drugs in use during the data year, and improving issuers' ability to plan for downstream implications of changes to RXC mapping outweigh the benefits of the alternative approach of using the latest RXC mapping available at the time of recalibration. Based on the detailed comments received in response to the proposals for identifying the version of the RXC

mapping document used for the annual recalibration of the adult models, we do not believe that additional analysis or a technical paper of the approaches to identifying the RXC mapping document for recalibration purposes is needed at this time.

Comment: Several commenters inquired about the timing of RXC Crosswalk changes that occur outside of the model recalibration process. Some requested notification of RXC Crosswalk changes for drugs that could have large impacts on risk adjustment transfers in the spring prior to the applicable benefit year. Others requested HHS finalize and announce the RXC Crosswalk changes that occur outside of the model recalibration process for an applicable benefit year no later than the December preceding the applicable benefit year, examine opportunities to identify and release such changes ahead of applicable State Exchange pricing deadlines, and communicate the final mappings prior to the end of the applicable benefit year. For changes to the RXC mappings that occur during the risk adjustment benefit year, one commenter suggested that HHS consider the relative benefit of removing an RXC at a late stage (that is, the fourth quarter of data submission) relative to potential impact on market stability and financial outcomes for issuers. Another commenter asserted that the timely inclusion of new drugs in the model will help ensure the incentives created by risk adjustment do not contribute to delays in the coverage of new treatments and recommended HHS monitor trends in drug coverage on risk adjustment plans to ensure that specific RXC mapping updates are not negatively impacting patient access to needed medications.

Response: We acknowledge commenters' desire to receive RXC Crosswalk updates as early as possible in order to fit rating timetables and reduce uncertainty. We clarify that, as part of our regular Crosswalk review process, we make regular changes that do not typically meaningfully impact coefficients and we release this information at its earliest availability through DIY software updates posted on the CCIIO website and EDGE global reference updates published through REGTAP.⁹⁸ However, we have found that there may be a relatively small

⁹⁸ CMS Registration for Technical Assistance Portal (REGTAP), available at <https://regtap.cms.gov/index.php>.

number of drugs that require additional consideration given changes that can occur between the data year and the applicable benefit year of risk adjustment. As such, we continue to believe that it is appropriate to update the risk adjustment mapping of RXCUIs to RXCs, along with the list of NDCs and HCPCS that Crosswalk to each RXCUI, throughout a benefit year of risk adjustment, while also retaining the flexibility to make targeted removals of drugs from the RXC Crosswalk and mapping document during the annual recalibration process.

Based on our experience since the incorporation of RXCs into adult risk adjustment models in the 2018 benefit year, the removal of an RXCUI from the RXC mappings (and the associated removal of the NDCs and HCPCS associated with that RXCUI) has not typically been material to recalibration because most drug removals are not associated with utilization and cost levels that would have a meaningful impact on model coefficients. However, in extenuating circumstances where HHS believes there will be a significant impact, we will consider whether targeted RXC mapping changes for recalibration are necessary or appropriate, using the criteria outlined above.

As far as our regular crosswalk review process, we acknowledge commenter concerns over the relative benefit of late stage changes to RXC mappings relative to potential impact on market stability and financial outcomes for issuers, but we continue to believe that it is appropriate to update the risk adjustment mapping of RXCUIs to RXCs throughout a benefit year of risk adjustment. We also note that we rarely remove entire RXC categories from the risk adjustment models. Since the RXCs were introduced in 2018, only two RXC categories have been removed altogether and that type of structural change to the RXC factors was pursued through notice-and-comment rulemaking (83 FR 16941).

Comment: Some commenters requested clarification on how drugs with multiple indications are treated in considering changes to RXC mapping changes that occur outside the annual recalibration process and more clear criteria for these types of drug changes.

Response: We provided an explanation of the criteria used to develop the RXCUI to RXC Crosswalk in the 2017 Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXC) Crosswalk Memorandum.⁹⁹ In short, drugs with multiple indications are evaluated by clinical experts to determine if they have reliable specificity to the RXC-associated diagnoses. New drugs with multiple indications that are all associated with diagnoses in the drug-diagnosis pairs that a particular RXC represents are included in that RXC. Drugs associated with the drug-diagnosis pairs of multiple RXCs, or with diagnoses both paired and unpaired with an RXC, can be evaluated against existing drugs with the same active ingredients. Alternatively, these drugs need clinical evidence that the RXC-associated diagnosis is the primary intended clinical application. In the absence of evidence, such drugs with multiple indications would not be mapped to an RXC.

Comment: Some commenters requested a separate RXC for pre-exposure prophylaxis (PrEP).

Response: We did not propose and are not finalizing the addition of PrEP as an RXC to the adult risk adjustment models. As explained in the 2021 Payment Notice (85 FR 29187), we chose not to propose incorporating PrEP as an RXC because, as a general principle, RXCs are incorporated into the HHS risk adjustment adult models to impute a missing diagnosis or indicate severity of a diagnosis.¹⁰⁰ Since the use of PrEP is currently recommended as a preventive service for persons who are not infected with HIV and are at high risk of HIV infection, the use of PrEP does not adequately represent risk due to an active condition, and would be inconsistent with this principle to add it as an RXC at this time. However, we incorporate 100 percent of the

⁹⁹ *Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXC) Crosswalk.* (2017, September 18). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf>.

¹⁰⁰ See 81 FR 94058 at 94075. See also March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers. (2016, June 8). CMS. <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf>.

PrEP costs for enrollees without HIV diagnosis or treatment in the simulation of plan liability for purposes of recalibrating the adult and child models. We further note that enrollees in risk adjustment covered plans that use PrEP drugs in combination with another HIV treatment drug that maps to RXC 01 will still receive credit for RXC 01 in the 2023 benefit year of risk adjustment. We will continue to explore these issues and the potential inclusion of PrEP as an RXC in future benefit years, as may be appropriate.

Comment: One commenter supported the targeted removal of hydroxychloroquine sulfate from the data used for recalibration and supported our decision not to effectuate a targeted removal of Descovy[®], one commenter supported the removal of the mapping of hydroxychloroquine sulfate to an RXC, and one commenter generally asserted that Descovy[®] should not be mapped to RXC 01.

Response: We appreciate comments on our discussion of the treatment of hydroxychloroquine sulfate and Descovy[®]. For the 2023 benefit year, we are finalizing, as proposed, the removal of 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 recalibration of the adult risk adjustment models for the 2023 benefit year.¹⁰¹ In addition, we included Descovy[®] in the mapping to RXC 01 (Anti-HIV Agents) for 2023 benefit year risk adjustment model recalibration, as the benefits of maintaining this mapping outweigh the benefits of removing it.

e. List of Factors to be Employed in the Risk Adjustment Models

Consistent with our approach in previous benefit years, we will release the final 2023 benefit year coefficients in guidance after publication of the final rule, as we were unable to finalize them in time to publish in this final rule.¹⁰²

¹⁰¹ The same concern was not present for the 2017 enrollee-level EDGE dataset – the other data year that will be used for the 2023 benefit year adult model recalibration – because hydroxychloroquine sulfate was not included in the RXC Crosswalk until 2018.

¹⁰² See 45 CFR 153.320(b)(1)(i).

f. Cost-Sharing Reduction Adjustments

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 623), we proposed to continue including an adjustment for the receipt of CSRs in the risk adjustment models in all 50 States and the District of Columbia. We explained that while we continue to study and explore ways to update the CSR adjustments to improve prediction for CSR enrollees,¹⁰³ for the 2023 benefit year, to maintain stability and certainty for issuers, we proposed to maintain the CSR adjustment factors finalized in the 2019, 2020, 2021, and 2022 Payment Notices.¹⁰⁴ See Table 4. We also proposed to continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment PLRS calculation, as all of Massachusetts’ cost-sharing plan variations have AVs above 94 percent.¹⁰⁵

We sought comment on these proposals.

TABLE 4: 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

After reviewing the public comments, we are finalizing the CSR adjustment factors as proposed. We summarize and respond to public comments received on cost-sharing reduction adjustments below.

¹⁰³ See Appendix A. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

¹⁰⁴ See 83 FR 16930 at 16953; 84 FR 17454 at 17478 through 17479; 85 FR 29164 at 29190; and 86 FR 24140 at 24181.

¹⁰⁵ See 81 FR 12203 at 12228.

Comment: One commenter supported the use of CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans. Another commenter noted that HHS should continue to evaluate the purpose and appropriateness of the current CSR adjustment factors in light of continued non-funding of CSR subsidies and the potential socioeconomic health equity issues associated with the lower-than-anticipated induced utilization level identified in the 2021 RA Technical Paper. Another commenter recommended that HHS use a CSR-specific adult model that uses CSR enrollees' paid claims.

Response: We are finalizing the CSR adjustment factors as proposed. For the 2023 benefit year, we are maintaining the CSR adjustment factors finalized in the 2019, 2020, 2021, and 2022 Payment Notices to maintain stability and certainty for issuers. We did not propose and are not finalizing the addition of a CSR-specific adult model that uses CSR enrollees' paid claims. We agree continued study of the current CSR adjustment factors is warranted. We intend to consider different options for potential changes to the CSR factors for future benefit years, including those outlined in the 2021 RA Technical Paper.¹⁰⁶ We would pursue any changes to the CSR adjustment factors in future notice-and-comment rulemaking.

g. Model Performance Statistics

Each benefit year, to evaluate risk adjustment model performance, we examined 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.

¹⁰⁶ See Section A.3. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

A subpopulation that is predicted perfectly would have a PR of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the PRs are in the range of published estimates for concurrent risk adjustment models.¹⁰⁷ Because we blend the coefficients from separately solved models based on the 2017, 2018, and 2019 benefit years' enrollee-level EDGE data, we publish the R-squared statistic for each model separately to verify their statistical validity. We will publish the final 2023 benefit year R-squared statistics with the final 2023 benefit year risk adjustment coefficients in guidance.

We did not receive any comments in response to the model performance statistics discussion.

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.¹⁰⁸ We explained that under this approach, we will no longer republish these formulas in future annual HHS notices of benefit and payment parameters unless changes are being proposed. We did not propose any changes to the formula in this rule and therefore are not republishing the formulas in this rule. We will 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.¹⁰⁹

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.¹¹⁰ We did not propose any changes to the high-cost risk pool parameters for the 2023 benefit year; therefore, we will maintain the \$1 million threshold and 60 percent coinsurance rate.

¹⁰⁷ See Hileman, G. & Spenser S. (2016). Accuracy of Claims-Based Risk Scoring Models. Society of Actuaries.

¹⁰⁸ See 86 FR 24183 through 24186.

¹⁰⁹ For an illustration and further details on the State payment transfer formula, see 86 FR 24183 through 24186.

¹¹⁰ See 84 FR 17466 through 17468.

We did not receive any comments in response to the overview of the HHS risk adjustment methodology applicable to the 2023 benefit year.

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

We proposed to repeal the ability of States to request a reduction in risk adjustment State transfers under § 153.320(d) starting with the 2024 benefit year, with an exception for States that have requested such reductions in prior benefit years.¹¹¹ We also published and sought 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.

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.¹¹² 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. The State asserted that its 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).

¹¹¹ 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. See 84 FR 17484 through 17485 and 85 FR 29193 through 29194. 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. See 86 FR 24187 through 24189.

¹¹² 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.

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 other than 2020 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 sought 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 were posted under the "State Flexibility Requests" heading at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html>.

After reviewing the public comments and Alabama's supporting documentation, we are approving a 25 percent reduction in Alabama's individual market transfers and a 10 percent reduction in Alabama's small group market transfers for the 2023 benefit year.

We summarize and respond to the public comments on Alabama's requests for reduced risk adjustment transfers for the 2023 benefit year below.

Comment: A few commenters supported Alabama's requests to reduce risk adjustment transfers in its individual and small group markets for the 2023 benefit year, stating the State is best suited to decide whether an adjustment is needed within the market to maintain competition and program integrity. Some of these commenters reiterated the State's arguments that 2020 data for the small group market may be unreliable due to the COVID-19 PHE. One commenter

recommended that HHS not use 2020 data as the sole basis for the determination and analysis of the State's individual and small group market reduction requests. Another commenter suggested that HHS should use other metrics besides the *de minimis* threshold, such as the market share of issuers, to assess the State flexibility requests.

However, other commenters opposed Alabama's 2023 reduction requests, stating that the requested reductions would diminish the effectiveness of the HHS-operated risk adjustment program. One commenter who opposed the State's requests stated that there was no mathematical reason why the presence of one large issuer would preclude HHS-operated risk adjustment from functioning appropriately in Alabama. Many commenters opposed to Alabama's requests expressed more general concern with the transfer reduction request for the individual market than the small group market, stating that the approval of the request in the individual market would result in increased adverse selection.

Some commenters also asserted that the State did not meet its burden to substantiate the requests under the criteria established in § 153.320(d). One of these commenters provided detailed data suggesting the requested individual market transfer reduction would increase premiums for one impacted Alabama issuer by an amount greater than the *de minimis* threshold for the 2023 benefit year. This commenter noted based on their experience from the 2022 benefit year (the first year for which the State requested and HHS approved a 50 percent reduction in risk adjustment transfers in the individual market), their analysis showed a 50 percent reduction in the Alabama individual market for the 2023 benefit year is likely to lead to an approximately 2 percent increase in their premiums.¹¹³

Response: We continue to believe and recognize that risk adjustment is critical to the proper functioning of the individual and small group (including merged) markets, and we acknowledge commenters' concerns that approving requested reductions in risk adjustment

¹¹³ BCBSAL Comment Letter. (2022, January 27). CMS. <https://www.regulations.gov/comment/CMS-2021-0196-0195>

transfers could impact the effectiveness of the risk adjustment program. Therefore, our assessment of the relative benefits of allowing States to request a reduction in risk adjustment transfers has been and continues to be on-going, especially when a State always retains the option to operate its own risk adjustment program if the State believes that the HHS-operated risk adjustment program does not capture its State specific dynamics. As discussed in detail below, we are finalizing amendments to § 153.320(d) and the framework for State reduction requests¹¹⁴ applicable beginning with the 2024 benefit year; that is, beginning with the 2024 benefit year, only prior participants can make such requests and the requests will only be reviewed and approved under the *de minimis* threshold framework and criteria. In addition, in future rulemaking, we intend to propose to eliminate the prior participant exception and fully repeal the State flexibility framework beginning with the 2025 benefit year.

However, current regulation allows States to request to reduce risk adjustment State transfers, and if the State's reduction request meets the applicable standards under § 153.320(d)(1)(i), HHS will approve the requests, subject to § 153.320(d)(4)(ii). Therefore, HHS' review of and the approval process for the State flexibility requests submitted by Alabama for the 2023 benefit year are guided by the applicable framework and criteria established in regulation under § 153.320(d)(4), which provides that HHS will approve State reduction requests if HHS determines, based on a review of the State's submission, along with relevant public comments and other relevant factors, including the premium impact of the reduction, that (A) the State-specific factors warrant an adjustment to risk adjustment transfers and support the percentage reduction requested, or (B) the State-specific factors warrant an adjustment to risk adjustment transfers and the requested reduction would have a *de minimis* impact on transfers for issuers that would receive reduced transfer payments. Because Alabama's individual and small

¹¹⁴ As detailed further later, we are finalizing, as proposed, the removal of 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's individual, small group or merged market. We are also finalizing the amendments that limit this flexibility to prior participants beginning with the 2024 benefit year.

group market reduction requests included analysis of the premium impacts of the proposed reduction under the *de minimis* framework, HHS' review falls under the criteria established under §153.320(d)(4)(i)(B); that is, HHS will approve the State's reduction request if HHS determines that State-specific rules 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. Therefore, so long as this policy remains in place, it would not be appropriate to use other metrics besides the *de minimis* threshold, such as the market share of issuers, to review Alabama's 2023 benefit year reduction requests. Additionally, we do not believe that approving Alabama's 2023 benefit year requests will undermine the efficiency of risk adjustment in the State. We believe the minimal impact on transfers, which is further mitigated by the approval of lower amounts than requested, is outweighed by the benefit of continuing to support the State's efforts to regulate its market risk pools and leverage the flexibility currently available under § 153.320(d).¹¹⁵

For the individual market, the State provided information in support of its 50 percent reduction request, including information on the unique State-specific market dynamics that it identified as warranting an adjustment to HHS calculated transfers and its analysis that the reduction requested would have a *de minimis* impact on necessary premium increases. HHS also received public comments in opposition to Alabama's individual market request for the 2023 benefit year. Specifically, an issuer in Alabama shared its data analysis showing a 50 percent reduction would require it to increase its premiums by more than 1 percent.¹¹⁶ In the comment, the issuer stated that a 50 percent reduction would lead to an approximately 2 percent increase in

¹¹⁵ As detailed elsewhere in this rule, we are finalizing the amendments to the State flexibility to request transfer reduction framework, including the creation of the prior participant exception, as proposed, and intend to propose to fully repeal the framework in a future rulemaking.

¹¹⁶ *BCBSAL Comment Letter*. (2022, January 28). CMS. <https://www.regulations.gov/comment/CMS-2021-0196-0195>.

individual market premiums, which would fail to meet the *de minimis* threshold established for State requests and HHS approval of such requests under § 153.320(d)(1)(iii) and (d)(4)(i)(B), respectively.¹¹⁷ However, consistent with § 153.320(d)(4)(ii), HHS may approve a reduction amount that is lower than the amount requested in circumstances where the supporting evidence and analysis do not fully support the requested reduction amount.¹¹⁸ When exercising this flexibility, HHS may assess other relevant factors, including the premium impact of the transfer reduction for the applicable State market risk pool.

Following our consideration of the State’s submission and public comments, HHS determined that Alabama provided sufficient information on the unique State-specific market dynamics that it identified as warranting an adjustment to the HHS calculated transfers for the State’s individual market, but the supporting evidence and analysis did not fully support the requested reduction amount. Therefore, HHS assessed other relevant factors, including the premium impact of the reduction, as well as relevant factors (for example, detailed stakeholder analysis of the estimated impact of the reduction on price positions¹¹⁹). This included consideration and comparison of the data and supporting information submitted by the State and commenters, as well as plan selection and premium data for Alabama. Based on that assessment, HHS has determined that it would be appropriate to approve a reduction amount that is lower than the amount requested, consistent with § 153.320(d)(4)(ii). More specifically, we began our review of the State’s individual market reduction request with consideration of available 2020 data¹²⁰ and the State’s submitted analysis. We also considered detailed stakeholder comments

¹¹⁷ As explained in the 2019 Payment Notice, to satisfy the *de minimis* threshold applicable to these requests, the State request must demonstrate the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a *de minimis* effect on the necessary premium increase to cover the affected issuer’s or issuers’ reduced payments. See 83 FR 16955 through 16960.

¹¹⁸ See 45 CFR 153.320(d)(4)(ii).

¹¹⁹ Commenter’s analysis available at *BCBSAL Comment Letter*. (2022, January 28). CMS. <https://www.regulations.gov/comment/CMS-2021-0196-0195>. Issuer specific BY 2021 and 2022 EDGE enrollment and premium data are not publicly available. However, plan-level QHP rates are available in the *Health Insurance Exchange Public Use Files*. (2021, 2022). CMS. <https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf>.

¹²⁰ Similar to our approach in considering Alabama’s reduction requests in previous years, we considered the most recent data available (for example, for the 2022 benefit year, we considered 2019 data as part of the analysis). This included consideration of available EDGE premium and enrollment plan-level data and risk adjustment transfer data.

that provided tangible evidence of changing price and market share positions, using 2021 and 2022 data, that raised significant questions about the impact a 50 percent reduction in individual market transfers would have on premiums. These comments estimated a 50 percent reduction in individual market transfers would lead to an approximately 2 percent premium increase based on the stakeholder's experience and the impact of the approval of the State's request to reduce 2022 benefit year individual market transfers by 50 percent. Using open enrollment plan selection and premium data for the individual market in Alabama from the same benefit years as the commenter (2021 and 2022),¹²¹ HHS found the commenter's assumptions regarding the approximately 2 percent increase in premiums to be reasonable. Specifically, HHS' analysis supports the commenters' assertions that a 50 percent reduction in 2023 benefit year individual market transfers would lead to a greater than *de minimis* increase in necessary premiums to cover the reduced payments. HHS is therefore exercising the flexibility under § 153.320(d)(4)(ii) to approve Alabama's requested reduction to individual market transfers, but at an amount lower than requested. To ensure the transfer reduction meets the *de minimis* threshold and does not increase premiums by more than 1 percent, we are approving a 25 percent reduction to 2023 benefit year risk adjustment transfers in Alabama's individual market (including the catastrophic and non-catastrophic risk pools).

For the small group market, the State's reduction request acknowledges 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 using other prior years of data to analyze its small group market request for the 2023 benefit year, because the COVID-19 PHE renders an analysis based on 2020 data

¹²¹ Commenter's analysis available at *BCBSAL Comment Letter*. (2022, January 28). CMS. <https://www.regulations.gov/comment/CMS-2021-0196-0195>. BY 2021 and 2022 open enrollment plan selection and premium data are not publicly available. However, plan-level QHP rates are available in the *Health Insurance Exchange Public Use Files*. (2021, 2022). CMS. <https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf>.

unreliable. HHS also received comments expressing general opposition to the State's small group market request for the 2023 benefit year.

Following our consideration of the State's submission and public comments, HHS determined that Alabama provided sufficient information on the unique State-specific market dynamics that it identified as warranting an adjustment to the HHS calculated transfers for the State's small group market, but the supporting evidence and analysis did not fully support the requested reduction amount. Therefore, HHS assessed other relevant factors, including the premium impact of the transfer reduction for the applicable State market risk pool. This included comparison of the data and supporting information submitted by the State and commenters, as well as EDGE premium and enrollment plan-level data for Alabama's small group market.¹²² It also included consideration of the acknowledgement by Alabama in its request that a 50 percent reduction in 2023 benefit year small group market transfers would exceed the applicable *de minimis* threshold.

Based on our review of the unredacted supporting evidence submitted by the State, 2020 benefit year risk adjustment transfer data,¹²³ and 2020 benefit year EDGE premium and enrollment data available to HHS,¹²⁴ we determined it would be appropriate to approve a reduction amount for the small group market that is lower than the amount requested, consistent with § 153.320(d)(4)(ii). Using the most recent 2020 plan-level data available to HHS,¹²⁵ HHS estimated transfer calculations as a percent of premiums, which indicated that the risk adjustment payment recipient would have to increase premiums by approximately 5 percent to cover a 50

¹²² HHS does not have the same open enrollment plan selection and premium data on the small group market in Alabama as it does for the individual market in Alabama; therefore, EDGE premium and enrollment plan-level data was used for the small group market assessment.

¹²³ Issuer specific BY 2020 risk adjustment transfers can be found in *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year*. (2021, June 30). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf>.

¹²⁴ For BY 2020, issuer specific EDGE premium data have not been made public.

¹²⁵ Issuer specific BY 2020 risk adjustment transfers can be found in *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year*. (2021, June 30). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf>. For BY 2020, the issuer specific EDGE premium and enrollment data used for this analysis have not been made public. However, plan-level QHP rates are available in the *Health Insurance Exchange Public Use Files*. (2020). CMS.

percent reduction in transfers.¹²⁶ Based on this calculation, HHS concluded that a 10 percent reduction in risk adjustment transfers would lead to a *de minimis* (less than 1 percent) premium increase in the small group market and therefore approves a 10 percent reduction in transfers in Alabama’s small group market for the 2023 benefit year, exercising our flexibility under § 153.320(d)(4)(ii) to approve an amount lower than requested.

HHS disagrees with assertions that we should not consider 2020 data when considering the 2023 benefit year State flexibility reduction requests. As described in HHS’ “Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year,” risk adjustment State transfers as a percent of premiums remained relatively steady in 2020 compared to the 2019 benefit year, and the amount of paid claims remained strongly correlated with risk adjustment State payments and charges.¹²⁷ Therefore, to assess Alabama’s 2023 benefit risk adjustment reduction requests, we considered 2020 data, similar to our approach in considering Alabama’s risk adjustment reduction requests in previous years in which we use the most recent data available (for example, for the 2022 benefit year, we considered 2019 data as part of the analysis). Therefore, HHS followed the established precedent for review of these requests. We also considered other data years as part of our analysis of the State’s individual market request in response to the detailed comments and analysis using other data years submitted by an impacted stakeholder that called into question whether the requested transfer reduction amount for that market would meet the *de minimis* threshold. Other relevant factors HHS considered were the

¹²⁶ Alabama’s request acknowledged that reducing the risk transfer by 50 percent in the small group market will result in a more than *de minimis* impact of approximately 4 percent of premium. HHS’ analysis indicated that the impact would be approximately 5 percent of premium for the small group market risk payment recipient. HHS and Alabama’s estimates slightly differ because we used different data sources in our analysis. HHS used 2020 benefit year data, including risk adjustment transfers and total premiums, to calculate the impact, while Alabama used 2020 benefit year data from the NAIC’s Supplemental Health Care Exhibit for 2020. HHS believes our EDGE data most accurately reflects the risk adjustment transfer and premium data necessary to calculate the impact of the reduced transfers. Therefore, we based our approval of a 10 percent reduction in Alabama’s small group risk adjustment State transfers based on the analysis showing that a 50 percent reduction would have an approximately 5 percent premium impact on the small group market payment recipient(s).

¹²⁷ *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year*. (2021, June 30). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf>.

limited experience with reduction requests in the individual market,¹²⁸ the larger magnitude of risk adjustment transfers under the State payment transfer formula in the individual market compared to the small group market,¹²⁹ as well as the increased opportunities for adverse selection in the individual market.¹³⁰ In addition, the State's individual market request included an analysis that estimated the transfer impact of its requested reduction would meet the *de minimis* threshold, while its request for the small group market acknowledged the requested reduction to transfers would exceed the *de minimis* threshold.

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

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 625), we proposed numerous amendments to § 153.320(d) to 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).

Following our consideration of the State flexibility framework consistent with the instructions in EO 14009¹³¹ and prior comments we received on this policy, as well as the general low level of interest States have expressed in the policy, we proposed, 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 that previously requested this flexibility in prior benefit years, namely, Alabama.

¹²⁸ The 2022 benefit year was the first year Alabama requested, and HHS approved, a reduction request for the individual market under the State flexibility framework. See, for example, 86 FR 24187 through 24189. In contrast, Alabama requested, and HHS approved, reductions to small group market transfers for several years, beginning with the 2020 benefit year and continuing through the approval, in this rule, of an amount lower than requested for the 2023 benefit year.

¹²⁹ *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year*. (2021, June 30). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf>

¹³⁰ In the small group market, employers select the plans offered to their employees and often pay a significant portion of employees' premiums to encourage enrollment. Depending on the participation rules and market dynamics in a particular State, risk selection can be significantly less in a State's small group market compared to the individual market.

¹³¹ EO 14009; 86 FR 7793 (2021, February 2).

For prior participant reduction requests for the 2024 benefit year and beyond, we also proposed to remove the option for the State to demonstrate that State-specific 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. Instead, we proposed prior participants would be required to demonstrate their requests satisfy the *de minimis* impact standard. Under this standard, the requesting State is required to show that the requested transfer reduction would not cause premiums in the relevant market risk pool to increase by more than 1 percent. We proposed conforming amendments to the HHS approval framework under § 153.320(d)(4)(i) and clarified that HHS would retain the flexibility under § 153.320(d)(4)(ii) to approve a lower reduction amount than requested if the State’s supporting evidence and analysis do not fully support the requested amount. We also clarified 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, not to automatically apply previously approved transfer reductions to future benefit years. Instead, a prior participant would 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).

We sought comment on this proposal.

After reviewing the public comments, we are finalizing as proposed the amendments to § 153.320(d) that repeal the State flexibility framework for States to request reductions in risk adjustment State transfer payments for the 2024 benefit year and beyond, with an exception for prior participants. We are also finalizing that beginning with the 2024 benefit year, States submitting reduction requests must demonstrate that the requested reduction satisfies the *de minimis* standard – that is, the premium increase necessary to cover the affected issuer’s or issuers’ reduced payments does not exceed 1 percent in the relevant State market risk pool.¹³²

¹³² 83 FR 16957.

We are finalizing the conforming amendments to the HHS approval framework in § 153.320(d)(4)(i) to reflect the changes to the applicable criteria (that is, only retaining the *de minimis* criterion) beginning with the 2024 benefit year, as well as the proposed definition of “prior participant” in § 153.320(d)(5). In future rulemaking, HHS intends to propose to eliminate the prior participant exception beginning with the 2025 benefit year.

We summarize and respond to public comments received on repeal of risk adjustment State flexibility to request a reduction in risk adjustment State transfers § 153.320(d) below.

Comment: Several commenters supported the proposal to repeal the ability for States to request a reduction in risk adjustment State transfers in both the individual and small group markets due to concerns that the reduction in transfers would contribute to adverse selection, increase premiums, and reduce plan options. Commenters stated that reducing the risk adjustment State transfers incentivizes issuers to avoid enrolling chronically ill consumers in the individual market and companies whose workers have above-average costs in the small group market. Commenters supporting the repeal also noted that States can run their own risk adjustment programs if they do not think the HHS-operated risk adjustment program works for their State. Many of the commenters supporting the repeal also opposed the proposal to make an exception for prior participating States and requested that HHS instead repeal this policy in its entirety.

Conversely, several commenters opposed the proposal to repeal the ability for States to request a reduction in risk adjustment State transfers because they support the ability for States to make their own decisions about how best to address the unique circumstances of their insurance markets. Some of these commenters also noted that HHS has the ability to review and reject these requests, indicating that there are appropriate guardrails in place such that States should continue to be offered this flexibility. Additionally, some of these commenters generally opposed the proposed repeal, and in particular opposed limiting the ability to request reductions to prior participants, noting that other States may develop the same market dynamics as the one prior

participating State and should have the same ability to request reductions. One of the commenters opposed to the repeal noted concerns with the ability for States to run their own risk adjustment programs, due to the costs to implement such a program within a State.

Response: We are finalizing, as proposed, the repeal of 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 prior participants.¹³³ As detailed in the proposed rule, our further consideration of prior stakeholder feedback, along with consideration of the proposals in light of EO 14009,¹³⁴ and the very low level of interest from States since the policy was adopted, resulted in an evaluation of whether the policy should be continued and if so, in what manner. After reviewing public comments in response to the proposed amendments to § 153.320(d), including the proposed creation of the prior participant exception, and further consideration of the State flexibility framework under EO 14009, we are finalizing this policy as proposed with the intention to propose in future rulemaking to repeal the exception for prior participants beginning with the 2025 benefit year to provide impacted stakeholders additional time to prepare for this change and the potential elimination of this flexibility.

For the 2024 benefit year and beyond, we are also finalizing, as proposed, the removal of the option for States 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 market risk pool as the justification for the State's request and the criteria for HHS approval under § 153.320(d)(4)(i). This retains the *de minimis* standard as the only option for prior participants to justify the reduction and for HHS to approve a request and is designed to 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 EO 14009 to ensure that health care remains affordable for consumers.

¹³³ This includes finalizing, as proposed, the definition in § 153.320(d)(5) for prior participants.

¹³⁴ 86 FR 7793 (Feb. 2, 2021).

Therefore, the only State to have requested risk adjustment transfer reductions from benefit year 2020 to benefit year 2023, Alabama, will be the only State permitted to request reductions in benefit year 2024. However, the *de minimis* standard will be the only option for Alabama to justify the reduction and for HHS review and approval of the requests. We recognize other States may develop the same or similar market dynamics in future benefit years. However, currently, only one State has sought to exercise the flexibility under § 153.320(d) to tailor HHS risk adjustment, which is calibrated using a national dataset, pointing to these unique market dynamics. We therefore believe it is appropriate to provide a transition for this prior participant State, starting with the policies and amendments finalized in this rule that apply beginning with the 2024 benefit year. However, we are concerned about the potential long-term impact of allowing reductions to risk adjustment transfers in any State market risk pool, including the potential negative impacts on the program's ability to mitigate adverse selection and support stability in the individual and small group (including merged) markets. We therefore intend to propose a full repeal of the State flexibility framework (for all States) beginning in the 2025 benefit year in a future rulemaking.

We agree with commenters who noted that States are best able to make their own decisions about how to address the unique circumstances of their insurance markets and remain the primary regulators of their insurance markets. At the same time, however, States have had a low level of interest in this flexibility. Since the 2020 benefit year, all States had the opportunity to submit reduction requests under § 153.320(d), and yet only one State has done so. Similarly, since the 2014 benefit year, all States have had the opportunity to operate the risk adjustment program and, to date, only one State has done so – Massachusetts operated a State-based risk adjustment program from the 2014 through 2016 benefit years. Despite a broad range of market conditions across the 50 States and the District of Columbia, only two States have expressed interest in tailoring risk adjustment to address the unique circumstances of their insurance markets, which suggests that States generally do not want to operate their own risk adjustment

program and demonstrates that the HHS-operated risk adjustment can work across a broad range of market conditions to mitigate adverse selection in the individual and small group (including merged) markets. Additionally, many commenters had concerns about the potential negative impacts of the transfer reductions on the State’s insurance markets. Although, we note these outcomes have not entirely come to bear in Alabama, as new entrants have entered Alabama’s individual market and QHP offerings have increased per county in benefit year 2022¹³⁵, other potential negative impacts include reduced plan quality and increased risk selection in the market. We reiterate that a strong risk adjustment program is necessary to support stability and address adverse selection in the individual and small group markets, and under EO 14009, we have concerns that this policy could undermine these goals in the long-term and therefore intend to propose a full repeal of the State flexibility framework under § 153.320(d) in a future rulemaking. Finally, we appreciate there are a number of different factors States consider when weighing whether to operate a State-based risk adjustment program, including but not limited to the costs associated with establishing and maintaining such a program. HHS remains committed to working with States and other stakeholders to encourage new market participants, mitigate adverse selection, and promote stable insurance markets through strong risk adjustment programs.

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

In the proposed rule, we proposed that issuers collect and make available for HHS’ extraction from issuers’ EDGE servers five new data elements – ZIP Code,¹³⁶ race, ethnicity, an ICHRA indicator, and a subsidy indicator¹³⁷ – as part of the required risk adjustment data that issuers make accessible to HHS in States where HHS operates the risk adjustment program,¹³⁸ beginning with the 2023 benefit year. We also proposed that we would extract these five new

¹³⁵ *Plan Year 2022 Qualified Health Plan Choice and Premiums in HealthCare.gov States*. (2021, October 15), CMS. <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2022QHPPremiumsChoiceReport.pdf>.

¹³⁶ ZIP Code™ is a trademark of the United States Postal Service.

¹³⁷ The subsidy indicator is intended to indicate whether a particular enrollee is (or is not) receiving APTC.

¹³⁸ HHS has been operating the risk adjustment program in all 50 states and the District of Columbia since the 2017 benefit year.

data elements beginning with the 2023 benefit year. Additionally, beginning with the 2022 benefit year, we proposed HHS would extract from issuers' EDGE servers the following three data elements that issuers already make accessible to HHS as part of the required risk adjustment data— plan ID, rating area, and subscriber indicator. We proposed 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 proposed to expand and clarify the scope of permissible HHS uses for the data and the reports extracted from issuer EDGE servers (including summary reports and ad hoc query reports). Related to these proposals, we also considered the burden associated with the collection and extraction of these data elements, and solicited comments on 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, associated burdens, and accompanying comment solicitation.¹³⁹

a. Collection and Extraction of New Data Elements and Extraction of Current Data Elements

We proposed, beginning with the 2023 benefit year, 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, specifically: (1) ZIP Code, (2) race, (3) ethnicity, (4) subsidy indicator, and (5) ICHRA indicator. For race and ethnicity data, we proposed 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),¹⁴⁰ which is collected at a granular level that would allow HHS to analyze more subpopulations than our current data allows, thereby allowing us to better identify and consider policies to address discrimination in

¹³⁹ For a full discussion of the background of the HHS-operated risk adjustment program and the required risk adjustment data, as well as the proposals, see the proposed rule (87 FR 627 through 632).

¹⁴⁰ *HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status*. (2011, October 30), CMS. <https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0>.

health care and health disparities.^{141,142} In addition to collecting and extracting these new data elements, we also proposed, beginning with the 2022 benefit year, to extract plan ID, rating area, and subscriber indicator from issuers' EDGE servers.¹⁴³

We sought comments on these proposals.

After reviewing the public comments, we are finalizing the proposal to collect and extract ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator as part of the risk adjustment data issuers of risk adjustment covered plans are required to make accessible to HHS on their EDGE servers in States where HHS operates the risk adjustment program, beginning with the 2023 benefit year. Specifically, we are finalizing that starting with the 2023 benefit year, issuers will be required to populate the ZIP Code and subsidy indicator fields as part of their EDGE data submissions. The ZIP Code field will be formatted at the five-digit level, and the subsidy indicator will indicate whether a particular enrollee is (or is not) receiving APTC. We are also finalizing that starting with the 2023 benefit year, issuers will be required to report race, ethnicity, and ICHRA indicator information as part of their EDGE data submissions. The ICHRA indicator will indicate whether a particular enrollee's health care coverage involves (or does not involve) an ICHRA. Regarding formatting for race and ethnicity data, we are finalizing the collection of these data elements to be consistent with the 2011 HHS Data Standards,¹⁴⁴ which are the standards used by the FFE to collect these data through the Exchange application.¹⁴⁵

For the 2023 and 2024 benefit years, we are adopting a transitional period during which issuers are required to populate the fields for race and ethnicity using only data they already

¹⁴¹ As detailed later, we recognize issuers may not have race or ethnicity data for certain enrollees since enrollees are generally not required to provide race and ethnicity data, and we intend to include an option that could be used by issuers in these situations.

¹⁴² See 87 FR 628 through 630.

¹⁴³ Ibid.

¹⁴⁴ *HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status*. (2011, October 30) CMS. <https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0>.

¹⁴⁵ As detailed later, we recognize issuers may not have race and/or ethnicity data for certain enrollees since enrollees are generally not required to provide race and ethnicity data and intend to include a version of "unknown" reporting option that could be used by issuers in these situations.

collect or have accessible regarding their enrollees. For example, for the 2023 and 2024 benefit years, for race and ethnicity data, issuers will be deemed in compliance if they submit these data elements using data they already have or collect through existing means, including, for example, through enrollee data captured and reported to the issuer by the FFE, SBE-FPs, and State Exchanges at the time of enrollment. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the fields using available sources and, in the absence of such an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the race and ethnicity data for these enrollees.

We are also finalizing, with slight modification to the transitional approach, collection of the ICHRA indicator. For the 2023 and 2024 benefit year, similar to the transitional approach for race and ethnicity data, issuers are required to populate the field for the ICHRA indicator using only data they already collect or have accessible regarding their enrollees.¹⁴⁶ Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the field using available sources (for example, information from Exchanges and small employers, and requesting information directly from enrollees) and, in the absence of an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the ICHRA indicator for these enrollees.

HHS will provide additional details on what constitutes a good faith effort to ensure collection and submission of the race, ethnicity, and ICHRA indicator data elements in the future. For example, HHS intends to monitor and leverage ongoing work to outline industry-wide standards for collecting health plan demographic data, such as the work by the NAIC's Special Committee on Race & Insurance. As part of this NAIC Committee's efforts to examine and determine which practices or barriers exist in the insurance sector that potentially

¹⁴⁶ In the proposed rule, we proposed a transitional approach whereby the ICHRA indicator would be optional for the 2023 and 2024 benefit years. See 87 FR at 631. We are finalizing the adoption of a transitional approach for the ICHRA indicator; however, as detailed further later, after consideration of comments, for simplicity and to mitigate burdens, we are adopting the same approach for assessing compliance during the transition for populating the race, ethnicity and ICHRA indicator data fields.

disadvantage people of color or historically underrepresented groups, it will consider enhanced data reporting and record keeping requirements across product lines to identify race and other sociodemographic factors of insureds, including consideration of legal and privacy concerns.¹⁴⁷ We also intend to seek input from issuers and other stakeholders as we develop this good faith standard and determine the most feasible methods for issuers to ensure collection and submission of these data elements.¹⁴⁸

Beginning with the 2023 benefit year, HHS will provide additional operational and technical guidance on how issuers should submit these new data elements to HHS through issuer EDGE servers via the applicable benefit year's EDGE Server Business Rules and the EDGE Server Interface Control Document, as may be necessary.¹⁴⁹ For example, even though the submission of race and ethnicity data to issuer EDGE servers must conform to the 2011 HHS Data Standards, we intend to provide further instruction to issuers on how to appropriately map information issuers collect to the race and ethnicity EDGE data fields. In addition, we recognize that enrollees are not required to submit race and ethnicity information to the FFE through the eligibility application process, and that SBE-FPs and State Exchanges similarly permit enrollees to decline to provide this information. We anticipate similar practices and flexibility for enrollees to decline to provide this information also currently exists for enrollees seeking coverage off-Exchanges, and that such flexibility will continue to exist in the future for consumers enrolling in coverage on and off-Exchange. As such, we intend to include an option that will allow issuers to indicate that race or ethnicity information is not known in these situations.

Additionally, we are finalizing, as proposed, 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 generally be subject to notice and comment rulemaking. Furthermore, we would not use

¹⁴⁷ For a full explanation of the work of the NAIC Special (EX) Committee on Race and Insurance, see https://content.naic.org/cmte_ex_race_and_insurance.htm

¹⁴⁸ If the burden estimate for collection of the race, ethnicity, and/or ICHRA indicator data elements changes beginning with the 2025 benefit year, the information collection under OMB control number 0938-1155 would be revised accordingly and stakeholders would be provided the opportunity to comment through that process.

¹⁴⁹ 45 CFR 153.610(a), 153.700(a), and 153.710.

the additional data elements or any analysis of them to pursue changes to our policies until we conduct data quality checks and ensure the response rate is adequate to support any analytical conclusions. These data quality and reliability checks would generally be consistent with other data standard checks that HHS performs related to data collected through issuers’ EDGE servers.

We are also finalizing the proposals to extract the three data elements issuers already report to their EDGE servers – plan ID, rating area, and subscriber indicator – with a modification to the applicability date for extraction of two of these data elements. As detailed further later, we will begin extraction of plan ID and rating area as part of the enrollee-level EDGE data and reports extracted from issuers’ EDGE servers beginning with the 2021 benefit year and will begin extraction of subscriber indicator beginning with the 2022 benefit year. Table 5 provides a summary of the EDGE data collection requirements being finalized in this rule.

TABLE 5: Summary of EDGE Data Collection Requirements Finalized in this Rule

Summary of EDGE Data Collection Requirements Finalized in this Rule					
Data Element	Submission	Included in Enrollee Level Data	Format Requirements for Data Element	Transitional Approach for 2023 and 2024	Included in Limited Data Set
ZIP Code	2023	2023	5 digits	Not Needed	No
Race	2023	2023	2011 HHS Data standards	Yes	Yes
Ethnicity	2023	2023	2011 HHS Data standards	Yes	Yes
Subsidy Indicator	2023	2023	To be set forth in guidance	Not Needed	Yes
ICHRA Indicator	2023	2023	To be set forth in guidance	Yes	Yes
Subscriber Indicator	2014 ¹⁵⁰	2022	To be set forth in guidance	Not Needed	Yes
Plan ID	2014	2021	16 digits	Not Needed	No
Rating Area	2014	2021	2 digits	Not Needed	No

We summarize and respond to public comments received on the proposed collection and extraction of five new data elements and the extraction of three current data elements, along with the other risk adjustment issuer data requirements proposals, in the risk adjustment issuer data requirement proposals comments and responses section of this rule.

¹⁵⁰ Since the 2014 benefit year, issuers have been required to submit plan ID, rating area, and subscriber indicator to their EDGE servers to support HHS’ calculation of risk adjustment transfers (81 FR 94101).

b. Limited Data Set

In conjunction with the collection and extraction of the new and current data element proposals, we proposed 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.¹⁵¹ However, we proposed to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in the limited data set once they are available.¹⁵²

We sought comments on this proposal.

After reviewing the public comments, we are finalizing the proposal 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, and to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in the limited data set once they become available. As explained earlier in this rule, race, ethnicity, ICHRA indicator, and subsidy indicator will become available beginning with the 2023 benefit year, and subscriber indicator will become available beginning with the 2022 benefit year.

We summarize and respond to public comments received on the enrollee-level EDGE limited data set proposals, along with the other risk adjustment issuer data requirements proposals, below.

c. Expansion of Permissible Uses of EDGE Data

We also proposed 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.¹⁵³ This proposed expansion would apply to data that HHS already collects and extracts, as well as the 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

¹⁵¹ See 87 FR 630. See also 84 FR 17487.

¹⁵² See 87 FR 630.

¹⁵³ See 87 FR 630 through 631.

proposed expansion to the permitted uses of the EDGE data and reports would apply as of the effective date of this final rule. Specifically, HHS proposed 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 (84 FR 17488) — 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. We also noted that the enrollee-level EDGE data, including the data elements proposed for collection and extraction, may be subject to disclosure as otherwise required by law.¹⁵⁴

We sought comment on the proposed expansion of the permissible uses of the data and reports HHS extracts from issuers' EDGE servers.

After reviewing the public comments, we are finalizing, as proposed, the expansion of the permitted uses of the data and reports HHS extracts from issuers' EDGE servers.

We summarize and respond to public comments received on the proposed expansion of the permissible uses of EDGE data, along with the other risk adjustment issuer data requirement proposals, below.

d. Burden for Collecting and Extracting Additional Data Elements

As stated above, we included information in the proposed rule (87 FR 631 through 632) on the burdens related to the proposals to collect and extract additional data elements.

We summarize and respond to public comments received on the burden for collecting and extracting additional data elements, along with the other risk adjustment issuer data requirement proposal below.

¹⁵⁴ See, for example, 2 U.S.C. 601(d).

e. Encouraging the Use of Z Codes

In the proposed rule (87 FR 631), we sought 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 SDOH.¹⁵⁵ We solicited 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 EO 13985 and EO 14009, HHS is interested in analyzing z code data to learn about the relationship between risk and the SDOH.

We summarize and respond to the public comments related to encouraging the use of z codes or additional data elements to support the operation of the HHS-operated risk adjustment program below.

f. Risk adjustment issuer data requirement proposals comments and responses

After reviewing the public comments submitted, we are finalizing, with slight modification, the collection and extraction of the five new data elements (ZIP Code, race, ethnicity, ICHRA indicator, and subsidy indicator) beginning with the 2023 benefit year. Additionally, we are finalizing the extraction of plan ID and rating area beginning with the 2021 benefit year, and the extraction of the subscriber indicator beginning with the 2022 benefit year. We are also finalizing, as proposed, the expansion of 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, as well as coverage offered by non-Federal governmental plans.¹⁵⁶ Lastly, we are finalizing the proposal to exclude plan ID, ZIP Code, and

¹⁵⁵ See *Using Z Codes: The Social Determinants of Health; Data Journey to Better Outcomes*. (2021). CMS. <https://www.cms.gov/files/document/zcodes-infographic.pdf>. See also *Utilization of Z Codes for Social Determinants of Health Among Medicare Fee-for-Service Beneficiaries*. (2019). CMS. <https://www.cms.gov/files/document/z-codes-data-highlight.pdf>.

¹⁵⁶ Non-federal governmental plans are subject to many PHS Act federal market reform requirements. See, for example, 42 U.S.C. 300gg-21(a)(1)(A). See also 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, for example, 42 U.S.C. 300gg-22(b)(1)(B) and 45 CFR 150.301, *et seq.*

rating area from the limited data set HHS makes available to requestors for research purposes, but to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in that limited data set once available.

We summarize and respond to public comments received on all of the risk adjustment issuer data requirement proposals (§§ 153.610, 153.700, and 153.710) below.

Comment: Many commenters supported the proposal to collect and extract the five new data elements – ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator. Many of these commenters stated that they believe collecting ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator would assist in identifying health equity issues by allowing for improved tracking of the SDOH and discrimination in health care.

However, several commenters opposed the proposal to collect and extract the five new data elements due to general concerns related to release of information that issuers consider proprietary and enrollees' personally identifiable information (PII). Some of these commenters stated that collecting and extracting these additional data elements would increase the potential risk of a data security breach. Most of these commenters expressed concerns that the extraction of plan ID and rating area, and the collection and extraction of ZIP Code, may enable outside entities to identify issuers and individual members based on identifiers such as State and rating area, particularly when there is a small number of issuers in a State. Some of these commenters expressed concern about the security of enrollees' PII, explaining that the EDGE servers were initially designed so that HHS would receive only aggregate, summary-level data to address privacy concerns regarding transmitting and storing enrollees' personal information, and that in subsequent rulemaking HHS established the policy to receive enrollee-level data, which raised privacy concerns; therefore, collecting and extracting the proposed additional data elements also raises privacy concerns. One commenter recommended that HHS maintain the existing risk adjustment data collection approach and not collect and extract additional EDGE data elements, stating that the existing distributed data approach is implemented in a manner that alleviates

privacy concerns by allowing health plans to control their data assets, which allows private health information to be retained by issuers without additional risk of transmitting and storing large amounts of sensitive data in a central database. This commenter also noted that the existing distributed data approach minimizes the risk of data security breaches.

Response: We are finalizing, with slight modification, the collection and extraction of ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator beginning with the 2023 benefit year. We believe that the collection and extraction of these five new data elements will allow HHS to better analyze and assess risk patterns in the individual, small group, and merged markets in relation to geographic details (including ZIP Code) and demographic data (including ZIP Code, race, ethnicity, subsidy indicator, and ICHRA indicator). Specifically, collection and extraction of these data elements will allow HHS to analyze data at a more granular level than our current data allow and assess risk patterns and the impact of risk adjustment policies based on geographic, income, and other demographic differences. HHS will also be able to consider whether there are cost differentials for certain conditions based on demographic factors like race, ethnicity, or subsidy indicator.

We also agree with commenters that these new data elements will allow HHS to better identify and analyze health equity issues within the individual, small group, and merged market programs. As explained in the proposed rule, HHS' ongoing efforts to continuously improve HHS programs include considering ways to improve our analytical capacity to assess equity impacts of these programs. This includes improving our ability to identify potential refinements to the HHS risk adjustment methodology and consider demographic and geographic data when considering policy and operational changes to improve other HHS individual, small group, and merged market programs.¹⁵⁷ For example, we believe that collecting and extracting these data elements may help HHS assess the costs and use of benefits by various subpopulations related to

¹⁵⁷ As detailed later, we are finalizing the proposed expansion of permitted uses of the enrollee-level EDGE data to include other HHS Federal health-related programs outside of the commercial individual and small group (including merged) markets, as well as coverage offered by non-Federal governmental plans.

our individual, small group, and merged market programs, and may allow HHS to better determine whether new policies, regulations, or guidance may be necessary or appropriate to advance equity within these programs. We note that any changes to the risk adjustment methodology or other policies based on HHS' analysis of these data elements would generally be set forth through notice-and-comment rulemaking.

In response to commenters' concerns that collecting and extracting additional data elements would mean transmitting and storing enrollees' PII and that there would be increased risk of data security breaches, we note that we did not propose and are not finalizing any changes to the existing distributed data collection model applicable to the HHS-operated risk adjustment program. As noted by some commenters, HHS set up the distributed data environment to address privacy and security concerns regarding transmitting and storing enrollees' PII. In the proposed 2014 Payment Notice (77 FR 73118), we explained that using a distributed data collection model means that HHS does not directly collect data from issuers,¹⁵⁸ which limits transmission of data containing PII.¹⁵⁹ Instead, HHS accesses enrollment, claims, and encounter data on issuers' secure distributed data environments,¹⁶⁰ called EDGE servers.¹⁶¹ Under this model, each issuer submits to its EDGE server the required data in HHS-specified electronic formats and must make these data accessible to HHS for use in the HHS-operated risk adjustment program.¹⁶² This general framework remains unchanged. As is current procedure, issuers of risk adjustment covered plans will continue to provide HHS access to the applicable required risk adjustment data elements through the distributed data environment (that is, the issuer's EDGE server) in the HHS-specified electronic formats by the applicable deadline.¹⁶³ This includes providing HHS

¹⁵⁸ 77 FR 73162, 73182 through 73183. This policy was finalized in the 2014 Payment Notice final rule. See 78 FR 15497 through 15500.

¹⁵⁹ See 78 FR 15500. We explained that data are particularly vulnerable during transmission, and that the distributed data collection model eliminates this risk.

¹⁶⁰ 77 FR 73162.

¹⁶¹ 81 FR 94101.

¹⁶² 78 FR 15497.

¹⁶³ See 45 CFR 153.610(a). See also 45 CFR 153.700, et. seq.

access to install, update, and operate common software and specific reference tables,¹⁶⁴ and executing commands provided by HHS to generate the EDGE reports within the designated timeframes. In addition, issuers will continue to retain control over their data assets subject to the requirements of the risk adjustment program operated under sections 1343 and 1321(c) of the ACA.¹⁶⁵

Furthermore, HHS remains committed to protecting the privacy and security of enrollee health information and will continue to require issuers to use masked enrollee identification numbers.¹⁶⁶ Specifically, consistent with the requirement first established in the 2014 Payment Notice, issuers must establish a unique masked enrollee identification number for each enrollee that cannot include PII. As we explained in the 2018 Payment Notice (78 FR 15500), use of masked enrollee-level data safeguards enrollee privacy and security because masked enrollee-level data does not include PII.¹⁶⁷ The policies finalized in this rule also do not alter this approach or the existing privacy protections for enrollee PII or individual claim-level information, such as masked enrollee IDs and masked claims IDs.¹⁶⁸ We also note that the final policy adopted in this rule to exclude plan ID, rating area, and ZIP Code from the limited data set is part of our commitment to protect enrollee PII and strategy to mitigate the risk that entities that receive the limited data set could identify individual members, particularly in areas with a small number of issuers. Therefore, we generally disagree that the collection and extraction of these new data elements will increase risk of disclosure of enrollee PII.

We also appreciate the sensitivities related to protecting issuers' proprietary information and note that HHS has also taken several steps to protect information that issuers may consider to be proprietary. First, as noted above, the adoption and continued use of the distributed data collection model ensures each issuer retains control of their respective data. Second, only a

¹⁶⁴ See, for example, 78 FR 15497 through 15498.

¹⁶⁵ See 42 U.S.C. 18063 and 18041(c).

¹⁶⁶ See 45 CFR 153.720. See also 78 FR 15509 and 81 FR 94101.

¹⁶⁷ See 45 CFR 153.720(b).

¹⁶⁸ In addition to use of masked enrollee IDs and masked claims IDs, another existing protection for enrollee PII is the exclusion of enrollee date of birth from the data issuers must make accessible to HHS on their EDGE servers.

limited data set of certain masked enrollee-level EDGE data elements is made available and this limited data set is available only to qualified researchers if they meet the requirements for access to such file(s), including entering into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information.^{169,170} Among other requirements, the data use agreement requires qualified researchers to explain the specific research purpose for which the data will be used and generally prohibits disclosure of the data.¹⁷¹ We also strictly adhere to all requirements and CMS guidelines related to providing the limited data set to qualified researchers.¹⁷² Third, the policy adopted in this final rule that excludes plan ID, rating area, and ZIP Code from the limited data set further mitigates the risk of disclosure of information that issuers may consider to be proprietary. These are the data elements that could present an increased risk that entities that receive the limited data set file could identify issuers based on identifiers such as State and rating area, particularly in areas with a small number of issuers.

For these reasons, we believe the policies finalized in this rule appropriately balance the different competing interests. More specifically, there are sufficient mitigation strategies in place such that the collection and extraction of these additional data elements presents no significant additional risk of disclosure of information that issuers may consider to be proprietary and it will improve HHS' ability to assess health equity impacts of HHS commercial individual and small group (including merged) market programs, including the HHS-operated risk adjustment program, as well as other HHS Federal health-related programs outside these commercial markets and coverage offered by non-Federal Governmental plans.

¹⁶⁹ See Data Use Agreement. CMS. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-0235L.pdf>. See also 84 FR 17486 through 17490.

¹⁷⁰ Data Use Agreement. CMS. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-0235L.pdf>.

¹⁷¹ *Ibid.* at paragraphs 3, 7.

¹⁷² Further details on limited data set files available at *Limited Data Set (LDS) Files*. (2021, December 1). CMS. https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.

Comment: Several commenters noted the limitation of ZIP Code as a geographic identifier, asserting that ZIP Codes are not able to specifically identify a county or a State in certain situations. They also noted that ZIP Codes can change from year-to-year because ZIP Codes are established by the United States Postal Service to address mail delivery needs, not geographic boundaries. One commenter explained that census tract data would be a more accurate data element for geographic analysis than use of ZIP Codes because it can be used with the Social Vulnerability Index (SVI) to obtain measures for SDOH, race, and ethnicity at the population level. This commenter also noted, however, that census tract data is not currently used by issuers and thus may not be readily available. In contrast, some commenters agreed it would be relatively easy for issuers to submit ZIP Code, as issuers readily have access to this data element.

Response: We are finalizing, as proposed, the collection and extraction of ZIP Code for several reasons. First, ZIP Code is a widely understood unit of geography. Second, while we recognize there are some advantages for using census tract data to conduct certain assessments and analysis of risk patterns based on geographic differences, we are concerned that issuers do not currently collect census tract data and we believe it would be more burdensome for issuers to collect and extract this data element than ZIP Code. In contrast, we believe that issuers already have access to enrollees' ZIP Code information. Third, while ZIP Codes can change over time, the majority of changes to ZIP Code occur at the level of the nine-digit ZIP+4 Code, while five-digit area codes generally remain stable from year to year. Therefore, to balance the desire to collect more granular geographic data with easing the burdens on issuers associated with collection of new data elements, we are finalizing the collection and extraction of the five-digit ZIP Code beginning with the 2023 benefit year.

Comment: Some commenters requested that HHS clarify which ZIP Code issuers would be required to report to their EDGE servers, for example, whether issuers should collect the ZIP Code associated with an enrollee's mailing address or rating area.

Response: Issuers will be required to report the enrollee's mailing address ZIP Code as reported by the enrollee. This means that small group market issuers will be required to report the employee ZIP Code and not employer ZIP Code. Consistent with prior practice, additional technical instructions related to how issuers must submit these new data elements, including ZIP Code, will be made available to issuers through the applicable benefit year's EDGE Server Business Rules and the EDGE Server Interface Control Document.

Comment: Some commenters expressed concern that there is no industry standard for collecting the race and ethnicity data elements and recommended that these data elements not be collected until such a standard is established. These commenters also explained that this lack of an industry standard means that the race and ethnicity data elements collected may not be accurate, and that there is no way to ensure that these data elements are accurate. Some of these commenters also noted that some state laws limit the manner by which issuers or SBE-FPs and State Exchanges can collect the race and ethnicity data elements, which may prevent issuers from collecting and submitting these data to HHS, but they did not offer citations or otherwise identify specific State laws.

Response: We are finalizing the proposal to collect and extract race and ethnicity data beginning with the 2023 benefit year and are also finalizing the accompanying proposal to require issuers to report race and ethnicity data in accordance with the 2011 HHS Data Standards beginning with the 2023 benefit year. While not an industry standard, the 2011 HHS Data Standards were developed under section 4302 of the ACA, which requires the Secretary of HHS to establish data collection standards for race, ethnicity, sex, primary language, and disability status. The 2011 HHS Data Standards¹⁷³ were promulgated to create a set of uniform data collection standards for inclusion in surveys conducted or sponsored by HHS. They are also the standards used by HHS, as the FFE administrator, to collect these data through the Exchange

¹⁷³ *HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status*. (2011, October 30). HHS. <https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0>.

application. Therefore, we believe that the 2011 HHS Data Standards are an appropriate standard to guide the collection of race and ethnicity data by issuers of risk adjustment covered plans.

We also believe that by using the 2011 HHS Data Standards, we will be supporting the creation of a uniform industry standard that can help improve the accuracy and consistency of the data over time. As explained earlier, we are finalizing the proposal to structure the race and ethnicity data elements similar to current collections, where possible. Since the 2011 HHS Data Standards are consistent with how these data elements are captured in the current FFE online eligibility application, we believe that it is most appropriate to require data submission that conforms with the 2011 HHS Data Standards. However, we recognize that issuers may currently collect or have race and ethnicity data that does not conform to the 2011 HHS Data Standards. To address these situations, we intend to provide further instruction to issuers in guidance on how to appropriately map information they may currently collect or have to the race and ethnicity data fields for EDGE data submission.

We are also finalizing, as proposed, that we will provide a value for the race or ethnicity data elements that allows issuers to indicate that race or ethnicity are not known for a specific enrollee. This option will be available to issuers during the transitional approach. After the transitional approach ends (beginning in the 2025 benefit year), this option will similarly be available to issuers who comply with the good faith standard but are unable to populate the race or ethnicity EDGE data field for one or more enrollees.

We also note that although there may be State laws that limit the reporting and collecting of race and ethnicity data elements, the risk adjustment issuer data requirements, including but not limited to the proposals finalized in this rule related to collection and extraction of race and ethnicity data, are rooted in section 1343 of the ACA. Consistent with section 1321(c)(1) of the ACA, the Secretary is responsible for operating the risk adjustment program in any State that fails to do so. Since the 2017 benefit year, HHS has operated risk adjustment in all 50 States and the District of Columbia. 45 CFR 153.610(a) requires issuers of risk adjustment covered plans to

submit and make accessible all required risk adjustment data in accordance with the data collection approach established by HHS in States where the Department operates the program. Specifically, HHS requires issuers of risk adjustment covered plans to submit specified data elements to their EDGE servers to support the calculation of risk adjustment transfers.¹⁷⁴ We also previously finalized policies related to the extraction and use of enrollee-level EDGE data (81 FR 94101 and 84 FR 17488). This rulemaking expands on those requirements and policies, including by expanding the list of data fields issuers must submit to their EDGE servers as part of the required risk adjustment data beginning in the 2023 benefit year.

As detailed in the proposed rule (87 FR 628 through 629), we believe that collecting and extracting these new data elements serves a 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. Collecting and extracting race and ethnicity data will allow HHS to further assess and analyze actuarial risk, and risk patterns in the individual, small group and merged markets more than current data allows. HHS will also be able to analyze more subpopulations than our current data allows, thereby allowing consideration of more areas of health equity, as well as to better address discrimination in health care and health disparities, through pursuit of new risk adjustment policies. This policy is also narrowly tailored and represents the minimum data anticipated at this time to allow HHS to engage in this additional, more granular analysis. We also reiterate that HHS will conduct quality checks of the newly collected data elements and ensure that the response rate is adequate to support any analytical conclusions that could inform policy decisions.

¹⁷⁴ 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 *Supporting Statement For Paperwork Reduction Act Submissions*. OMB. <https://omb.report/icr/201712-0938-015/doc/79644301.pdf>. The previous version is available at *Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS-10401)*. HHS. https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201712-0938-01.

Further, to the extent that race and ethnicity data could be considered protected health information (PHI),¹⁷⁵ the HIPAA Privacy Rule¹⁷⁶ generally permits health plans and covered health care providers to disclose PHI without obtaining authorization from the individual where such disclosures are required by law, such as when Federal or State statutes or regulations require the disclosure.¹⁷⁷ Additionally, as industry standards and State laws applicable to the collection and use of race and ethnicity data elements evolve, HHS will consider whether any changes to the risk adjustment program’s approach for collection of these data elements would be appropriate.

Comment: Some commenters questioned the need for HHS to collect and extract race and ethnicity data as part of the risk adjustment data submissions when the FFE already collects these data.

Response: We acknowledged in the proposed rule (87 FR 631) that these data elements may also be collected by HHS from FFE or SBE-FP enrollees through the eligibility application process and by some State Exchanges from State Exchange enrollees. We further explained how this new risk adjustment data collection requirement would provide HHS with more uniform and comprehensive information. More specifically, the race and ethnicity data collected would represent all enrollees in risk adjustment covered plans in States where HHS operates the risk adjustment program, including coverage offered inside and outside of Exchanges – rather than just reflecting enrollees in coverage offered through Exchanges. Additionally, this new data collection provides HHS the ability to extract and aggregate race and ethnicity 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.¹⁷⁸

¹⁷⁵ 45 CFR 164.103 (definition of “Protected health information”).

¹⁷⁶ 45 CFR 164.512(a).

¹⁷⁷ 45 CFR 164.512(a), 164.103 (definition of “Required by law”). See 65 FR 82462, 82485 (December 28, 2000) for a discussion of 45 CFR 164.512(a) in the context of other mandatory Federal or state laws.

¹⁷⁸ For information on the challenges associated with linking the extracted enrollee-level EDGE data to other sources, see 87 FR 631 through 632.

Comment: Some commenters inquired whether issuers would be penalized if enrollees decline to provide race and ethnicity information, pointing to the fact that Exchange enrollees can decline to share these details on their application. One commenter requested that HHS consider approaching collection of race and ethnicity the same way HHS proposed collection of the ICHRA indicator, with an optional data field for the 2023 and 2024 benefit years, so that issuers can develop processes for collection, validation, and submission of these data elements.

Response: We are finalizing the proposal to collect and extract race and ethnicity data beginning with the 2023 benefit year. More specifically, issuers will be required to use the information they already have or ensure collection of race and ethnicity information to submit to their EDGE servers consistent with the 2011 HHS Data Standards.

Similar to how we have approached other new data collection requirements in the past, we agree with the commenter and are adopting a transitional approach for the 2023 and 2024 benefit years for the race and ethnicity data fields.¹⁷⁹ During this time, issuers are required to populate race and ethnicity data using data the issuers already have or collect. As such, an issuer will be required to report the race and ethnicity data in situations where a particular enrollee has provided these data to the issuer or if the issuer otherwise has these data for that particular enrollee. For example, QHP issuers may already receive race and ethnicity data elements from the applicable FFE, SBE-FP, or State Exchange at the time of enrollment, and reporting these data as collected through that process would be compliant with standards applicable during the 2023 and 2024 benefit years. We intend to provide further instruction to issuers in guidance on how to appropriately map information issuers have or collect to the race and ethnicity data fields for EDGE data submission.

¹⁷⁹ After consideration of comments, for simplicity and to minimize burden, we are adopting the same transitional approach for the ICHRA indicator for the 2023 and 2024 benefit years. For the 2023 and 2024 benefit year, issuers are required to populate the field for the ICHRA indicator using only data they already collect or have accessible regarding their enrollees. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the field using available sources and, in the absence of an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the ICHRA indicator for these enrollees. The transition provides issuers with additional time to develop processes for collection, validation, and submission of these data elements.

Beginning with the 2025 benefit year, issuers will be required to populate the field using available sources and, in the absence of an existing source to populate these data elements for particular enrollees, they will be required to make a good faith effort to ensure collection of race and ethnicity data. HHS will provide additional details on what constitutes a good faith effort to ensure collection of the race and ethnicity data elements in the future. We intend to seek input from issuers and other stakeholders as we develop this good faith standard and determine the most feasible methods for issuers to ensure collection and submission of these data elements.¹⁸⁰

Finally, we recognize that enrollees are not required to submit race and ethnicity information to the FFE through the eligibility application process, and that SBE-FPs and State Exchanges, and off-Exchange issuers, may similarly permit enrollees to decline to provide this information. As such, we will include an option for issuers to indicate that race or ethnicity are not known for a specific enrollee when submitting data to their EDGE servers. For example, an issuer that meets the good faith standard and reports this option in its 2025 benefit year EDGE data for a particular enrollee in these situations will be compliant with the applicable standard, and we would not penalize an issuer in such situations, as enrollees may decline to provide this information.

Comment: Several commenters expressed concern that collecting and extracting the race, ethnicity, or ICHRA data elements would impose additional administrative burden, require costly IT system builds, and mandate other operational updates to develop and test the submission of these data elements to issuer EDGE servers.

Response: We acknowledge concerns that the new data collection, particularly the data on race, ethnicity, and ICHRA indicator, could impose additional administrative burden and may require operational changes to develop, test, and validate submission of these data elements. As further detailed in the Information Collection section of this rule, we are updating our estimates

¹⁸⁰ If the burden estimate for collection of the race, ethnicity, and/or ICHRA indicator data elements changes beginning with the 2025 benefit year, the information collection under OMB control number 0938-1155 would be revised accordingly and stakeholders would be provided the opportunity to comment through that process.

of the burden and costs associated with this new data collection. Currently, all issuers that submit data to their EDGE servers¹⁸¹ have automated the creation of data files that are submitted to their EDGE servers for the existing required data elements, and each issuer will need to update their file creation process to include the five new data elements, which will require a one-time administrative cost. In addition to adding this one-time cost, we also update the estimate to reflect that collection and submission of all five of the new data elements will require 5 hours of work by a management analyst (one hour of work per new data element collected) on an annual basis. We also will revise the information collection under OMB control number 0938–1155 to reflect these additional costs.

This estimate recognizes that information to populate the ICHRA indicator data field is not routinely collected by all issuers at this time, though most issuers currently collect race, ethnicity, ZIP Code, and a subsidy indicator information in some manner.¹⁸² Because we are adopting a transitional approach under which issuers will be required to populate the race, ethnicity, and ICHRA indicator data fields using data they already have or collect for the 2023 and 2024 benefit years, issuers are not required to make any changes to the manner in which they currently collect the race, ethnicity, and ICHRA data elements for the 2023 and 2024 benefit year submissions. This transition period allows additional time for issuers to develop processes for collection and validation of the data required for the new data fields. After consideration of comments, including those related to the burden estimates, we are finalizing the collection and extraction of the five new data elements, with the modifications discussed in this section. We continue to believe that the benefits of collecting and extracting these data elements, including

¹⁸¹ Issuers that elect a risk adjustment default charge are not required to submit EDGE data. See 45 CFR 153.740(b) and 81 FR at 12237 -12238. See also, for example, Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year at 36 (2021, June 30). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf>.

¹⁸² The estimated burden associated with collection of the race, ethnicity, ZIP Code, and the subsidy indicator data is the additional effort and expense for issuers to compile and submit these additional data elements to their EDGE servers and to retain them as part of their risk adjustment records. If the burden estimate for collection of the race, ethnicity, or ICHRA indicator data elements changes beginning with the 2025 benefit year (after the transitional approach ends), the information collection under OMB control number 0938-1155 would be revised accordingly and stakeholders would be provided the opportunity to comment through that process.

race, ethnicity, and the ICHRA indicator, outweigh the burdens and costs associated with the new requirement.

Comment: Several commenters expressed support for the collection and extraction of the ICHRA indicator. One of these commenters explained that collecting and extracting ICHRA indicator would allow HHS to better understand the types of employers offering ICHRAs and the characteristics of the employees enrolling in coverage using ICHRAs.

Conversely, several commenters stated that the ICHRA indicator was not readily available to issuers, and thus issuers would be unable to collect and submit information to populate the ICHRA indicator data field. Specifically, these commenters stated that requiring collection of information to populate the ICHRA indicator data field would require issuers to collect this data element directly from employers, as the FFE, SBE-FPs, and State Exchanges do not currently collect this data outside of SEP enrollments. These commenters also noted that collecting this data element from employers would be administratively burdensome. One commenter requested further guidance on how issuers would be expected to collect and report this data element.

Response: We agree that collecting and extracting ICHRA indicator data will allow HHS to better understand the characteristics of the employees enrolling in coverage using ICHRAs and will allow HHS to conduct analyses to examine whether there are any unique actuarial characteristics of the ICHRA population, (such as the health status of enrollees with ICHRAs), and to investigate what impact (if any) ICHRA enrollment is having on State individual (or merged) market risk pools. After considering public comments, we are finalizing this policy with slight modification to the transitional approach.

In the proposed rule (87 FR 631), we acknowledged that the ICHRA indicator may be collected by HHS from FFE or SBE-FP enrollees through the eligibility application process and that our intention would be to structure these data elements for EDGE data submissions similar to current collections, where possible. As noted above, the ICHRA indicator data element is

intended to indicate whether a particular enrollee's health care coverage involves (or does not involve) an ICHRA. Issuers will be permitted to populate the ICHRA indicator with information from FFE or SBE-FP enrollees or enrollees through State Exchanges, or from other sources for collecting this information from these enrollees.

Currently, the FFE collects information about ICHRA availability from all applicants to determine whether they are eligible for a SEP, as individuals and their dependents who become newly eligible for an ICHRA may be eligible for a SEP. The FFE will also collect information about ICHRA affordability from applicants seeking financial assistance who attest to having ICHRA offers, as the details of the offer impact APTC eligibility. However, recognizing that issuers may not currently routinely collect or otherwise have access to the information for all of their enrollees needed to populate the ICHRA indicator, we are finalizing the adoption of a transitional approach for the 2023 and 2024 benefit years.¹⁸³ Under this transitional approach, similar to the race and ethnicity data fields, issuers will be required to populate the ICHRA indicator using information the issuer currently has access to or otherwise collects that could be used to populate the ICHRA indicator. For example, where an FFE enrollee is using a SEP, information about ICHRA availability is collected by the FFE, and the FFE may make these data available to issuers. In addition, an issuer may currently have or collect information that could be used to populate the ICHRA indicator in situations where the issuer is being paid directly by the employer through the ICHRA for the individual market coverage.¹⁸⁴ Then, beginning with the 2025 benefit year, the transition period will end, and issuers will be required to populate the ICHRA indicator data field using available sources (for example, with information from Exchanges, small employers, or by requesting information directly from enrollees) and, in the

¹⁸³ In the proposed rule, we proposed a transitional approach whereby the ICHRA indicator would be optional for the 2023 and 2024 benefit years. See 87 FR at 631. After consideration of comments, for simplicity and to mitigate burdens, we are adopting the same approach for assessing compliance during the transition for populating the race, ethnicity and ICHRA indicator data fields.

¹⁸⁴ Employers have flexibility to reimburse employees enrolled in ICHRAs for covered medical expenses they incur (including premiums for individual health insurance coverage) or to make the payment on behalf of the enrollee (including premiums for individual health insurance coverage).

absence of such an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the ICHRA indicator for these enrollees. HHS will provide additional details on what constitutes a good faith effort to ensure collection of this data element in the future.¹⁸⁵

As we typically do with other EDGE data elements, we will provide technical guidance to instruct issuers on the format and manner for submission of this data element via the applicable benefit year's EDGE Server Business Rules and the EDGE Server Interface Control Document.¹⁸⁶ We believe that providing a transitional period for the 2023 and 2024 benefit years balances the need to provide additional time for issuers to develop and test available options for collection, validation, and population and submission of the ICHRA indicator, with HHS' efforts to better analyze the ICHRA population, the employers that offer ICHRAs, as well as to investigate the impact of ICHRAs on the individual (and merged) market single risk pools and the HHS-operated risk adjustment program. HHS intends to seek input from issuers and other stakeholders to inform development of the good faith standard and determine the most feasible method for issuers to collect the information used to populate this data field.¹⁸⁷

Comment: Many commenters supported the proposal to extract the three data elements issuers already submit to their EDGE servers – plan ID, rating area, and subscriber indicator – noting that extraction of these data elements would further HHS' ability to analyze and consider policy changes to the risk adjustment methodology. Two commenters supported the proposal because they believe extracting these data elements would allow HHS to assess and consider a plan-based approach to risk adjustment. One commenter suggested that HHS consider extracting plan ID and rating area earlier, beginning with the 2020 or 2021 benefit year enrollee-level

¹⁸⁵ If the burden estimate for collection of ICHRA indicator changes beginning with the 2025 benefit year (after the transitional approach ends), the information collection under OMB control number 0938-1155 would be revised accordingly and stakeholders would be provided the opportunity to comment through that process.

¹⁸⁶ 45 CFR 153.610(a), 153.700(a), and 153.710.

¹⁸⁷ If the burden estimate for collection of ICHRA indicator changes beginning with the 2025 benefit year (after the transitional approach ends), the information collection under OMB control number 0938-1155 would be revised accordingly and stakeholders would be provided the opportunity to comment through the information collection process.

EDGE data extractions and reports. This commenter noted that issuers already collect these data elements, and that waiting until the 2022 benefit year to extract these data and then using these data to further analyze risk patterns would delay any future modifications to improve the risk adjustment methodology until the 2026 benefit year at the earliest.

However, several commenters expressed concern that the extraction of plan ID, rating area, and subscriber indicator data would pose a risk to information that issuers consider proprietary and enrollee privacy, and that plan ID and rating area data are unnecessary for risk adjustment purposes since the risk adjustment program analyzes risk at the enrollee-level.

Response: We are finalizing the extraction of plan ID, rating area, and subscriber indicator with slight modification to the applicability date for extraction of two of these data elements. We will extract plan ID and rating area beginning with the 2021 benefit year, and will extract subscriber indicator beginning with the 2022 benefit year. HHS is committed to continuously considering ways to improve HHS programs, including ways to better assess risk patterns in the individual or small group (including merged) market programs, and believes that extracting plan ID and rating area as soon as feasible will improve HHS' ability to assess risk patterns and the impact of risk adjustment policies at a plan level. We are finalizing an earlier applicability date for extraction of plan ID and rating area because we share the commenter's concern that waiting until the 2022 benefit year could result in a significant delay in the pursuit of future modifications to improve the risk adjustment methodology and program requirements. Additionally, taking into consideration that issuers already submit plan ID and rating area data elements to their EDGE servers, extracting these data sooner would result in little to no additional issuer burden. Extracting plan ID and rating area will also improve HHS' ability to estimate the transfers impact of potential future policies using the enrollee-level EDGE data while minimizing additional burden to issuers with respect to analysis of such potential future policies.

While we acknowledge commenters' concerns that the extraction of plan ID, rating area, and subscriber indicator could pose a risk to information that issuers may consider to be proprietary and enrollee privacy, we believe that there are sufficient mitigation strategies in place such that the collection and extraction of these additional data elements presents no significant additional risk of disclosure of information that issuers consider to be proprietary or to enrollee privacy. For example, as discussed above in response to comments regarding privacy and security concerns related to the collection of new data elements, the adoption and continued use of the distributed data collection model ensures that each issuer retains control of their respective data. Additionally, HHS releases only a limited data set of select masked enrollee-level EDGE data elements only to qualified researchers and only if they meet the requirements for access to such file, including entering into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information. Finally, the policy adopted in this final rule that excludes plan ID, rating area, and ZIP Code from the limited data set further mitigates the risk of disclosure of information that issuers may consider to be proprietary and enrollee PII.

In response to commenters' assertion that plan ID and rating area are unnecessary for risk adjustment purposes since the risk adjustment program analyzes risk at the enrollee-level, we note that, since the 2014 benefit year, issuers have been required to submit plan ID, rating area, and subscriber indicator to their EDGE servers to support HHS' calculation of risk adjustment transfers (81 FR 94101). Furthermore, while the risk adjustment models are recalibrated on enrollee-level EDGE data, HHS uses available plan-level data, summary reports, and enrollee-level EDGE data to evaluate and analyze the performance of the risk adjustment program and inform future policy changes for the program. As explained in the proposed rule (87 FR 628), we will use rating area and plan ID to further assess risk patterns and the impact of risk adjustment policies. For example, the extraction of rating area will provide HHS more granular data to

assess risk patterns and impact based on geographic differences. We therefore disagree that plan ID and rating area are unnecessary for risk adjustment purposes.

Comment: Several commenters supported the proposed exclusion of plan ID, ZIP Code, and rating area from the limited data set. These commenters explained that excluding these data elements from the limited data set would mitigate concerns related to increased exposure of enrollees' PII, data security, and release of information issuers consider proprietary. One commenter also recommended that HHS consider excluding subscriber indicator from the limited data set, also noting concerns surrounding exposure of enrollees' PII.

Other commenters opposed the proposed exclusion of plan ID, ZIP Code, and rating area from the limited data set because exclusion of these data elements would limit qualified researchers' abilities to gain insight that could better inform policy and would also significantly restrict the actuarial use of the limited data set. One commenter recommended including a geographic variable in the limited data set in lieu of ZIP Code, plan ID, and rating area that would indicate placement on the urban-rural continuum. Another commenter recommended that HHS adopt a data use standard that would, for example, only include geographical data (such as plan ID, ZIP Code, and rating area) when there is more than one issuer with at least 5 percent of the enrollment in the rating area to mitigate the concerns with release of information issuers consider proprietary. Another commenter suggested that HHS evaluate whether there is a way to include ZIP Code in the limited data set, as this data element is particularly useful in community-based health equity research.

Response: We recognize and agree with commenters' that including plan ID, ZIP Code, and rating area would enhance the usefulness of the limited data set. However, we are finalizing the exclusion of these data elements from the limited data set to address stakeholder concerns related to providing geographic information, which they believe could result in the identification of certain issuers and the release of data these issuers perceive as competitive and proprietary. Specifically, we also recognize and agree with the concerns that including plan-level data, like

plan ID (which represents the HIOS ID, State, product ID, standard component ID, and variant ID) and rating area in the limited data set could increase the risk of disclosure of information that issuers may consider to be proprietary and the risk that outside entities that receive the data for research may be able to identify issuers using State and rating area, particularly when there is a small number of issuers in a State.

We considered whether we could implement a formal data use standard that would only include geographical data based on the number of issuers in a rating area and on a threshold percentage of enrollment in that rating area. However, in considering this option, we recognize that the appropriate threshold percentage may vary based on market conditions, which could make it difficult to establish and maintain a non-arbitrary threshold. In addition, we would want to solicit comments on the establishment of any such threshold. Therefore, since we did not propose any such threshold, we are not finalizing one at this time. However, we will continue to consider if we can develop a standard for including geographical data in the limited data set based on certain characteristics in a rating area (for example, number of issuers) and would outline such a proposed threshold in future notice-and-comment rulemaking.

We similarly considered whether we could include a geographic variable to indicate placement on the rural-urban continuum. However, in collecting and extracting plan ID, rating area, and ZIP Code, we recognize that we may not have the appropriate data elements to accurately determine where on the rural-urban continuum an enrollee should be placed because areas are often defined as rural or urban based on county data, which we believe we may not be able to accurately identify using only plan ID, ZIP Code, and rating area.¹⁸⁸ In addition, “rural” and “urban” are not defined consistently. For example, the Federal government uses two main definitions for “rural,” and generally determines which geographic regions are considered urban

¹⁸⁸ See, for example, 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas, 75 FR 37246 at 37246 (2010 June 28).

based on the regions that meet the rural classification.¹⁸⁹ For these reasons, if we were to consider including any such geographic variable in the limited data set based on collection and extraction of plan ID, ZIP Code, and rating area, we would want to solicit comments before implementing such an approach. Since we did not propose including any such variable, we are not finalizing one at this time. However, we will continue to consider if we would be able to develop a geographic variable to indicate enrollee placement on the rural-urban continuum and would propose any such policy in future notice-and-comment rulemaking.

Although one commenter noted that inclusion of ZIP Code in the limited data set would be particularly useful for community-based health equity research, we believe that including ZIP Code, similar to plan ID and rating area, presents the risk that outside entities that receive the data for research may be able to identify issuers when there is a small number of issuers in a State. At this time, we believe that the risk of potential release of information that issuers may consider to be proprietary and the risk of identification of individual issuers by outside entities outweighs the additional benefits qualified researchers would gain from access to the ZIP Code data, as well as plan ID and rating area data. As such, we believe excluding ZIP Code, plan ID, and rating area from the limited data set but including race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator as they become available¹⁹⁰ represents the appropriate balance between these concerns and providing a limited data set that is useful to qualified researchers.

As detailed above, we also note that HHS has taken several steps to protect information that issuers may consider to be proprietary. With respect to the limited data set, we strictly adhere to all the requirements and CMS guidelines related to providing the limited data set to

¹⁸⁹ See, for example, *Defining Rural Population*. (2020, June 25). HHS.

<https://www.hhs.gov/guidance/document/defining-rural-population>. The two main definitions for “rural” used across the Federal government are developed by the U.S. Census Bureau and OMB. In addition, the Federal Office of Rural Health and Policy takes components from both of these main definitions when determining how to classify a geographic region.

¹⁹⁰ The subscriber indicator data field will be included in the limited data set beginning with the 2022 benefit year because it will be extracted beginning with the 2022 benefit year. The race, ethnicity, ICHRA indicator, and subsidy indicator data fields will be included in the limited data set beginning with the 2023 benefit year because they will be extracted beginning with the 2023 benefit year.

qualified researchers. This includes a requirement that, prior to receiving the limited data set file, qualified researchers must enter into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information.¹⁹¹ The data use agreement also requires qualified researchers to explain the specific research purpose for which the data will be used and generally prohibits disclosure of the data.

We also note that the limited data set includes masked enrollee-level data, and that inclusion of subscriber indicator in the limited data set would not create risk to enrollee privacy or security because it is intended to identify only whether a masked enrollee is the subscriber or dependent on a plan. Further, the limited data set file is subject to Federal laws and regulations in addition to CMS guidelines, and does not contain specific direct identifiers as set forth in the HIPAA Privacy Rule.¹⁹² Specifically, a limited data set must exclude certain direct identifiers of the individual or relatives, employers, or household members of the individual, including, but not limited to, names, telephone numbers, social security numbers, medical record numbers, account numbers, health plan beneficiary numbers, biometric identifiers like finger and voice prints, and postal address information (not including town or city, State, and ZIP Code).¹⁹³ We note that race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator are not direct identifiers that must be excluded from a limited data set and would not add to the risk of enrollees being identified. In addition, consistent with how we created the limited data set in prior years, HHS will continue to exclude data from the limited data set that could lead to identification of certain enrollees.¹⁹⁴

¹⁹¹ See Data Use Agreement. CMS. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-0235L.pdf>. Further details on LDS files available at *Limited Data Set (LDS) Files*. (2021, December 1). CMS. https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS

¹⁹² See 45 CFR 164.514(e)(1) and (2).

¹⁹³ For the complete list of direct identifiers that are excluded from the limited data set, see 45 CFR 164.514(e)(2)(i)-(xvi).

¹⁹⁴ See, for example, Creation of the 2019 Benefit Year Enrollee-Level EDGE Limited Data Sets: Methods, Decisions and Notes on Data Use. (2021, August 25). CMS. <https://www.cms.gov/files/document/2019-data-use-guide.pdf>.

Comment: Several commenters supported expanding the permissible uses of the enrollee-level EDGE data as it would help inform HHS policy analysis and assessment of equity in health coverage and care, identify and address health disparities, and allow HHS to better understand the full impact of its policies, including changes to risk adjustment methodologies.

However, several commenters opposed the proposed expansion of the permissible uses of enrollee-level EDGE data beyond the uses established in the 2020 Payment Notice. Some of these commenters expressed concern that issuers submit data to their EDGE servers with the belief that the data's primary purpose would be for risk adjustment purposes or for development of the AV Calculator. These commenters noted that because of this belief, data collected through the EDGE servers may not be appropriate, reliable, or sufficiently quality checked for the proposed expanded uses.

Some of these commenters stated specific concerns with data quality and reliability of the race, ethnicity, and ICHRA indicator data. These commenters also explained that they believed race, ethnicity, and ICHRA indicator data were out of scope and not necessary for the purposes of operating the risk adjustment program. Several commenters noted that the proposal to expand the permissible uses of EDGE data would be inconsistent with the intended use of the distributed data environment to administer the HHS-operated risk adjustment program. One commenter requested that HHS adopt a requirement prohibiting use of EDGE data for purposes other than for recalibration of the risk adjustment model and development of the AV Calculator.

Response: In the 2014 Payment Notice (78 FR 15497 through 15500), we established the distributed data collection approach and other requirements related to data collection and reporting for purposes of the HHS-operated risk adjustment program. We also explained that we intended for issuers to provide HHS only those data that we believed were reasonably necessary for the risk adjustment program.¹⁹⁵ We disagree that expanding the permissible uses of data collected through the EDGE servers is inconsistent with the intent to establish the distributed

¹⁹⁵ 78 FR 15500.

data collection approach for collecting risk adjustment data. We also do not agree that the collection of the race, ethnicity, and ICHRA indicator data elements are out of scope; instead, we believe they are reasonably necessary for risk adjustment purposes. As explained in the proposed rule, the collection and extraction of these data elements, in combination with the other extracted data elements, will further HHS' ability to consider more areas of health equity when assessing risk patterns, better address discrimination in health care and health disparities, and identify ways to address health equity issues with regard to the HHS-operated risk adjustment program. More specifically, the additional data elements will allow HHS to conduct analysis at a more granular level than our current data allow, further assess risk patterns and the impact of the risk adjustment policies based on geographic, income, or other demographic differences, and investigate, by sub-population, whether there are cost differentials for certain conditions based on demographic differences (such as race, ethnicity, or subsidy indicator). For example, HHS believes that analysis of the race and ethnicity data elements will help HHS better monitor trends in the health insurance markets and identify potential refinements to the HHS risk adjustment methodology, including ways to address health equity issues and ensure that risk adjustment is not designed in a manner that furthers health inequities. Collection of the ICHRA indicator will allow HHS to investigate whether there are any unique characteristics of the ICHRA population and if ICHRA enrollment is impacting State individual (or merged) market risk pools. This analysis will help inform potential refinements to the risk adjustment methodology and policies for future benefit years. Therefore, the primary purpose and use for the data remains the risk adjustment program. We further note that HHS continuously evaluates the risk adjustment program and the data elements that we believe are reasonably necessary for risk adjustment purposes. For example, we have previously updated EDGE server data collection requirements to include two new data elements: (1) regarding pharmacy claims, the number of days' supply for

prescription drugs, and (2) an in/out-of-network claims indicator.¹⁹⁶ The proposal to collect and extract the race, ethnicity, and ICHRA indicator data elements followed a similar process.

After consideration of public comments, we are finalizing, as proposed, the expansion of the permitted uses of enrollee-level data to allow for more comprehensive study and analysis of potential changes of other HHS Federal health-related programs alongside HHS commercial market programs. In the 2018 Payment Notice (81 FR 94101), we noted that data collected through the EDGE servers will be most useful for risk adjustment purposes. However, we explained that we believed these data would also provide valuable information to validate the AV Calculator and to calibrate other HHS programs in the individual and small group (including merged) markets and finalized our policy to use the data provided to HHS through the EDGE servers for these additional purposes.¹⁹⁷ Similarly, we believe these data will be valuable in assessing policy and operational issues that are not in connection with programs centered around the individual or small group (including merged) commercial health insurance markets. For example, these data will allow HHS to assess the impact of potential policy changes to PHS Act requirements enforced by HHS that are applicable market-wide¹⁹⁸ and those that are applicable to non-Federal governmental plans.¹⁹⁹ In addition, many PHS Act provisions added by the *No Surprises Act*²⁰⁰ apply to group health plans and health insurance issuers offering group or individual health insurance coverage, as well as to providers and facilities, rather than being centered around only non-grandfathered individual and small group health insurance coverage. As we consider policy changes related to implementing the new PHS Act requirements added by the *No Surprises Act*, we will be able to consult the enrollee-level EDGE data.

¹⁹⁶ 81 FR 94101.

¹⁹⁷ Ibid.

¹⁹⁸ See, for example, 42 USC 300gg – 300gg-28.

¹⁹⁹ Non-Federal governmental plans are subject to many PHS Act Federal market reform requirements. See, for example, 42 USC 300gg-21(a)(1)(A). See also 42 USC 300bb-1, et. seq. HHS is generally responsible for enforcement of PHS Act provisions applicable to non-Federal governmental plans. See, for example, 42 USC 300gg-22(b)(1)(B) and 45 CFR 150.301, et. seq.

²⁰⁰ The Consolidated Appropriations Act, 2021 (CAA) was enacted on December 27, 2020 and includes Title I (No Surprises Act) in Division BB.

We also acknowledge stakeholders' concerns about the reliability and quality of these newly collected data elements. As detailed elsewhere in this rule, we will ensure that data quality and reliability checks are consistent with other data standard checks that HHS performs. Additionally, we will ensure that the response rate with respect to the submission of race, ethnicity, and ICHRA indicator data is adequate to support any analytical conclusions that could inform policy decisions.

Comment: Most commenters generally supported HHS pursuing efforts to improve more consistent collection and use of z codes by providers, with several of these commenters stating that using z codes in the HHS-operated risk adjustment program may incentivize more consistent use of z codes by providers. Some commenters also provided specific policies for HHS to consider to encourage increased and consistent use of z codes, including focusing on increased outreach to providers to improve provider awareness of coding guidelines for z codes, working to develop a uniform data collection approach and standardized definitions to support consistent z code use, developing electronic health records certification standards for capturing z codes, and incorporating reporting metrics for z codes into value-based programs.

Some commenters explained that because z codes are immature as a clinical tool and can be subjective in nature, HHS should first focus on steps to ensure z codes accurately reflect SDOH before pursuing other policies. One commenter stated that using z codes in the HHS-operated risk adjustment program without substantial preparation could widen existing gaps in recognized coding standards, and HHS should instead focus on promoting consistent and comprehensive diagnostic reporting using these recognized coding standards. Similarly, one commenter recommended that HHS increase awareness to encourage more consistent use of z codes by providers and revise z codes to ensure proper documentation of significant socioeconomic barriers to health before considering incorporating z codes into the risk adjustment program. Other commenters explained that requiring providers to use z codes would

create additional administrative burden and thus providers should not be penalized for not using z codes.

Response: Given that we only solicited comments on how to encourage the use of z codes and did not propose specific policies in this area, we are not finalizing any specific policies related to the collection and extraction of z codes at this time. We appreciate the feedback and will continue to review and consider the public comments related to the collection and extraction of z codes to support the operation of the HHS-operated risk adjustment program.

Comment: Several commenters suggested that HHS consider collecting and extracting sexual orientation, gender identity, and additional diagnosis codes related to obesity to support the operation of the HHS-operated risk adjustment program. One of these commenters also suggested HHS collect and extract data related to nutritional deficiencies and excess alcohol use. Another commenter suggested HHS collect and extract disability and veteran status, as self-reported by enrollees.

Response: We appreciate these comments but did not propose and are not finalizing the collection or extraction of the additional data elements suggested by these commenters at this time. We may consider the additional data elements presented by these commenters for future benefit years and generally note that we would want to research whether there are existing data sources for the information as part of the consideration of whether to propose changes the risk adjustment data collection requirements as suggested. We also note that the more severe manifestations of nutritional deficiencies (for example, HCC 023 Protein-Calorie Malnutrition) and excess alcohol use (HCC 083 Alcohol Use with Psychotic Complications and HCC 084 Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications) are among the current payment HCCs in the risk adjustment models.²⁰¹

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

²⁰¹ There are also less severe manifestations of alcohol use disorder and nutritional deficiencies, but it was determined they did not meet the criteria for inclusion in the HHS risk adjustment models.

HHS proposed a risk adjustment user fee for the 2023 benefit year of \$0.22 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.²⁰² As described in the 2014 Payment Notice, HHS' operation of risk adjustment on behalf of States is funded through a risk adjustment user fee.²⁰³ 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.

For the 2023 benefit year, HHS proposed to use the same methodology to estimate our administrative expenses to operate the risk adjustment program as used for the 2022 benefit year. 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 estimated 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. We projected a small increase in billable member months in the individual and small group (including merged)

²⁰² For the 2023 benefit year, HHS will be operating the risk adjustment program in every state and the District of Columbia.

²⁰³ 78 FR 15409 at 15416 through 15417.

markets overall in the 2023 benefit year based on the enrollment increases observed between the 2019 and 2020 benefit years (prior to implementation of the ARP in 2021). As such, we proposed the 2023 benefit year risk adjustment user fee rate as \$0.22 PMPM. We sought comment on the proposed risk adjustment user fee for the 2023 benefit year.

After consideration of comments, we are finalizing the 2023 benefit year risk adjustment user fee as proposed.

We summarize and respond to public comments received on the 2023 risk adjustment user fee below.

Comment: We received several comments in support of the 2023 risk adjustment user fee rate.

Response: We appreciate the support and are finalizing, as proposed, a risk adjustment user fee rate for the 2023 benefit year of \$0.22 PMPM.

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

In the proposed rule (87 FR 633), HHS proposed 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 pool²⁰⁴ 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 proposed 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.

²⁰⁴ The high-cost risk pool calculations under the HHS risk adjustment methodology involve 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 94080 through 94082.

Notwithstanding any reduction to a national high-cost risk pool's charges for a given benefit year, this 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 high-cost risk pool charges and payments would continue to be calculated in accordance with the established policies, terms and factors.^{205,206}

We also clarified 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 proposed 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 sought comment on these proposals.

²⁰⁵ See 81 FR 94058, 94081. See also 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 did not propose changes to the high-cost risk pool parameters for the 2023 benefit year and therefore will maintain the \$1 million threshold and 60 percent coinsurance rate.

²⁰⁶ For a visual illustration of the high-cost risk pool terms and factors, see 86 FR 24184 through 24185.

After review of the comments received, we are finalizing these policies as proposed.

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

Comment: Commenters expressed general support for these proposals.

Response: After consideration of the relevant comments, we are finalizing, as proposed, the policies related to disbursement of high-cost risk pool funds recouped as a result of audits of risk adjustment covered plans under § 153.620(c), actionable high-cost risk pool-related discrepancies filed pursuant to § 153.710(d), and successful high-cost risk pool administrative appeals filed pursuant to § 156.1220.

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.²⁰⁷

In the proposed rule, we proposed 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 (87 FR 634 through 639).

We continue to 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.

²⁰⁷ HHS has operated the risk adjustment program in all 50 states and the District of Columbia since the 2017 benefit year.

We received some comments on HHS-RADV generally that were unrelated to any proposal in the proposed rule. As these comments are outside of the scope of this rulemaking, we will not address them at this time. We further describe the proposed refinements, as well as summarize and respond to comments on the proposals, in the sections that follow.

a. Coefficient Estimation Groups in Error Estimation

First, we proposed to modify our process for grouping coefficient estimation groups in error estimation. In the 2020 HHS-RADV Amendments Rule (85 FR 76984 through 76989), 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 PLRS values and HHS-RADV error estimation. To address these rare situations,²⁰⁸ we proposed 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 throughout HHS-RADV error estimation, rather than just at the sorting step that assigns HCCs to failure rate groups, beginning with the 2021 benefit year of HHS-RADV. 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 would be calculated under the State payment transfer formula.

We also explained in the proposed rule that this update to the Super HCC policy would necessitate a change to the policy finalized in the 2021 Payment Notice (85 FR 29196 through

²⁰⁸ 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.

29198), 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.²⁰⁹

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, 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, we proposed to generally maintain the outlier identification approach adopted in the 2021 Payment Notice and proposed 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 (85 FR 29196 through 29198), we also proposed 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 clarified 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 sought comment on these proposals 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.

²⁰⁹ 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.

After reviewing the public comments, we are finalizing the proposal to extend the application of Super HCCs to apply coefficient estimation groups throughout the HHS-RADV error rate calculation methodology as proposed. Additionally, as proposed, we are finalizing the policy to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 de-duplicated EDGE Super HCCs. However, we will 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. Issuers with fewer than 30 de-duplicated EDGE Super HCCs in a failure rate group may still be considered an outlier in other failure rate groups in which they have 30 or more de-duplicated EDGE Super HCCs.

We summarize and respond to public comments received on the coefficient estimation groups in error estimation proposal below.

Comment: Several commenters supported the proposal to extend the application of Super HCCs to apply coefficient estimation groups throughout the error rate calculation process. A few of these commenters asserted that this change better aligns the error rate calculation with the intent of the HHS-RADV program and will enhance the integrity of HHS-RADV. Another commenter asserted this change will contribute to market stability and improve predictability.

Response: We are finalizing this methodological change and the accompanying policies as proposed. HHS agrees that these changes will contribute to market stability and improve issuers' ability to predict HHS-RADV adjustments. More specifically, extending the application of Super HCCs to apply coefficient estimation groups through the error rate calculation process better ensures that an issuer only needs to validate one HCC in a coefficient estimation group to avoid further impacting an adjustment to an enrollee's risk score in HHS-RADV and aligns the HHS-RADV methodology with the enrollee risk score calculation under the State payment transfer formula.

Comment: One commenter requested more information about the prevalence of enrollees that have multiple diagnoses in a Super HCC Group.

Response: As described in the proposed rule, the majority of HCCs in a Super HCC are in the same hierarchy, but in rare instances an individual enrollee may be recorded as having multiple conditions in a coefficient estimation group for HHS-RADV. Specifically, only 0.07 percent of enrollees sampled for HHS-RADV in 2018 had multiple HCCs recorded on EDGE that shared a coefficient estimation group but did not share an HCC hierarchy.

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

In conjunction with the proposal to modify the application of coefficient estimation groups in section III.C.8.a. of this final rule, we also proposed 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 finalized in the 2020 HHS-RADV Amendments Rule (85 FR 76987), coefficient estimation group logic from the adult models is applied to all enrollees, including those subject to the child and infant models. For a full description of the current and proposed Super HCC policies see the proposed rule (87 FR 635 through 639). In the proposed rule, we proposed 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. These definitions are described in the relevant rows in the applicable benefit year's DIY software adult variable logic, child variable logic and infant variable logic. For example, for 2021 HHS-RADV, in the 2021 Benefit Year DIY Software,²¹⁰ the adult coefficient group definitions are in the "HCC group" rows in Table 6: Additional Adult Variables, the child coefficient group definitions are in the "HCC group" rows in Table 7: Additional Child Variables, and the infant coefficient group definitions are in 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.

²¹⁰ The January 7, 2022 version of the DIY software is available at *2021 Benefit Year Risk Adjustment Updated HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software*. (2022). CMS.

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 proposed to apply this change beginning with the 2021 benefit year of HHS-RADV.

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

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

We summarize and respond to public comments received on defining Super HCCs separately for adults, children, and infants below.

Comment: Several commenters supported the proposal to define Super HCCs for each age group according to the age group risk adjustment model to which they are subject as this change better aligns the error rate calculation with the intent of the HHS-RADV program and will enhance the integrity of HHS-RADV. A few commenters opposed defining Super HCCs separately for adults, children and infants and expressed concerns with the volatility of the HHS-RADV methodology. One of these commenters stated that this change would add more complexity to predicting failure rate groups without providing significant benefit. Another commenter opposed to this proposal stated that an increase in the number of factors used in sorting, compounded by relatively small sample sizes, would lead to greater volatility and higher

premiums and that separating child conditions from adult conditions when defining Super HCCs would create more volatility for conditions that are potentially more similar to each other than conditions that are grouped together in other Super HCCs.

Response: We appreciate the support for these proposals and are finalizing the changes to define Super HCCs for each age group according to the age group risk adjustment model to which they are subject beginning with the 2021 benefit year of HHS-RADV, as proposed. When we established the current Super HCC grouping policy, we acknowledged the possibility of defining Super HCCs based on each model separately; however, we proposed and finalized Super HCCs based on only the adult models for a number of different reasons. These included concerns that using the child and infant models separately could lead to less stable failure rate group assignments year-over-year due to some infant model Super HCCs with very small sample sizes and recognition of the fact that the adult models' HCC coefficient estimation groups would be applicable to the vast majority of enrollees (including most children, considering the strong overlap between the structure of the adult and child models). We also believed that the use of the HCC coefficient estimation groups present in the adult models sufficiently balanced the representativeness and accuracy of HCC failure rate estimates across the entire population in aggregate.

However, in recognition of the differences in each age group model's definitions and due to the updates to HCC hierarchies used in the risk adjustment models beginning with the 2021 benefit year, we 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. Based on the results of the further analysis, we do not believe that defining Super HCCs separately for adults, children and infants, except for where child and adult coefficient estimation groups have identical definitions, will increase volatility. Rather, as described in the proposed rule, our simulated analysis found evidence that this methodological change would increase model stability. The analysis found that 93.2 percent of factors would remain in the same failure rate

group across subsequent benefit years, which contrasts with the 91.4 percent of factors that we would expect to remain stable between subsequent years if Super HCCs were only based on the definitions in the adult models. This minor improvement to stability in failure rate groupings may reduce uncertainties issuers face when modeling pricing, and thus is unlikely to have a negative impact on premiums, contrary to the concerns voiced by the commenter that the proposed refinement to the definition of Super HCCs will lead to greater volatility and higher premiums increase. Moreover, under the policy we are finalizing in this rule, beginning with the 2021 benefit year of HHS-RADV, Super HCCs will only be defined separately in cases where the child and adult coefficient estimation groups do not have identical definitions. This limits the number of cases in which the child and adult models diverge, thereby further limiting the volatility in the HHS-RADV methodology. Therefore, we generally disagree that the adoption of this methodological update and accompanying policies would add more complexity without providing significant benefit. Instead, we believe this is an appropriate refinement to the HHS-RADV methodology and error estimation process based on our experience operating the program and analysis of additional years of available data.

c. Negative Failure Rate Constraint

In the 2020 HHS-RADV Amendments Rule (85 FR 76994 through 76998), 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 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 the proposed rule, we proposed 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. To address cases where a positive error rate outlier issuer has a negative failure rate in one failure rate group and a positive failure rate in another failure rate group, we proposed 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 proposed to adopt this policy beginning with the 2021 benefit year HHS-RADV.

We sought comment on this proposal.

After reviewing the public comments, we are finalizing the negative failure rate constraint policy, as proposed.

We summarize and respond to public comments received on the negative failure rate constraint policy below.

Comment: All commenters supported this proposal 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. Some of these commenters asserted that this modification of the negative failure rate constraint better aligns the error rate calculation with the intent of the HHS-RADV program and will enhance the integrity of HHS-RADV.

Response: We appreciate these comments and are finalizing the negative failure rate constraint policy as proposed and will apply it beginning with the 2021 benefit year of HHS-RADV. Although our experience to date leads us to believe that this scenario is unlikely to occur often, we agree this refinement is consistent with the intent of the HHS-RADV program and will enhance the integrity of HHS-RADV by further reducing potential incentives for issuers to use HHS-RADV to identify more HCCs than were reported to their EDGE servers for an applicable benefit year.

Comment: One commenter who supported the proposed policy stated that this change will address instability caused by negative error rates. This commenter also suggested it would

help issuers understand the implications of the policy if HHS provided data to demonstrate the impact of extending the negative failure rate constraint from negative error rate outlier issuers to all outlier issuers, regardless of whether the outlier issuer has a negative or positive error rate.

Response: As explained in the proposed rule (87 FR 638), we believe this is an appropriate modification of the policy adopted in the 2020 HHS-RADV Amendments Rule 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. It is rare, but possible, for a positive error rate outlier to have a negative failure rate in one failure rate group and a positive failure rate in another failure rate group. Specifically, across 2017, 2018 and 2019 HHS-RADV, there was only one instance in which an issuer had a negative failure rate in a failure rate group for which that issuer was an outlier, but had a total error rate that was positive. Despite the relative rarity of these cases, we continue to believe that this is an appropriate modification of the policy adopted in the 2020 HHS-RADV Amendments Rule. Therefore, to address these types of cases in future years of HHS-RADV, we are finalizing, as proposed, the amendment to the application of the negative failure rate constraint policy. Beginning with the 2021 benefit year of HHS-RADV, for the purposes of calculating the GAF, we will 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.

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

HHS proposed 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 proposed to use the high-cost risk pool funds recouped based on an actionable 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, we also proposed 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 also clarified 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 funds as a result of an actionable discrepancy in the next MLR reporting cycle consistent with § 153.710(h). We sought comment on these proposals.

After consideration of the relevant comments, we are finalizing these policies as proposed.

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

Comment: We received several comments expressing general support for these proposals.

Response: We are finalizing, as proposed, the policies related to disbursement of high-cost risk pool funds recouped as a result of audits of risk adjustment covered plans under § 153.620(c), actionable high-cost risk pool-related discrepancies filed pursuant to § 153.710(d), and successful high-cost risk pool administrative appeals filed pursuant to § 156.1220.

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

In the proposed rule (87 FR 639), we explained that 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.²¹¹ For example, because risk adjustment transfer amounts are factors in an issuer's MLR calculations, a delay in 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 final risk adjustment transfer amounts could occur due to audits, actionable discrepancies, or successful appeals. Therefore, we clarified in § 153.710(h)²¹² how issuers should report certain ACA program amounts that could be subject to reconsideration for risk corridors and MLR reporting purposes.

In the proposed rule, we proposed 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.²¹³ We also proposed to add a reference to HHS-RADV discrepancies under § 153.630(d)(2) to the introductory sentence in § 153.710(h)(1).

We also proposed 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

²¹¹ See 45 CFR 153.710(h).

²¹² These instructions were previously codified in 45 CFR 153.710(g) and recently redesignated to 45 CFR 153.710(h). See 79 FR 13789 through 13790 and 86 FR 24194 through 24195.

²¹³ For example, the 2022 benefit year HHS-RADV Summary Report for non-exiting issuers will be published in summer of 2024 and those issuers would be expected to report those amounts in their 2023 MLR Reports (filed by July 31, 2024).

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.

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.²¹⁴

Finally, we proposed 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 (85 FR 786 through 78605 and 86 FR 24194 through 24195) 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).

We sought comments on these proposals.

After reviewing the public comments, we are finalizing the proposed amendments to § 153.710(h) to make clear that HHS expects issuers to report HHS-RADV adjustments as part of

²¹⁴ See, for example, Treatment of Risk Corridors Recovery Payments in the Medical Loss Ratio and Rebate Calculations. (2020, December 30). CMS. <https://www.cms.gov/files/document/mlr-guidance-rc-recoveries-and-mlr-final.pdf>.

their MLR reports in the same manner as they report risk adjustment payment and charge amounts (including high-cost risk pool payments and charges). For greater clarity, the regulation text we adopt in this final rule at § 153.710(h)(2) contains a non-substantive change to also include a reference to HHS-RADV adjustments in the second sentence to align with the addition of the same reference in the first sentence.²¹⁵ We are also finalizing the technical correction to § 153.710(h)(3) to point to the correct sections that contain the relevant reporting instructions.

We summarize and respond to public comments received on proposed medical loss ratio (MLR) reporting requirements (§ 153.710(h)) and policies below.

Comment: One commenter supported the proposal to amend § 153.710(h) 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). We received two comments on the MLR reporting cycle and its interaction with the risk adjustment payment and charge timing, including a suggestion that HHS consider changing the deadline for reporting during the current MLR reporting year any adjustment (including HHS-RADV adjustments) made or approved by HHS before August 15, or the next applicable business day, to June 30 to avoid creating the need for issuers to refile MLR reports after the July 31 deadline to account for these adjustments.

Response: We appreciate these comments and are finalizing the amendments, as proposed, to address and explicitly capture a reference to HHS-RADV adjustments. The changes to the regulation make clear and codify HHS' expectation that issuers report HHS-RADV adjustments as part of their MLR reports in the same manner as they report and with the same deadlines associated with the risk adjustment payment and charge amounts (including high-cost risk pool payments and charges) that were established in the 2017 Payment Notice (81 FR 12236).

²¹⁵ This editorial revision in no way changes or otherwise affects the requirements under the proposed text and more clearly and consistently captures 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.

As for the MLR reporting cycle, we continue to believe that the August 15 date provides the necessary flexibility to account for adjustments to issuers' MLR reports as a result of risk adjustment payment and charge amounts, including HHS-RADV adjustments. Therefore, we did not propose, and are not finalizing, changes to the existing reporting deadlines in § 153.710(h) as applied to HHS-RADV adjustments or other payments and charges that could be subject to reconsideration for purposes of risk corridors and MLR reporting.

11. Deadline for submission of data (§ 153.730)

A risk adjustment covered plan must submit data that is necessary for HHS to calculate risk adjustment payments and charges to HHS in States where HHS is operating the risk adjustment program.^{216,217} In the 2014 Payment Notice (78 FR 15434), 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.

In the proposed rule (87 FR 639 through 640), we did not propose to change this deadline but proposed 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 exercises enforcement discretion to extend the deadline to the next applicable business day.²¹⁸ Recognizing there will be future benefit years when April 30 does not fall on a business day, HHS proposed 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 sought comments on this proposal.

²¹⁶ 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.

²¹⁷ 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.

²¹⁸ See 81 FR 12204 at 12234 n.20; see also Evaluation of EDGE Data Submissions for 2016 Benefit Year. (2016, December 23). CMS. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2016-Q_Q-Guidance_20161222v1.pdf.

After consideration of the comment received, we are finalizing the amendment to § 153.730 as proposed.

Comment: One commenter supported this proposal because this amendment would clarify expectations for when reporting must be completed.

Response: We are finalizing the amendment to § 153.730 to clarify that when the April 30 following the applicable benefit year deadline for issuers to submit the required risk adjustment data falls on a non-business day, the deadline for issuers to submit the required risk adjustment.

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))

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 640), we proposed to amend 45 CFR 155.120(c) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. As explained in the Supplementary Information section earlier in the preamble, HHS will address this policy, as well as the public comments submitted in response to this proposal, in future rulemaking.

2. Civil money penalties for violations of applicable Exchange standards by consumer assistance entities in Federally-facilitated Exchanges (§ 155.206)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 640 through 641), we proposed to make a technical correction to 45 CFR 155.206(i) to add language that would cross-reference 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).²¹⁹ Because of an oversight, this language was not added

²¹⁹ Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114-74, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C.A. § 2461 note 2(a)).

to § 155.206(i) as part of prior efforts and rulemaking to implement the 2015 Act.²²⁰

Additionally, a reference to § 155.206 and any accompanying adjusted CMP amounts have not been included in HHS' annual inflation update rulemakings.²²¹ Therefore, we proposed to amend § 155.206(i) to add the phrase “as adjusted annually under 45 CFR part 102” after the phrase “\$100 for each day” to correct this oversight. The associated CMP table in 45 CFR 102.3 is updated annually, and § 155.206(i) was added in the recent annual update.²²² To date, no CMPs have been imposed under this authority, but any that are imposed 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.

We did not receive any comments in response to the proposed amendments to § 155.206(i) or the accompanying policies detailed in the related preamble discussion. For the reasons stated in the proposed rule, we are finalizing the proposed amendments to § 155.206(i).

3. 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

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 641 through 643), we proposed 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)(6),²²³ a list of the QHP comparative information

²²⁰ See Department of Health and Human Services; Adjustment of Civil Monetary Penalties for Inflation; Interim Final Rule, 81 FR 61538 (2016, September 6).

²²¹ See, for example, the Department of Health and Human Services; Annual Civil Monetary Penalties Inflation Adjustment; Final Rule, 85 FR 2869 (2020, January 17). See also 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 (2021, November 15).

²²² See the Department of Health and Human Services; Annual Civil Monetary Penalties Inflation Adjustment, 87 FR 15100 (2022, March 17).

²²³ While the citation in the preamble in the proposed rule referred to amendments to add new § 155.220(c)(3)(i)(A)(1) through (c)(3)(i)(A)(5), the discussion of the proposal and the proposed regulations made clear that the proposal would add new § 155.220(c)(3)(i)(A)(1) through (c)(3)(i)(A)(6). See, for example, 87 FR 641– 642 and 721 – 722.

web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We also proposed 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.

We proposed to codify new §§ 155.220(c)(3)(i)(A)(I) through (6) 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.

In addition, we proposed to modify the language in § 155.220(c)(3)(i)(A) that served as the basis for the current plan detail disclaimer requirement²²⁴ 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 proposed to revise § 155.220(c)(3)(i)(A) to state that web-broker websites must disclose and display the 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

²²⁴ The current plan detail disclaimer states: “[Name of Company] isn’t able to display all required plan information about this Qualified Health Plan at this time. To get more information about this Qualified Health Plan, visit the Health Insurance Marketplace® website at HealthCare.gov.” See Section 5.3.2. Federally-Facilitated Exchanges (FfEs) and Federally-Facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual (*pp.*53). (2021, August 18). <https://www.cms.gov/files/document/ffeffshop-enrollment-manual-2021.pdf>.

standardized disclaimer provided by HHS. This disclaimer would state that enrollment support for the QHP is available on the Exchange website, and provide a web link to the Exchange website. This proposal to modify the disclaimer requirement in § 155.220(c)(3)(i)(A) would ensure that consumers still receive information on those QHPs for which a web-broker website does not provide enrollment support and directions to where they can obtain enrollment support.

We sought comments on these proposals. After reviewing the public comments, and for the reasons discussed in this final rule and the proposed rule, we are finalizing these requirements as proposed.

We summarize and respond to public comments received on the proposals related to required QHP comparative information on web-broker websites and the associated disclaimer.

Comment: Most commenters supported the proposals to require web-broker websites to display QHP comparative information and the associated disclaimer. Numerous commenters stated the proposals would ensure that consumers who use web-broker websites have access to standardized comparative information on QHPs so they can review, understand, and compare all available options and select the one that best fits their needs. Some commenters indicated these proposals would increase transparency on web-broker websites and reduce the risk that consumers are influenced based on the financial interests of web-brokers or by providing a favorable display of QHP information for QHPs for which the web-broker receives compensation for enrollments.

Response: We appreciate the support for the proposals related to required QHP comparative information on web-broker websites and the associated disclaimer. We agree that these proposals will increase transparency and better enable consumers using web-broker websites to compare and understand the QHP options available to them.

Comment: Some commenters stated that the proposals were a positive step, but that HHS should do more to support consumers' ability to compare plans, such as requiring web-broker

websites to display all plans neutrally and refrain from segregating some QHPs at the bottom of their website pages.

Response: HHS is committed to continuing to consider ways to expand support for consumers using non-Exchange websites. However, we did not propose a requirement for the neutral display of plans in the proposed rule and note that a neutral display requirement generally is inconsistent with HHS' proposal under § 155.205(b)(1) to require web-broker websites to differentially display HHS-designed standardized plan options beginning with the PY 2023 open enrollment period in a manner consistent with how standardized plan options are displayed on HealthCare.gov, unless HHS approves a deviation.

We also recognize that some web-broker websites historically have displayed limited comparative information for some QHPs at the end of a list or the bottom of a website page. HHS disagrees, however, that requirements stricter than those we finalize in this rule are necessary to address these practices. Current HHS rules prohibit web-broker websites from displaying QHP recommendations based on compensation²²⁵ an agent, broker, or web-broker receives from QHP issuers.^{226,227} Additionally, in the August 17, 2021 Web-broker Website Display Bulletin,²²⁸ we reminded web-brokers that, consistent with the prohibition in § 155.220(c)(3)(i)(L), their websites must refrain from filtering the display of QHPs in a manner that favors QHPs for which the web-broker receives compensation from issuers for enrollments. Based on our observations and experience, web-brokers that in past years displayed limited comparative information on certain QHPs at the bottom of their website pages did so because the web-broker did not have an appointment or other financial relationship with the QHPs' issuers. With the adoption of the amendments and policies in this rule, which we believe will further

²²⁵ The term "compensation" includes commissions, fees or other incentives as established in the relevant contract between an issuer and the web-broker.

²²⁶ See 45 CFR 155.220(c)(3)(i)(L). See also 84 FR 17515 through 17521 and 17552 through 17553.

²²⁷ As detailed in this rule, we are also finalizing the proposals to further expand upon and clarify the prohibition on web-broker non-Exchange websites from displaying QHP recommendations based on compensation received from QHP issuers in 45 CFR 155.220(c)(3)(i)(L).

²²⁸ Web-broker Website Display Bulletin. (2021, August 17). CMS. <https://www.cms.gov/files/document/web-broker-website-display-bulletinfinal08172021.pdf>.

limit the behavior and practices identified by the commenter, we are of the view that adopting more stringent or different guidelines is not necessary at this time. Rather, the combination of the existing requirements and the changes finalized in this rule, place sufficient limitations to prevent web-broker websites from inappropriately segregating some QHPs at the bottom of their non-Exchange website pages.

Comment: Two commenters requested that we provide flexibility in terms of how the new standardized disclaimer under § 155.220(c)(3)(i)(A) must be displayed. Specifically, they expressed a preference for web-brokers to be permitted to display the disclaimer in a manner that would not require the disclaimer to be repeated next to each QHP for which it applied, so long as the website design otherwise clearly indicated to consumers for which QHPs the disclaimer applied (for example, by displaying a visual cue beside each QHP for which the disclaimer applied that references the text of the disclaimer in a single location elsewhere on the website page).

Response: We are finalizing as proposed the amendments to § 155.220(c)(3)(i)(A), to require a web-broker's non-Exchange website, to the extent that enrollment support for a QHP is not available using its non-Exchange 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 link to the Exchange website. Historically, one of the criteria to satisfy the prominent display requirement for the plan detail disclaimer required that it be provided separately for each QHP where plan information is not displayed, and the text we provided informed consumers that the web-broker's website is not able to display all required plan information about the specific QHP(s) where the disclaimer appeared.²²⁹ However, we recognize that our historical approach governing the prominent display of the plan detail disclaimer and the accompanying text does not translate well to the new disclaimer requirement in §

²²⁹ Federally-Facilitated Exchange (FFE) and Federally-Facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual (pp. 53-54). (2021, August 18). https://www.regtap.info/uploads/library/ENR_FFEFFSHOPErollmentManual2021_5CR_090921.pdf.

155.220(c)(3)(i)(A) finalized in this rule that shifts the focus to informing consumers about any limitations on enrollment support. Therefore, we generally agree with these commenters and intend to provide some flexibility in terms of how we will interpret and apply the requirement to prominently display the new standardized enrollment support disclaimer under § 155.220(c)(3)(i)(A). Our goal in implementing and enforcing this new requirement will be to ensure consumers are clearly informed about any enrollment limitations on a web-broker's non-Exchange website and similarly have clear instructions for accessing HealthCare.gov if they wish to enroll in those QHPs. We note our intent to generally apply the standards for prominent display of this new standardized disclaimer as have been described and applied previously in relation to the prominent display of other required disclaimers on web-broker websites.²³⁰ For example, we will consider this new disclaimer to be prominently displayed if it is displayed in close proximity to where QHP plan information appears, so that it is noticeable to the consumer. As such, the new enrollment support disclaimer must be written in a font size no smaller than the majority of text on the website page, be noticeable in the context of the website by (for example) using a font color that contrasts with the background of the website page, using the exact language provided by HHS, and including a functioning link to HealthCare.gov. We also clarify that we will consider the display of the new enrollment support standardized disclaimer where the enrollment button (or other similar mechanisms) would otherwise appear for a particular QHP on the web-broker's non-Exchange website to comply with the criterion that the disclaimer is noticeable to consumers. We further clarify that we would similarly consider a web-broker website in compliance with this criterion if a visual cue is displayed where the enrollment button (or another similar mechanism) would otherwise appear for a particular QHP that clearly directs the consumer to the required standardized disclaimer on the same website page or otherwise displays the required standardized disclaimer (for example, in a pop-up bubble that appears while

²³⁰ Ibid. Also see *Guidance for Web-brokers on Displaying Mandatory Standardized Disclaimers*. (2015, April 24). CMS. <https://www.cms.gov/ccio/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-web-brokers-displaying-disclaimers.pdf>.

hovering over the visual cue on the website). In both circumstances, to be considered fully compliant with the prominent display framework, the enrollment support disclaimer must also be noticeable using a font color with appropriate contrasts in the context of the website page or pop-up bubble, be written in a font size that is no smaller than the majority of the surrounding text, use the exact language provided by HHS, and include a functioning link to HealthCare.gov. We will provide additional operational and technical guidance on the display of the enrollment support disclaimer in advance of the start of the plan year 2023 open enrollment period to allow time for implementation. We will also take appropriate steps to similarly finalize the exact language for the new disclaimer so it can be implemented in advance of the start of the next open enrollment period.

Comment: One commenter suggested we establish a safe harbor such that web-brokers are not held responsible for the accuracy of QHP comparative information obtained from Exchange public use files or the Marketplace API and displayed on their websites.

Response: Although we recognize that the Exchange public use files and Marketplace API data may contain errors, we did not propose and decline to adopt the suggested safe harbor at this time. First, we note that typically when we have discovered incorrect QHP comparative information on web-broker websites, it has not been due to incorrect Exchange data. Instead, in these circumstances, the errors have been attributable to faulty processes adopted by web-brokers to ingest and display QHP comparative information, whether the data is sourced from the Exchange or directly from QHP issuers. Second, HHS has processes in place for addressing Exchange data corrections, which includes making necessary updates to the Exchange public use files to reflect the corrections.²³¹ Web-brokers are expected to update the QHP comparative information on their websites when such Exchange data errors are corrected, which in cases when web-brokers are using the Marketplace API will occur automatically. We also notify web-

²³¹ Health Insurance Exchange Public Use Files (Exchange PUFs) General Information. (2022). CMS. <https://www.cms.gov/files/document/exchange-pufs-geninfofacts-py22.pdf>.

brokers when updates are made to the Exchange public use files so web-brokers that do not use the API may make updates to their systems as needed. However, we also clarify that we would not otherwise hold web-brokers responsible in circumstances where the incorrect QHP comparative information is the result of data errors in the Marketplace public use files or Marketplace API. Consistent with the standard in § 155.220(j)(3), HHS would consider the circumstances for why a web-broker website fails to provide correct information if the web-broker otherwise acted in good faith.

Comment: One commenter requested clarification that requiring web-broker websites to display all available QHPs does not constitute a web-broker endorsing QHP issuers with which it is not appointed.

Response: The amendments to § 155.220(c)(3)(i)(A) that we are finalizing in this rule do not modify or otherwise change the long-standing requirement in § 155.220(c)(3)(i)(B) for web-broker non-Exchange websites to provide consumers the ability to view all QHPs offered through the Exchange.²³² Instead, the revisions to § 155.220(c)(3)(i)(A) that we finalize in this rule identify the required minimum QHP comparative information that must be displayed on web-broker non-Exchange websites for all available QHPs in the applicable consumer's area. In response to the comment, we further acknowledge that requiring web-broker websites to display all available QHPs regardless of appointment status with QHP issuers should not be perceived as an endorsement of QHP issuers with which the web-broker is not appointed.

Comment: One commenter requested that we clarify whether § 155.220(c)(3)(i)(A)(6) requires web-broker websites to host static files or whether they are permitted to provide links to issuers' websites in instances where information is subject to change and may be best presented dynamically (for example, in the case of provider directories).

²³² This requirement was previously codified at § 155.220(c)(3)(ii) and first established in regulations that were effective in 2012. See 77 FR 18309 at 18334 through 18336 and 18449. It is designed to ensure that web-broker websites provide consumers with access to the same information they would have if they used the Exchange website. See 77 FR 18335 - 18336.

Response: We clarify that, as finalized, § 155.220(c)(3)(i)(A)(6) requires web-broker non-Exchange websites that assist consumers with Exchange enrollments to include the provider directory made available to the Exchange under § 156.230 as part of the required minimum QHP comparative information. We further clarify that web-broker websites that provide a link to the appropriate provider directory webpages on the applicable QHP issuer's website would satisfy this requirement. The provider directory field in the Exchange public use files consists of links to the applicable QHP issuers' provider directory website pages. Finally, we remind web-brokers and other stakeholders, that web-broker websites may obtain the required QHP comparative information from the Exchange (that is, from the Exchange public use files or Marketplace API) or directly from QHP issuers, as reflected in the introductory clause at § 155.220(c)(3)(i)(A).

Comment: Two commenters opposed these proposals. One commenter stated that these proposals will add little value for consumers; harm the consumer experience when using web-broker websites; and make it more difficult for web-brokers to serve their consumers. This commenter suggested that the goal of these changes may be to drive consumers to use HealthCare.gov. Another commenter expressed concern that these proposals encroach on State authority to regulate the business of insurance and mentioned a possible, unspecified conflict with existing State regulations.

Response: We respectfully disagree that these changes will harm consumers. We believe that these changes will instead make it easier for consumers to compare QHPs when using web-broker websites and identify the best option for their unique circumstances. For example, if web-broker websites are not required to provide basic QHP comparative information for all available QHPs, such as premium and cost-sharing information, there is no reasonable way for consumers using those websites to compare all available options other than navigating to multiple websites. Therefore, we also believe these changes will make it easier, rather than more difficult, for web-brokers to assist their customers. This also is not an attempt to drive consumers away from non-Exchange websites. The existing web-broker plan detail disclaimer requirement mandates that

consumers are provided a functional link to HealthCare.gov. The maintenance of such a requirement for the new disclaimer that must appear when the web-broker website does not support enrollment in a QHP is an appropriate and necessary exercise of HHS' authority to establish requirements governing web-broker participation in FFEs and SBE-FPs. We remain committed to the FFE direct enrollment program and believe consumers should have access to multiple options to enroll in coverage. In addition, we emphasize that these changes largely codify existing policies for the interim approach in place beginning with the PY 2022 open enrollment period pending future rulemaking on these issues. They also represent an appropriate evolution of our enforcement approach regarding the required display of QHP comparative information on web-broker websites under § 155.220(c)(3)(i)(A). While we released more limited QHP details in the early years of Exchanges, that is no longer the case. QHP plan information has been more readily accessible for some time, both through public use files and the Marketplace API. In addition, enrollment through direct enrollment channels (including web-broker websites) has continued to grow year after year.²³³ Therefore, we continued to consider these issues over the years and continue to believe the approach finalized in this rule is in the best interests of Exchange consumers using web-broker websites because it will aid them in comparing QHP options without having to navigate to multiple websites.

With respect to the commenter that expressed concern about encroachment on State regulatory authority or alleged conflict with State regulations, we note that the requirement to display QHP comparative plan information and use an appropriate disclaimer has been part of the framework governing the use of web-broker websites since the inception of the Exchanges.²³⁴ We are not aware of any potential conflicts with existing State regulations and generally welcome information from State regulators or other stakeholders about any specific suspected

²³³ See, for example, *CMS Releases Final Snapshot for the 2021 Federal Exchange Open Enrollment Period*. (2021, January 12). CMS.<https://www.cms.gov/newsroom/press-releases/cms-releases-final-snapshot-2021-federal-exchange-open-enrollment-period>.

²³⁴ We note at the time this regulatory provision was codified at § 155.220(c)(3)(i). See 78 FR 54134 and 54135.

conflicts. We also remain committed to working collaboratively with States with respect to issues related to agent and broker participation in the FFEs and SBE-FPs, including with respect to any issues that may cause confusion for web-brokers as to what is expected of them with respect to website display requirements applicable in FFE and SBE-FP States.

b. Prohibition of QHP Advertising on Web-broker Websites

Section 155.220(c)(3)(i)(L) currently prohibits web-broker non-Exchange websites from displaying QHP recommendations based on compensation²³⁵ an agent, broker, or web-broker receives from QHP issuers. In the proposed rule (87 FR 643), we proposed to amend § 155.220(c)(3)(i)(L) to provide 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 are finalizing the proposal to amend § 155.220(c)(3)(i)(L) to ensure that QHP advertisements are not mistakenly understood as QHP recommendations that the web broker deems to be in the best interest of the consumer. As we discuss in greater detail in the responses to the comments in this section, the intent of this amendment is to ensure that consumers are able to make informed decisions about the best option for their specific circumstances, and are not influenced by favorable placement based on advertising or compensation from issuers to agents, brokers, or web-brokers. However, this amendment is not intended to stifle innovative developments, such as filtering, that can help inform customers of the options that best fit their needs.

We sought comment on the proposed amendments to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising on web-broker websites, which we summarize and respond to below.

²³⁵ The term “compensation” includes commissions, fees or other incentives as established in the relevant contract between an issuer and the web-broker. See 84 FR 17515.

Comment: Most commenters supported the proposals related to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising on web-broker websites, or otherwise providing favored or preferred placement in the display of QHPs based on compensation agents, brokers, or web-brokers receive from QHP issuers. One commenter asserted that the display of QHPs on web-broker websites should be based on factors that will help consumers choose the best option for their needs and allowing preferred placement of QHPs based on compensation from issuers does not place consumer interests first. Another commenter noted that agents, brokers, and web-brokers have not been required to provide unbiased information to consumers, and this proposal would help improve transparency for consumers. One commenter stated that this proposal will improve the shopping experience on web-broker websites by increasing the likelihood that consumers select plans that are the best fit for them based on costs, benefits, provider networks, and drug formularies instead of advertising paid for by issuers. Another commenter stated web-broker websites should not direct a consumer toward a plan unless the direction is based on that consumer's needs. One commenter indicated they were supportive of the proposals to ensure consumers using web-broker websites are not provided biased information in a way that benefits the advertiser rather than the consumer. Many other commenters shared similar sentiments as those described above.

Response: We appreciate comments in support of the proposed amendments to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising on web-broker websites. We agree that the display of QHPs on web-broker websites should be based on factors that assist consumers in making informed decisions about the best option for their specific circumstances, and should not be influenced by favorable placement based on advertising or compensation from issuers to agents, brokers, or web-brokers. After consideration of comments, we are finalizing as proposed the amendments to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising on web-broker websites.

At the same time, we remain committed to the development and use of innovative consumer-assistance tools by web-brokers to help consumers select QHPs that best fit their needs. As such, we also clarify that web-brokers will continue to be able to offer filtering capabilities or decision support tools that the consumer can use to navigate or refine the display of QHPs consistent with existing CMS guidelines.²³⁶ For example, a web-broker can offer consumers additional sort functionality to alter the order of the QHPs listed, as long as the web-broker website still provides consumers the ability to view all QHPs offered through the Exchange regardless of how the consumer chooses to sort the QHPs (for example, from lowest to highest premium or deductible). A web-broker may also allow the consumer to apply filters (for example, metal level, provider network type, issuer) to the full list of available QHPs to refine the consumer's search. If a consumer selects a certain filter (for example, bronze metal level), the web-broker website must display all QHPs offered through the relevant Exchange that satisfy that filter's description. The use of any filters or tools must comply with other applicable requirements; for example, the use of filters or other tools to refine the display of QHPs cannot result in the favorable placement of those QHPs for which a web-broker receives compensation for enrollments in relation to all other available QHPs consistent with § 155.220(c)(3)(i)(L) and applicable guidance on permissible filtering of QHPs on web-broker websites. We believe that the framework for the display of QHP information captured in § 155.220(c)(3)(i), as amended by this rule, coupled with the flexibility to develop innovative consumer assistance tools to filter or refine the list of available QHPs strikes the right balance to protect and support consumers enrolling in Exchange coverage through web-broker websites.

In response to commenters stating web-broker websites have not been required to provide unbiased information, we note a variety of requirements have been in place for some time that require web-broker websites to provide consumers information about QHPs in an unbiased

²³⁶ Web-broker Website Display Bulletin. (2021, August 17). CMS. <https://www.cms.gov/files/document/webbroker-website-display-bulletinfinal08172021.pdf>.

fashion. For example, § 155.220(c)(3)(i)(B) requires web-broker websites to provide consumers the ability to view all QHPs offered through the Exchange without respect to compensation arrangements web-brokers have with QHP issuers. Similarly, § 155.220(c)(3)(i)(A) has required web-broker websites to provide certain QHP comparative information for all available QHPs or a standardized disclaimer with a link directing consumers to the Exchange in cases when the comparative information is not provided; we note that we are also taking additional steps in this rule to ensure consumers using web-broker websites have access to the same information for all available QHPs as they would if they used the Exchange website. In addition, § 155.220(c)(3)(i)(L) already prohibited web-broker websites from displaying QHP recommendations based on compensation agents, brokers, or web-brokers receive from QHP issuers and will be further enhanced by the changes to § 155.220(c)(3)(i)(L) finalized in this rule that will further protect consumers by prohibiting QHP advertising and preferred placement of QHPs on web-broker websites based on compensation from QHP issuers.

Comment: One commenter did not oppose the proposal if it is limited to advertising or preferred placement based on compensation from issuers on web-broker website pages for enrollment through the Exchange (that is, if the prohibition does not apply to web-broker website pages marketing non-QHPs and QHPs for enrollment outside the Exchange). Another commenter requested clarification that the proposal was not intended to prohibit advertising on website pages marketing other non-QHP product types, and that the proposal was instead intended only to apply the prohibition to web-broker website pages supporting enrollment in QHPs through the Exchange.

Response: We clarify the amendment to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising only applies to web-broker website pages displaying or marketing QHPs for enrollment through the Exchange. In other words, this framework would extend to web-broker websites and pages for which enrollment would occur through a direct enrollment pathway (including both the Classic and Enhanced direct enrollment pathways). It would not, however,

extend to other web-broker website pages, such as those marketing products – whether QHPs or non-QHPs – for enrollment outside the Exchange. We did not propose to extend it in this manner because the framework in § 155.220 is part of the procedures the Secretary established under section 1312(e) of the ACA under which agents and brokers (including web-brokers) can enroll consumers in QHPs offered through Exchanges.

Comment: One commenter recommended that the proposed prohibition on QHP advertising and preferred placement on web-broker websites not be interpreted to prohibit the display of additional QHP information beyond the required QHP comparative information for a subset of QHPs. The commenter explained that some web-brokers have arrangements with issuers to display information about plan designs or features that include the display of information not available in Exchange public use files or the Marketplace API, and that the display of this additional information can highlight distinctions between plans and help consumers select plans that best meet their needs.

Response: We did not propose and are not finalizing a general prohibition on web-broker websites displaying QHP information beyond what is provided by the Exchange (for example, made available in the Exchange public use files or through the Marketplace API) or directly from QHP issuers. Similarly, we confirm that the requirement to display minimum required QHP comparative information captured in § 155.220(c)(3)(i)(A)(1) through (6) as finalized in this rule does not prohibit the display of additional QHP information the web-broker obtains directly from QHP issuers. We further note and confirm that the regulatory text at § 155.220(c)(3)(i)(A) envisions that QHP information would be provided to web-brokers by Exchanges and QHP issuers. At the same time, however, web-brokers that elect to display such additional information must ensure compliance with other applicable requirements. For example, the display of additional information received from an issuer for its QHPs cannot result in the favorable placement of those QHPs in relation to all other available QHPs consistent with § 155.220(c)(3)(i)(L) and applicable guidance on permissible filtering of QHPs on web-broker

websites.²³⁷ Similarly, any payments received from QHP issuers to display additional information on web-broker websites cannot result in favored or preferred placement in the display of QHPs on the web-broker's website.

Comment: One commenter supported the proposal only in the context of consumer-facing web-broker websites, and requested different treatment of agent/broker-facing web-broker websites.²³⁸ The commenter expressed concern that if the proposal applied to agent/broker-facing web-broker websites, it could inadvertently jeopardize innovation by web-brokers related to educating agents and brokers about a large number of QHP offerings, in particular those offered by new market entrants, and differences in the design of those QHPs' benefits, networks, and other plan features. Similarly, the commenter further explained that web-brokers often host issuer direct enrollment websites²³⁹ based on compensation from issuers and in doing so often provide additional features or integrations associated with those issuer partnerships that are available to agents and brokers using their web-broker websites (for example, better premium payment integration, the ability to enroll in the issuers' plans outside the Exchange), and was concerned the proposed amendments to § 155.220(c)(3)(i)(L) would disincentivize the development of these additional features.²⁴⁰ Lastly, the commenter requested clarification that visual cues associated with the display of particular issuers' QHPs on a web-broker's website (for example, to indicate the availability of additional functionality such as payment integration) are not prohibited by this proposal.

²³⁷ *Ibid.*

²³⁸ Consumer-facing web-broker websites are those used independently by consumers without the assistance of an agent or broker. Agent/broker-facing web-broker websites are used by agents or brokers assisting consumers; in this case, the consumers agents or brokers are assisting may never view the web-broker websites that are being used by the agents or brokers assisting them. Generally, Exchange rules governing web-broker websites do not distinguish between consumer-facing and agent/broker-facing web-broker websites. However, this commenter requested that we create such a distinction.

²³⁹ Web-brokers may function as QHP issuer direct enrollment technology providers. See § 155.20.

²⁴⁰ In this case, we believe the commenter is intending to convey that a QHP issuer relying on a web-broker as a QHP issuer direct enrollment technology provider would be less likely to engage the web-broker to provide these additional features (whether only on its issuer-specific direct enrollment website or through the web-broker's own website) if it could not also pay the web-broker to advertise the availability of its QHPs and these additional features to agents and brokers using its web-broker website.

Response: We appreciate that some web-brokers may wish to have additional flexibility and provide additional resources to their agent and broker partners. The amendments to § 155.220(c)(3)(i)(L) and the prohibition of QHP advertising on web-broker websites, which we are finalizing as proposed, apply to web-broker websites used to enroll consumers in Exchange coverage whether or not the web-broker websites are consumer-facing (that is, intended to be used by consumers independently) or agent/broker-facing (that is, intended to be used by agents or brokers assisting consumers). They are intended to prohibit these activities to the extent they constitute advertising, preferred placement, favorable display, or other types of promotion of particular QHPs based on payment from the issuers offering those QHPs. These changes build on the existing prohibition on the display of QHP recommendations based on the compensation received by the agent, broker, or web-broker from QHP issuers.

As finalized, § 155.220(c)(3)(i)(L) does not prohibit web-brokers from educating agents and brokers generally about the availability and nature of new plan designs or plan features, or the existence of QHPs offered by issuers that have newly entered a market. Web-brokers may educate agents and brokers by offering filtering capabilities that enable agents and brokers to quickly identify particular QHPs with certain characteristics and corresponding training on the existence and purpose of those filtering capabilities. Similarly, § 155.220(c)(3)(i)(L) does not apply to additional features web-brokers may make available to QHP issuers that engage them to develop or maintain an issuer-specific direct enrollment website through which individual consumers—or persons assisting consumers such as agents and brokers—may view information on and complete enrollment in the issuers' QHPs,²⁴¹ so long as the means through which web-brokers inform agents and brokers of such features do not constitute advertising, preferred placement, favorable display, or other types of promotion of particular QHPs based on

²⁴¹ Here, and elsewhere, when we refer to a web-broker's website without indicating it is an issuer-specific website hosted by a web-broker acting as a QHP issuer direct enrollment technology provider, we are referring to the web-broker's own non-Exchange website subject to the requirements of § 155.220(c) and other applicable rules governing such web-brokers and their non-Exchange websites subject to the requirements of § 155.220(c).

compensation from the issuers offering those QHPs. For example, § 155.220(c)(3)(i)(L) is not intended to prohibit a web-broker from informing its agent or broker clients of the availability of particular features on its web-broker website that may only be available for particular issuers' QHPs,²⁴² such as enhanced payment integration or the ability to enroll in an issuer's plans outside the Exchange, because it is possible to provide that information without it being presented as advertising, preferred placement, favorable display, or other types or means of promotion of particular QHPs. Lastly, in response to comments, we clarify that visual cues (such as an icon) associated with the display of particular issuers' QHPs (for example, to indicate the availability of additional functionality such as payment integration) are also not prohibited. However, we reiterate that any related compensation or payment received by such web-brokers from QHP issuers to display additional information must not result in the favorable placement of those QHPs in relation to all other available QHPs consistent with § 155.220(c)(3)(i)(L) and our guidance on permissible filtering of QHPs on web-broker websites.

Comment: One commenter expressed concern that the proposal could limit the ability of web-broker websites to offer tools, such as filtering capabilities, that enhance the user experience. The commenter requested we clarify that functionality that allows plan filtering based on user preferences (presumably consumer or agent/broker users) is not prohibited, even if the result of a particular user's filtering choices is to favor the display of plans for which the web-broker receives compensation for enrollments.

Response: We agree that it is important that web-brokers continue to have the flexibility to offer certain permissible filtering tools to assist Exchange consumers shopping for QHPs on web-broker non-Exchange websites. As noted earlier, we remain committed to supporting the development and use of innovative consumer-assistance tools by web-brokers to help consumers

²⁴² As described earlier in this rule, web-broker websites may not support enrollment in all available QHPs. Web-broker websites may provide additional comparative information about some QHPs that they have obtained directly from QHP issuers (for example, comparative information not available in the Exchange public use files or Marketplace API). Similarly, web-broker websites may provide additional features that may only be available for particular issuers' QHPs, such as enhanced payment integration or the ability to enroll in an issuer's plans outside the Exchange.

select QHPs that best fit their needs, but reiterate that such tools must comply with other applicable requirements. This includes, but is not limited to, the existing prohibition on the display of QHPs based on the compensation received by the agent, broker, or web-broker, as well as the amendment to § 155.220(c)(3)(i)(L) and the prohibition of QHP advertising on web-broker websites we are finalizing in this rule. When used in this context, “advertisements” include any form of marketing or promotion of QHPs based on payment from QHP issuers. Consistent with existing CMS guidance on permissible filters,²⁴³ this would not prohibit a web-broker non-Exchange website from offering consumers filtering capabilities that, when applied neutrally, happen to result in the favorable display of QHPs offered by issuers from whom the web-broker receives compensation for enrollment in those QHPs. For example, HHS would not deem a web-broker website out of compliance with applicable requirements, as finalized in this rule, if a neutral filter selected by the consumer orders all available QHPs from lowest to highest premium and the lowest premium QHPs happen to be ones for which the web-broker received compensation or payment from QHP issuers. In such circumstances, the web-broker website would need to include the required minimum QHP comparative information (including premium) for all available QHPs and the default listing of QHPs on the web-broker website would need to provide that information for all QHPs offered on the Exchange by all QHP issuers, unless the consumer or agent/broker using the web-broker’s non-Exchange website actively removes that default filter. Similarly, if an otherwise neutral filter is available for a consumer that, if selected, produces a list favoring a particular issuer’s QHPs (for example, a filter that limits the display of QHPs to those offered by specific issuers actively selected by the consumer), making that filter available is not prohibited so long as the web-broker website complies with other applicable requirements. This would include the use of a default listing of

²⁴³ Web-broker Website Display Bulletin. (2021, August 17). CMS.
<https://www.cms.gov/files/document/webbroker-website-display-bulletinfinal08172021.pdf>.

QHPs that includes the required minimum QHP comparative information for all QHPs offered on the Exchange unless the consumer actively removes the default filter.

Comment: One commenter expressed concern that the proposal would prohibit web-brokers from listing QHPs offered by issuers with which it is appointed and from whom it receives compensation for enrollments favorably as compared to those offered by issuers with which it is not appointed (that is, listing all of the former before all of the latter).

Response: In the 2020 Payment Notice (84 FR 17454), we codified the existing prohibition on the display of QHP recommendations based on compensation the agent, broker, or web-broker receives from QHP issuers. In addition, as explained above, we have transitioned from the use of enforcement discretion that permitted web-brokers to only display issuer marketing name, plan marketing name, product network type, and metal level for some QHPs, beginning with the PY 2022 open enrollment period. As part of this transition, we also previously clarified that with web-broker websites displaying standardized QHP comparative information for all available QHPs beginning with the PY 2022 open enrollment period, to comply with the current standard in § 155.220(c)(3)(i)(L) that prohibits the display of QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers, web-broker websites must refrain from filtering the display of QHPs in a manner that favors QHPs for which the web-broker receives compensation from issuers for enrollments. In other words, consistent with currently applicable requirements, web-brokers must not display some QHPs at the bottom of their website pages simply because they are not appointed with the issuers that offer those QHPs. We did not propose to change the prohibition on the display of QHPs based on the compensation received by an agent, broker, or web-broker from QHP issuers for enrollment in QHPs. Instead, we proposed and are finalizing the extension of the prohibition under § 155.220(c)(3)(i)(L) to also prohibit advertising of QHPs on web-broker websites. As outlined above, to comply with the new framework and applicable requirements, web-broker websites cannot more favorably display QHPs for which the agent, broker, or web-broker

receives compensation from issuers for enrollment in QHPs and also cannot more favorably display QHPs for which the agent, broker, or web-broker receives payment for advertising purposes. This includes a prohibition on the favorable display based on which QHPs are offered by issuers with whom the agent, broker, or web-broker has an appointment.²⁴⁴

Comment: Two commenters were opposed to this proposal. One commenter asserted that prohibiting QHP advertising on web-broker websites lessens the incentive for web-brokers to become direct enrollment entities and continue to innovate. Instead, the commenter suggested we allow QHP advertising, but require that advertisements be identified as such. Another commenter conveyed concern about this proposal encroaching on State authority to regulate the business of insurance and mentioned a nonspecific possible conflict with existing State regulations.

Response: We appreciate the concern that prohibiting QHP advertising on web-broker websites may reduce incentives to become a direct enrollment entity, but do not believe that risk outweighs the benefit to consumers of the prohibition. We considered the option of allowing some form of QHP advertising so long as the advertisements were clearly identified as advertisements. However, as described in the proposed rule (87 FR 643), even if QHP advertisements are clearly identified, we believe it is not in the interest of consumers to allow them on web-broker websites that facilitate enrollment in Exchange coverage.

With respect to commenters that expressed concern with encroachment on State regulatory authority or alleged conflict with State regulations, we note that the requirement at § 155.220(c)(3)(i)(L) prohibiting web-broker websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers is not new.²⁴⁵ For additional information in response to this comment, please see the response to the same comment on the prior proposal in III.D.3.(a).

²⁴⁴ See the previous preamble regarding the new standardized disclaimer under § 155.220(c)(3)(i)(A), as amended, for details on how information about which QHPs the web-broker website does not support enrollment in should be shared with consumers. Not having an appointment with a particular issuer is the primary reason why web-broker websites would not support enrollment in particular QHPs.

²⁴⁵ See 84 FR 17563.

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

In the proposed rule (87 FR 643), we proposed to amend § 155.220 to add a 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 a plan name, from lowest to highest premium, etc.).

We are finalizing this requirement because we believe it will provide consumers with a better understanding of the information being presented to them on web-broker websites and enable them to make better informed decisions and select QHPs that best fit their needs. We believe that a clear explanation for the bases of the recommendations displayed to them on web-broker websites (whether explicit or implicit), will help consumers assess the value of the recommendations (for example, whether a recommendation is based on the factors most important to them).

We sought comment on this proposal, which we summarize and respond to below.

Comment: Most commenters supported this proposal and the addition of § 155.220(c)(3)(i)(M). Several commenters stated that requiring web-broker websites to disclose the basis for their plan recommendations and display of plans increases transparency. Numerous other commenters who supported these changes stated these changes would help consumers be better informed. One commenter indicated this would enhance decision support tools for consumers and increase the chance they find the plan that best meets their needs.

Response: We agree that this proposal and the addition of § 155.220(c)(3)(i)(M) will increase transparency and ensure consumers are better informed and more likely to choose the plan that is best for them.

Comment: Several commenters requested web-broker websites be afforded flexibility in terms of the content and placement of the required explanations. In particular, some commenters

requested that the required explanations not be so detailed that they are difficult for consumers to understand and may dissuade some consumers from completing the enrollment process.

Response: We appreciate the desire for flexibility and do not intend to be prescriptive in terms of the content or placement of the required explanations of the rationale for QHP recommendations or the methodology for the default display of QHPs. We understand there are currently many variations in the design and content of web-broker websites and it would be difficult to develop a one-size-fits all standardized approach with respect to the content or placement of the explanations. In addition, there will necessarily be variations in the rationales for the plan recommendations and methodologies for the default display of plans used by different web-broker websites and they may also frequently change. For those reasons, we intend to allow web-broker websites significant flexibility in terms of the content and placement of the required explanations as long as the explanations are prominently displayed, clearly articulated, and provide consumers reasonable insight into the rationale for the QHP recommendations and the methodology for the default display of QHPs. We expect explanations to be short and easy for consumers to understand. Generally, we believe that a single phrase or a few sentences will suffice (for example, “we recommend this plan because it has the lowest monthly premium and includes your preferred providers in-network”; “plans are displayed alphabetically”; “plans are displayed from lowest to highest premium”). To be considered prominently displayed, web-broker websites must adhere to the same general requirements that apply to disclaimers that must be prominently displayed on web-broker websites.²⁴⁶ For example, the explanations must be written in a font size no smaller than the majority of text on the website page and be noticeable in the context of the website by (for example) using a font color that contrasts with the background of the website page.

²⁴⁶ See, for example, Federally-Facilitated Exchange (FFE) and Federally-Facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual (pp. 53-54). (2021, August 18). https://www.regtap.info/uploads/library/ENR_FFEFFSHOPENrollmentManual2021_5CR_090921.pdf. Also see *Guidance for Web-brokers on Displaying Mandatory Standardized Disclaimers*. (2015, April 24). CMS. <https://www.cms.gov/ccio/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-web-brokers-displaying-disclaimers.pdf>.

Comment: Several commenters expressed concerns that the complex algorithms web-broker websites may have developed to produce their plan recommendations or default plan displays are likely too complicated to explain in a consumer-friendly manner. Some other commenters worried that requiring these explanations may require the disclosure of closely-held proprietary information.

Response: As explained previously, the intent of § 155.220(c)(3)(i)(M) is not to require lengthy or complicated explanations, but to provide consumers basic insight into the key factors underlying the information web-broker websites are presenting to consumers (or agents/brokers assisting consumers). We understand that in some cases web-broker websites may have adopted very complex algorithms for plan recommendations or default display of plans, and we do not intend that the intricate details underlying those proprietary models be described or disclosed. However, we expect in all cases there are core principles or criteria that form the foundation for QHP recommendations or default display methodologies and we do expect those to be disclosed to assist the consumer with making informed choices. We continuously review web-broker websites and will consider future updates and clarifications to this policy based on lessons learned and our experience implementing this new standard for web-broker websites.

d. Federally-facilitated Exchange standards of conduct (§ 155.220(j))

In the proposed rule (87 FR 644), we proposed to amend § 155.220(j)(2)(i) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. As we explain in the Supplementary Information section earlier in the preamble, HHS will address this policy, as well as the public comments submitted in response to this proposal, in future rulemaking.

i. Providing Correct Information to the FFEs

In the proposed rule (87 FR 644), we proposed to add new § 155.220(j)(2)(ii)(A) through (D) to codify additional details regarding the requirement that agents, brokers, and web-brokers provide correct information to FFEs and SBE-FPs. More specifically, we proposed to capture

specific examples of what it means to provide correct information to the FFEs and SBE-FPs for 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 Exchanges rely. We also proposed 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 listed in new § 155.220(j)(2)(ii)(A) through (D) are not exhaustive, but are simply illustrative of areas where HHS has identified a need for more direct and clear guidance. We refer readers to the proposed rule (87 FR 644 through 647) for additional information and background on these proposals.

We are generally finalizing as proposed § 155.220(j)(2)(ii)(A) through (D), except that we are not finalizing the proposal to add § 155.220(j)(2)(ii)(A)(I) that would have prohibited agents, brokers, and web-brokers from entering consumer email addresses with 'disposable' domains that expire after a set period of time.^{247, 248} We considered that agents, brokers, and web-brokers do not control the type of email domains consumers choose to use, own, or have access to. We also considered that there are available alternatives that HHS could use to systematically block the entry of disposable email addresses that expire after a set period of time.

We are finalizing the other provisions we proposed to under new § 155.220(j)(2)(ii)(A), which 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 belongs to the consumer or the consumer's authorized representative. The regulation text also clarifies that email addresses may only be entered on applications submitted to an Exchange with the consent of the consumer or the consumer's authorized representative, and that properly

²⁴⁷ Gibbs, M. (2006) Disposable e-mail addresses foil marketing plan, Real but temporary e-mail addresses to get you through the verification process. *NetworkWorld*. <https://www.networkworld.com/article/2301492/disposable-e-mail-addresses-foil-marketing-plans.html>.

²⁴⁸ We also removed the reference to this standard (that is, the phrase "that is secure, not disposable" was removed) in the introductory language in § 155.220(j)(2)(ii)(A). In addition, we are capturing the email address guidelines proposed to be added at new § 155.220(j)(2)(ii)(A)(2) and (3) in new § 155.220(j)(2)(ii)(A)(I) through (2) instead. We also make a non-substantive change to eliminate duplicate references to information "on an Exchange application" in § 155.220(j)(2)(ii)(A) through (D).

entered email addresses are required to adhere to certain guidelines. The guidelines we are finalizing in this rule, which were proposed to be added at new § 155.220(j)(2)(ii)(A)(2) and (3), will be captured in new § 155.220(j)(2)(ii)(A)(1) through (2), which are renumbered consistent with our decision to not finalize § 155.220(j)(2)(ii)(A)(1). We are otherwise finalizing these two guidelines for email addresses as proposed.

We are also finalizing the proposal to add new § 155.220(j)(2)(ii)(B), which provides 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 reiterate that a telephone number belongs to the consumer if they, or their authorized representative, are accessible at the number and have access to the number. We are also finalizing the addition of text to § 155.220(j)(2)(ii)(B) to provide that telephone numbers entered on applications submitted to an Exchange 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.

We are finalizing the proposal to add new § 155.220(j)(2)(ii)(C), which requires that an agent, broker, or web-broker may only enter a mailing address on an application for Exchange coverage or application for 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. We reiterate that consumer mailing addresses entered on applications submitted to an Exchange 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. We are also finalizing that mailing addresses entered on applications submitted to an Exchange 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.

Fourth, to minimize consumer harm stemming from the APTC reconciliation process on the tax return, as well as to protect Exchange operations from inaccurate APTC and CSR determinations, we are finalizing § 155.220(j)(2)(ii)(D), which requires that, when submitting household income projections used by 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 of their household income. Failure to provide correct information on household income can harm consumers by creating liability during the APTC reconciliation process on the tax return or delaying the issuance of a tax refund, as well as preventing the efficient operation of the Exchange. CSRs are similarly tied to a consumer's household income reducing 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 QHP issuers and prevent the efficient operation of the Exchange. We reiterate that good-faith income projections, versus an income projection designed to achieve the lowest monthly rate, would better protect the consumer from the unexpected cost and burden of repaying large amounts of APTC.

Finally, for greater clarity, the regulation text we adopt in this final rule at § 155.220(j)(2)(ii)(A) through (D) contains a non-substantive change to each proposed paragraph (A) through (D) to eliminate duplicate references to information "on an Exchange application" or "entered on an Exchange application." These editorial revisions in no way change or otherwise affect the requirements under the proposed versions of the text and more clearly and consistently indicate that the applications that are the subject of these provisions are applications submitted to Exchanges for coverage under a QHP, with or without APTC and CSR.

We sought comment on these proposals. After reviewing the public comments, and as stated above, we will not finalize § 155.220(j)(2)(ii)(A)(I) concerning disallowing agents, brokers, and web-brokers entry of temporary email addresses on consumers' behalf because agents, brokers, and web-brokers do not control the type of email domains consumers choose to use, own, or have access to. However, we are finalizing the other sections as proposed.²⁴⁹ While we are not finalizing § 155.220(j)(2)(ii)(A)(I), we strongly encourage agents, brokers, and web-brokers to avoid using such temporary email addresses in applications as a best practice.

We summarize and respond to public comments received on the proposals related to the standard in § 155.220(j)(2)(ii) that agents, brokers, and web-brokers provide correct consumer information to the FFEs below.

Comment: A number of commenters supportive of the proposal generally requested that HHS dedicate funds to compliance, monitoring, and enforcement efforts in order to address agent, broker, and web-broker compliance with relevant Exchange standards of conduct. While the majority of comments pertaining to monitoring and enforcement were general in nature, several commenters indicated they supported continuing to clarify standards of agent, broker, and web-broker conduct. One commenter also recommended that Exchange user fees could be used to fund future oversight initiatives.

Response: We are finalizing, as proposed, the amendments to § 155.220(j)(2)(ii) and the accompanying policies related to the provision of correct consumer information by agents, brokers, and web-brokers to the FFEs. These finalized amendments and policies also apply to agents, brokers, and web-brokers assisting with enrollments in SBE-FPs.²⁵⁰ The amendments to § 155.220(j)(2)(ii) provide clear, concise, and direct guidance to agents, brokers, and web-brokers assisting consumers with enrollment in QHPs sold on the FFEs and SBE-FPs about the

²⁴⁹ Consistent with the decision to not finalize § 155.220(j)(2)(ii)(A)(I), the phrase “that is secure, not disposable” was removed from the introductory language in § 155.220(j)(2)(ii)(A). In addition, the email address guidelines proposed to be added at new § 155.220(j)(2)(ii)(A)(2) and (3) will instead be captured in new § 155.220(j)(2)(ii)(A)(I) through (2). These guidelines are otherwise being finalized as proposed.

²⁵⁰ See 45 CFR 155.220(l).

standards of conduct and behavior expected of them. We also generally note that we intend to include these new, clarifying standards as part of existing monitoring and oversight of agents, brokers, and web-brokers assisting consumers with enrollments through FFEs and SBE-FPs. We appreciate the recommendations provided. They will be taken into consideration for future rulemaking and policy development. However, we are not finalizing the amendment to § 155.220(j)(2)(ii)(A)(I) because agents, brokers, and web-brokers do not control the type of email domains consumers choose to use, own, or access.

Comment: Many commenters supportive of the proposal requested that HHS add regulatory text to require agents, brokers, and web-brokers to check consumers' eligibility for Medicare and Medicaid in addition to their eligibility for private insurance through the FFEs.

Response: We agree with the commenters that consumers eligible for Medicare and Medicaid should be informed about those options. Indeed, in order to enroll a consumer in QHP coverage on the Exchange, agents, brokers, and web-brokers must use the Exchange's Single Streamlined Application, which first verifies Medicare and Medicaid eligibility, where applicable. If a web-broker's website is used to complete the application, the application and website must, among other requirements, request the minimum amount of information to verify eligibility for the programs and benefits included in the Single Streamlined Application as enumerated in § 155.405(a), which, again, would include a requirement to collect information necessary to verify Medicare and Medicaid eligibility, as applicable.²⁵¹ HHS also provides training to agents, brokers, and web-broker entities participating in the FFEs and SBE-FPs on how to help connect Medicare-eligible consumers to Medicare and potentially Medicaid-eligible consumers with Medicaid enrollment resources.²⁵² HHS is finalizing the amendment to § 155.220(j)(2)(ii)(D) to require agents, brokers, and web-brokers only to enter a household

²⁵¹ See 45 CFR 155.220(c)(1) and (c)(3)(ii)(B).

²⁵² See *Returning Agents' and Brokers' Guide to Plan Year 2022 Marketplace Registration and Training*. (2021). CMS. <https://www.cms.gov/files/document/plan-year-2022returning-agents-and-brokers-guide-marketplace-registration-and-training.pdf> and *New Agents' Guide to Training*. (2021). CMS. <https://www.cms.gov/files/document/plan-year-2022new-agents-and-brokers-guide-marketplace-registration-and-training.pdf>.

income projection for a consumer that the consumer, or the consumer's authorized representative, has authorized and confirmed as an accurate estimate. However, we did not propose and are not finalizing regulatory text to mandate agents, brokers, and web-brokers assisting with enrollments in FFEs and SBE-FPs to check a consumer's eligibility for Medicare and Medicaid.

Comment: Some commenters who were neutral on the proposal stated that HHS already has the established infrastructure which allows for agents, brokers, and web-brokers to be penalized for their misconduct, and additional standards of conduct, including submitting an attestation to the accuracy of the information, relying on consumers to provide accurate household income projections, and clarifying parameters around consumer contact information, create an extra burden on compliant agents, brokers, and web-brokers.

Response: With the exception of § 155.220(j)(2)(ii)(A)(I), we are generally finalizing, as proposed,²⁵³ the amendments to § 155.220(j)(2)(ii) and the accompanying policies related to the FFE standard of conduct that agents, brokers, and web-brokers provide correct consumer information to the FFEs. HHS does not agree that these revisions will create an extra burden on compliant agents, brokers, and web-brokers because the revisions only further elucidate what was already required under HHS' rules. The proposals we finalize do not create new obligations or standards of conduct, and should not cause an appreciable increase in the burden on agents, brokers, and web-brokers that already comply with the FFE standards of conduct. Rather, they provide clarity and additional examples consistent with existing guidance on how to provide correct consumer information on applications submitted to the FFEs or SBE-FPs. As detailed in the proposed rule, these amendments and clarifications were developed in response to common errors HHS identified on applications submitted by agents, brokers, and web-brokers to the FFE,

²⁵³ Consistent with the decision to not finalize § 155.220(j)(2)(ii)(A)(I), the phrase "that is secure, not disposable" was removed from the introductory language in § 155.220(j)(2)(ii)(A). In addition, the email address guidelines proposed to be added at new § 155.220(j)(2)(ii)(A)(2) and (3) will instead be captured in new § 155.220(j)(2)(ii)(A)(I) through (2). We also make a non-substantive change to eliminate duplicate references to information "on an Exchange application" in § 155.220(j)(2)(ii)(A) through (D). These guidelines are otherwise being finalized as proposed.

and will help supplement existing guidance to facilitate the submission of accurate information to the FFEs. The supplementary guidance clarifies how to come into compliance with the existing requirements in § 155.220(j)(2)(ii), which HHS believes will make the process of enrolling consumers more straightforward, due to clearer expectations concerning existing standards from the agency and a reduction in errors filling out the application. Moreover, it protects consumers and enhances the efficient operation of the Exchange.

ii. Prohibited Business Practices

In the proposed rule (87 FR 647), we proposed to amend § 155.220(j)(2) to add several 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 (81 FR 12203), these additional standards are also intended to protect against agent, broker, and web-broker conduct that is harmful to consumers or frustrates the efficient operation of the Exchange. Specifically, we proposed to codify standards related to the use of scripting and other automation interactions with our 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 proposed 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. We described these proposals, as well as summarize and respond to the comments on each, in the sections that follow.

iii. Prohibited Automated Interactions with CMS Systems

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.²⁵⁴ 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),”²⁵⁵ 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 the regulation. Therefore, we proposed to amend § 155.220(j)(2) to add the 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 (87 FR 647). The codification of the requirements and limitations in the 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.

HHS proposed this standard of conduct because it has observed instances where unauthorized automated browser-based interactions with Exchange systems have led to unauthorized enrollments or unauthorized application changes. 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

²⁵⁴ 45 CFR 155.220(d).

²⁵⁵ *Agent Broker General Agreement for Individual Market Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform*. (2019). HHS. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ab_py2020_im_general_agreement_final_1.pdf.

process. Allowing automation would also create significant traffic in the system, which could result in an 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. We sought comments on these concerns and this proposal.

We also sought comments on the appropriate uses of automation that may contribute to the efficient operation of the FFEs and SBE-FPs, and the DE Pathways.

We received one comment generally supportive of the proposal because it would codify HHS' enforcement authority and align the regulation with requirements applicable to agents, brokers, and web-brokers in agreements with the FFE and SBE-FPs.

After considering the responsive comments, we are finalizing the addition of the new § 155.220(j)(2)(vi) as proposed.

iv. Identity Proofing

HealthCare.gov utilizes identity proofing to verify the identity of a consumer when a new Exchange account is created. We proposed to amend § 155.220(j)(2) to add the 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 (87 FR 648 through 649).

We are finalizing this amendment to § 155.220(j)(2) because we have observed situations, despite the current identity proofing process,²⁵⁶ in which agents have used the same identity information to complete the identity proofing process for multiple consumer Exchange accounts, which can harm consumers and prevent the efficient operation of the Exchange. Such

²⁵⁶ 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. Under the existing process, 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.

behavior also undermines the purpose of identity proofing consumers and is often associated with unauthorized enrollments, identity theft, and fraud.

We sought comment on this proposal.

We received one comment responsive to and supportive of the proposed amendment to add new § 155.220(j)(2)(vii) clarifying that agents, brokers, and web-brokers must use a consumer's correct information for RIDP process and only for the RIDP process for that consumer.

After considering the responsive comment, we are finalizing the addition of a new § 155.220(j)(2)(vii) as proposed.

v. Providing Information to Federally-facilitated Exchanges in Connection with Special Enrollment Periods.

Section 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 proposed to amend § 155.220(j)(2) to add the 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 (87 FR 648). Under this 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 proposed this requirement to address circumstances HHS has observed during 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 the proposed new § 155.220(j)(2)(viii) is to ensure the validity and integrity of the SEP process, avoid Exchange destabilization, and 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 sought comment on these proposals.

We received one comment responsive to and generally supportive of the proposal that when providing information to the Exchange related to an SEP enrollment, agents, brokers, and web-brokers must obtain authorization from the consumer to submit the request for an eligibility determination, make the consumer aware of the specific triggering event, and of the specific SEP for which the agent, broker, or web-broker is submitting the eligibility determination request on the consumer's behalf.

After considering the responsive comment, we are finalizing the addition of a new § 155.220(j)(2)(viii) as proposed.

4. Premium Calculation (§ 155.240(e))

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 648), we proposed 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. 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 final rule

where we proposed 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 sought comment on these proposals.

We received public comments on the proposed amendments to the premium calculation at § 155.240(e). After considering of the comments received, we are not finalizing any amendments to § 155.240.

Comments related to the proposed amendments at § 155.240(e) are addressed in section III.D.9 of the preamble, regarding the Administration of Advance Payments of the Premium Tax Credit and Cost Sharing (§ 155.340), where we present a unified summary of comments on the proposal to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of APTC. We are codifying the proposed APTC proration methodology as the methodology Exchanges on the Federal platform (FFE and SBE-FP) will continue to use, but we are not finalizing the requirement for State Exchanges to use the FFE's methodology to prorate premium or APTC amounts. Additional information on the policy we are finalizing is also provided in section III.D.9. of the preamble of this final rule.

5. Eligibility standards (§ 155.305)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 648), we proposed 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 that 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 noted 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.

We are finalizing the proposal as proposed.

Comment: Two commenters provided general support for this technical amendment and no commenters opposed it.

Response: We thank the comments for their general support of this technical amendment and believe this change aligns with current practice and will ensure greater consistency going forward.

6. Eligibility for advance payments of the premium tax credit (§ 155.305(f)(5))

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 648), we proposed to amend § 155.305(f)(5) to require that Exchanges must calculate APTC in accordance with 26 CFR 1.36B-3, which defines the calculation of the PTC amount, and subject to the prorating methodology at proposed § 155.340(i). We further discussed these proposals in the Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340) section of the proposed rule. We sought comment on this proposal.

We received public comments on the proposed amendments to § 155.305(f)(5). In the following comments and responses, we discuss comments specific to the proposal for this section. We are codifying the proposed APTC proration methodology as the methodology Exchanges on the Federal platform (FFE and SBE-FP) will continue to use, but we are not finalizing the requirement for State Exchanges to use the FFE's methodology to prorate premium or APTC amounts. For a unified summary of all comments on the proposal (to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of APTC and for more information on the policy we are finalizing), we refer

readers to the section III.D.9 of the preamble on Administration of Advance Payments of the Premium Tax Credit and Cost Sharing (§ 155.340).

Comment: A few commenters noted that the proposed regulatory amendment to part § 155.305(f)(5) did not appear in the corresponding section of the Regulatory Text section of the proposed rule.

Response: HHS appreciates the comments identifying this technical error. The proposed regulatory amendment at § 155.305(f)(5) was inadvertently omitted from the published proposed regulation text. HHS is correcting this technical error by including amendments to § 155.305(f)(5) in the Regulatory Text section of this final rule as described in the preamble to the proposed rule, and consistent with the policy adopted in this final rule, as described in the section III.D.9 of the preamble on Administration of Advance Payments of the Premium Tax Credit and Cost Sharing (§ 155.340).

7. 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, in the proposed rule (87 FR 649 through 651), we proposed 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.

Specifically, we proposed 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. We refer to the proposed rule (87 FR 649), where we provided additional background and rationale for the proposals.

First, we proposed 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 and 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 proposed 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 proposed 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.

Third, we proposed to remove 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 continue to believe that 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 the 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 proposed 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.²⁵⁷ 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 the preamble.

We are finalizing these proposals as proposed. Specifically, we require that any risk-based verification process be reasonably designed to ensure the accuracy of the data and be based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's enrollment data. We expect 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. 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 are allowed APTC/CSRs.

Given that the 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

²⁵⁷ In the proposed rule, we neglected to delete a reference to § 155.320(d)(4)(ii) in the regulation text. We are deleting that reference in the regulation text in this final rule, consistent with the proposal.

an Exchange's assessment of risk and unique populations, we noted in the proposed rule that we believe 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 does not 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.

Because we found that the risk for improper APTC payment is low in Exchanges using the Federal eligibility and enrollment platform, these 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?". We would also accept attestations related to employer sponsored coverage because we

currently lack 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, we 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. We 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. We noted that additional data source access, such as the NDNH, would improve accuracy and reduce the administrative burden to consumers for the income verification step during the eligibility process.

Finally, under this proposal, we clarified 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 us. 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 proposing this policy was to ensure that only applicants eligible for APTC/CSRs benefit from 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 continue to believe that 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 continue to believe that the new policy we proposed 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.

We sought comment on these proposals.

After reviewing the public comments, we are finalizing these proposals as proposed, with some non-substantive revisions for clarity. These include removing the reference to paragraph (d)(4)(ii) in paragraph (d)(4), as this paragraph has been removed and is no longer necessary, and streamlining language under paragraph (d)(4)(i)(A) to make it clearer that Exchanges must notice employers, if employer notification is part of an Exchange's risk-based approach.

We summarize and respond to public comments received on the verification process related to eligibility for insurance affordability programs – employer sponsored plan verification (§ 155.320) below.

Comment: The majority of commenters supported HHS' proposal to provide all Exchanges with the flexibility to tailor their employer sponsored coverage verification procedures based on the Exchange's own assessment of the risk for inappropriate payments of APTC/CSRs in their enrolled populations. The commenters agreed with HHS' prior study findings that the current sampling process outlined in paragraph (d)(4)(i) requires significant Exchange resources with little return on investment given the low volume and risk of consumers with offers of employer sponsored coverage who inappropriately enroll in Exchanges with APTC/CSRs and stated that HHS' study results were consistent with State Exchanges' own

observations. Commenters also agreed with HHS that an employer sponsored coverage verification approach should provide State Exchanges with enough flexibility and more opportunities to use verification processes that are evidence-based, while imposing the least amount of burden on consumers, States, employers, and taxpayers. Commenters also noted that increased flexibility to use a risk-based approach allows all Exchanges to focus and expend resources on expanding coverage. Finally, commenters stated that they appreciated how the proposed risk-based approach provides State Exchanges with the freedom to review their own data and determine the most appropriate verification approach for employer sponsored coverage that accurately reflects the risk for inappropriate APTC/CSR payments within their unique populations.

Response: HHS agrees that the current random sampling process required under § 155.320(d)(4)(i) is not only burdensome for States, employers, consumers, and taxpayers, but it also does not provide enough flexibility to all Exchanges to develop a process for employer sponsored coverage verification that more accurately reflects their respective enrolled Exchange populations. As discussed in the proposed rule (87 FR 649), HHS shares the same concerns regarding the feasibility and effectiveness of sampling and agrees that a verification process should be evidence-based and informed by certain risk-factors for inappropriate payment of APTC/CSRs. HHS also agrees that additional flexibilities are important to help States better serve their populations and to allow for Exchange staff time and resources to be better spent on activities that help promote and retain enrollment in Exchanges.

Comment: A few commenters supported the proposed changes, but also recommended that HHS revise paragraph (d)(4)(i) to state that all Exchanges can accept an applicant's attestation when an Exchange determines that the risk for improper APTC/CSR payment is low and does not have access to an available, approved data source to verify whether an applicant has an offer of or is enrolled in coverage offered through an employer. Some of these commenters further questioned what additional information or value a State's own study or risk assessment

would bring if HHS already conducted studies on the risk for inappropriate APTC/CSR payments and as discussed in the preamble of the proposed rule that, as part of their risk-based approach, Exchanges using the Federal eligibility and enrollment platform would accept attestations in absence of an approved data source, and requested that HHS clarify who is responsible for conducting the risk assessment, how it should be conducted, and how State Exchanges can meet this assessment requirement.

Response: HHS reiterates and reminds State Exchanges that it is their responsibility to conduct their own risk-assessments for inappropriate APTC/CSRs payments; while HHS determined based on its study that the Exchanges that use the Federal platform will use an attestation-based approach to employer sponsored coverage verification, State Exchanges cannot rely on the findings of the studies that HHS conducted to serve as the basis for their risk-based approaches for employer sponsored coverage verification as this study pertained to Exchanges that use the Federal eligibility and enrollment platform. Similarly, the risk-based approach and subsequent verification processes for employer sponsored coverage verification must be based on an Exchange's own data analysis and research, and State Exchanges may not solely rely on previously published literature, research, and/or the studies conducted by HHS as justification for their risk-based approach. Furthermore, State Exchanges have the sole responsibility and flexibility to determine the manner of assessment that is suitable for their respective populations and markets, and should propose their assessment approach to HHS for review. However, the process that is appropriate for some State Exchanges may not be to solely accept attestation for all applicants. Therefore, HHS disagrees with commenters that changes to paragraph (d)(4)(i) to explicitly state that all Exchanges may accept attestation when an Exchange does not have access to an available data source are necessary.

Comment: A few commenters stressed the importance of and urged HHS to explore other relevant, reliable third-party data sources that could be used to verify offers of or enrollment in employer sponsored coverage, such as whether HHS could gain access to firm-level data about

employer sponsored insurance through the annual ACA reports that are filed with the IRS or access to the NDNH to help Exchanges determine whether certain companies offer coverage to their employees.

Response: We agree with the importance of relevant and reliable third-party data sources to verify offers of or enrollment in employer sponsored coverage such as the NDNH. As part of the 2019 study discussed in the preamble to the proposed rule and this final rule, HHS explored the feasibility of using the NDNH, or other data sources such as reporting from IRS, the Department of Labor (DOL), or State quarterly wage data to verify eligibility for employer sponsored coverage. However, HHS determined that either available data sources were insufficient and did not provide the necessary information to satisfy the requirement, or, in the case of the NDNH, legislative changes would be required to give Exchanges permission to access and use the data source for verification of employer sponsored coverage.

For example, HHS found that these data sources, such as IRS Forms 1095-B and 1095-C, DOL, and State wage quarterly data, are subject to significant time lags and that HHS would not have access to reliable, up-to-date information regarding employment when needed the most, immediately before and after the annual individual market Exchange open enrollment period. Finally, HHS also considered using data available to Exchanges using the Federal eligibility and enrollment platform to automatically verify the loss of minimum essential coverage for verification of special enrollment period eligibility (see preamble discussion at § 155.420 in section III.D.10. of the final rule). However, not all employers participate in the database to verify loss of minimum essential coverage nor does it provide information on whether an applicant has an offer of employer sponsored coverage so it would not be a reliable verification source for verifying employer sponsored coverage.

Additionally, Exchanges are not among the entities Congress authorized to access NDNH data.²⁵⁸ HHS explored the feasibility of creating a new database that Exchanges could leverage with employer contact information and information on the coverage offered, but because HHS currently lacks the statutory authority to require employers to share contact information or information about coverage offered for this purpose, employer participation in such a database would be purely voluntary, and therefore, may not be sufficiently effective. Granting HHS and Exchanges the authority to pursue either of these options would require an act of Congress.

Comment: Two commenters that were neutral in their support of the proposed changes, stressed that Exchanges should be prohibited from implementing risk-based approaches that are discriminatory in nature, specifically that Exchanges cannot target consumers solely based on income status, as a targeted, income-based verification process for employer sponsored coverage would have disproportionate, adverse impacts on applicants of color and other underserved groups. One commenter further recommended that HHS modify the language under paragraph (d)(4) to prevent States from needlessly imposing procedural burdens on consumers seeking to enroll in coverage offered through Exchanges.

Response: HHS agrees with commenters that an Exchange's risk-based approach to verify whether an applicant is enrolled in or has been offered coverage through an employer must not be discriminatory in nature, especially towards applicants who have household income levels within a certain percentage of the Federal Poverty Level (FPL), as applicants of color or other underserved groups are more likely to be targeted by such practices. As such, HHS reminds States and Exchanges that per § 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, nor should an Exchange

²⁵⁸ See 42 U.S.C. § 653(j) (identifying the entities that are authorized to access NDNH data and the permissible purposes for which those entities may use NDNH data).

and/or a State's risk-based approach place any additional, unnecessary procedural burdens or barriers to enrollment for consumers seeking to enroll in Exchange coverage.

Comment: Two commenters opposed HHS' proposal that Exchanges use a risk-based approach to determine the best process to verify whether an applicant has an offer of or is enrolled in coverage through an employer. One commenter stated that HHS should continue to verify offers of or enrollment in employer sponsored coverage and that Exchanges using the Federal eligibility and enrollment platform should not rely solely on consumer attestations as the ACA states that these applicants are not eligible to receive APTC/CSRs; this is similar to how Exchanges verify other eligibility criteria like annual household income, or enrollment in other qualifying coverage such as Medicare, Medicaid, CHIP, or, if applicable, the Basic Health Program (BHP). Another commenter opposed the proposal and stated that, in addition to many individuals with offers of or enrollment in coverage offered through an employer benefitting from APTC/CSRs inappropriately, HHS should consider the tax consequences for individuals and liability concerns for applicable large employers (ALE) that receive IRS 226-J letters because one or more of their employees received APTC through an Exchange. The commenter further noted that the process of penalty enforcement is arduous and costly for the IRS and affected ALEs and that more effective employer sponsored coverage verification could significantly reduce the volume of enforcement actions that are ultimately resolved in the favor of the ALE and that HHS should work with the IRS to improve the verification process at the national level and not pursue the risk-based approach.

Response: As discussed in the preamble, HHS has confirmed via two separate research studies conducted multiple years apart that the risk of an applicant choosing to forego enrolling in employer sponsored coverage that is affordable and meets minimum value standards to enroll in an Exchange QHP with APTC/CSR remains low. Also, HHS has determined that reliable and accurate data sources exist for the other eligibility criteria that commenters flagged, such as IRS data for annual household income, Medicare enrollment data that is provided to CMS via the

Social Security Administration, and State Medicaid Agency data to verify Medicaid/CHIP enrollment. As HHS has noted, the same quality and caliber of data on employer sponsored coverage do not exist due to the various limitations discussed earlier in the preamble.

Furthermore, HHS understands the concerns raised by the commenter regarding the process of assessing employer shared responsibility payments (ESRP), and that more robust real-time verification of consumers' access to employer sponsored coverage may result in some employers avoiding the ESRP process. However, as noted in an earlier response in this section of the preamble, options for obtaining the necessary data are limited. In the absence of Congressional action to provide access to the NDNH or to create a new database with mandatory employer reporting, HHS remains committed to working with IRS to use the information currently available to ensure our processes are fair to both consumers and employers.

8. Annual eligibility redetermination (§ 155.335)

We solicited 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 on additional criteria or mechanisms HHS could consider to ensure the Exchange hierarchy for re-enrollment aligns with plan generosity and consumer needs, with consideration for the potential impact of the proposed amendments to the actuarial value *de minimis* guidelines. 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. Please see the proposed rule preamble (87 FR 651 through 652) for a complete description of the comment solicitation.

We will consider proposing amendments to the re-enrollment hierarchy at § 155.335(j) in future rulemaking.

We summarize and respond to public comments received on annual eligibility redetermination (§ 155.335) below.

Comment: Some commenters opposed the proposal to revise the re-enrollment hierarchy and explicitly expressed that HHS should retain the current re-enrollment hierarchy. These commenters stated that consumers choose to enroll in plans for a number of reasons and that the Exchange cannot accurately predict the factors most valuable to consumers; thus, revising the re-enrollment hierarchy could lead to consumer confusion and dissatisfaction. A few commenters noted that the discretion to select the most appropriate plans for consumers should be left to the issuers. Two commenters expressed concern about enrollees being auto enrolled without their knowledge or explicit approval.

A few commenters encouraged HHS to focus on enhancing the consumer shopping experience and decision support tools to improve initial plan selection and alert consumers of plans that better meet their needs instead of altering the re-enrollment hierarchy in the Exchanges. A couple of commenters explained that improving consumer education can help ensure consumers understand all aspects of cost-sharing and how they impact coverage, which will help consumers make an initial plan selection that best meets their needs. One commenter suggested that HHS could rebrand the concept of metal levels to make actuarial values more accessible to consumers.

Response: HHS understands the importance of ensuring a revised re-enrollment hierarchy does not result in consumer confusion or harm and will take these comments into account in considering whether to revise the current re-enrollment hierarchy as part of future rulemaking.

Comment: Commenters submitted comments regarding the incorporation of consumer cost into the re-enrollment hierarchy. Several commenters encouraged HHS to take net premium and/or total OOPC into account for the re-enrollment hierarchy. Some commenters cited research in Covered California's market which showed that 30 percent of households whose coverage was automatically renewed were certain to be better off in a different plan. Furthermore, these

commenters referenced that, on average, families in California were charged an extra \$466 a year in annual premiums, as a result of remaining with a plan that no longer served their interests. For this reason, a number of commenters expressed that re-enrollment should prioritize consumer affordability rather than continuity of issuer and product line, stating that the vast majority of consumers who do not make active selections during the OEP care more about cost than issuer or provider network. One commenter cautioned that net premium itself is not always a reliable factor to determine the best plan for a consumer. Another commenter recommended that the plan's net premium, MOOP, deductible, and annual OOPC be considered only when 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. A few commenters stated that including OOPC and plan generosity into re-enrollment rules will be particularly beneficial for when enrollees are eligible for cost-sharing reductions and are not enrolled in a silver plan. One commenter explicitly requested that if an enrollee is shifted to a different metal level plan, then that enrollee should remain enrolled in a plan offered by the same issuer to prevent potential adverse consequences of an enrollee losing access to medications or experiencing increased drug costs. However, two commenters expressed that incorporating OOPC into the hierarchy would likely lead to increased enrollment in plans with lower OOPC for prescription drugs. Two other commenters explained the critical importance of auto re-enrollment policies for immigrants and racial and ethnic minorities who face barriers, such as lack of in language outreach and notices, and are disproportionately impacted by cost increases due to lower wealth and discretionary income.

Response: HHS will take comments regarding the incorporation of consumer costs into the re-enrollment hierarchy into account in future rulemaking.

Comment: We received multiple comments with specific recommendations regarding how the priority of the current hierarchy could be modified. Multiple commenters raised concerns with § 155.335(j)(1)(i) which ensures the enrollee's coverage will be renewed in the

same plan as their current QHP, unless the current QHP is not available through the Exchange. Commenters explained that the current policy does not provide flexibility for enrollees to be re-enrolled into a different plan even if market conditions increase costs. For this reason, some commenters recommended that § 155.335(j)(1)(i) be amended to allow the enrollee's coverage to be renewed into a different plan if there is no change in the issuer, product, service area, provider network, and prescription drug formulary, and the new plan is more generous and has lower net premiums. These commenters urged the Exchange to provide accessible notices and reasonable opportunities for the consumer to return to their former plan or drop coverage. Furthermore, a few commenters recommended that enrollees should be eligible for a 60-day special enrollment period after the close of the annual individual market Exchange Open Enrollment Period or at the start of the plan year to allow enrollees whose coverage was shifted to choose a different plan. This commenter stated that if the *de minimis* guidelines proposed in this rule at §§ 156.135 and 156.140 are finalized HHS should not alter the hierarchy for within-metal level changes.

Some commenters raised concerns with § 155.335(j)(1)(ii) through (iv) and (j)(2)(iii), which outline the re-enrollment rules when an enrollee's current QHP is no longer available, since consumers may be re-enrolled in a plan with far higher costs if the issuer and provider networks types are prioritized. These commenters expressed that the vast majority of enrollees who do not make active selections during the open enrollment period care more about cost than the issuer or provider network. All of these commenters recommended that HHS prioritize keeping the consumer's net premium and approximate actuarial value (AV) at levels as close as possible to the enrollee's current QHP. One commenter recommended HHS should perform targeted outreach to consumers who have been auto re-enrolled and whose premium has increased and should extend the open enrollment period, outlined in § 155.410, to January 31 and require coverage to begin February 1.

Response: HHS will take comments on factors to consider prioritizing in the re-enrollment hierarchy into account in future rulemaking. HHS understands the importance of

comments that urged the Exchange to provide accessible notices and reasonable opportunities for enrollees to select a QHP that is different from their auto reenrollment option. Currently, 45 CFR 156.1255 and its implementing guidance outline the information a QHP issuer must provide in renewal and re-enrollment notices to qualified individuals. Additionally, a qualified individual is eligible under § 155.420(d)(1)(i) for a special enrollment period (SEP) to enroll in or change from one QHP to another if the qualified individual loses minimal essential coverage. If the enrollee's current plan is no longer available for renewal, HHS would consider this a loss of minimum essential coverage that would trigger a SEP.

Comment: Several commenters recommended provider network considerations be incorporated into any revised re-enrollment hierarchy. Commenters explained that a revised hierarchy that does not incorporate provider networks could result in enrollees losing access to their providers, increased out-of-network costs, and/or being placed in narrower network plans. Furthermore, two commenters cautioned that not including provider network considerations in the re-enrollment hierarchy could have negative consequences for racial and ethnic minority groups and those living with disabilities who rely on providers with certain cultural backgrounds or longtime key providers. Two commenters recommended that HHS use provider network as the foremost criterion.

Response: HHS will take these comments regarding incorporating provider networks in the re-enrollment hierarchy into account in future rulemaking.

Comment: A few commenters recommended that SBEs, SBE-FPs, or States performing plan management functions should have the flexibility to determine the appropriate criteria for re-enrollment determinations with respect to their unique markets. One commenter explained that incorporating new criteria and mechanisms into re-enrollment determinations could impose significant operational and financial burdens on SBEs. Another commenter stated that a substantial number of enrollees actively select their auto re-enrollment option which could indicate enrollees trust their State or issuer. One commenter proposed HHS should work with

States to design safe and appropriate flexibility for issuers to facilitate plan changes after open enrollment, but only when the change would lower premiums and/or OOPC for members with everything else (network, benefits, deductibles, MOOPs) being the same or better for consumers. This commenter raised the concern that the examples HHS provided in the comment solicitation could conflict with State law requirements.

Response: HHS will take these comments regarding State flexibility into account in future rulemaking.

Comment: A few commenters urged HHS to conduct stakeholder engagement and provide transparency on the re-enrollment process to all stakeholders. Two commenters requested additional clarification on the proposed changes to the re-enrollment hierarchy for the Exchanges while one commenter requested that HHS provide further transparency into the alternate enrollment process. One commenter recommended that HHS conduct further stakeholder feedback and consumer testing prior to finalizing any revisions to the re-enrollment hierarchy.

Response: HHS will take these considerations into account in future rulemaking, including how to incorporate transparency and stakeholder feedback into a revised re-enrollment hierarchy.

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

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 648 through 653), we proposed 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. The proposed APTC proration methodology was 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 on that policy during the applicable month. HHS proposed to require all Exchanges, including the Exchanges on the Federal platform (FFE and SBE-FP) and State Exchanges that operate their own eligibility and enrollment platforms, to implement this proposed proration methodology beginning with PY 2024. Please see the proposed rule preamble (87 FR 648 through 649 and 652 through 653) for a complete description of the proposed policy.

After considering the comments received, under HHS' authority to administer APTC, we are codifying the proposed APTC proration methodology as the methodology Exchanges on the Federal platform will continue to use, but we are not finalizing the requirement for State Exchanges to use the proposed methodology to prorate premium or APTC amounts. Rather, we will formalize additional efforts under existing Exchange program integrity and oversight authorities to ensure that, beginning with PY 2024, State Exchanges will implement an APTC methodology consistent with the requirement we are finalizing at § 155.305(f)(5) at 155.340(i), described later in this section, that will not cause the amount of APTC applied to an enrollee's monthly premium to exceed their total monthly PTC amount as defined in 26 CFR 1.36B-3. We note that all the Exchanges on the Federal platform (FFE and SBE-FP) would implement HHS' codified methodology because all Exchanges on the Federal platform rely on the Federal platform to perform the proration calculations, and the Federal platform is not designed to implement different methodologies by State. We believe that this final policy will ensure Exchange compliance with IRS rules and equal treatment for enrollees across Exchanges, while minimizing the burden for State Exchanges and granting State Exchanges flexibility in how to comply with these APTC calculation requirements 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. We will require State Exchanges to prospectively report their PY 2024 methodology in the year prior to implementation (in 2023) and will allow State Exchanges the option to report their PY 2023

methodology in 2022. Any State that begins operating a State Exchange for PY 2024, or for subsequent plan years, will also be required to comply with this timeline by prospectively reporting the methodology for the following plan year during their first reporting cycle.

To support this policy, we are finalizing a series of conforming amendments to parts §§ 155.305(f)(5) and 155.340. We are not amending as proposed § 155.240(e), which establishes the methodology the Exchanges on the Federal platform (FFE and SBE-FP) use to prorate premiums, to add new paragraph § 155.240(e)(2), which would have established a methodology for State Exchanges using their own platform to prorate premiums. However, we are amending § 155.305(f)(5), which currently provides that Exchanges must calculate APTC in accordance with 26 CFR 1.36B-3, by adding that Exchanges must also calculate APTC in accordance with new paragraph § 155.340(i) where we describe the requirements for calculating APTC when policy coverage lasts less than the full coverage month. In new paragraph § 155.340(i)(1), we establish that Exchanges on the Federal platform will be required to use the APTC proration methodology described at § 155.340(i)(1)(i) and (ii), and at new paragraph § 155.340(i)(2) we establish that State Exchanges will be required to calculate APTC in accordance with a methodology that does not cause the amount of APTC applied to an enrollee's monthly premium to exceed their expected total monthly PTC amount when an 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, and to report the methodology to HHS in accordance with the requirements of 155.1200(b)(2).

Most of the comments on proposed amendments to the administration of APTC (§ 155.340) were presented in combination with comments on the other proposed amendments that made up the proposal to require premium and APTC proration (§§ 155.240(e), 155.305(f)(5)). We summarize and respond to public comments received on all three sections in a unified summary below.

Comment: Several commenters expressed their support for the proposal to require that all Exchanges prorate both premium amounts and APTC amounts and noted that the proposal would ensure accurate and consistent calculation of APTC which would support consumer protection. One commenter observed that the proposal would lower the operational burden for issuers participating across multiple types of Exchanges. One commenter stated that the proposed policy would encourage enrollees to enroll in a new QHP if enrollment was terminated mid-month.

However, the majority of commenters opposed the proposal and criticized the proposed APTC proration methodology, and its potential impact on enrollees. Several commenters asserted that the proposed methodology is not necessary to ensure that the calculation of APTC does not cause excess APTC because calculating APTC in the same way as PTC; that is, using the calculations defined at 26 CFR 1.36B-3(d) will not result in excess APTC. Several commenters included examples of how the proposed proration methodology would result in less generous amounts of APTC for enrollees, and asserted that the proposed methodology would reduce plan affordability, in contrast to the stated goals of HHS and the Administration. Others stated that the requirement to prorate premiums is not supported by the PTC regulation.

Response: We are not finalizing the policy as proposed. We will codify the method of APTC proration as proposed for the Exchanges using the Federal platform, but we will grant flexibility to State Exchanges to use a methodology that does not cause the amount of APTC applied to an enrollee's monthly premium to exceed their expected total monthly PTC amount when an 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. We will require State Exchanges to report their methodology to HHS in accordance with the requirements of § 155.1200(b)(2).

PTC is calculated for each month of the tax year retrospectively, and therefore can account for the changes in an applicable enrollee's premium month to month before the final amount is calculated at the time of tax filing. However, Exchanges administer APTC

prospectively to issuers by advancing premium assistance to issuers based on enrollees' eligibility determinations and elections, which may also change month-to-month (and before final reconciliation occurs), putting affected enrollees at risk of repaying the excess APTC.

The proposal sought to align the manner in which HHS administers APTC with the IRS' PTC calculation for all Exchanges, by establishing a consistent methodology for administering APTC in instances when there is a change in the applicable enrollee's coverage mid-month, which the PTC regulation accounts for at 26 CFR 1.36B-3(d)(1)(i) by retrospectively calculating the monthly enrollment premiums to ensure that PTC does not exceed that amount. We believe the ability to account for mid-month coverage changes is most important when an enrollee is enrolled in two policies in the same coverage month. The examples included by commenters take into consideration only mid-month terminations, but do not consider mid-month terminations followed by mid-month enrollments into a new plan. In such instances when there are multiple policies in a single policy month, HHS data on APTC payment reflects that some State Exchanges are not prorating or otherwise accounting for a potential over-payment of APTC.

Under 26 CFR 1.36B-3(d), PTC eligibility for a partial month of coverage is calculated as the lesser of the premiums for the month (reduced by any amount of such premiums refunded), or the adjusted monthly premium for the applicable second lowest cost silver plan (SLCSP) reduced by the taxpayer's monthly contribution amount.

HHS remains concerned that when an enrollee is enrolled in more than one policy during a single coverage month, and the Exchange applies APTC to each of those policies based on the eligibility requirements under 26 CFR 1.36B-2 without prorating both policies or conducting a reconciliation between them, the calculation will in some cases cause the total monthly APTC to exceed the amount that would be calculated under 26 CFR 1.36B-3(d). HHS data indicate that when Exchanges do not link the two policies to account for the excess APTC, the Exchanges tend to apply the maximum eligible APTC amounts, capped at the prorated premium amount, for

both policies. When added together the total applied APTC often exceeds the maximum expected PTC amount for which the enrollee will be eligible for that month.

However, if the Exchange applied the proration methodology used by the Exchanges on the Federal platform (that is, FFE and SBE-FPs) which is the product of (1) the APTC applied on the 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 for that policy during the applicable month, the calculation would not cause the total APTC for the month to exceed the PTC allowed for the month.

Further, we acknowledge the concern raised by commenters that under the proposed policy, prorating the APTC amounts applied to enrollee's monthly premium could result in a lower total amount of APTC than if the non-prorated amounts of APTC capped at the reduced premium were applied to an enrollee's monthly premium. We appreciate the perspective on affordability, and agree that the non-prorated amount of APTC would likely be more generous than the prorated amount if a mid-month termination was not followed by enrollment in another plan. However, since many mid-month terminations are followed by enrollment in a new plan, we remain concerned that applying both plans' non-prorated APTC amounts could exceed the maximum expected monthly PTC amount for which the enrollee taxpayer will be eligible. When an enrollee is enrolled in more than one plan during one coverage month and has APTC from both policies applied to their premium, the generosity of non-prorated APTC amounts described by commenters has the potential to result in APTC over-payments and to trigger a costly tax liability which could surprise the enrollee later. Income tax liability due to excess APTC could pose a significant financial burden to applicable enrollees, particularly low-income enrollees. Further, if this partial month of coverage triggered a higher applied APTC, it has the potential to confuse enrollees about their true monthly member responsibility for their new plan, creating confusion about the affordability of health care coverage offered by an Exchange. Therefore, we determined that the benefit of avoiding potential, unexpected tax liability and of reducing

potential confusion outweighs the cost to enrollees of potentially lower APTC payments for those enrolled in two policies for partial months within one coverage month.

We acknowledge that proration based on the number of coverage days, like the methodology currently used by Exchanges on the Federal platform, is not the only approach to address the issue of excess APTC. For example, a monthly calculation linking two partial month policies for an applicable taxpayer to account for changes in APTC could also align with the current PTC regulation at 26 CFR 1.36B-3(d). However, in practice, HHS has noticed that State Exchanges often do not prorate or link the two mid-month policies, which leads to APTC payments that exceed an enrollee's expected monthly PTC amount.

However, in an effort to preserve State Exchange flexibility and to be responsive to the concerns regarding the proposed methodology, we are modifying the finalized policy to require only that State Exchanges use a methodology that ensures that their calculation of APTC does not cause the amount of APTC applied to an enrollee's monthly premium to exceed their expected monthly PTC amount when an 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, and to report the methodology to HHS in accordance with the requirements of § 155.1200(b)(2).

Comment: A few commenters who supported the proposal expressed hesitancy regarding the State Exchanges' ability to implement the proposed methodology and requested maximum flexibility for the State Exchanges in their implementation of the policy and the timing of implementation. Additionally, many opposing commenters, specifically several State Exchanges, noted that the proposal would impose significant implementation burden on States Exchanges. These commenters expressed concern that the estimated implementation cost would be extremely burdensome to State Exchanges, and the complex, resource-intensive IT and administrative systems builds would require them to divert large portions of their budget away from other priority operations such as Medicaid unwinding related to the PHE among other

projects. In addition, several commenters explained that State Exchanges are already implementing their own successful methods of ensuring that their calculation of APTC does not cause excess APTC, some of which already include prorating premiums, and that these State Exchanges should not be required to cease their effective methods, in favor of the proposed proration methodology. One commenter asserted that HHS does not have the authority to require Exchanges to implement the proposed proration methodology for premium and APTC amounts. Several of these commenters remarked that State Exchanges have the best insight into their Exchange populations and HHS should defer to their authority on how to approach the issue of APTC over-payment in their jurisdiction without limiting their flexibility.

Response: We maintain that regulating the administration of APTC is within HHS' statutory authority, as defined in section 1412 of the ACA, which grants authority to the Secretary of HHS to establish a program for APTC, and in HHS regulation under § 155.340, which establishes HHS' requirements regarding administration of the APTC. However, in light of comments regarding the need for more State Exchange flexibility, as noted earlier, we are not finalizing the policy as proposed.

We appreciate the competing priorities of State Exchanges and the potential costs of implementing the proposed policy. In the proposed rule, we acknowledged that implementing the proposed methodology would require implementation and operational costs and time on the part of most State Exchanges. We estimated a one-time implementation cost of approximately \$1 million dollars for each State Exchange, and we address specific comments on the estimated cost of implementation further in the comment and response section of the Regulatory Impact Analysis in this final rule. In an effort to be responsive to State Exchange concerns, we are finalizing the method of APTC proration as proposed for the Exchanges using the Federal platform, but HHS will require only that, beginning with PY 2024, State Exchanges use a methodology that ensures that the calculation of APTC does not cause APTC applied to an enrollee's monthly premium to exceed the enrollee's expected monthly PTC amount when 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, and to report the methodology to HHS in accordance with the requirements of § 155.1200(b)(2). We estimate that State Exchanges will be required to prospectively submit their planned PY 2024 methodology for the first time through the State-based Marketplace Annual Reporting Tool (SMART) tool in the summer of 2023 and will provide the option for State Exchanges to submit their methodology for PY 2023 through the SMART tool in the summer of 2022. HHS believes that finalizing this modification will provide the State Exchanges flexibility and sufficient time to implement a new methodology, if necessary, and to report the methodology to HHS.

HHS will be available to work with State Exchanges and address questions as they prepare to report on their methods to ensure that APTC calculations do not cause excess APTC for enrollees.

Comment: Several commenters opposing the proposal asserted that there is no need to issue regulations on the issue of APTC over-payment. Some of these commenters noted that the topic of APTC over-payment and the potential resulting income tax liability is not being reported as a problem by States Exchanges, consumers, or consumer advocacy groups. A few commenters noted that if this type of over-payment does occur, it is rare, and affects very few enrollees. Further, some of these commenters stated that if State Exchanges were over-paying APTC and exceeding premium amounts for partial-month coverage, enforcing compliance with the existing PTC rule would sufficiently address the issue.

Response: We remain concerned about the issue of APTC over-payments among State Exchanges, as described in the previous response. Recent APTC payment data indicates that APTC over-payments due to mid-month coverage changes cost the Federal government approximately \$0.5 million to \$1 million annually. While the issue of APTC over-payment may not impact very many enrollees annually, we believe that these over-payments are a legitimate source of consumer harm and may trigger a Federal income tax liability for the applicable

enrollee. However, we agree that the reference at § 155.305(f)(5) to current PTC regulations at 26 CFR 1.36B-3(d) sets a clear enough standard to hold all Exchanges sufficiently accountable to making correct payments of APTC. In an effort to ensure compliance with the existing IRS PTC rules, we are finalizing the requirement that State Exchanges use a methodology that ensures that their calculation of APTC does not cause the amount of APTC applied to an enrollee's monthly premium to exceed their expected monthly PTC amount when an 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, and to report the methodology to HHS in accordance with the requirements of § 155.1200(b)(2).

10. Special Enrollment Periods – Special enrollment period verification (§ 155.420)

In 2017, the 2017 Market Stabilization final rule preamble (82 FR 18346, 18355 through 18358) explained that HHS would implement pre-enrollment verification of eligibility for certain special enrollment periods in all Exchanges on the Federal platform. HHS also clarified its intention to not establish a regulatory requirement that all Exchanges conduct special enrollment period verifications to allow State Exchanges additional time and flexibility to adopt policies that fit the needs of their State (82 FR 18355 through 18358). 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.

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 653), we proposed 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 in special circumstances, which could include natural disasters or public health emergencies that impact consumers or the Exchange. We further proposed that Exchanges' pre-enrollment verification process must be implemented in a manner that is not

based on a prohibited discriminatory basis. This is 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 (82 FR 18355 through 18360), 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.

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 also proposed that the Exchanges on the Federal platform would conduct pre-enrollment verification of

eligibility for only one type of special enrollment period—the special enrollment period for new consumers who attest to losing minimum essential coverage.²⁵⁹ 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 sought comment on these proposals.

After reviewing the public comments, we are finalizing this provision as proposed, except that we have added a specific reference to § 155.120(c) to the new regulation text at § 155.420(g) to clarify the precise nondiscrimination standards that are applicable to an Exchange’s process for granting exceptions to pre-enrollment verification for special enrollment periods.

We summarize and respond to public comments received on the special enrollment period verification proposal.

Comment: The majority of commenters supported HHS’ proposal. Many commenters agreed that this policy helps minimize barriers to enrollment while still maintaining program integrity. Most also agreed that this policy will advance health equity by alleviating barriers to enrollment for historically disadvantaged and marginalized communities. Several commenters mentioned that pre-enrollment special enrollment period verification can be especially burdensome for low-income individuals, since they are more likely to have inadequate internet access at home and are more likely to use a primary language other than English. Commenters also noted additional groups that would benefit from this policy: immigrants, Native Americans, and those living in rural areas who may not have high-quality internet access.

²⁵⁹ See 45 CFR 155.420(d)(1)(i).

Several commenters agreed that special enrollment period verification requirements can cause gaps in coverage and stated that reducing these barriers will encourage continuous coverage. Commenters mentioned that it can be difficult to verify life events, such as proving a change in household size when someone becomes a tax dependent. One commenter noted that pre-enrollment verification is not only time consuming for consumers, but also for brokers who could be using that time to help more clients enroll in coverage. Many commenters agreed that this proposal will encourage younger and healthier consumers who are eligible for a special enrollment period to enroll and that this will be good for the risk pool. Several commenters highlighted that concerns from issuers about scaling back pre-enrollment verification for special enrollment periods harming market stability have not been proven.

Response: We appreciate the comments highlighting that this policy will have a positive impact on consumers from historically disadvantaged and marginalized communities. We agree that this policy will decrease consumer burden and barriers to enrollment for eligible consumers, while still supporting program integrity. We also agree that this policy will increase enrollments among younger and healthier consumers and that this will have a positive impact on the risk pool.

Comment: Several commenters mentioned that, as written, this proposal would still pose a barrier for consumers, particularly those who face disproportionately high rates of being uninsured, such as immigrants and Black and African American consumers. Some commenters explained accessing documents from past employers to prove loss of minimum essential coverage can be challenging, especially for immigrants or those who are more likely to have unstable employment or work in the informal economy. One commenter also raised concern that losing coverage can place significant stress on a household and consumers may not have the bandwidth to complete a pre-enrollment verification process for a special enrollment period. Several commenters recommended that HHS further act to reduce consumer burden and barriers to enrollment by eliminating pre-enrollment verification for all special enrollment period types.

A few commenters advocated for self-attestation in lieu of document verification and mentioned that many other Federal programs rely on self-attestation.

Response: We appreciate commenters' concerns related to health equity and consumer burden. We believe that by scaling back pre-enrollment verification for special enrollment periods, this policy will decrease consumer burden and barriers to enrolling through a special enrollment period. At this time, we believe that pre-enrollment verification for special enrollment periods is appropriate for the most commonly used special enrollment period type in order to support program integrity. HHS works to reduce consumer burden imposed by pre-enrollment verification for special enrollment periods based on loss of minimum essential coverage while still supporting program integrity by using available data to automatically verify loss of minimum essential coverage for a large portion of consumers requesting a loss of minimum essential coverage special enrollment period, which requires no additional consumer action and does not delay enrollment. We will continue to evaluate whether additional changes are appropriate.

Comment: Some commenters supported the clarified flexibility for State Exchanges. Commenters stated that this change will enable State Exchanges to implement pre-enrollment special enrollment period verification processes that are tailored to their respective Exchanges and consumer populations. One commenter also appreciated that Exchanges may provide an exception to pre-enrollment special enrollment period verification for special circumstances. A couple of commenters highlighted that the new paragraph (g) language is redundant since State Exchanges already have flexibility to exercise discretion under current rules.

Many commenters expressed concern that State Exchanges may conduct pre-enrollment verification for additional special enrollment period types – outside of loss of minimum essential coverage - which could cause barriers to enrollment in those States, particularly for younger and Black and African American consumers. Due to this concern, these commenters recommended

that HHS should not permit State Exchanges to have broader pre-enrollment verification of eligibility for special enrollment periods than the FFEs.

One commenter urged HHS to monitor how State Exchanges implement pre-enrollment verification for special enrollment periods to ensure their processes are not discriminatory. Another commenter suggested that HHS prohibit State Exchanges from implementing pre-enrollment verification that differs from that of the FFEs, unless the State Exchange can prove that pre-enrollment verification for special enrollment periods will not have a disproportionate impact on communities of color in their State.

Response: We agree that the new paragraph (g) allows State Exchanges to continue to implement pre-enrollment verification processes for special enrollment periods that are tailored to their respective populations and needs. We also agree that clarifying that Exchanges may provide an exception for pre-enrollment special enrollment period verification for special circumstances will enable Exchanges to be flexible so that eligible consumers can easily enroll in coverage when they may need it most, such as during the current COVID-19 PHE unwinding period. HHS is committed to equity in health care and plans to monitor use of SEP pre-enrollment verification in State Exchanges to ensure that they are following the non-discrimination standards under § 155.120(c).

Comment: Several commenters, particularly issuers, opposed this proposal due to concerns that scaling back pre-enrollment verification for special enrollment periods would lead to an increase in fraud and abuse that would negatively impact market stability and premium costs. A few of these commenters mentioned concerns about consumers temporarily relocating to a State for medical care, which could lead to increased costs in areas with renowned medical centers. Commenters stated that HHS should encourage year-long continuous coverage. One commenter cautioned that this policy, combined with other recent policy changes such as a longer open enrollment period and the special enrollment period for individuals with incomes under 150 percent of the Federal poverty level, will harm market stability.

Several commenters stated that before the 2017 Market Stabilization final rule (82 FR 18346), the market was unstable and costs were higher due to fraud and abuse in consumers' use of special enrollment periods as consumers would wait to enroll until they needed care. One commenter noted that data from a 2018 CMS report showed that most consumers with special enrollment period verification issues submitted the necessary documents to resolve their issue.²⁶⁰ In addition, the report revealed that fewer consumers enrolled through an exceptional circumstance SEP (suggesting less abuse), and that the average age of special enrollment period enrollees was younger than that of open enrollment period enrollees.

Commenters also stated that risk adjustment data suggests that consumers with chronic conditions are abusing special enrollment periods and are waiting to enroll until they need care. One commenter highlighted that the loss ratios after risk adjustment for special enrollment period enrollments, relative to open enrollment period enrollments, has increased for some of their plans since 2019. They stated that this is likely due to Exchanges relaxing pre-enrollment verification for special enrollment periods during the PHE.

Response: We disagree that this policy will destabilize the market and cause large increases in premium costs. We believe that while pre-enrollment special enrollment period verification can decrease the risk of 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. By verifying eligibility for the most commonly used special enrollment period type and removing verification for other special enrollment periods, we believe that the Exchanges on the Federal platform will successfully mitigate the negative impacts of special enrollment period verification without substantially sacrificing program integrity or market stability.

²⁶⁰ The Exchanges Trends Report (2018, July 2). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-3.pdf>.

We acknowledge the data from the 2018 CMS report regarding special enrollment period verification. While most SEP verification issues have been resolved, current HHS data shows that younger 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 as younger consumers are often healthier. We believe that improving access for younger and healthier eligible consumers will be good for the risk pool and offset the effect of potential increased adverse selection. Current HHS data also shows that Black and African American consumers submit acceptable documentation at much lower rates than White consumers. This suggests that pre-enrollment verification may be a barrier to enrollment for eligible Black and African American consumers. This policy change may improve health equity, and access to affordable, quality coverage for all.

Comment: Many commenters who opposed this proposal, agreed that document verification for special enrollment periods can be a barrier to enrollment for some eligible consumers. Therefore, they expressed support for more automation of special enrollment period verification. One commenter also encouraged HHS to evaluate why some consumers submit acceptable documents at lower rates and recommended redesigning the document collection process accordingly.

Response: We acknowledge these concerns and will continue to conduct automated, pre-enrollment verification when possible for the loss of minimum essential coverage SEP type. We note that automated verification is not always possible. However, we continue to believe that the approach we are adopting balances the priorities of reducing consumer burden with supporting program integrity. HHS continues to evaluate document submission rates and consumer outcomes to inform process and policy improvements for successful SEP verification.

11. General program integrity and oversight requirements (§ 155.1200)

The Payment Integrity Information Act of 2019 (PIIA)²⁶¹ 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 Payment Integrity Information Act of 2019 (PIIA),²⁶² 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.

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. 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.

We proposed 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, under the proposal, 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 had also proposed to amend § 155.1200(c) to cross-reference proposed § 155.1200(e) to ensure the coordination of these two requirements. Please see the proposed rule preamble for a complete description of the proposed policy and the SEIPM program.²⁶³

We sought comment on these proposals.

After reviewing the public comments, we are not finalizing this proposed provision at this time as it is interrelated with the SEIPM program proposal, which will not be finalized at this

²⁶¹ Pub. L. 116-117 (2020, March 2).

²⁶² Pub. L. 116-117 (2020, March 2).

²⁶³ 87 FR 654 through 660.

time through this final rule. HHS will continue to engage with the State Exchanges as we continue to develop the SEIPM program, which we plan to codify in future rulemaking. Please refer to section 12 for further details.

We summarize and respond to public comments received on general program integrity and oversight requirements (§ 155.1200) below.

Comment: Several commenters generally opposed the amendment to the programmatic audit requirement to permit a State Exchange to meet the requirement under § 155.1200(c) by completing the SEIPM program process, as proposed under subpart P. Commenters noted that the proposed change is duplicative because the existing programmatic audit requirement under § 155.1200(d) already addresses eligibility and enrollment compliance. One commenter explained that imposing a new audit requirement under SEIPM creates additional burden that is not offset by the amendment to the programmatic audit requirement under § 155.1200(e). Another commenter stated that while HHS is permitting a State Exchange to meet the programmatic audit requirement under § 155.1200(c) by completing the SEIPM program process, State Exchanges will need to spend substantial time and resources to prepare for SEIPM. Commenters noted that State Exchanges are already subject to extensive oversight under §§ 155.1200 and 155.1210 and requested HHS clarify how the SEIPM will impact the SMART for Plan Years 2023-2025.

Another commenter requested that HHS grant programmatic audit relief while State Exchanges prepare to comply with the SEIPM program and also consider how the existing programmatic audit requirement may be able to meet SEIPM goals. A few commenters requested that HHS consider alternative approaches to the implementation of the proposed SEIPM program, such as enhancing the current programmatic audit requirement under § 155.1200 to review for improper payments or maintain the programmatic audit requirement intact, as it permits flexibility and does not add undue burden. One commenter recommended that HHS use onsite audits to reduce burden on the State Exchanges resulting from the SEIPM program.

Response: HHS will continue to evaluate how to minimize duplicative requirements and reduce burden on State Exchanges as we work toward implementation of the proposed SEIPM program. After considering the comments received, we are not finalizing this provision at this time, as it is interrelated with the SEIPM program proposal, which will not be finalized through this final rule. We clarify that the existing oversight and audit requirements under §§ 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, and updated through PIIA. The maintenance of records requirement under § 155.1210 requires that State Exchanges keep eligibility and enrollment records, but it does not establish requirements specific to improper payments. The independent external programmatic audits required under 155.1200(c) do not review, estimate, or report the amounts or rates of improper payments and do not allow for standardized comparison or analysis across State Exchanges. In order to comply with the PIIA, HHS will continue to develop the SEIPM program and plans to engage in future rulemaking to codify the SEIPM program.

Regarding the SMART, we clarify that State Exchanges will continue to report on Exchange compliance through the annual SMART process, as required under § 155.1200(b)(2).

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.²⁶⁴ At that time, we also announced that we would undertake rulemaking before implementing the improper payment measurement methodology.

²⁶⁴ Presentation and materials provided to the then operational State Exchanges as part of ‘All States’ meeting held on February 21, 2019.

In line with our prior announcement,²⁶⁵ and as mentioned in section 11 of the preamble, HHS proposed regulations governing HHS' SEIPM program.

As noted in the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 655), 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. The regulations at § 155.1200(c) require State Exchanges to hire an independent qualified auditing entity and submit the external audit results to HHS. The 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 proposed to update programmatic auditing requirements such that the completion of the annual SEIPM program would satisfy the current auditing requirements prescribed in § 155.1200(c). Therefore, we proposed to establish a new subpart P under 45 CFR part 155 (containing §§ 155.1500 through 155.1540) to codify the SEIPM program requirements. Please see the proposed rule preamble (87 FR 654 through 655) for a complete description of the proposed policy.

After reviewing and considering the public comments, we will not finalize the SEIPM proposals at this time due to commenters' concerns surrounding the proposed implementation timeline and other burdens that would be imposed by the proposed SEIPM program.

We summarize and respond to public comments received on the State Exchange Improper Payment Measurement Program (§§ 155.1500 through 1540) below.

Comment: Several commenters addressed the implementation timeline for the SEIPM program. One commenter expressed concerns with the relatively short implementation time frame and questioned whether it was operationally, fiscally, and technologically feasible for

²⁶⁵ Ibid.

State Exchanges to comply with the program's requirement by the proposed PY 2023 effective date. A few commenters characterized the timeline for SEIPM implementation as inadequate. One commenter recommended several years of implementation in a pilot before HHS publishes error rates to ensure the data accurately reflect errors. One commenter characterized the implementation timeline as administratively and financially burdensome and unrealistic because State Exchanges would need to implement new processes and possibly technology changes by the end of 2022 to meet the proposed 2024 reporting requirements. One commenter proposed an effective date of plan year 2024 rather than 2023. One commenter requested extending the deadline for SEIPM.

Response: Given the additional burden that was placed upon State Exchange resources during the PHE, we agree that additional time should be provided for implementation and consequently we are not finalizing the provision at this time to allow for a longer implementation timeline. We also generally agree with the commenter who stated that additional piloting is needed. Because piloting efforts have also been hindered by the PHE, HHS will consider more robust piloting options in which the State Exchanges can participate prior to HHS publishing estimates of improper payment rates.

Comment: Several commenters supported the need for review of eligibility determinations that result in improper payments of APTC and encouraged HHS to collect more detailed documentation of eligibility denials.

Response: We thank the commenters for their support of the SEIPM program and we will consider this feedback as we continue to develop the program. We address the commenters' specific suggestions in the data collection section below.

Comment: One commenter indicated that it was neutral as to the establishment of the SEIPM program. The commenter noted that there are obvious potential benefits to the Federal oversight model instead of the programmatic audit model currently in use by State Exchanges, and the commenter also noted that it is currently too early to fully assess whether the tradeoffs

regarding the cost and work related to the audit model will be more or less than the cost and work to meet the reporting requirements of the proposed Federal oversight model.

Response: We thank the commenter for sharing its view of the SEIPM program.

Comment: Many commenters expressed opposition regarding the SEIPM proposal noting it is duplicative because the existing SMART and programmatic audit requirements under § 155.1200 address eligibility and enrollment compliance.

Response: We address these comments under section 11 of the preamble.

Comment: A few commenters stated that the SEIPM program is duplicative because consumers already reconcile APTC on their tax returns.

Response: We appreciate the commenters' observation, but note that the APTC reconciliation process on the tax return only addresses the APTC calculation and not the accuracy of the eligibility determination. The IRS uses the annual enrollment data and monthly reconciliation data provided by HHS to calculate the PTC and to verify reconciliation of APTC made to the QHP issuers on enrollees' individual tax returns. However, the IRS does not address other issues related to the APTC calculation, particularly in examining the eligibility and enrollment processes including the verification of citizenship, social security number, residency, minimum essential coverage, special enrollment period circumstance, income, family size, and data matching issues related to document authenticity. Examination of these areas would be necessary to identify any underlying issues that could lead to improper payments, and therefore may need to be addressed through corrective action as stipulated under the PIIA.

Comment: A few commenters stated that the data HHS is proposing to collect are already available to HHS through the Federal Data Services Hub (FDSH), the State-based Marketplace Inbound (SBMI), or enrollment and disenrollment reports, making the additional SEIPM collection effort burdensome and duplicative.

Response: We appreciate the feedback regarding the potential duplication of Federal requirements and increased burden. As we continue to develop the SEIPM program, we intend to

work collaboratively with State Exchanges to continue to evaluate how to best minimize duplicate requirements and reduce burden on the State Exchanges, as well as how HHS can use data submitted by State Exchanges under existing Federal requirements to help streamline SEIPM processes. We note that as of this writing, HHS does not collect data regarding verification and eligibility determination, enrollment reconciliation, or plan management from the State Exchanges to determine whether they comply with existing regulations. While the FDSH does provide applicant verification information, it does not provide evidence that the State Exchange used FDSH data to conduct verifications or whether verification inconsistencies were resolved properly. Moreover, the FDSH does not provide the information needed to determine whether a State Exchange evaluated the verified information properly to determine an applicant's eligibility for enrollment in a QHP and receipt of APTC. We recognize that the State-Based Marketplace Inbound (SBMI) data provides the policies and payments for an applicant, however, that data cannot be matched to a specific application submission, which prevents HHS from using the data to verify that eligibility determinations and associated APTC payments were made correctly. Further, the SBMI data does not include the reconciliation that occurs with the State Exchange and its issuers to provide evidence that the State Exchange resolved any data discrepancies with the issuers that may result in incorrect APTC payments being made. Additionally, the SBMI data does not indicate whether policies were certified as QHPs. HHS currently uses this data to understand the sampling of policies from each State Exchange and to determine an appropriate sample that would be selected to reflect the State Exchange's applicant population. We will continue to evaluate this and other data that HHS currently collects and will use it to the maximum extent feasible as we continue to develop the SEIPM program.

Comment: A few commenters expressed concern that the proposed rule does not provide enough information to assess the SEIPM program proposal or to evaluate the tradeoffs related to the current Federal programmatic audit requirements under § 155.1200(c) compared to the proposed audit processes under the SEIPM program.

Response: Although commenters did not specify what additional information would have been helpful in assessing the program, HHS believes that this concern is related to potential duplication of effort and whether current requirements under § 155.1200(d) are consistent with SEIPM requirements. Though we are not finalizing this proposed provision, we will consider these comments as we continue to develop the SEIPM program.

Comment: One commenter requested that the SEIPM program not collect data from the State Exchanges during the annual individual market Exchange Open Enrollment Period (OEP) timeframe, which is from the end of October (final preparation for annual OEP) to the end of January (distribution of Forms 1095-A).

Response: We will consider this feedback as we continue to develop the SEIPM program. As we continue to develop the program, we aim to coordinate with State Exchanges to offer maximum flexibility to account for State's enhanced workloads during the OEP.

Comment: One commenter noted that despite the provision allowing completion of the SEIPM requirements to satisfy the existing independent external programmatic audit requirement under § 155.1200(c), State Exchanges would have to spend time and resources to prepare for and procure a separate audit when participating in the SEIPM program.

Response: We appreciate the feedback around potential duplication of Federal requirements and increased burden. We address these concerns in section 11 of the preamble.

Comment: One commenter suggested that HHS convene an HHS and State Exchanges working group to identify approaches to the specific areas that HHS wants to address through current Federal audit requirements.

Response: We appreciate the commenter's suggestion and value the feedback we have received from the State Exchanges during the SEIPM pilot process. We have been engaging in discussions regarding the SEIPM with the State Exchanges since 2019 and we continue to meet with State Exchanges individually to gather feedback on the SEIPM approach. We will continue these efforts as we move forward in the development of the SEIPM program.

Comment: One commenter recommended that the SEIPM program operate as a minimum threshold for State Exchanges to meet the proposed SEIPM requirements and to allow flexibility for any individual State Exchange to create more stringent auditing criteria above and beyond what is required in the proposed SEIPM program. The commenter suggested allowing State Exchanges to meet their independent external programmatic audit requirements by complying with the SEIPM program. In cases where the State Exchange has more stringent auditing criteria than the SEIPM program, the commenter suggested that the State Exchange should be able to maintain its criteria.

Response: We understand that the State Exchanges may expand on the Federal regulations to create more stringent policies and procedures. In addition to evaluating compliance with Federal requirements during the planned SEIPM review process, our goal is to also measure compliance with State Exchange specific policies and procedures to the extent that State Exchange specific policies and procedures do not conflict with Federal requirements. As we continue to develop the SEIPM program, we will collaborate with each State Exchange to modify the review criteria so that each State Exchange is evaluated against their own policies and procedures.

Comment: One commenter encouraged HHS to take a risk-based approach that focused on reviews of a specific area or areas that have a higher risk of over-payments. The commenter suggested HHS use a more proactive approach that used test scenarios to demonstrate APTC accuracy.

Response: We appreciate the feedback and recognize that certain State Exchange system functions may have more risk than others in implementing Federal regulations. We appreciate the recommendation to use test scenarios and have begun to do so, in some instances, as we engage with State Exchanges on SEIPM pilot and preparatory activities. We will consider this comment as we continue to develop the SEIPM program.

Comment: One commenter recommended modifying the SEIPM's scope to focus on APTC in addition to the SEIPM process replacing the annual programmatic audit requirement.

Response: As we continue to develop the SEIPM program, we plan for the SEIPM review process to focus on identifying, measuring, estimating, and reporting errors made in determining eligibility for APTC greater than \$0 that resulted in improper payments. We plan for this to include the examination of eligibility and enrollment processes, which consists of verifications of citizenship, social security number, residency, minimum essential coverage, special enrollment period circumstance, income, family size, and data matching issues related to document authenticity. Examination of these areas would be necessary to identify any underlying issues that could lead to improper payments, and therefore would need to be addressed through corrective action, as stipulated under the PIIA.

Comment: One commenter suggested that HHS observe trends that emerge during SEIPM implementation and propose Corrective Action Plan parameters in future rulemaking, and then release the first improper payment report in November 2025, at the earliest.

Response: We appreciate the comments offering support to defer the CAP parameters. We plan to engage in future rulemaking to codify the SEIPM program and will solicit comments regarding the CAP at that time.

a. Purpose and definitions (§ 155.1500)

We proposed 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 proposed the purpose of subpart P as setting forth the requirements of the SEIPM program for State Exchanges.
- At paragraph (b), we proposed to codify the definitions that are specific to the SEIPM program and key to understanding the process requirements.

- We proposed 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 proposed the definition of “Corrective action plan (CAP)” to mean the plan a State Exchange develops to correct errors resulting in improper payments.

- We proposed 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 QHP; APTC, including the calculation of APTC; redeterminations of eligibility determinations during a benefit year; or annual eligibility redeterminations.

- We proposed 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 proposed 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 proposed 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 proposed the definition of “State Exchange improper payment measurement (SEIPM) program” to mean the process for determining 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.

After reviewing the public comments, we are not finalizing this provision at this time. We summarize and respond to public comments received on purpose and definitions (§ 155.1500) below.

Comment: One commenter recommended that HHS also define the following terms: (1) Annual Program Schedule, (2) Measurement Cycle, (3) Measurement Year, and (4) Reporting Year. The commenter also recommended clarifying the meaning of two statistical terms: (1) Pre-sampling Data and (2) Sampled Unit Data.

Response: HHS agrees that the defining these additional terms would provide greater clarity to State Exchanges regarding SEIPM program requirements. We will consider defining these terms in future rulemaking.

b. Program notification and planning process (§ 155.1505)

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

- At paragraph (a), we proposed 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 proposed notification would occur during the benefit year (that is, the year under review for which data would be collected), which immediately precedes the proposed measurement year (that is, the year in which the measurement will be completed). The proposed 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 proposed the requirements associated with HHS' responsibility to notify the State Exchanges prior to the proposed measurement year regarding SEIPM schedules, which will include relevant timelines. For example, among other things, the proposed SEIPM

annual program schedule would detail the time period during which HHS would provide the proposed SEIPM data request form to State Exchanges with instructions regarding how to complete each part of the form. The proposed SEIPM annual program schedule would also provide the deadlines prescribed for State Exchanges to complete each part of the form.

- At paragraph (c), we proposed 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 proposed 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. Please see the proposed rule preamble (87 FR 656) for a complete description of the proposed policy.

We did not receive any comments in response to the proposals on the program notification and planning process.

As previously stated, we are not finalizing this provision at this time.

c. Data collection (§ 155.1510)

We proposed to add new § 155.1510 to address the data collection requirements to support the SEIPM process.

- At paragraph (a)(1), we proposed the requirement that the State Exchange annually provide pre-sampling data to HHS by the deadline provided in the annual program schedule. The proposed pre-sampling data request would provide HHS with essential information about the composition of the State Exchange's application population to appropriately stratify and sample the population.

Please see the proposed rule preamble for a complete description of the sampling methodology for this proposal (87 FR 656).

- At paragraph (a)(2) we proposed annual requirement that the State Exchange provide sampled unit data to HHS. To meet this requirement under the proposal, 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 proposed sampled unit data request would include the list of sampled units and the associated information specific to each unit. The information required under the proposal 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 proposed the State Exchange submit the pre-sampling and sampled unit data specified in paragraph (a) to be submitted to HHS in a manner and within a deadline specified in the annual program schedule. We also proposed language regarding requests for extension which may be submitted by State Exchanges. Given the importance of the time frames associated with the measurement process, through this proposal, we did not anticipate granting extensions in most situations. Rather, the approval of extension requests was envisioned to be reserved for extreme circumstances that would directly impact operations of the particular State Exchange. Such situations might include natural disasters, interruptions in business operations such as major system failures, or other extenuating circumstances.

- At paragraph (c), we proposed 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). Under the proposal, as a result of not timely providing required data, we may have cited errors due to lack of documentation to support the State's eligibility or payment decisions.

After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on data collection (§ 155.1510) below.

Comment: A few commenters pointed out that there may be differences between State Exchanges in terms of database structures, data fields, and reporting. A few commenters stated that implementing the SEIPM data requirements will create a financial and operational burden as it will require them to change their information technology systems, and they will need to employ new staff or forgo other activities such as standing up other programs.

Response: We appreciate these comments and will take them into consideration as we continue to develop the SEIPM program. However, we emphasize that it was not the intention of the proposed SEIPM program to drive changes to a State Exchange's information technology systems. One goal of HHS is to reduce burden by requesting State Exchanges to populate the information elements of the data request form by using existing data elements from their current IT system. Still, we recognize there is a cost burden related to the employment of staff resources required to conduct data analysis, perform data mapping activities, and extract data to support submission requirements. We will consider these costs in future rulemaking to codify the SEIPM program.

Comment: A few commenters noted a desire for flexibility in the data fields they provide to HHS. One commenter appreciated that under the pilot program, State Exchanges were allowed flexibility in what data fields could be provided.

Response: We recognize that State Exchange systems and business processes may vary in the way that data is used and stored. For this reason, we are conducting information review sessions with State Exchanges to address State Exchange-specific needs. There are many complex elements that must be met for any applicant who is deemed eligible for APTC. Because of the complexity and breadth of those elements, a very structured review methodology is required. To meet that need, certain data fields have been identified that are required for the purposes of conducting a review of this nature. The data request form was designed to aid in the

matching of information fields that are needed by HHS with the States' data in order to conduct the required measurement in a consistent manner across all State Exchanges. The ongoing review sessions will allow opportunities to identify the most efficient means for collecting the information that is ultimately deemed necessary. We will continue to engage with State Exchanges through such sessions as we continue to develop the SEIPM program.

Comment: A few commenters suggested changes to the program sample size. One commenter recommended that the sample size be from 100 – 1,000 tax households to account for the variation in State Exchange populations. One commenter suggested that HHS choose a different method for sampling and auditing eligibility and enrollment data to instead allow a State Exchange to pull data records for a "reasonable" sample size, which it did not further define, and work with an HHS auditor for data review.

Response: We appreciate and thank commenters for their suggestions regarding sample size. We clarify that the PIIA and OMB Circular A-123, Appendix C require HHS to produce a statistically valid point estimate of the improper payment rate aggregated across all State Exchanges. This requires determining the sample size that is necessary for meeting the targeted margin of error to estimate a total improper payment rate across all State Exchanges and determining the sample sizes for the individual State Exchanges under that parameter. To reduce State burden, we plan to assess various stratification variables which may optimize the sample size and will continue to assess the benefits and deficiencies of various other sampling methodologies.

Comment: A few commenters suggested that HHS require State Exchanges to collect additional information such as data on erroneous coverage denials and incorrect financial assistance allocations.

Response: We appreciate the commenters' suggestions to expand the scope of CMS data collection to include erroneous coverage denials and incorrect financial assistance allocations. The focus of the planned SEIPM program, however, is to identify, measure, estimate, and report

on erroneous determinations of eligibility for APTC payments in an amount greater than \$0 that result in improper payments. We continue to assess and identify improvements to the planned SEIPM review process with a focus on the statutory and regulatory requirements and compliance with OMB guidance.

Comment: A few commenters suggested requiring State Exchanges to disaggregate eligibility and enrollment data by race and ethnicity. One commenter also suggested disaggregating data by primary language, sex, sexual orientation, gender identity, and disabilities. One commenter suggested disaggregating data by applicants who indicate their primary language is other than English.

Response: We will consider the commenters' suggestions as we continue to develop the SEIPM program. We also respectfully remind commenters that the focus of the planned SEIPM program is to identify, measure, estimate, and report on erroneous determinations of eligibility for APTC payments in an amount greater than \$0 that result in improper payments. As we continue to develop the SEIPM program, we plan to audit State Exchanges in compliance with the PIIA and OMB guidance to estimate improper payments.

Comment: One commenter suggested that HHS explicitly require any protected health information (PHI) or personally identifying information (PII) shared with HHS or contractors be transmitted using a secure file transfer mechanism such as Secure File Transfer Protocol (SFTP).

Response: HHS will consider how to establish a secure file transfer mechanism between the State Exchanges and HHS to support the exchange of files that may contain PII and PHI data.

Comment: A few commenters noted that they had worked in pilots of the SEIPM program with CMS and that the process was difficult either because the program based its effort to standardize audits across State Exchanges on the FFE data model or because the program required manual review of records.

Response: We recognize that State Exchange systems and business processes may vary in the way that data is used and stored. For this reason, we are conducting information review

sessions with State Exchanges to address State Exchange-specific needs. The data request form was designed to aid in the matching of information fields that are needed by HHS in order to conduct the required measurement in a consistent manner across all State Exchanges. The information review sessions allow opportunities to identify the most efficient means for collecting this information from each State Exchange. We will continue to engage with State Exchanges through such sessions as we continue to develop the SEIPM program. HHS developed a review modules document (RMD) to establish the baseline set of review criteria that will be applied across all State Exchanges. Each review criterion is based on specific Federal regulations or on a State Exchange's own policies that may expand on how a regulation is implemented in their State Exchange. In support of the review criteria in the RMD, CMS developed the data request form detailed above. We note that CMS developed the data request form to define a set of generalized data elements that are not specific to the FFE data model. These data elements should be common to all State Exchanges as they would be needed to execute general Federal regulation requirements established for the enrollment and eligibility process.

Comment: One commenter noted that there are not clear standards for the data that would satisfy an SEIPM audit. The commenter noted that the State Exchanges may not have the requested data available where self-attestation is accepted.

Response: We recognize the need for clear standards for data to satisfy an SEIPM review. As we continue to develop the SEIPM program, we will continue with our current communications with State Exchanges to address State Exchange-specific needs and to convey planned standards and data requirements that can be found in the corresponding PRA package, including the pre-sampling and sampled unit data request. State Exchanges that have voluntarily chosen to participate in the current engagement process will continue to benefit from receiving guidance regarding planned standards and data requirements. HHS encourages all State Exchanges to voluntarily engage with HHS to better understand the planned data collection

requirements. During these engagement sessions, HHS can better understand the unique business rules and environment the State Exchange is operating within and make appropriate modifications to the review criteria and data that is requested to evaluate the State Exchange against those criteria. In addition, HHS recognizes that utilization of self-attestation may limit the availability of certain data and is taking this into account as we continue to develop the SEIPM program. Finally, we note that additional detail regarding the proposed SEIPM data request form is provided above in the preamble to the data collection process.

d. Review process and improper payment rate determination (§ 155.1515)

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

- At paragraph (a), we proposed 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 proposed 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 proposed 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 proposed 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.

We did not receive any comments in response to the proposals on the review process and improper payment rate determination.

As previously stated, we are not finalizing this provision at this time.

e. Error findings decisions (§ 155.1520)

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

- At paragraph (a), we proposed 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 under the proposal, 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, we proposed that, should these types of events warrant the 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 would still issue an error findings decision to the State Exchange indicating that no errors were identified. As proposed, 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 proposed language regarding the specific information that would be included in error findings decisions. We proposed 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.

After reviewing the public comments, we are not finalizing this provision at this time.

Comment: One commenter expressed concern that each State Exchange's error findings decision would not be made easily accessible to the public and requested that HHS post each State Exchange's error findings decision on the HHS website to ensure transparency.

Response: We thank the commenter for the recommendation to make each State Exchange's error findings decisions easily accessible to the public by posting each State Exchange's error findings decision on the HHS website to ensure transparency. We will take the recommendation into consideration as we continue to develop the SEIPM program.

f. Redetermination of error findings decisions (§ 155.1525)

We proposed 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 proposed 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. As proposed, 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, as proposed, 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 the publication of the improper payment rate.

- At paragraph (a)(1), we proposed language requiring that the State Exchange identify the specific error(s) for which the State Exchange would be requesting a redetermination. As proposed, this identification may pertain to a single individual's application or to a type of error affecting a class of applications. As proposed, a redetermination would constitute a review of the initial decision and not a de novo investigation. Thus, we proposed that the State Exchange would base its request on documentation and other information already submitted to HHS (for example, we proposed that if the application lacked income information, the State Exchange may not retrospectively seek this documentation and add it to the record). As proposed, any issues unrelated to an error identified by HHS in the initial error findings decision would not be addressed.

- At paragraph (a)(2), we proposed language that the State Exchange must include all data and information that support the State Exchange's request for a redetermination. Note that,

as proposed, while State Exchanges can 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. In the proposal, we explained that 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 proposed 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) specified in paragraph (a)(1). In the proposal, we stated that the State Exchange should clearly articulate how the data and information is related to HHS' findings, and how it impacts HHS findings. We proposed that if a State Exchange did 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 proposed language regarding the issuance of redetermination decision. As proposed, the redetermination of an error findings decision would be issued within the deadline prescribed in the annual program schedule. The goal of this proposal was 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. Thus, we also proposed that if circumstances like natural disasters or other extenuating circumstance resulted in HHS needing additional time to render the redetermination decisions, a State Exchange would be notified of the delay.

- At paragraph (c), we proposed language conveying the minimum content requirements for HHS' redetermination decision.

- At paragraph (c)(1), we proposed 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 proposed 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.

After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on redetermination of error findings decisions (§ 155.1525) below.

Comment: A few commenters expressed concern that HHS would consider only the initial data submitted in response to the data request form when a State Exchange requests redetermination of an error findings decision. These commenters requested that HHS allow State Exchanges to introduce new information that could help clarify the process used by a State Exchange and possibly negate the need for an error findings decision.

Response: We will take this feedback into consideration as we continue to evaluate any adjustments that may be needed to the redetermination process as State Exchanges participate in the pilot program, prior to SEIPM implementation.

g. Appeal of redetermination decision (§ 155.1530)

We proposed to add a 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 proposed 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 proposed 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.

- At paragraph (b), we proposed 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. As proposed, no additional new data or information submitted in support of the request for appeal would be considered.

- At paragraph (c), we proposed language that the appeal decision would be issued within the deadline prescribed in the annual program schedule unless there is a delay, and that the State Exchange will be notified in the event of any delay in the appeal entity’s ability to reach a decision.

- At paragraph (d), we proposed the content of the appeal decision.

- At paragraph (d)(1), we proposed that the appeal decision would include the findings on the error for which an appeal was requested and that those findings would be limited to the errors that were identified in the request for appeal.

- At paragraph (d)(2), we proposed that the appeal decision would include the final disposition of the appeal request.

- At paragraph (e), we proposed that upon completion of the review and the closure of all appeals, HHS may issue to each individual State Exchange, a report containing the error findings and the estimated improper payment rate for their respective program. As proposed, that report would not be made public. Additionally, through the proposal, it was described that the estimated improper payment rates for each State Exchange would be used to estimate an aggregate improper payment rate across all State Exchanges and that the aggregate rate would be published in the agency’s Annual Financial Report.

After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on the appeal of the redetermination decision (§ 155.1530) below.

Comment: One commenter requested that HHS provide more detail regarding the effects of a fully adjudicated error and specifically asks whether an enrollee would be retroactively impacted by a fully adjudicated error or whether the IRS would require changes through Form 1095-A reporting.

Response: At this time, HHS has not determined to what extent, if at all, fully adjudicated error findings decisions may impact an enrollee. HHS, in collaboration with IRS, the Department of the Treasury, and other agencies as required, will make this decision based on further research and evaluation of how recoveries could be implemented, including the authority to pursue any such recoveries. Further, any decision relating to the recovery will be communicated through future rulemaking. HHS is not aware of any intended changes in Form 1095-A reporting to support the planned SEIPM program.

Comment: One commenter expressed concern that publishing aggregate error rates across all State Exchanges rather than publishing error rates for each State Exchange could negatively reflect on higher-performing State Exchanges. The commenter also stated that SEIPM design flaws could result in a higher assessed rate of improper payments.

Response: We appreciate the comment. As we continue to develop the SEIPM program, HHS will consider methodologies for identifying errors with the goal of determining an accurate estimate of improper payments that meet OMB criteria. With regard to SEIPM design flaws, HHS is continuing to engage State Exchanges in order to test the planned SEIPM data collection, sampling, and review processes to determine if any adjustments are needed.

h. Corrective action plan (§ 155.1535)

Under the proposed rule, we proposed to add a new § 155.1535 to address the scenario in which a State Exchange's improper payment rate for a given benefit year, in HHS' reasonable discretion, necessitates a CAP to correct the causes of any payment errors. With regard to the CAP process, we proposed the minimum set of requirements with the intent to define full CAP parameters 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.

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.

- At paragraph (a), we proposed that, depending on a State Exchange's error rate for a given benefit year, we would require the State Exchange to develop and submit a CAP to HHS to correct errors resulting in improper payments.

- At paragraph (b), we proposed 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.

- At paragraph (c), we proposed 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.

- At paragraph (d), we proposed 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.

After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on the corrective action plan (§ 155.1535) below.

Comment: A few commenters supported the proposal to implement CAP under § 155.1535. One commenter supported deferring the CAP parameters to future rulemaking to observe trends that emerge from the SEIPM implementation. One commenter requested that all State Exchange CAPs be made public. Another commenter stated that State Exchanges are already subject to CAPs to remedy eligibility and enrollment errors.

Response: We appreciate the comments offering support to defer the CAP parameters to future rulemaking. Based on the public comments received, we are not finalizing this provision at this time.

i. Failure to comply (§ 155.1540)

We proposed to add a new § 155.1540 that would address failures to comply with SEIPM requirements. At paragraph (a), we proposed that if a State Exchange fails to substantially comply with the SEIPM collection requirements or CAP provisions and HHS determines such failures undermine or prohibit HHS' efficient administration of improper payment measurement activities of the State Exchange, HHS would have the discretion to address failures of compliance with audit data submission and CAP requirements contained in subpart P under paragraph (a)(1), and consistent with authorities HHS possesses under title I of the ACA or any other Federal law as proposed under paragraph (a)(2).

HHS considered exercising its authority under § 1313(a)(5) of the ACA 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 State Exchange personnel capable of displaying requested data directly to HHS personnel or contractors.²⁶⁶ 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 sought comment on these measures and invited 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 APTC.

²⁶⁶ 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).

Please see the proposed rule preamble (87 FR 658 through 659) for a complete description of the proposed policy. After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on failure to comply (§ 155.1540) below.

Comment: One commenter expressed support for the failure to comply with provisions that allow HHS to require a State Exchange to revise their corrective action plan and implementation plan where there is a compliance failure to curtail flawed eligibility processes and ensure CAP compliance in a timely fashion.

Response: We clarify that the purpose of this proposed provision was to incentivize compliance with the planned data collection and CAP requirements. As we continue to develop the SEIPM program, we do not anticipate broad or willful noncompliance with planned requirements.

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 health insurance issuers offering a QHP through an FFE or SBE-FP 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 an 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

Based on estimated costs, enrollment, and premiums for the 2023 benefit year, in the HHS Notice of Benefit and Payment Parameters proposed rule (87 FR 584, 660), we proposed a 2023 benefit year user fee rate for all issuers offering a plan through an FFE of 2.75 percent of monthly premiums charged by the issuer for each policy under the plan where enrollment is through an FFE. This is the same user fee rate that we established for the 2022 benefit year (86 FR 53412). We stated that we believe the proposed 2023 user fee rate would not result in a substantial increase to consumer premiums from prior years, and would also ensure adequate funding for Federal Exchange operations. We refer readers to the proposed rule (87 FR 660) for further discussion of this proposal and a description of the cost, premium, and enrollment projections that went into calculating the proposed 2023 FFE user fee rates.

As we explained in the proposed rule (87 FR 660), activities performed by the Federal government that do not provide issuers offering a plan 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 offering a plan 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).

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

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 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, in the proposed rule (87 FR 661), we proposed 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 sought comment on these proposed user fee rates. We refer readers to the proposed rule (87 FR 660 through 661) for a complete description of the proposal and calculation methodology.

After reviewing the public comments, for the reasons discussed in this rule and the proposed rule, we are finalizing for the 2023 benefit year, as proposed, a user fee rate for all issuers offering QHPs through an FFE of 2.75 percent of the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE, and a user fee rate for all issuers offering QHPs through an SBE-FP of 2.25 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE-FP.

We summarize and respond to public comments received on FFE and SBE-FP user fee rates for the 2023 benefit year (§ 156.50).

Comment: Several commenters supported the proposed user fee rates and appreciated the rates being held constant with 2022. One supporting commenter stated that avoiding an increase in user fees may help to incentivize additional issuers to participate in the Exchanges, providing consumers with additional choice. Another commenter noted that maintaining the user fee level has the benefit of steady administrative costs to issuers, which translates to stable premiums for consumers.

Other commenters disagreed with the proposed user fee rates, asking HHS to either increase or decrease the user fee rates. One commenter encouraged HHS to lower user fee rates based on decreasing technology costs. Another suggested decreasing the user fee rates noting that higher rates raise premiums and are unnecessary due to user fee collections that could have carried over from prior years. Other commenters requested that HHS increase the user fee rates in order to improve Exchange functions, and requested that HHS increase funding for

Navigators, HealthCare.gov, appeals, investments in technology, investments in language services, investments in disability accessibility, and access to back-end data with approval from clients.

Response: We appreciate the support for the proposed user fee rates of 2.75 percent of monthly premiums charged by FFE issuers and 2.25 percent of monthly premiums charged by SBE-FP issuers and are finalizing the user fee rates as proposed. We will continue to examine cost estimates for the special benefits provided to issuers offering QHPs on the FFEs and SBE-FPs for future benefit years, and will continue to establish the user fee rates that are reasonable and necessary to fully fund user fee eligible Exchange operation costs.

As we discussed in the proposal to maintain the user fee rates for the 2023 benefit year (87 FR 660), we developed the user fee rates based upon estimated costs, enrollment, and premiums. We specifically noted that the user fee rates incorporate our estimates of premium and enrollment changes for the 2023 benefit year, and are not solely a reflection of the total expenses estimated to operate and maintain the Federal platform and FFE operations. Finally, we noted that technology upgrades and maintenance efforts will continue to be evaluated annually and funded at levels appropriate to ensure a smooth enrollee experience. We do not believe that a decrease in user fee rates is appropriate as HHS remains committed to providing a seamless enrollment experience for Federal platform consumers and applying resources to cost-effective, high-impact enrollment activities that offer the highest return on investment. While we did not anticipate any new services or contracts to require the expenditure of additional FFE user fees for the 2023 benefit year, we believe that we have estimated adequate funding for these services in the 2023 benefit year user fees.

As for commenters requesting increased funding for language services and disability accessibility, we note that under § 155.205(c)(2)(i)(A), HHS currently provides telephonic interpreter services in at least 150 languages at no cost to applicants and enrollees. Translation services are provided telephonically and for written communications at no cost to the consumer.

HHS additionally notes that under § 155.205(c)(1), information must be provided to applicants and enrollees in plain language and in a manner that is accessible and timely to individuals living with disabilities including accessible web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act. We have included the costs of these services in the estimates used in setting the 2023 benefit year user fees.

For the request that we increase funding for Navigators, HealthCare.gov, and access to back-end data, we anticipate spending on the management of a Navigator program and consumer assistance tools will be similar to what was estimated for the 2022 benefit year, as we believe that was an adequate level of funding for these activities, and thus we do not believe it is necessary to increase user fees for these purposes. As discussed in the proposed rule (87 FR 660), for the 2023 benefit year, we anticipate that spending on consumer outreach and education, eligibility determinations, and enrollment process activities will increase above the 2022 benefit year level.

Comment: Some commenters believed that changes should be made to how user fees are charged. Specifically, several commenters requested that HHS explore a PMPM user fee structure.

Response: HHS did not propose any changes to the user fee structure, as such the user fee rates will continue to be set as a percent of the premium. However, HHS will continue to engage with stakeholders regarding how the FFE and SBE-FP user fee policies can best support consumer access to affordable, quality health insurance coverage through the Exchanges that use the Federal platform.

Comment: Some commenters requested additional transparency into user fees; specifically, one commenter requested a report reflecting how much of the user fee is used for the Navigator program. Other commenters requested additional information about how funds generated by the user fees are allocated across Exchange functions, as well as greater

transparency regarding the cost of the Federal platform, call center, other programs associated with running the Exchanges, individual State usage of Federal resources, allocated costs, and how State user fees compare with each State's applicable costs. To further transparency of the development of the SBE-FP user fee rates, one commenter urged HHS to provide the enumeration and specific calculation of costs associated with FFE infrastructure and services provided to each State.

Response: HHS provided additional information in the proposed rule (87 FR 660 through 661) to show how we expect costs to grow under certain categories. We are limited by two main constraints when it comes to projecting costs. First, we are projecting contracts and costs into the future. Second, we are projecting revenues against these costs, which are based on estimated enrollments and premiums. Additionally, HHS is not permitted to publicly provide information that is confidential due to trade secrets associated with contracting. As such, we believe that providing a range of premium and enrollment projections in setting the 2023 benefit year FFE and SBE-FP user fee rates is sufficient to project revenues for user fee rate setting purposes. 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 2023 FFE and SBE-FP user fee rates. The assumption that the enhanced PTC 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. We expected 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 waivers. We projected that 2023 benefit year premiums will generally increase at the rate of medical inflation after expiration of the enhanced PTC subsidies in section

9661 of the ARP. After considering the range of costs, premium and enrollment projections, we proposed a 2023 user fee rate that will not result in a substantial increase in consumer premiums from prior years, and that also ensures adequate funding for Federal Exchange operations.

As for transparency in the Navigator program, the Navigator program makes the most recent awards public.²⁶⁷ We anticipate spending on consumer assistance tools, management of a Navigator program, regulation of agents and brokers, and certification of QHPs will be similar to what was estimated for the 2022 benefit year, as we believe that was an adequate level of funding for these activities.

FFE and SBE-FP user fee costs are not allocated to or provided to each State. User fees cover activities performed by the Federal government that provide issuers offering a plan in an FFE or SBE-FP with a special benefit. As stated, these services are generally IT, eligibility, enrollment, and QHP certification services that are more efficiently conducted in a consolidated manner across the Federal platform, rather than by State, so that the services, service delivery, and infrastructure can be the same for all issuers in the FFEs and SBE-FPs. For example, all FFE and SBE-FP issuers send their 834 enrollment transactions to the Federal platform database, which are processed consistently regardless of State. Contracts are acquired to provide services for the Federal platform. The services do not differ by State, and therefore, we do not calculate costs on a State-by-State basis.

As we explained in the proposed rule (87 FR 660 through 661), to calculate the SBE-FP rates for the 2023 benefit year, we used the same assumptions on contract costs, enrollment, and premiums as we use to develop 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 benefits provided to issuers in SBE-FPs by the Federal government include the use of the Federal Exchange information technology and call center infrastructure in connection with eligibility

²⁶⁷ *CMS Navigator Cooperative Agreement Awardees*. (2021). CMS. <https://www.cms.gov/files/document/2021-navigator-grant-recipients.pdf>.

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.

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.

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 (86 FR 53412, 53424 through 53429, 53445),²⁶⁸ in the HHS Notice of Payment and Benefit Parameters for 2023 proposed rule (87 FR 584, 661), we proposed a technical correction to remove from § 156.50 all references to the Exchange DE option and cross-references to § 155.221(j). In part 3 of the 2022 Payment Notice (86 FR 53429), 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. As such, in the proposed rule (87 FR 661), we proposed 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 proposed 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

²⁶⁸ 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 53427.

(d)(7) to remove the references to the Exchange DE option. We sought comment on these proposed technical amendments.

We received one comment offering general support for these technical amendments. After consideration of this comment, for the reasons set forth in this rule and in the proposed rule, we are finalizing, as proposed, the amendments to § 156.50(c) and (d) to remove all references to the Exchange DE option and § 155.221(j); specifically, we are removing § 156.50(c)(3), and amending §§ 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.

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.

Accordingly, in the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 661), we proposed that the first Wednesday in May that is 2 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 proposed corresponding edits to § 156.111(d) and (e) to reflect the proposed deadline. We stated in the proposed rule that 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. We refer readers to the proposed rule (87 FR 661) for further background and information regarding this proposal. We invited comments on this approach, including whether there are any unforeseen consequences to establishing this perpetual deadline.

After reviewing the public comments, for the reasons set forth in this rule and in the proposed rule, we are finalizing the proposal with minor edits to the language for clarity. Specifically, in the proposed rule, we proposed 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, and we gave the example that the deadline for PY 2025 would be May 3, 2023, and the deadline for PY 2026 would be May 4, 2024. To more clearly reflect the examples provided in the proposed rule, we are finalizing minor edits to the proposed regulation text to establish the permanent deadline for States to submit the required documents for the State's EHB-benchmark plan selection as the first Wednesday in May "of the year" that is 2 years before the effective date of the new EHB-benchmark plan. Moving forward, we will not be proposing deadlines for the process in annual Notices of Benefit and Payment Parameters. We summarize and respond to public comments received on States' EHB-benchmark plan options below.

Comment: All commenters expressed support for the proposed deadline. Some noted that the set deadline would make the process more predictable for both States and stakeholders involved with EHB-benchmark development. Others noted that the proposed timeline should give States and HHS sufficient time to solicit comments and opinions on proposed benchmarks while also enabling issuers to determine how they will provide EHB consistent with the new EHB-benchmark plan.

Response: We agree with commenters that the permanent deadline will provide more predictability to the EHB-benchmark plan selection process for all parties involved. Since we finalized the 2019 Payment Notice, we have set an early-May deadline for the submission of

EHB-benchmark plans by States for each year from PY 2021-2024.²⁶⁹ We believe that requiring these submissions in the first week of May of the year 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 plan submissions. It also provides us 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-benchmark plan changes.

Comment: We also received several comments that were outside the scope of the proposal. One commenter noted that most States currently have no established process for updating their EHB-benchmark plans and could add benefits to address unmet health care needs in their States without exceeding generosity limits. They urged HHS to identify best practices in EHB-benchmark plan selection and provide additional guidance and training for States to update their EHB-benchmark plans. Several commenters urged HHS to strengthen the transparency of the public comment process for EHB-benchmark plan selection to ensure that stakeholders and other interested parties have ample opportunity to provide meaningful input. A commenter suggested that HHS should require States to adopt standards for public commenting that mirror those specified by HHS for States requesting demonstration projects through section 1115 of the Act. One commenter expressed support for the flexibility provided to States under the EHB-benchmark plan selection policy. Another commenter cautioned HHS to remain vigilant that any changes in a State's EHB-benchmark plan do not result in a decreased availability of EHB. The commenter requested that HHS collect and report data on States that utilize flexibility under the policy to allow consumers, advocates, and other stakeholders to better identify and understand any trends with regard to EHB-benchmark plans.

²⁶⁹ For PY 2021, the deadline was May 6, 2019 (see 84 FR 17534); for PY 2022, it was May 8, 2020 (84 FR 17534); for PY 2023, it was May 7, 2021 (85 FR 29226); for PY 2024 it is May 6, 2022 (86 FR 24232).

Response: Although these comments are outside the scope of HHS' proposal regarding the deadline for EHB-benchmark plan submissions, we note that HHS is committed to ensuring access to EHB while providing States with flexibility under the EHB-benchmark plan selection policy. We will consider these comments and requests for future guidance or proposals. However, as they are out-of-scope with regard to this specific proposal, we decline to comment further on them at this time.

b. Annual Reporting of State-Required Benefits

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 662), we proposed 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 proposed 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.” As we explained in the proposed rule, 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 commenters on the annual reporting requirement in the 2021 and 2022 Payment Notices. Although some commenters agreed 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. We refer readers to the proposed rule (87 FR 661 through 662) for further information and background regarding this proposal. We solicited comment on this proposal, including on whether we should retain the reporting requirement or make it voluntary.

After considering the public comments, for the reasons set forth in this rule and in the proposed rule, we are finalizing, as proposed, repeal of the annual reporting requirement at §

156.111(d) and (f), including revising the section heading to § 156.111 to instead read, “State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.” Thus, States will no longer be required 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” or any benefits the State has identified as not in addition to EHB and not subject to defrayal. We note that we will 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 and will 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 also note that, although this policy will relieve States of the annual reporting requirements, it will not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170.

We summarize and respond to public comments on the proposal to eliminate the annual reporting of State-required benefits.

Comment: The majority of commenters supported the repeal of the annual reporting policy at § 156.111(d) and (f), reiterating many of the same objections and concerns raised by commenters on the initial proposal for this policy in the 2021 Payment Notice and echoed by States and stakeholders since the finalization of the policy. Many commenters stated that the annual reporting policy is unnecessary and overly burdensome as the requirements already in regulation at § 155.170 are sufficient at instructing States and issuers on how to comply with the defrayal requirement. Many commenters supporting repeal of the policy also noted the policy was an unjustified new administrative burden and duplicative of State efforts, as many States already engage in in-depth processes with their State legislatures to evaluate State defrayal obligations, make actuarially sound analyses regarding State benefit requirements, and subsequently make defrayal payments if necessary in compliance with § 155.170. These

commenters stated that the reporting requirement would unnecessarily burden both State and Federal officials, requiring State officials to either procure consultants or divert existing staff from other work to comply with an entirely new reporting process.

One commenter expressed that States are the primary regulators of the individual and small group markets, and therefore, maintain the authority to mandate benefits in those markets and monitor issuer compliance, which is at odds with the duplicative oversight required through the annual reporting requirement.

Many commenters stated that HHS already has the requisite authority to investigate States that the agency believes are not in compliance with the defrayal requirement. Such commenters emphasized that there is therefore no demonstrated need to require States to report all State mandates on an annual basis to show compliance and that this is particularly true for States that do not have any State-required benefits that are in addition to EHB. Other commenters supporting repeal of the policy stated HHS had not demonstrated evidence of widespread State noncompliance with defrayal requirements to warrant the policy and expressed concern regarding ambiguity around how HHS would enforce the annual reporting policy.

Some commenters expressed support for repealing the annual reporting policy because they believe it was designed to discourage States from expanding upon EHB in their State to improve benefit coverage, which one commenter explained is concerning as enhanced EHB benefits are particularly beneficial for people with chronic conditions and disabilities, who are disproportionately women, LGBTQI+ people, and people of color. As an example, one commenter explained that Colorado's enhanced EHB-benchmark plan effective beginning in plan year 2023 includes coverage of an annual mental wellness exam, services related to substance use disorder, and comprehensive gender-affirming care.

Commenters objecting to the repeal of the annual reporting policy expressed that the policy was justified to protect Federal expenditures as only a small number of States have actually identified State-required benefits that are in addition to EHB and have transparent

processes in place to identify and defray costs as required by section 1311(d)(3)(B) of the ACA. Commenters objecting to repeal further explained that the policy would have supported transparency and increased understanding of the costs of State-required benefits and promoted uniformity in the application of the ACA. Commenters also stated that the policy would have promoted accountability and helped to ensure that benefit packages remain affordable. Some commenters noted that requiring States to report in this manner would have made issuer compliance with defrayal requirements easier to manage and others explained it would have promoted a more consistent understanding of new benefit mandates that a State enacts to better inform policymaking. One commenter noted that absent State reporting, it is unclear how the defrayal requirement may be enforced.

Commenters objecting to the repeal of the annual reporting policy also challenged claims that the policy was overly burdensome. Such commenters noted that States should already have determined the status and cost of State-required benefits and that, therefore, the reporting requirement should not place a burden on States of conducting new analyses. Commenters further noted that the minimal administrative burden on States would decrease further after the initial reporting cycle.

Response: We continue to believe that repealing the annual reporting policy at § 156.111(d) and (f) is warranted and would not weaken State compliance with the defrayal requirement. Therefore, we are finalizing the repeal of the policy, as proposed, including revising the section heading to § 156.111 to instead read, “State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.”

We understand the frustration expressed by States that already may appropriately identify which State-required benefits are in addition to EHB and provide defrayal, for which reporting this information to HHS on an annual basis would have added burden without increasing compliance. However, we acknowledge the concerns of many commenters that emphasized the importance of the annual reporting policy to address inconsistent State compliance and

application of the defrayal requirements at § 155.170. Although we continue to share concerns that some States may not be properly identifying all State-required benefits that are in addition to EHB, we also believe alternative approaches to the annual reporting policy—such as expanded technical assistance and issuing clarifying guidance—can achieve improved State adherence with § 155.170 without imposing a requirement on States to submit detailed annual reports on State-required benefits.

We acknowledge that the information States would have submitted through annual reporting would have supported increased oversight over whether States are appropriately identifying which State benefit requirements are in addition to EHB and promoted increased transparency for stakeholders. We further acknowledge that receipt of such reports by HHS would have been helpful for identifying noncompliant States, although this would not have been accomplished without also requiring already compliant States to submit reports. However, after carefully considering the comments, we believe that a more targeted approach where HHS provides written guidance on how to assess State-required benefits, paired with continued individualized technical assistance and outreach to States better balances the goal of increased State compliance with the competing priority of preserving State resources and reaffirming State authority as the entity responsible for identifying which State-required benefits are in addition to EHB.

We reiterate that the obligation for a State to defray the cost of QHP coverage of State-required benefits in addition to EHB is a statutory requirement independent from the annual reporting policy we are now repealing at § 156.111(d) and (f). Therefore, even with the repeal of the annual reporting policy, States remain responsible for identifying which State-required benefits are in addition to EHB and require defrayal, making payments to defray the cost of additional required benefits to either the issuer or the enrollee, and note that issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the State. With regard to future HHS enforcement of the defrayal policy in instances where we have State

compliance concerns, we intend to work closely with any such State to monitor compliance and address any areas of confusion through continued outreach and technical assistance.

Even though defrayal is a statutory requirement, we understand the critique that it can function as a restriction on States in mandating coverage of benefits in addition to EHB by requiring States to absorb new State expenditures. We are very supportive of States making improvements to the scope of EHB in their markets within the limits imposed by the generosity and typicality standards at § 156.111(b)(2) and encourage State utilization of any of the three methods available to States for selecting a new EHB-benchmark plan at § 156.111, a process Colorado used to select a new EHB-benchmark plan that will be effective for the 2023 plan year and many other States utilized in years past. We note as a reminder that the act of selecting a new EHB-benchmark plan does not alone create new State mandates, but it also does not relieve the State of its obligation to continue defraying the cost of QHPs covering any State-mandated benefits that are in addition to EHB. The annual reporting policy would not have changed that standard, nor does repeal of the annual reporting policy.

Although we are finalizing the repeal of the annual reporting policy, we maintain that it would have imposed a minimal burden on States as the information that States would have been required to report to HHS should already be readily accessible to States, as every State should already be identifying which State-required benefits are in addition to EHB and should be defraying any such costs. However, even if the State burden from the annual reporting policy would have been minimal, we still believe it is appropriate to repeal the annual reporting policy and instead take a more targeted approach of engaging with individual States on questions of compliance with the defrayal requirement. We believe this modified approach will yield similar results to the annual reporting policy without requiring all States, including compliant States, to expend additional time and resources submitting a report with this detailed information.

Comment: The majority of all commenters—both those supporting and those objecting to repeal of the annual reporting policy—encouraged HHS to issue additional technical assistance

and guidance clarifying the defrayal policy. Commenters supporting repeal expressed gratitude for the existing technical assistance HHS provides. Such commenters further agreed it would be helpful for HHS to issue additional written guidance paired with additional outreach regarding how HHS analyzes and expects States to analyze whether a State mandate is in addition to EHB, especially given how often questions regarding defrayal arise in States.

Commenters objecting to the repeal of the annual reporting policy stated that if the policy is ultimately rescinded, HHS should still take the alternative, but a less effective step, of publishing technical guidance. Such commenters urged HHS to include guidance on the standards, including required actuarial analyses, to determine if a benefit exceeds EHB and, if so, the cost of the mandated benefit, to ensure States and issuers have a consistent understanding of whether a State-mandated benefit will actually increase health care costs. Other commenters acknowledged that there are other ways to achieve the oversight goals of the annual reporting policy if the reporting requirement is removed, such as providing additional written guidance or performing targeted audits of States. Other commenters stated that, although technical assistance and outreach are important, the periodic reporting that would have been required under the annual reporting policy would have had a valuable sentinel effect that cannot be duplicated through simple outreach and assistance.

Response: We agree that engaging in technical assistance with States to help ensure State understanding of when a State-benefit requirement is in addition to EHB and requires defrayal will bolster State compliance with defrayal requirements in the absence of the annual reporting policy. We also reaffirm our intent to provide additional written guidance 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 that a more targeted approach where HHS provides written guidance on how to assess State-required benefits, paired with continued individualized technical assistance and

outreach to States will still effectively promote State compliance with the defrayal requirement. It will enable us to instead concentrate HHS efforts on providing better, more tailored technical assistance to States rather than reviewing detailed reports for compliance across all States, even those that are already compliant. Although we acknowledge that the annual reporting policy may have ultimately had a sentinel effect on State adherence to the defrayal policy, we also believe continued ad hoc monitoring of States will yield similar compliance results without requiring all States to report each year. We believe our future technical assistance and guidance will ultimately facilitate an environment where States are more confident that their analysis of State-required benefits aligns with § 155.170 and will be instructive for States that need to subsequently make any necessary adjustments to State policy to comply with the defrayal policy.

Comment: Many commenters that supported issuing additional technical assistance provided policy recommendations with regard to the content of such guidance that are not within the scope of HHS' proposal regarding annual reporting of State-required benefits, such as requesting that HHS interpret the defrayal policy to be more lenient for States (for example, interpreting more State mandates to fall within the "benefit delivery method" exception that would not require defrayal or otherwise allowing States to change their benefit requirements to keep up with medical advancements without being required to defray). Other commenters urged HHS to include additional guidance on the defrayal requirements for habilitative services. One commenter urged HHS to require that State calculations for defrayal also be performed by a member of the American Academy of Actuaries.

Response: Although such comments are out-of-scope, we will consider such recommendations as we continue to develop guidance and conduct outreach. We encourage States to reach out to CMS with specific defrayal questions in the interim.

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.

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 662 through 663), we proposed to withdraw this flexibility by amending § 156.115 to no longer allow States to permit issuers to substitute benefits between EHB categories.

In addition, in the event we did not finalize the proposal to eliminate the State option for between-category substitution, we proposed to establish a static, permanent annual deadline for States to notify HHS that they wish to permit issuers to substitute benefits between EHB categories.

We sought comment on these proposals. We refer readers to the proposed rule for further discussion of these proposals and our rationale (87 FR 662 through 663).

After reviewing the public comments, for the reasons set forth in this rule and in the proposed rule, we are finalizing, as proposed, an amendment to § 156.115 to no longer allow States to permit issuers to substitute benefits between EHB categories. We are therefore not establishing a static, permanent annual deadline for States to notify HHS that they wish to permit issuers to substitute benefits between EHB categories.

We summarize and respond to public comments regarding the proposal to eliminate substitution of benefits between EHB categories.

Comment: The majority of the commenters supported the proposal to amend § 156.115 to no longer allow States to permit issuers to substitute benefits between EHB categories. Many of the commenters opposed the between-category substitution when it was proposed in the 2019 Payment Notice. Some of these commenters noted that Congress expressly included each EHB category in the ACA to ensure a comprehensive and appropriate range of benefits to meet patients' needs across their lifespan. They added that Congress selected those benefits because they were not often covered by private insurance prior to the ACA and recognized that they were not interchangeable. A few commenters expressed concerns that substitution of benefits between

EHB categories would result in issuers creating narrowed plans that would not ensure access to and would increase out-of-pocket costs for the items and services consumers need to manage their health conditions, particularly for consumers with chronic conditions and disabilities. They added that between-category substitution could lead to adverse selection and discrimination by allowing issuers to cut benefits needed by people with significant health needs and substituting them with benefits meant to attract healthier enrollees.

One commenter noted that the argument that benefit substitution will allow consumers to find a plan that is better tailored to their needs is based on the false assumption that consumers can accurately predict their health needs. The commenter noted that this rationale undercuts the purpose of health insurance: to ensure access to affordable and comprehensive coverage even when one enters a period of unanticipated, increased health care need.

Commenters noted that if a State were to permit issuers to substitute benefits between EHB categories, it would make it difficult for regulators to ensure that issuers are actually covering the EHBs they are required to provide and confusing for consumers who expect to have coverage for all EHBs in ACA plans. Many commenters noted that any potential benefit of flexibility to States in selecting EHB-benchmark plans does not justify the policy given the potential harm to consumers.

Response: We agree with commenters that the negative effects on consumers of allowing States to permit issuers to substitute benefits between EHB categories outweigh any flexibility it could have afforded to States and issuers. For example, we agree with commenters that allowing States to permit issuers to substitute benefits between EHB categories could negatively affect access to and increase out-of-pocket costs for the items and services consumers need to manage their health conditions, and could lead to adverse selection and discrimination by allowing issuers to substitute benefits needed by people with significant health needs with benefits meant to attract healthier enrollees. In addition, we agree that allowing such substitution would make it

difficult for regulators to ensure that issuers are actually covering the EHBs they are required to provide and could be confusing for consumers.

As we stated in the proposed rule (87 FR 662), to date, no State has ever notified HHS that it would permit issuers to substitute benefits between EHB categories. 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, as we explained in the proposed rule (87 FR 662), HHS is of the view that it may only create potential harm for consumers with chronic conditions and disabilities and that whatever theoretical flexibility this policy could have afforded to States is not justified given the potential negative effects on consumers.

Comment: One commenter opposed eliminating the option for States to permit issuers to substitute benefits across categories and stated that theoretical harm from allowing substitution of benefits between EHB categories and the fact that this option has not been used are not sufficient justifications for withdrawing the policy. The commenter noted that States' use of other flexibilities to make changes to their EHB-benchmark plans is an indication of their continued interest in exploring flexibilities and that States may have been too overwhelmed with the COVID-19 PHE to avail themselves of this particular flexibility. They requested that HHS leave the flexibility in place.

Response: We do not agree with the commenters that opposed eliminating the option for States to permit issuers to substitute benefits across categories. HHS is of the view that whatever untapped theoretical flexibility this policy could have afforded to States is not justified given the potential negative effects on consumers, including increased out-of-pocket costs for consumers with chronic conditions and disabilities and adverse selection and discrimination of consumers with significant health needs. We note that States continue to be able to use existing flexibilities to make changes to their EHB-benchmark plans.

Comment: Several of the supportive commenters included additional points that were outside the scope of the proposal. Many commenters urged HHS to prohibit substitution within EHB categories. They noted that the potential harm to consumers with chronic conditions and disabilities that may arise from substitution between EHB categories may also arise from substitution within EHB categories. Commenters noted that benefit components are not interchangeable within EHB categories that list multiple components, such as the “mental health and substance use disorder services including behavioral health treatment,” the “preventive and wellness services and chronic disease management,” and the “rehabilitative and habilitative services and devices” categories.

One commenter expressed concerns that the flexibility to adopt benchmark plans from other States and replace EHB categories with categories of benefits from another State’s less generous benchmark plan could lead to a “race to the bottom” and erode EHB benefits. The commenter noted the effect could be even more damaging if a State chose the least generous coverage categories from various EHB-benchmark plans around the country to aggregate as their new EHB-benchmark plan. One commenter requested that CMS collect and publish data on State EHB-benchmark plan substitution so that interested parties can better assess the coverage of specific services.

Response: Although these comments are outside the scope of the proposal, we will consider these comments and suggestions and also note that benefit designs that are discriminatory or intended to discourage enrollment by certain populations or individuals with significant health needs are prohibited under 45 CFR 156.125(b). In addition, we note that States may collect data on EHB benefit substitution. However, as the comments are outside the scope of this specific proposal, we decline to comment further on them at this time.

5. Prohibition on discrimination (§ 156.125)

Section 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. In the proposed rule (87 FR 584, 671), we proposed to amend § 156.200(e) to explicitly prohibit different forms of discrimination based on sex—specifically, discrimination based on sexual orientation and gender identity. As explained in the Supplementary Information section earlier in this preamble, HHS will address this policy, as well as the public comments submitted in response to this proposal, in a future rulemaking.

6. Refine EHB nondiscrimination policy for health plan designs (§ 156.125)

We proposed to refine HHS' EHB nondiscrimination policy under § 156.125 and proposed a regulatory framework for entities that are required to comply with the EHB nondiscrimination policy.

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.²⁷⁰ Section 156.125(b) requires that issuers must also comply with § 156.200(e), which provides that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex.²⁷¹ Section 156.110(d) states that an EHB-benchmark plan may not include a discriminatory benefit design that contravenes § 156.125. In the 2016 Payment Notice (80 FR 10750, 10822), we provided examples of potentially discriminatory practices,²⁷² and in the 2017 Payment Notice (81 FR 12244), we noted that we would consider providing further guidance regarding discriminatory benefit designs in the future.

²⁷⁰ 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.

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

²⁷² 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. 80 FR 10750, 10822.

In the proposed rule, we first proposed to revise § 156.125(a) to provide that a nondiscriminatory 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.

Second, we proposed examples of health plan designs and practices that HHS would deem to be presumptively discriminatory. HHS identified these examples as presumptively discriminatory practices based on whether the issuer's benefit design or coverage decisions were adequately supported by appropriate clinical evidence relevant to each circumstance. Through these examples, HHS sought to further clarify its EHB nondiscrimination policy to better ensure that unlawful discrimination does not impede consumers' ability to access benefits for medically necessary treatment.

Third, we proposed to further refine our EHB nondiscrimination policy by describing and identifying examples of guidelines and resources (such as medical journals) that HHS would deem appropriate to counter a claim that an issuer's benefit design or its implementation of the design is discriminatory. We proposed that unscientific²⁷³ 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. We stated that we did not intend to limit 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 proposed that HHS 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. Notwithstanding, we also proposed that articles that are not peer-reviewed or that are written

²⁷³ Merriam-Webster.com Dictionary, s.v. "unscientific," Retrieved November 5, 2021, from <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").

primarily for a lay audience would be insufficient to dispute a claim that an issuer's benefit design is discriminatory. We proposed that we would not consider sufficient a peer-reviewed journal article that has not been accepted for publication in a reputable medical publication.

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

We stated in the proposed rule that presumptively discriminatory practice examples may point to a State's EHB-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. We stated that a benefit design that is discriminatory and inconsistent with § 156.125 must be cured regardless of how it originated. For example, if a State EHB-benchmark plan has a discriminatory benefit design, we explained that a 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 discriminatory design. Similarly, if a State-mandated benefit has a discriminatory benefit design, the State may attempt to remedy this by revising the mandate or issuing guidance. Regardless, we stated that 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 sought comment on whether there are any unforeseen barriers in the ability to remedy inconsistencies with this refined EHB nondiscrimination policy.

We also stated in the proposed rule that, in ensuring that benefit designs are not discriminatory, issuers should also consider the method in which EHBs 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 noted that some issuers have designed health plans that deliver services virtually with no copay, compared to in-person health care services with a copay. We stated that this type of health plan design could inadvertently incentivize enrollees to access

EHB using a certain delivery method. We further stated that although this approach may not amount to a discriminatory practice under § 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 noted that we intend to monitor the issue and remind issuers that while we encouraged expanded use of EHB virtually, it should be done in a nondiscriminatory manner.

In relation to the proposed refinements of the nondiscrimination standard under § 156.125, we proposed that the policy would become effective 60 days after the publication of the final rule in the **Federal Register**. We sought comments regarding whether the proposed effective date would be sufficient to allow issuers to come into compliance with our proposed refinements to our EHB nondiscrimination policy.

In addition, we recognized 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 generally, but a parallel provision applies to EHB furnished by Medicaid Alternative Benefit Plans.²⁷⁴ We sought comment on the examples of presumptively discriminatory benefit designs.

After reviewing the public comments, we are finalizing the proposed revisions to § 156.125(a) to provide that a nondiscriminatory health plan design that provides EHB is one that is clinically based, but we do not finalize the proposed regulation text that would have provided that a nondiscriminatory health plan design that provides EHB is one that incorporates evidence-based guidelines into coverage and programmatic decisions, and relies on a current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources. We also do not finalize our proposal to further refine our

²⁷⁴ See 42 CFR 440.347(e).

EHB nondiscrimination policy by describing and identifying examples of guidelines and resources (such as medical journals) that HHS would deem appropriate to counter a claim that an issuer's benefit design or its implementation of the design is discriminatory. Rather, under § 156.125(a), we finalize only that 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; and that a non-discriminatory benefit design that provides EHB is one that is clinically based. As we explain in further detail in the comment responses later in this section, we credit commenter concerns that information relevant to whether a benefit design is unlawfully discriminatory could appear in reputable publications or come from sources that are not peer-reviewed medical journals or those that are otherwise dissimilar to the sources and information HHS discussed in the proposed rule's preamble discussion on § 156.125(a). Although we do not finalize the proposal to specifically define the evidence and sources that would be sufficient to counter a claim that a plan's benefit design is discriminatory, this should not be construed to mean that HHS will deem unscientific²⁷⁵ evidence, disreputable sources, or other bases or justifications that lack the support of relevant, clinically-based evidence as sufficient to dispute a claim that an issuer's benefit design is discriminatory.

We are also providing final versions of the examples of presumptively discriminatory benefit designs outlined in the proposed rule, except that we do not address the example related to gender-affirming care. For the reasons explained in the Supplementary Information section earlier in the preamble, HHS will address the gender-affirming care example, including the public comments that addressed this example, in future rulemaking.

For the final examples included in this final rule, we have revised the examples in response to commenter questions and concerns to clarify key points in relation to HHS' refined

²⁷⁵ Merriam-Webster.com Dictionary, s.v. "unscientific," Retrieved November 5, 2021, from <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").

EHB nondiscrimination policy. First, we clarify that the requirement § 156.125 and HHS' refined EHB nondiscrimination policy apply only to services that are covered as EHB under a plan and do not require a plan to cover services that the plan does not already cover as EHB. Second, we clarify that neither § 156.125 nor the examples reflecting HHS' refined EHB nondiscrimination policy require health care professionals to perform services outside of their normal specialty area or scope of practice.

Lastly, we do not finalize the proposed applicability date of HHS' refined EHB nondiscrimination policy. Instead, to allow issuers sufficient time to come into compliance with our refined nondiscrimination policy and to better align with the ability of plans to make uniform modifications of coverage at the time of renewal, we are finalizing that the refined EHB nondiscrimination policy will be applicable starting on the earlier of January 1, 2023 (the start of PY 2023) or upon renewal of any plan subject to the EHB requirements. We have added text to § 156.125(a) to reflect this applicability date.

General comments on the proposal to refine EHB nondiscrimination policy for health plan designs (§ 156.125)

Comment: Many commenters broadly supported the proposals to refine the EHB nondiscrimination policy, implement a clinical evidence framework, and provide discriminatory benefit design examples in an effort to reduce discriminatory benefit designs and safeguard consumers who depend on nondiscrimination protections. Such commenters recognized the need for such safeguards and stated that many aspects of health plan design may be arbitrary, not clinically based, and have discriminatory impacts. These commenters noted that these proposals would reduce the incidents of discriminatory benefit design, which still occur despite the ACA's nondiscrimination protections. One commenter provided feedback that, by implementing consistent requirements under § 156.125, the proposal ensures that enrollees can fairly access covered benefits.

Response: We agree with commenters that despite current EHB nondiscrimination protections, enrollees may be harmed by discriminatory health plan designs. We also agree with commenters that requiring nondiscriminatory benefit designs to be clinically based will help ensure that plan limitations on benefits covered as EHB will not discriminate on the bases prohibited under § 156.125. Specifically, § 156.125(a) prohibits plans from discriminating in their benefit design, or the implementation of its benefit design, 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. Further, § 156.125(c) requires that an issuer providing EHB must comply with the requirements of § 156.200(e). Section 156.200(e) currently prohibits discrimination on the basis of race, color, national origin, disability, age, and sex. Thus, any limitation on coverage of an EHB in a plan (that is subject to EHB standards) based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, other health conditions, race, color, national origin, disability, age, or sex, must be based on clinical evidence. We believe that the clinical evidence standard that we are finalizing at § 156.125 in this rule will reduce incidents of discriminatory benefit design of EHBs by ensuring that any plan design limiting coverage of an EHB on a protected basis in § 156.125 is clinically based, better safeguarding all consumers' access to medically necessary care.

We emphasize that issuers of EHB-compliant plans may continue to utilize reasonable medical management techniques in accordance with § 156.125(c). Further, our refined EHB nondiscrimination policy does not require issuers subject to § 156.125 to cover services under a health plan that are not already covered by the plan as EHB; and it does not create a general requirement that a health plan cover any and all medically necessary services.

Even when not intended, health plan designs that limit coverage of EHBs on the basis of characteristics protected from discrimination in § 156.125 can lead to negative health outcomes when such limitations lack clinical justification. We believe the refinements to our EHB

nondiscrimination policy will improve issuer compliance with the nondiscrimination standards at § 156.125 and help ensure that enrollees can fairly and more easily access benefits covered as EHB, ultimately promoting improved health outcomes.

Comments on the impact on issuers and States

Comment: One commenter expressed concern that the proposal would require States to update their EHB-benchmark plans to remove unjustifiable discriminatory benefit designs, like age limitations and limitations based on health conditions. Some commenters requested that HHS clarify whether issuers modifying existing plan designs to conform with nondiscriminatory benefit design requirements would meet uniform modification exceptions to uniformly modify the benefits in their plans.

Response: As we stated in the proposed rule, a plan's benefit design that is discriminatory and inconsistent with § 156.125 must be cured regardless of how it originated. The nondiscrimination requirements at § 156.125, including the clinical evidence standard we are finalizing, apply to an issuer's benefit design or implementation of a benefit design for all benefits the issuer covers as EHB. Because some current EHB-benchmark plans continue to be based on plan year 2014 plans, some of the EHB-benchmark plan designs may not comply with current Federal requirements such as nondiscrimination requirements at § 156.125. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers may need to further conform plan benefits, including coverage and limitations, to comply with current Federal requirements, such as the nondiscrimination requirement of § 156.125. This requirement is not new. Plans subject to the EHB requirement have always been required to comply with the nondiscrimination requirements in § 156.125 regardless of the presence of any noncompliant discriminatory language in the relevant EHB-benchmark plan.

Under the guaranteed renewability provision at 45 CFR 147.106, a health insurance issuer offering non-grandfathered health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the

plan sponsor or the individual, unless the issuer discontinues all coverage, the product is discontinued, or the issuer's action is otherwise excepted from this requirement. One such exception is for the modification of coverage made uniformly and solely pursuant to applicable Federal or State requirements, as described at § 147.106(e)(2). This allows an issuer to, at the time of renewal, modify its plans uniformly if the modification is made within a reasonable time period after the imposition or modification of a Federal or State requirement and the modification is directly related to the imposition or modification of the Federal or State requirement. An issuer revising its benefit design to conform with these nondiscrimination requirements could constitute a modification under a Federal requirement; thus, issuers may exercise the exception at § 147.106(e)(2) to uniformly modify their plans in accordance with guaranteed renewability requirements. As explained later in this section, we are finalizing that the refined EHB nondiscrimination policy at § 156.125 will be applicable on the earlier of PY 2023 or upon renewal of any plan subject to the EHB requirements and, therefore, this policy should not conflict with uniform modification requirements.

To address State EHB-benchmark plan compliance with the non-discrimination standards, we further stated in the proposed rule that, if a state EHB-benchmark plan has a discriminatory benefit design, the State may issue guidance to issuers in the State explaining that plans providing benefits that are substantially equal to the EHB-benchmark must not replicate that discriminatory benefit design. We clarify that we will not consider State EHB-benchmark plan designs to be out of compliance with § 156.110(d) or § 156.111(b)(2)(v) if the State provides such guidance or otherwise directs issuers to comply with these refined nondiscrimination standards, notwithstanding any aspects of the EHB-benchmark plan that are not consistent with these refined nondiscrimination standards. Under this approach, States are not required at this time to go through the formal process at § 156.111 to update their EHB-benchmark plans solely for the purpose of removing any such discriminatory benefit designs. But States that do elect to update their EHB-benchmark plans at any point going forward will be

expected to ensure their new EHB-benchmark plans are compliant with Federal discrimination law and policy.

Comment: Several commenters asserted that the proposed rule violates the Administrative Procedure Act (APA). Some commenters expressed concern that the lack of a cost-benefit analysis in the proposed rule could be a violation of the APA, noting HHS did not cite how many plans already cover the procedures specified in the examples in a nondiscriminatory manner, how the refined EHB policy will impact utilization, and any premium impact. Other commenters asserted that the proposed changes to § 156.125 are overly broad. Some of these commenters expressed concerns that the proposed rule may impede States' ability to regulate and put forth benefit packages that are affordable and best meet the needs of their residents and recommended that HHS should alternatively continue to work with States and issuers to develop sufficient coverage for enrollees while applying protections against discrimination. Other commenters expressed concern that issuers may see increased utilization of benefits and therefore higher costs. Some commenters recommended that HHS should conduct and publish the results of a detailed cost study demonstrating premium impacts for consumers prior to finalizing the proposal.

Response: We do not agree with commenters that our proposals under § 156.125 violate the APA. Additionally, the revisions we are finalizing in this rule do not impose an unreasonable burden on States, are not overly broad, and do not impede States' ability to regulate or put forth benefit packages that are affordable and meet the needs of consumers. The revisions to § 156.125 clarify existing Federal regulation regarding the prohibition on discriminatory benefit designs for plans subject to the requirement to provide EHB.

Specifically, this final rule affirms the existing requirement that an issuer provides EHB when its benefit design or implementation of its benefit design does not discriminate on bases prohibited under § 156.125. This final rule further clarifies that a plan design that includes limitations on EHB on a basis prohibited under § 156.125 must be clinically based in order to be

considered nondiscriminatory. We reiterate that these nondiscrimination requirements at § 156.125 apply to any benefit design or implementation of a benefit design to the extent that the issuer covers benefits as EHB. This does not substantively alter or broaden the regulatory requirements under this section, as issuers of non-grandfathered individual and small group health insurance are already prohibited from offering plans with discriminatory benefit designs under § 156.125 in the provision of EHB.

We explained in the proposed rule the potential that there would be administrative burden on States and issuers when coming into compliance with the proposal to require clinical evidence to support EHB limitations that may otherwise be considered discriminatory under § 156.125. However, we clarify that States are not required at this time to formally update their EHB-benchmark plans through § 156.111 solely for the purpose of removing any such discriminatory benefit designs. Therefore, any such administrative burden on the part of States would be limited to instances where, at the State's discretion, the State updates its EHB-benchmark plans to remove discriminatory benefit designs or otherwise issues guidance to issuers on how to comply with § 156.125 in spite of any discriminatory limits that may be present in the State's EHB-benchmark plan. The examples in the final rule of presumptively discriminatory plan designs do not substantively change the existing regulatory EHB nondiscrimination requirements, but provide further guidance for plans to design benefit limitations that follow those requirements. Accordingly, we are unable to isolate and identify the burdens of providing those additional examples as a tool to guide issuers' efforts to comply with the existing requirements.

We disagree with commenters that suggest that the proposals we are finalizing in this rule will result in increased utilization and higher costs due to an unintended adverse impact on issuers' ability to administer packages that are safe and clinically effective. We stated in the proposed rule that, based on our experience with States updating benefits²⁷⁶ covered as EHB in

²⁷⁶ See, for example, Colorado 2023 EHB- Benchmark Plan Actuarial Report. CMS. <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb> Suite of Gender-affirming care benefits to treat gender

their EHB-benchmark plans under § 156.111, any actions necessary to come into compliance with the requirement to justify potentially discriminatory benefit limitations with clinical evidence will cause only a minimal increase in premiums. Thus, we do not find credible those assertions that the policy finalized in this rule will have a significant cumulative effect on issuers' ability to administer packages of benefits that are affordable.

We acknowledge that States are generally the primary enforcers of EHB requirements and HHS will continue to provide technical assistance to assist States as applicable. HHS will also consider whether additional guidance is necessary as we monitor issuer compliance with EHB nondiscrimination requirements and States' oversight and enforcement activities.

Comments on the requirement that health plan designs be supported by clinical evidence

Comment: Many commenters were broadly supportive of including a clinical evidence standard at § 156.125, but disagreed with or had recommendations regarding the appropriate scope of such a standard. For example, many commenters noted that the clinical evidence required under § 156.125 should not be limited to evidence provided by doctors of medicine and that HHS should allow evidence provided by other qualified, licensed health professionals, including nurses. Such commenters also urged HHS to include the relevant "standard of care" within the list of appropriate clinical evidence to rely upon as standards of care are the leading guide for treatment. Other commenters urged HHS to clarify that the list of reputable sources is only illustrative and recommended that HHS add more peer-reviewed journals to the sources list in the preamble. One commenter noted the concern of overlapping or potentially inconsistent standards as issuers already use clinical evidence in plan designs.

Other commenters strongly supported the incorporation of evidence-based guidelines and recommendations from appropriate governing bodies into coverage decisions, but recommend that HHS not further define the acceptable types of clinical evidence. Some commenters

dysphoria resulted cost estimate was 0.04 percent of the total allowed claims assuming utilization would be for adults.

recommended that the opinion of recognized, disease-specific experts be included as additional appropriate evidence sources.

Response: In light of the myriad comments we received regarding the appropriate scope of clinical evidence to include at § 156.125, we have reconsidered whether the proposed clinical evidence standard appropriately reflects the breadth and types of clinical evidence that issuers may rely upon to demonstrate that a plan design limitation is not discriminatory under § 156.125. We are therefore finalizing § 156.125 only to require that a nondiscriminatory benefit design that provides EHB be one that is clinically based. We are declining to finalize that a nondiscriminatory benefit design that provides EHB must incorporate evidence-based guidelines into coverage and programmatic decisions, and rely on current and relevant peer-reviewed medical journal articles, practice guidelines, recommendations from reputable governing bodies, or similar sources, or the related examples of acceptable sources included in the preamble of the proposed rule. We believe that requiring plan designs providing EHB to be clinically based, without these additional requirements, is sufficient to protect consumers from discriminatory benefit designs. We will reassess whether refining this standard in future rulemaking is warranted as we continue to monitor issuer compliance with the nondiscrimination standards at § 156.125.

We did not propose a requirement that clinically-based benefit designs be supported by evidence provided by individuals with specific credentials or areas of expertise, and we do not finalize any such requirement in this final rule. The presence or absence of any specific degree by the individual(s) that develops resources for clinical evidence is not by itself sufficient to satisfy or preclude compliance under this rule, nor is inclusion of particular types of expert.

When designing nondiscriminatory plan designs and ensuring that any limitations on EHB on a basis prohibited under § 156.125 are clinically indicated, we encourage issuers to seek current and relevant clinical evidence, rather than utilizing standards that tend to overlap or are potentially inconsistent with the scope of the plan design. However, we also acknowledge that

limitations in medical research may restrict availability of such clinical evidence. Since we are not finalizing our proposal to specify sources of acceptable clinical information an issuer may use to show that a coverage limitation or a benefit design is not discriminatory, we also decline to include any specific “standard of care” within a list of appropriate clinical evidence that issuers may rely upon. HHS is of the view that the requirements of this rule and the guidance provided are sufficient to enable issuers to set coverage limitations that comply with the EHB requirements. We will continue to assess issuer compliance under this rule and will consider if future rulemaking is warranted.

We also clarify that HHS would not consider a plan design subject to § 156.125 to be discriminatory when the plan design limits coverage of an EHB on a basis that is prohibited under the regulation, but the limitation is a direct result of the issuer’s compliance with other applicable Federal coverage requirements. For example, Federal law requires issuers of plans that must meet EHB standards to cover all evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF).^{277,278} However, evidence-based items and services with A or B ratings in effect by USPSTF often contain age limits. We would not consider a plan design subject to § 156.125 to be discriminatory when the plan design limits an EHB on a prohibited basis under § 156.125 but such limitation is due to compliance with an otherwise applicable Federal requirement. As explained in greater detail later in this final rule in relation to the finalized example of discrimination based on age, this policy is not meant to conflict with or supersede the policy at § 156.115(d), which prohibits coverage of, among other things, routine non-pediatric dental services and eye exam services as EHB.

Comment: Many commenters supported the proposal to require clinical evidence for health plan designs. Some commenters who supported the proposal cautioned HHS that clinical

²⁷⁷ 45 CFR 156.115(a)(4).

²⁷⁸ U.S. Preventative Services Task Force (n.d.) *USPSTF A & B Recommendations*.

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations>.

evidence used to defend plan designs may itself be discriminatory due to embedded systemic racism and bias in medical research.

Response: We recognize that embedded systemic racism and bias are pervasive and limit many aspects of medical research. HHS is committed to reducing the effects of such racism and bias on consumers and consumer health outcomes, which is why we are finalizing that a nondiscriminatory plan design that provides EHB is one that is clinically based, without specifying that the plan design must rely on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources. Overall, we are working to advance health equity by designing, implementing, and operationalizing policies and programs that promote and support health coverage that provides fair access to covered health care services for all person who purchase (or would purchase) the plan, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing access to the care and support that enrollees need to thrive.

Finalizing this proposal is another step towards achieving that goal, but we recognize that this policy, by itself, is insufficient to address broader concerns that the existing clinical evidence on which issuers may design nondiscriminatory benefit limitations cannot be cured of the effects of embedded systemic racism, bias, and limits in available medical research. We expect issuers to work cooperatively with States to design nondiscriminatory plans and expect States to evaluate the clinical evidence for plan designs while conducting form reviews and issuing guidance.

Comment: Some commenters expressed concern that clinical evidence may be used by issuers as justification to perpetuate discriminatory plan designs and urged HHS to clarify that lack of clinical evidence does not provide the license to deny access to new innovations or therapies that are difficult to research. They noted that some services and treatments that may be

beneficial may not be conducive to conventional methodologies for developing a clinical evidence-base, such as some treatments for rare diseases.

Response: The policy finalized in this final rule at § 156.125(a) provides mandatory guidelines to issuers to support their design and implementation of benefit packages that conform to EHB nondiscrimination requirements. Under § 156.115, plans subject to the requirement to provide EHB must provide benefits that are substantially equal to the EHB-benchmark plan, including covered benefits; limitations on coverage, including benefit amount, duration, and scope; and prescription drug benefits. Thus, issuers cannot omit coverage of an EHB by asserting a lack of clinical evidence to support a discriminatory limitation on that EHB. However, separate from the policy finalized in this rule, issuers continue to have the ability to substitute benefits provided in the EHB-benchmark plan under § 156.115(b). In fact, utilizing the flexibility available under § 156.115(b) to substitute benefits may be a way for issuers to cover new and innovative benefits.

Comment: Some commenters expressed concern that the new proposed policy will unintentionally limit plan designs that strive to address health disparities. They noted that HHS should clarify that actions taken to reduce health disparities would not violate EHB nondiscrimination requirements. They expressed concern that limitations in clinical evidence may hinder innovative plan designs and issuers' ability to respond to a public health emergency.

Response: We disagree with commenters that assert this policy will inhibit efforts to advance health equity or efforts to address public health emergencies. We also do not find credible any assertion that the pursuit of sound clinical evidence in coverage decisions will in any way hinder the creation of innovative plan designs. We believe that requiring issuers to ensure their plan designs are clinically based is essential to achieving health equity and reducing health disparities.

Comment: One commenter expressed concern that relying on clinical guidelines exclusively to determine discriminatory design may lead to issuers using clinical evidence or

research as a shield to escape valid claims of discriminatory benefit. The commenter noted that if issuers begin to counter enrollee's arguments with clinical evidence, it may be hard to evaluate the validity of their sources as there is often a lack of transparency about the data or underlying assumptions in research. The commenter suggested that HHS should continue to employ other tools such as outlier analyses to reveal problematic plan design and consider approaches to compliance borrowed from mental health parity enforcement, such as disclosure requirements.

Response: We appreciate these recommendations and are exploring ways to improve our nondiscrimination reviews and develop new tools to detect discriminatory practices. In addition, we note that previously awarded State grants have focused on enhancing policy filing review processes to enhance enforcement of nondiscrimination (among several others).

Comments on unforeseen barriers and remedying inconsistencies with the EHB nondiscrimination policy

Comment: Some commenters expressed concern that the proposed changes may preempt State benefit mandates, which could create inconsistencies and impact health care affordability and accessibility. One commenter expressed concerns that State legislatures may enact mandates that are limited to a specific sub-population, as they often balance expanding coverage with the potential additional cost to those purchasing health insurance and their defrayal obligations pursuant to § 155.170. As such, this commenter noted that it is not appropriate for HHS to designate benefits being offered in accordance with State law as presumptively discriminatory. The commenter further stated that HHS should clarify that benefits offered in accordance with a duly enacted State law would not be considered presumptively discriminatory and that HHS finalize a process by which a health insurer could rebut any allegations that a benefit design is discriminatory. Another commenter urged HHS to provide additional compliance resources to allow plans and States to assess both what State mandates may not be allowed under this proposal, and how plans and States can work together to ensure consistent benefit coverage. Some commenters expressed concern that it is premature and inappropriate for

HHS to include the examples given in the proposed rule without further analysis of how the examples relate to existing State and Federal nondiscrimination policies.

Response: We disagree with the premise that it is inappropriate to apply this policy to issuer plan designs that are the result of State-required benefits. We also clarify that § 156.125 would only apply to State-required benefits that are considered EHB. For example, benefits required by a State mandate enacted on or after January 1, 2012, are generally not considered EHB pursuant to § 155.170. Therefore, an issuer covering a State-required benefit that is not EHB would not be required to modify the benefit in its plan design to comply with the nondiscrimination standards under § 156.125. A State-required benefit enacted on or before December 31, 2011, is considered EHB, and issuers covering that State-required benefit would therefore be required to comply with the nondiscrimination standards in § 156.125 when including that State-required benefit in their plan designs.

If a State-mandated benefit that is considered EHB is discriminatory under this policy, the State may attempt to remedy this through various ways, including revising the mandate, issuing guidance as described earlier in this section of the preamble, or otherwise furthering issuer compliance such as by amending form filing checklists or providing technical assistance to issuers. Regardless, issuers subject to § 156.125 would need to modify any discriminatory benefit designs for benefits the issuer is covering as EHB or be prepared to justify their approach with clinical evidence when designing plans that meet EHB nondiscrimination requirements. We would expect an issuer to be able to rebut a presumption of discriminatory plan design by demonstrating that such plan designs are clinically based.²⁷⁹ This policy does not disallow any benefit mandates required under State law, but does require issuers to comply with the non-discrimination provisions if benefits mandated by the State are EHB.

²⁷⁹ See proposed example of Age Limits for Infertility which provides a rationale when plans include age limitation due to variations in clinical effectiveness of treatment for infertility, defined as not being able to achieve pregnancy after 1 year of having regular, unprotected intercourse, or after 6 months if the woman is older than 35 years. *Infertility and Fertility*. (2017, January 31). NIH. <https://www.nichd.nih.gov/health/topics/infertility>.

The preceding clarifications should address the concerns raised by commenters regarding how this policy impacts State mandates and potential defrayal implications. As noted in relation to the policy we are finalizing to repeal the annual reporting requirement for State benefit requirements at § 156.111, we intend to provide additional guidance regarding the defrayal of State-required benefits in the future. We encourage States to reach out to HHS when regulatory concerns arise in this area in the interim. We further note that, under defrayal regulations at § 155.170, State mandates imposed for purposes of coming into compliance with Federal requirements are not ‘in addition to EHB’ and do not require defrayal.

Comments on telehealth oversight

Comment: Many commenters supported oversight to ensure that telehealth is not being utilized in a discriminatory fashion. They noted that telehealth utilization is often preferred for clinical reasons or to increase convenience. One commenter recommended that HHS continue to monitor this issue closely and ensure that the decision for an in-person or virtual visit is made between the health care provider and the patient, based on medical necessity and convenience, and not based on preferential plan structuring. Another commenter noted that telehealth is best utilized when it is provided within the context of the medical home and utilized as a component of, and coordinated with, longitudinal care. Some commenters noted that some issuers have arbitrarily terminated coverage of telehealth services which they noted is not based on any clinical rationale. Further, some commenters stated that the arbitrary and inconsistent coverage impedes care coordination and transition care planning, and adds to the stress on the patient, their family, and the treatment team. Some commenters provided consumer survey information related to patients’ concerns that telehealth coverage may be denied as an available option upon the expiration of the COVID-19 PHE. They urged HHS to not define plan designs that incentivize the use of virtual services as discriminatory.

Response: We are aware that States have primary oversight of telehealth practices and coverage. We encourage the commenters to work with States to help ensure consistent coverage

considering the increased availability of telehealth services experienced during the COVID-19 PHE. As we noted in the proposed rule, we do not currently believe that the practice of health plans covering services delivered virtually with no copay while requiring a copay for in-person health care services amounts to be a discriminatory practice under § 156.125. However, we intend to monitor telehealth utilization as it pertains to the delivery of benefits and how the utilization of telehealth may impact nondiscriminatory access to EHB.

General comments relating to examples of presumptively discriminatory benefit designs

As noted earlier, we made some clarifying changes to the examples of presumptively discriminatory benefit designs after considering public comments, and the final examples follow later in this section of this preamble. Our explanations and rationale for the changes are noted in this response to comments section.

Comment: Several commenters supportive of the examples of presumptively discriminatory plan designs asked HHS to include additional specific examples or provided their own examples of what they believed to be presumptively discriminatory plan designs.

Response: We acknowledge and appreciate the additional examples from the commenters. As discussed in the proposed rule, we provided examples that illustrate presumptively discriminatory practices that HHS believes amount to prohibited discrimination under § 156.125. However, it is not the intent of HHS to imply that any of the services or specific benefits noted in the examples are always EHB, as that can vary among States. We also do not plan at this time to add additional examples. The examples provided are non-exhaustive and provide adequate guidance for setting coverage limitations that comply with existing regulatory requirements prohibiting discriminatory benefit design. We emphasize that it is not the intent of HHS to list every possible instance of presumptively discriminatory plan design and that the absence of a specific plan design practice within these examples does not mean it does not constitute a presumptively discriminatory practice. Rather, the refined policy provides

guidance to issuers on the kind of evidence that we would find acceptable to justify limitations to benefits, to the extent they are EHB.

Comments on the example illustrating a discriminatory benefit design based on age

Comment: One commenter supporting the age limitation example asserted that labeling certain benefits as “pediatric” should be considered age discrimination as this labeling could potentially exclude coverage for adults with chronic health conditions.

Response: As finalized at § 156.125, plan designs may include age limitations on coverage for EHB so long as those limitations are supported by or consistent with relevant clinical guidelines or standards. We also recognize that in defining the EHB package at section 1302(b) of the ACA, Congress included pediatric services among the items and services that must be covered as EHB. As such, in implementing this section, we recognize that the statute explicitly requires certain medically necessary services to be covered as EHBs, such as those services required under the preventive services and pediatric service category. Therefore, plan designs may be limited to pediatric enrollees without running afoul of discriminatory benefit design concerns when such limitations are permitted under Federal law. Further, the policy is not meant to conflict with or supersede the policy at § 156.115(d), which prohibits coverage of, among other things, routine non-pediatric dental services and eye exam services as EHB. However, to the extent an issuer’s plan provides coverage of an EHB other than oral and vision care only for pediatric enrollees and no applicable Federal requirement only requires covering such EHB for that limited age group, the issuer will be held to the clinically based standard finalized at § 156.125. HHS will continue to monitor issuer compliance with EHB nondiscrimination requirements to discern whether additional assistance, policy changes, or rulemaking is necessary.

Finalized Examples: Discrimination based on age

We are finalizing these examples as proposed, but with minor clarifications to the conclusion of each example to clarify that these examples apply and are presumptively discriminatory to the extent issuers cover benefits as EHB.

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.²⁸⁰ 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.”²⁸¹

b. Circumstance: 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 a 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 is for “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.²⁸²

d. Conclusion: Age limits are presumptively discriminatory under § 156.125 when applied to EHB and there is no clinical basis for the age limitation. A plan subject to § 156.125

²⁸⁰ National Institute on Deafness and Other Communication Disorders FAQ on Hearing Aids (2017). NIH. https://www.nidcd.nih.gov/health/hearing-aids#hearingaid_01.

²⁸¹ 21 CFR 801.420(a)(1). Please note that this provision is subject to a pending rulemaking. See 86 FR 58150.

²⁸² Blazer, D. G., Domnitz, S., & Liverman, C. T. (2016). *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. National Academies of Sciences, Engineering, and Medicine. National Academies Press (US). <https://doi.org/10.17226/23446>.

that covers medically necessary hearing aids as an EHB, but limits such coverage based on age is presumptively discriminatory under § 156.125 unless the limitation is clinically based. For example, it would be presumptively discriminatory for an issuer subject to § 156.125 to cover medically necessary hearing aids as EHB under its plan, but limit such coverage to a subset of individuals, such as enrollees who are 6 years of age or younger, since hearing aids may be medically necessary for enrollees over the age of 6.²⁸³ The policy reflected in this example does not apply to benefits that are not covered by a plan as EHB. For example, pursuant to § 155.170, a health benefit an issuer covers under a plan pursuant to a State mandate adopted on or after January 1, 2012, other than for purposes of compliance with Federal requirements, is not considered EHB and would not be subject to the policy reflected in this example.

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.”²⁸⁴

b. Circumstance: We noted that some States have mandated coverage for the diagnosis and treatment for of 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’ EHB-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

²⁸³ In the 2016 Payment Notice proposed rule, 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.

²⁸⁴ *Autism Spectrum Disorder*. (2013). American Psychiatric Association. https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/DSM/APA_DSM-5-Autism-Spectrum-Disorder.pdf.

help diagnose ASD.²⁸⁵ Under the DSM-5 criteria, individuals with ASD must show symptoms from early childhood, but may not be fully recognized until later in life.²⁸⁶ We noted 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.²⁸⁷

d. Conclusion: Age limits are presumptively discriminatory under § 156.125 when applied to services that are covered as EHB and there is no clinical basis for the age limitation. A plan subject to § 156.125 that covers diagnoses and treatment of ASD as an EHB, but limits such coverage in its plan benefit design based on age is presumptively discriminatory under § 156.125 unless the limitation is clinically based. This example does not apply to benefits that are not EHB. For example, pursuant to § 155.170, a benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with federal requirements, is not considered EHB, and this example would not apply.

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 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).²⁸⁸

b. Circumstance: We noted 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

²⁸⁵ *Autism Spectrum Disorder (ASD)*. (2020, June 29). CDC. <https://www.cdc.gov/ncbddd/autism/hcp-dsm.html>.

²⁸⁶ American Psychiatric Association. *Diagnostic and statistical manual of mental disorders*. 5th ed. Arlington, VA: American Psychiatric Association; 2013.

²⁸⁷ *Key Findings: CDC Releases First Estimates of the Number of Adults Living with Autism Spectrum Disorder in the United States*. (2020, April 27). CDC. <https://www.cdc.gov/ncbddd/autism/features/adults-living-with-autism-spectrum-disorder.html>.

²⁸⁸ *Infertility Statistics*. (2021, December 20). CDC. <https://www.cdc.gov/nchs/fastats/infertility.htm>

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 noted 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.²⁸⁹ However, we also noted that the mean age for individuals experiencing their first childbirth has increased in recent years.²⁹⁰ 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 under § 156.125 when applied to EHB services and there is no clinical basis for the age limitation. A plan subject to § 156.125 that covers treatment of infertility as an EHB but limits such coverage in its plan benefit design based on age is presumptively discriminatory under § 156.125 unless the limitation is clinically based. An issuer could rebut the presumption that the plan’s age limit on the 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. This example does not apply to benefits that are not EHB. For example, pursuant to § 155.170, a benefit required by State action taking place on or after

²⁸⁹ *Having a Baby After Age 35: How Aging Affects Fertility and Pregnancy*. (2020). American College of Obstetricians and Gynecologists. <https://www.acog.org/womens-health/faqs/having-a-baby-after-age-35-how-aging-affects-fertility-and-pregnancy>.

²⁹⁰ Mean Age of Mothers is on the Rise: United States, 2000–2014. (2016, January 14). CDC. <https://www.cdc.gov/nchs/products/databriefs/db232.htm>.

January 1, 2012, other than for purposes of compliance with federal requirements, is not considered EHB and this example would not apply.²⁹¹

Comments on the example illustrating a discriminatory benefit design based on health conditions

We did not receive substantive comments related to the example, Limitations on Foot Care Coverage Based on Diagnosis (Whether Diabetes or Another Underlying Medical Condition).

Finalized Example: 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.²⁹² 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 the perpetuation of chronic conditions.

b. Circumstance: We noted 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 billion for direct medical costs.²⁹³ The

²⁹¹ *Key Statistics from the National Survey of Family Growth*. (2017, June 20). CDC. https://www.cdc.gov/nchs/nsfg/key_statistics/i.htm.

²⁹² Routine Foot Care. *Medicare Benefit Policy Manual* (pp. 265). CMS. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>

²⁹³ *Statistics About Diabetes*. (2022, February 4). American Diabetes Association. <https://www.diabetes.org/resources/statistics/statistics-about-diabetes>.

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.²⁹⁴

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.²⁹⁵

d. Conclusion: Benefit designs that restrict coverage on the basis of health condition are presumptively discriminatory under § 156.125 when applied to EHB services and there is no clinical basis for the limitation. A plan subject to § 156.125 that covers routine foot care as EHB in its health plan but limits such coverage on the basis of health condition to only apply to individuals diagnosed with diabetes despite clinical evidence demonstrating that routine foot care may also be medically necessary for treatment of other conditions, such as metabolic, neurologic, or peripheral vascular disease, is presumed to be discriminatory under § 156.125. This example does not apply to benefits that are not EHB. For example, pursuant to § 155.170, a benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with federal requirements, is not considered EHB and this example would not apply.

Comments on the example illustrating a discriminatory benefit design based on adverse tiering of prescription drugs

After reviewing the public comments for the Adverse Tiering example (87 FR 667 through 668), we are finalizing this proposed example in our EHB nondiscrimination policy for health plan benefit designs under § 156.125 as proposed with some minor clarifications. We clarify that this example applies to benefits that are EHB. This example does not apply to benefits that are not EHB; for example, under § 155.170, coverage of a specific drug that a State

²⁹⁴ Hicks, C. W., Selvarajah, S., Mathioudakis, N., Sherman, R. E., Hines, K. F., Black, J. H., 3rd, & Abularrage, C. J. (2016). Burden of Infected Diabetic Foot Ulcers on Hospital Admissions and Costs. *Annals of vascular surgery*, 33, 149–158. <https://doi.org/10.1016/j.avsg.2015.11.025>.

²⁹⁵ *Foot Care Coverage Guidelines*. (2010). CMS. <https://wayback.archive-it.org/2744/20191012061156/https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1113.pdf>

mandated on or after January 1, 2012 be covered does generally not qualify as EHB and this example does not apply.

Comment: Many commenters supported the example related to discrimination in accessing prescription drugs for chronic health conditions and adverse tiering, as the further emphasis on the existing prohibition against adverse tiering would only further expand access to care and improve health outcomes. One commenter noted that the prohibition of adverse tiering under § 156.125 is consistent with Medicare Part D and emerging State practices. Commenters agreed with the application of § 156.125 to adverse tiering because using cost as the primary factor in formulary decisions can cause tangible patient harm including nonadherence and negative health outcomes.

Response: We agree with commenters that the inclusion of the Adverse Tiering example clarifies our existing position that adverse tiering, which occurs when an issuer assigns all or the majority of drugs for certain medical conditions to a high-cost prescription drug tier to discourage enrollment by people with those medical conditions, is presumptively discriminatory under § 156.125. Allowing this practice would allow issuers to discourage enrollment for entire segments of the population with a particular medical condition by placing all or the majority of drugs for that medical condition on a high-cost tier.

To be clear, and as reiterated below, in finalizing this example, we are not prohibiting issuers from considering drug cost in setting drug formularies. On the contrary, we believe that it is prudent for a plan to consider a drug's cost in determining on which tier to place a particular drug. For example, if there are two effective drugs available to treat a particular condition, and one drug is less expensive than the other, it may be appropriate for the issuer to place the less expensive drug on a lower tier to incentivize usage of the less expensive drug. However, under this example, it is presumptively discriminatory for an issuer to place both of these drugs on a high-cost prescription drug tier in order to actively discourage enrollment by those with that condition in the plan. HHS or the State, in determining whether the issuer has rebutted this

presumption that a formulary that places all drugs for a particular condition on a high-cost tier is discriminatory, will look at the totality of the circumstances, including whether the issuer demonstrated 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 pharmacy benefit manager (PBM) weighed both cost and clinical guidelines in setting tiers).

Thus, we urge issuers and PBMs to pay close attention to any instance where all or the majority of drugs to treat a particular condition are placed on the highest-cost tiers. As we noted in the proposed rule, 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 a specialty tier that has the highest cost sharing. We acknowledge that cost is often an important factor in how issuers and PBMs that service issuers 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.

We believe finalizing this example is consistent with the requirement finalized in this rule at § 156.125 to justify limitations on EHBs with clinical guidelines. As explained in the proposed rule and in more detail below, this example and the existing pharmacy and therapeutics (P&T) committee requirements at § 156.122(a)(3) operate together to require issuers to base their drug formulary tier decisions on clinically indicated evidence.

Comment: Some commenters recommended that HHS allow individual plan P&T committees to determine formularies, as P&T committee recommendations are flexible in the face of constant change in the clinical evidence and other industry considerations. These commenters stated that formulary plan designs developed through the P&T committee process should not be deemed discriminatory simply because the formularies place higher cost drugs in higher drug tiers. They noted that the proposed EHB policy would not only undermine the role of

the P&T committee, but would also impact the ability of issuers to develop cost-effective formulary plan designs and may compel plans to include at least some high-cost specialty drugs in lower tiers, contrary to clinical evidence. In addition, they asserted that the proposed EHB policy would encourage manufacturers of these drugs to impose higher drug prices, which will drive up premiums.

Response: We acknowledge the importance of P&T committees in setting clinically indicated, non-discriminatory drug formularies; since 2017, we have required plans subject to the requirement to provide EHB to utilize P&T committees that meet the standards at § 156.122(a)(3). Based in part on those standards, we expect that P&T committees for issuers of such plans provide recommendations consistent with the most current and relevant clinical evidence for their respective service area.

Formulary plan designs are not discriminatory simply because formularies place higher cost drugs in higher drug tiers. Under this finalized example, formularies are presumptively discriminatory when all or a majority of drugs for a particular condition are placed on a high-cost prescription drug tier to discourage enrollment by those with that condition. As we noted in the proposed rule, HHS or the State may determine that an issuer can rebut this presumption by a totality of the circumstances, including by showing that neutral principles were applied consistently across the entire formulary in assigning all or a majority of drugs for a particular condition on a high-cost prescription drug tier. These principles harmonize with the existing requirements for P&T committees at § 156.122(a)(3)(iii) in establishing and managing an EHB-compliant formulary drug list. In this way, this example places even greater importance on the independent nature and clinically-based endeavors of P&T committees. Further, we do not agree that a P&T committee's input would likely compel plans to include at least some high-cost specialty drugs in lower tiers. We do not agree with commenters who asserted that this example will encourage manufacturers of these drugs to impose higher drug prices, which will drive up

premiums. We believe this example will contribute to controlling the costs of drugs by ensuring that issuers do not inappropriately place additional drugs on higher cost drug tiers.

Comment: Some commenters suggested that HHS needs to promulgate clear parameters of what is considered discriminatory, including a tool for QHP issuers to perform their own verification that their formularies meet the new non-discrimination requirements in advance of their plan submission. One commenter urged HHS to monitor issuers for compliance with nondiscrimination requirements, and to assist States with oversight and enforcement. One commenter recommended HHS should review issuers' internal coverage guidelines for discriminatory benefit designs as part of the QHP certification process.

Response: We believe that this final rule provides issuers clear guidance regarding the EHB nondiscrimination policy and encourage issuers to utilize tools that are appropriate for their own practices to aid with meeting EHB nondiscrimination requirements. For example, HHS currently uses and makes available a non-discrimination cost sharing review tool to identify and analyze outlier plans seeking certification as QHPs on the FFEs, as a means to identify potentially discriminatory benefit designs and strives to enhance such techniques. In the proposed rule, we stated that we will continue to monitor issuer compliance with EHB nondiscrimination requirements and States' oversight and enforcement activities to discern whether additional guidance, policy changes, or rulemaking are necessary. HHS will also consider whether additional guidance is necessary as we monitor issuer compliance with EHB nondiscrimination requirements and States' oversight and enforcement activities.

Finalized Example: Discrimination based on health conditions

5. Access to Prescription Drugs for Chronic Health Conditions (Adverse Tiering)

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 that issuers make about their formulary structure, including decisions made on the basis of cost. 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.²⁹⁶

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, the 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.²⁹⁷ 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: It is presumptively discriminatory under § 156.125 for an issuer providing EHB to place all drugs for a particular condition on a high-cost tier to discourage enrollment by those with that condition. To rebut the presumption that a formulary that places all drugs for a particular condition on a high-cost tier is discriminatory, HHS or the State will consider the totality of the circumstances, including whether the issuer has demonstrated 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

²⁹⁶ Jacobs, D. B., & Sommers, B. D. (2015). Using drugs to discriminate--adverse selection in the insurance marketplace. *The New England journal of medicine*, 372(5), 399–402. <https://doi.org/10.1056/NEJMp1411376>.

²⁹⁷ Boersma, P., Black, L. I., & Ward, B. W. (2020). Prevalence of Multiple Chronic Conditions Among US Adults, 2018. *Preventing chronic disease*, 17, E106. <https://doi.org/10.5888/pcd17.200130>

example, demonstrating that the issuer or PBM weighed both cost and clinical guidelines in setting tiers).

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 could be found to discriminate against individuals who have those chronic high-cost conditions under the § 156.125(a) standard. We clarified that such instances of adverse tiering are presumptively discriminatory and that issuers and PBMs assigning tiers to drugs should weigh the 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 2016 Payment Notice and 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 are not based on clinically indicated, reasonable medical management practices.²⁹⁸²⁹⁹ 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.

Comments on implementing the refined EHB nondiscrimination policy 60 days after final rule publication

Comment: One commenter supported the proposed effective date of 60 days after the publication of the final rule, given the negative effects that discriminatory benefit designs can have on enrollees with chronic conditions, especially during a public health emergency. Another commenter supported the 60-day effective date, noting that since the proposed clinical standards

⁵¹ Letter to Issuers on Federally-facilitated and State Partnership Exchanges (pp.15). (2013, April 5). CMS. https://www.cms.gov/ccio/resources/regulations-and-guidance/downloads/2014_letter_to_issuers_04052013.pdf
²⁹⁹ 2015 Letter to Issuers in the Federally facilitated Marketplaces (pp.29). (2014, March 14). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf>

framework is consistent with HHS' earlier rulemaking and plan compliance reviews, it should not unduly burden issuers to review and update their plans for compliance.

Many commenters objected to the proposed implementation timeframe as too immediate. Commenters requested that HHS extend the effective date until one year after the publication of this final rule to allow time for review of benefits coverage and making necessary adjustments. Other commenters recommended implementation of the policy no earlier than the 2024 plan year, while two other commenters recommended that the policy become effective at the beginning of a plan year so that formularies do not change in the middle of a plan year. Commenters explained that issuers will need to work with States to assess this requirement and administrative changes while reviewing existing networks and any new benefits. Commenters also noted they need adequate implementation time to prevent duplicative health plan designs and potential inconsistent standards as many health plans already use clinical evidence-based guidelines.

Response: We recognize that issuers subject to § 156.125 requirements may choose to carefully review the refined EHB nondiscrimination final rule. We recognize that such reviews may take time and that issuers may experience added burden to the extent that issuers make additional changes to their EHB plan designs in response to those reviews. While we expect that issuers are already compliant with current § 156.125 requirements, we recognize that in reviewing and implementing the refined EHB nondiscrimination policy, issuers may still have to make changes to benefits covered as EHB to ensure compliance, which may not always be done mid-plan year. Therefore, the refined EHB nondiscrimination policy will be applicable starting on the earlier of PY 2023 or upon renewal of any plan subject to the EHB requirements. We encourage issuers to promptly update their practices to more immediately reduce the impact of presumptively discriminatory practices, consistent with applicable State and Federal requirements. HHS intends to work collaboratively to address compliance issues with issuers that are acting in good faith to comply with the refined EHB nondiscrimination 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. In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 668), we noted that these parameters were not included in the proposed rule, as HHS did not propose to change the methodology for these parameters for the 2023 benefit year, and therefore, HHS published these parameters in guidance on December 28, 2021 (Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage for the 2023 Benefit Year).³⁰⁰

8. Levels of Coverage (Actuarial Value) (§§ 156.140, 156.200, 156.400)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 668), HHS proposed 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,³⁰¹ for which HHS proposed a *de minimis* range of +5/-2. Under § 156.200, HHS proposed, as a condition of QHP certification, to limit the *de minimis* range to +2/0 percentage points for individual market silver QHPs; HHS also proposed under § 156.400 to specify a *de minimis* range of +1/0 percentage points for income-based silver CSR plan variations.

³⁰⁰ Letter for Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage for the 2023 Benefit Year (2021, December 28). CMS. <https://www.cms.gov/files/document/2023-papi-parameters-guidance-v4-final-12-27-21-508.pdf>.

³⁰¹ 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.

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 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.

We sought comments on this proposal. We refer readers to the proposed rule (87 FR 668 through 671) for further discussion of these proposals and our rationale.

After reviewing the public comments, for the reasons set forth in this rule and in the proposed rule, we are finalizing the proposed changes to the *de minimis* ranges at §§ 156.140(c), 156.200, and 156.400 as proposed.

First, beginning in PY 2023, we are finalizing that all individual and small group market plans subject to the AV requirements under the EHB package will be subject to a *de minimis* range of +2/-2 percentage points, except for expanded bronze plans, for which we finalize a *de minimis* range of +5/-2 percentage points.

As we explained in the proposed rule (87 FR 668), since we finalized these *de minimis* ranges in the 2018 Payment Notice (81 FR 94058, 94142) and the 2017 Market Stabilization final rule (82 FR 18346, 18368), 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 expect more bronze plans to have an AV of at least 64 percent in future PYs.

TABLE 6: 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 increased, the percentage of silver plans offered on HealthCare.gov within the lower end of the current +2/-4 percentage point range remained consistent, with less than a third of silver plans having an AV between 66 and 68 percent.

TABLE 7: 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 8: 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 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, with current *de minimis* ranges, 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 the expanded bronze plan and the base silver plan is also apparent.

TABLE 9: 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 high deductible health plans (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 are changing the *de minimis* range for standard silver plans as proposed.

Additionally, as shown in Tables 10 and 11, we stated that 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 10: 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 11: 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 believed it is appropriate, 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 change above, starting with PYs beginning in 2023, we are changing 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 final rule (82 FR 18369), we stated that States are the primary enforcers of AV requirements and can apply stricter AV standards that are consistent with Federal law. 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 sections 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 final rule, a State cannot apply an AV range that exceeds $+2/-2$ percentage points, except for under the expanded bronze range originally provided for in § 156.140(c).

In addition to the changes applicable to non-grandfathered individual and small group market health insurance coverage market-wide, we are also amending § 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 are finalizing this narrower *de minimis* range for individual market silver QHPs to maximize PTC and APTC for subsidized enrollees. We believe that narrowing the *de minimis* range of individual market silver QHPs will influence the generosity of the SLCS, the benchmark plan used to determine an individual's PTC. We note that a subsidized enrollee who has an SLCS that is currently below 70 percent AV will see the generosity of their current SLCS increase, likely accompanied by a corresponding increase in premium, resulting in an increase in PTC. As shown in Table 8, 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 ten to one.

In addition, as we stated in the proposed rule (87 FR 670), after the 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. We believe the amendment we are finalizing to the *de minimis* range for individual market silver QHPs will reduce the cost of insurance coverage for an increasing population of subsidized enrollees. It will 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 Exchanges.

Thus, we believe increasing PTC for all subsidized enrollees justifies a narrower *de minimis* range on individual market silver QHPs that have fewer enrollments each year.

Finally, we are changing the *de minimis* variation for individual market income-based silver CSR plan variations from +1/-1 to +1/0 with a revision to the definition of “*De minimis* variation for a silver plan variation” at § 156.400. Similar to the +2/0 *de minimis* change for individual market silver QHPs, we believe the change to the *de minimis* variation for individual market income-based silver CSR plan variations will 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 will be an expected increase to the premium for the CSR plan variations as a result of the increased generosity, it will be substantially offset by increases to the APTC and PTC.

We summarize and respond to public comments received on levels of coverage (actuarial value) (§§ 156.140, 156.200, 156.400).

Comment: Many commenters expressed general support for the proposed changes to the *de minimis* ranges, agreeing with the rationale from the proposed rule that narrowing the *de minimis* ranges would increase PTC and APTC, and make coverage more affordable for subsidized enrollees. Many other commenters did not support the proposal and expressed satisfaction with the current *de minimis* ranges, asserting that not every enrollee would be eligible for the increased subsidies that would offset any premium increases due to the narrowed *de minimis* ranges. These commenters noted that the expanded PTC under section 9661 of the ARP is set to expire after PY 2022.

Response: We agree with commenters that the proposed *de minimis* changes would increase PTC and APTC to make coverage more affordable for subsidized enrollees. As we noted in the proposed rule, 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, 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.

We recognize that this change will increase premiums for enrollees in the individual and small group market. We estimated that the premiums would increase approximately 2 percent on average because of this change, which accounts for changes after the expiration of the expanded PTC under section 9661 of the ARP. We received no comments that addressed the accuracy of this estimate or its effects as a whole. While we recognize that not every enrollee in plans subject to the AV requirement is eligible for APTC and lives in an area with a SLCSP that is currently below 70 percent AV, we believe that the benefit of increased PTC and APTC for the majority of enrollees in the Exchanges outweighs the effects of wider *de minimis* ranges and the burden of premium increases.

Comment: Some commenters requested clarification on the applicability of uniform-modification-of-coverage rules should the narrower *de minimis* ranges be finalized. One such commenter requested clarification that plans within the current *de minimis* ranges, but outside of the proposed narrower ranges for PY 2023, will be allowed to renew within the same metal level of coverage under the Federal uniform-modification-of-coverage rules. These commenters generally contended that discontinued plans not subject to those rules would cause disruption for enrollees.

Response: Under the guaranteed renewability provision at 45 CFR 147.106(e), a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, unless the issuer discontinues all coverage, the product is discontinued, or the issuer's action is otherwise excepted from this requirement. One such exception that applies to individual and small group coverage is the modification of coverage at the time of renewal made consistent with State law, effective uniformly and solely pursuant to applicable Federal or State requirements, as described at § 147.106(e)(1)-(2). This allows an issuer to modify its plans

uniformly if the modification is made within a reasonable time period after the imposition or modification of a Federal or State requirement and the modification is directly related to the imposition or modification of the Federal or State requirement. As finalizing these changes to the *de minimis* ranges constitutes a modification of a Federal requirement, issuers that, consistent with State law, uniformly modify their plans solely to bring the plans' AV levels into the narrower *de minimis* ranges to maintain the same metal level will be considered to have modified their plans consistent with the Federal uniform-modification-of-coverage rules outlined in 45 CFR 147.106(e). Such changes would not cause any product, or any plan within a product, to be a different product or plan, as explained in the definitions of product and plan in 45 CFR 144.103.

Comment: Many commenters opposed the proposed +2/0 *de minimis* range for individual market silver QHPs and +2/-2 *de minimis* range for other silver plans and recommended keeping the +2/-2 *de minimis* range consistent across the individual market. These commenters cited concerns about the effects of non-uniform *de minimis* ranges for silver plans across the individual market, asserting that applying different *de minimis* ranges on- and off-Exchange could destabilize the individual market. They further believe that the different *de minimis* ranges could adversely impact consumers who choose to buy health coverage off-Exchange.

Response: We strive to maintain consistency for the *de minimis* ranges as much as possible. A consistent *de minimis* range allows for the most reliable determination of the differences between metal levels of coverage which, overall, improves the consumer shopping experience. We diverge from that goal only to the extent necessary to achieve compelling policy interests. For example, we previously regulated by this guideline in the 2017 Market Stabilization final rule, changing the *de minimis* ranges to +2/-4 from the original +2/-2 allowable AV variation finalized in the Final 2018 Payment Notice, in an attempt to achieve the compelling policy interest of improving plan variability and choice. In this rule, we believe it is appropriate to adopt separate *de minimis* ranges for individual market silver QHPs to achieve the

compelling policy interest of addressing the rising costs of health insurance premiums by influencing the generosity of the SLCSP to increase the amounts of PTC and APTC.

Comment: Many commenters urged that we not finalize changes to *de minimis* ranges for small group market plans, asserting that the proposed rule's rationale for changing the *de minimis* ranges applies only to changes to individual market plans. These commenters pointed out that HHS did not describe similar shifts in enrollments in small group QHPs offered on HealthCare.gov that are towards the upper end of the expanded bronze *de minimis* range as done with enrollment in individual market QHPs offered on HealthCare.gov, and that enrollees in small group market plans would experience premium increases as a result of the proposal, without the benefit of increased PTC or APTC. Further, these commenters stated that, because small group enrollees purchase their coverage through employers, they are not involved with plan comparison in the same way as individual market enrollees and HHS' justification for maintaining the integrity between metal levels is inapplicable to the small group market. These commenters also asserted that sponsors of small group market plans prefer the variety of plan choices under a wider *de minimis* range, and explained that these employers would experience disruption to existing plans or decide to drop coverage entirely.

Response: We recognize the concern raised by commenters that the proposed *de minimis* changes will lead to increased premiums for small group market enrollees without any subsidies to offset the cost. We are of the view that the burden of small premium increases in the small group market does not outweigh the benefits of ensuring that all purchasers of health coverage, including small group employers and their employees, can discern the material differences in benefits provided under competing health insurance plans. In response to the assertion that sponsors of small group market plans prefer the variety of plan choices that wider *de minimis* ranges allow for, and that these employers would experience disruption to existing plans or decide to drop coverage entirely, we believe that the benefits of improved plan comparability outweigh the advantages of wider *de minimis* ranges.

We do not have sufficient data to confidently describe enrollment trends in small group market QHPs. However, enrollment trends were not the basis for proposing to change the *de minimis* range for small group market plans. As we explained in the proposed rule (87 FR 669 through 670), the rationale for making equivalent changes to the *de minimis* ranges across the individual and small group markets is to maintain consistency across the metal levels, as an effort to reduce potential consumer confusion. Maintaining consistency for the metal level *de minimis* ranges allows for the greatest degree of confidence that consumers can recognize and understand the differences between metal levels. We diverge from the standard +2/-2 *de minimis* range for expanded bronze plans (+5/-2) for the reasons described in the preamble of the proposed rule, and for individual market silver QHPs offered both on-Exchange and off-Exchange (+2/0) and income-based silver CSR plan variations (+1/0) only to further the compelling policy interests described elsewhere in this section.

Comment: Many commenters supported the proposed *de minimis* ranges by citing the expected improvement in consumers' ability to meaningfully compare plans and make informed decisions related to their health coverage. These commenters stated that the current *de minimis* ranges are too permissive and blur the distinction between the metal levels of coverage envisioned by the ACA, which makes the plan comparison process difficult for consumers. They noted that the proposed *de minimis* ranges would narrow the allowable variation in plan generosity per metal level and should improve the plan comparison process for consumers, leading to more informed decisions on effective health coverage. The commenters also stated that the proposed *de minimis* ranges could lead to higher enrollment, as consumers would better understand the difference between metal level QHPs and more efficiently choose their health coverage. Additionally, one of the commenters noted that narrowing the allowable levels of coverage would positively impact plan marketing and display practices across issuers and keep consistent thresholds across competitors. They particularly noted that the narrow *de minimis* ranges would end the "race to the bottom" of underbidding high generosity competitor plans by

offering plans with lower generosity that still display under the same metal level of coverage within marketing.

Opposing commenters expressed a preference for the current *de minimis* ranges, asserting that the proposed ranges are too disruptive to the current market of plan offerings and could lead to more difficulty for consumers during plan selection. According to these commenters, consumer feedback indicates a preference for consistently similar plan offerings year-over-year. These commenters also generally asserted that the proposed ranges would cause fluctuations in available plan offerings, and could lead to consumers choosing coverage that is not in their best interests. These commenters also noted that the proposal may eliminate popular plan options at lower bound levels of coverage and that the gap in the allowable *de minimis* range could lead to limited plan design flexibility. Some commenters raised concerns about the effect of the proposed *de minimis* ranges on future plan designs as well, stating that narrowing the ranges for plans on and off the Exchanges would reduce issuers' ability to create plan designs that meet the specific needs of enrollees. These commenters further contended that popular plan designs would become non-compliant, with one State Exchange commenting that a standardized gold plan design, currently at 76 percent AV and accounting for 51 percent of the Exchange's gold metal level enrollment, would be non-compliant under this proposal. Some commenters also expressed general concerns about market disruption and requested a delay of any changes to the *de minimis* ranges to at least PY 2024.

Response: We agree with commenters that this policy will improve comparability, ensuring that consumers can more meaningfully distinguish between plans in different metal levels of coverage, and ensure consistency across metal levels. Increased recognition by consumers of the fundamental differences between the benefits offered under different health plans means that consumers will be less likely to choose a health plan ill-fitted to their circumstances, which may discourage consumers from using and maintaining their coverage in the future.

Furthermore, we believe that the implementation of the proposed *de minimis* ranges can lead to higher enrollment in plans. Requiring that plans offer the levels of coverage described at section 1302(d) of the ACA promotes consumers' ability to more easily recognize, understand, and compare plan offerings. As commenters noted, there is a general consensus of a connection between the ease of consumer plan selection and their enrollment decisions. These narrower *de minimis* ranges will allow consumers to better differentiate between plan offerings and reduce consumer confusion, which we believe will motivate increased overall enrollment.

In response to comments that the new *de minimis* ranges may eliminate popular plan options at lower bound levels of coverage and could lead to limited plan design flexibility, we are of the view that the burdens to issuers of conforming their plan offerings to the new *de minimis* ranges will be offset by the positive impacts on the consumer plan selection process. We reiterate our note from the proposed rule that we have no evidence that the expanded variation in allowable levels of coverage under current rules actually improved the consumer experience, including a consumer's ability to choose the plan that best meets their needs. As we stated previously, we believe the revised *de minimis* ranges we are finalizing in this rule will improve comparability, ensuring that consumers can more meaningfully distinguish between plans in different metal levels of coverage.

Although initial compliance with the new *de minimis* ranges may require additional effort from stakeholders, we still believe that this change is necessary to respond to observed changes in consumer plan selection behavior. We note that any initial disruption to issuer plans in the -4 to -2 percentage point *de minimis* range will be limited to a one-time cost-sharing adjustment to conform with up to a 2-percentage point change in the AV (except for individual market silver QHPs, which would have up to a 4-percentage point change). Issuers will be permitted to make these changes to existing plans consistent with the uniform modification provisions under the guaranteed renewability statute and regulation. Furthermore, while we believe issuers can operationalize these changes in time for plan year 2023, we recognize that this one-time cost-

sharing adjustment may create substantial burden for issuers. This is a burden we do not impose lightly; in addition to increasing PTC and APTC for eligible enrollees, these changes to the *de minimis* ranges are necessary to assure consumers that a plan's generosity conforms to the appropriate metal level and to prevent overlap in plan generosity across metal levels.

Comment: Some commenters stated that plans within States requiring the individual and small group insurance markets to be merged into a single risk pool under § 156.80 would be disrupted by the proposal to establish different *de minimis* ranges for individual market silver QHPs and for other individual and small group plans.

Response: Vermont, which previously had merged its individual and small group markets transitioned to separate individual and small group market risk pools beginning January 1, 2022.³⁰² While both Massachusetts and the District of Columbia have State-specific factors that combine certain aspects of their individual and small group plans, we do not consider their individual and small group markets to be merged into a single risk pool under § 156.80.³⁰³ For example, Massachusetts permits issuers in its small group market to update their index rates once every quarter, allowing small group market rating to operate separately from individual market rating in a manner that does not reflect a merged single risk pool. Similarly, the District of Columbia permits issuers to use different premium rating factors for its individual and small group markets in a manner that does not reflect a merged single risk pool. As such, there are currently no States with individual and small group markets that meet the Federal definition of a merged market under § 156.80. Therefore, we do not agree with commenters that there will be disruption to existing plans in merged markets in 2023. However, we recognize that if a State chooses to merge risk pools in future plan years, plans in that State could not utilize separate *de*

³⁰² Information on state specific rating variation is available at *Market Rating Reforms*. (2021, December 10). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/state-rating>. Also see *Green Mountain Care Board Reduces Rate Requests for Individual and Family Plans for 2022*. (2021, August 5). Green Mountain Care Board.

<https://gmcboard.vermont.gov/sites/gmcb/files/documents/GMCB%20Press%20Release%20-%202022%20BCSVT%20and%20MVP%20Individual%20Decisions.pdf>.

³⁰³ Massachusetts is considered to have a merged market for purposes of the HHS-operated risk adjustment program. See https://regtap.cms.gov/uploads/library/RA_MergedMarketsFAQ_021522_5CR_021522.pdf.

minimis ranges for individual and small group market silver QHPs, and would need to conform all individual market silver QHPs to a +2/0 *de minimis* range, and income-based silver CSR plan variations to a +1/0 *de minimis* range.

9. QHP Issuer Participation Standards (§ 156.200)

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. In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 671), we proposed to amend 45 CFR 156.200(e) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. As explained in the Supplemental Information section earlier in this preamble, HHS will address this proposed policy, as well as the public comments submitted in response to this proposal, in future rulemaking.

10. Standardized Plan Options (§ 156.201)

In the 2023 Payment Notice proposed rule (87 FR 584, 671 through 680), HHS proposed a requirement that issuers offering QHPs through FFEs and SBE-FPs, for PY 2023 and beyond, must offer through the Exchange standardized QHP options designed by HHS 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. We did not propose to limit the number of non-standardized plan options that issuers can offer but noted that we were considering whether it would be appropriate to do so in a future plan year. Furthermore, we did not propose to subject issuers in State Exchanges to this requirement to avoid duplicative standardized plan option requirements on State Exchange issuers and because we are of the view that State Exchanges are best positioned to design and implement standardized plan option requirements for their State. We also proposed that FFE and SBE–FP issuers that are already required to offer standardized plan options under State action taking place on or before January

1, 2020, such as issuers in the State of Oregon,³⁰⁴ be exempt from the standardized plan option requirements in the proposal.

HHS proposed the following standardized plan options: one bronze plan, one bronze plan that meets the requirement to have an AV up to 5 points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan), one standard silver plan, one version of each of the three income-based silver CSR plan variations, one gold plan, and one platinum plan. We did not propose standardized plan options for the Indian CSR plan variations as provided for at § 156.420(b) since the cost sharing parameters for these plans are already largely specified.

HHS proposed two sets of standardized plan options to accommodate different States' cost sharing laws. HHS proposed that the first set apply to all FFE and SBE-FP issuers excluding issuers in Delaware and Louisiana, and that the second set apply to issuers in Delaware and Louisiana.

HHS also noted that it was considering exercising the existing authority under § 155.205(b)(1) to differentially display standardized plan options on HealthCare.gov. Similarly, HHS noted that it was considering resuming enforcement of the existing standardized plan 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 Direct Enrollment (DE) and enhanced direct enrollment (EDE) Pathways – at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. HHS noted that if it did exercise these existing authorities, these entities would be required to differentially display standardized plan options beginning with the PY 2023 open enrollment period in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized plan options are displayed on HealthCare.gov, unless HHS approves a deviation. We also noted that any requests from web-brokers and QHP issuers seeking approval for an alternate differentiation format would be

³⁰⁴ See Or. Admin. R. 836-053-0009.

reviewed based on whether the same or a similar level of differentiation and clarity is being provided under the requested deviation as is provided on HealthCare.gov.

We proposed this approach for several reasons. To begin, the 2019 Payment Notice final rule eliminated standardized plan options with the intention of maximizing innovation and variety at a time when the individual market was considered to be at risk of destabilization. In the proposed rule, we explained that we believe that current market conditions differ significantly from the market conditions that defined the individual market when standardized plan 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 plan options were discontinued in the 2019 Payment Notice final rule.

We explained in the proposed rule that with increased enrollment, increased issuer participation, decreased single issuer counties, and increased plan options available to consumers, HHS is of the view that resuming standardized plan options at this time could play a constructive role in enhancing the consumer experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs that disproportionately impact disadvantaged populations, and advancing health equity. We also explained that we 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 did not propose to require issuers in State Exchanges to offer standardized plan options for several reasons, including that eight State Exchanges already require or will require issuers to offer standardized plan options by PY 2023. In addition, imposing duplicative standardized plan option requirements on issuers in State Exchanges that already have existing State standardized plan option requirements runs counter to our goals of enhancing the consumer

experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs, and advancing health equity. We also explained that we believe that State Exchanges are uniquely positioned to best understand the nature of their respective markets as well as the consumers in these markets. As such, we explained in the proposed rule that we believe that State Exchanges are best positioned to design standardized plan options suitable for their respective markets.

We further explained in the proposed rule that we 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 explained that we do not wish to impede these innovative policies so long as they comply with existing legal requirements. However, because we proposed to impose this requirement in the FFEs, and because the SBE-FPs use the same platform as the FFEs, we proposed to apply these requirements equally on FFEs and SBE-FPs. We explained that 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.

In the proposed rule, we explained that we proposed to exempt FFE and SBE-FP issuers that are subject to State standardized plan option requirements from these standardized plan option requirements since we do not wish to impose duplicative requirements that could conflict with these existing State standardized plan option requirements and the QHP plan designs applicable in such States. Regardless, we proposed to differentially display these existing State standardized plan options on the Federal platform in the same manner as the standardized plan options in this rule to ensure a consistent experience for all consumers utilizing the Federal platform.

In the proposed rule, we explained that we designed two sets of standardized plan options to accommodate applicable State cost sharing laws in different sets of FFE and SBE-FP States. We also explained that we designed these standardized plan options to be similar to the most

popular QHPs in FFEs and SBE-FPs in PY 2021 in terms of cost sharing parameters, MOOPs, and deductibles in order to ensure these plans are similar to plans that most consumers are already currently enrolled in, thereby reducing the risk of disruption for consumers and issuers alike.

In the proposed rule, we explained that we believe that resuming the differential display of standardized plan options on HealthCare.gov per the existing authority at § 155.205(b)(1) would further streamline the plan selection and enrollment process for Exchange consumers, aid consumers in distinguishing standardized plan options from non-standardized plan options, and enhance consumer understanding of the benefits of standardized plan options, such as having more pre-deductible coverage. We also explained that we believe that resuming enforcement of the existing standardized plan options 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, and that doing so will ensure a consistent consumer experience whether consumers are selecting plans on or off the Exchanges.

We refer readers to the proposed rule (87 FR 671 through 680) for a complete description of the proposals and rationale.

After considering comments received, for the reasons set forth in this rule and in the proposed rule, HHS finalizes the policies as proposed. Specifically, HHS finalizes the requirement for PY 2023 and beyond that issuers offering QHPs through FFEs and SBE-FPs must offer through the Exchange standardized QHP options designed by HHS at every product network type (as described in the definition of “product” at § 144.103), at every metal level, and throughout every service area that they offer non-standardized QHP options in the individual market. We note that we added the phrase “at every” to the metal level component of the above requirement for additional clarification and to minimize the risk of misunderstanding these

requirements. We also clarify that these requirements are applicable to the FFE and SBE-FP issuers offering QHPs in the individual market but not the small group market.

Similar to its stance in the proposed rule, HHS will not 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. We also finalize, as proposed, that issuers in State Exchanges be exempt from the requirement to offer standardized plan options. Similarly, we finalize, as proposed, that issuers of QHPs in FFEs and SBE-FPs that are already required to offer standardized plan options under State action taking place on or before January 1, 2020, such as issuers in the State of Oregon,³⁰⁵ are exempt from these requirements.

HHS finalizes the following standardized plan options, as proposed: 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. HHS did not propose standardized plan options for the Indian CSR plan variations as provided for at § 156.420(b), and therefore is not finalizing standardized plan options for these plan variations.

HHS also finalizes two sets of standardized plan options to accommodate different States' cost sharing laws, as proposed. Specifically, the first set of standardized plan options will apply to all FFE and SBE-FP issuers, except issuers in Delaware and Louisiana. We add as a point of clarification that this first set of standardized plan options will also not apply to issuers in Oregon, since Oregon enacted standardized plan options requirements before January 1, 2020 and issuers in Oregon are thus exempt from these requirements. The second set of standardized plan options will apply only to issuers in Delaware and Louisiana in order to accommodate these two States' specialty tier prescription drug cost sharing laws.

³⁰⁵ See Or. Admin. R. 836-053-0009.

In the first set of standardized plan options finalized in this rule (see Table 12), applicable to all FFE and SBE-FP issuers, except issuers in Delaware, Louisiana, and Oregon, 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 copay for the mental health/substance use disorder in-network outpatient office visit sub-classification is equal to the least restrictive level for copays for medical/surgical benefits in the in-network, outpatient office visit sub-classification (and copays apply to substantially all medical/surgical benefits in this sub-classification), to ensure issuers can 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.³⁰⁶

The second set of standardized plan options finalized in this final rule (see Table 13), applicable only to issuers in Delaware and Louisiana, has copays of \$150 or less for the specialty drug tiers of standardized plan options at all metal levels. This copay limitation for specialty drug tiers is the key feature that distinguishes the second set of standardized plan options from the first.

The two sets of standardized plan options finalized in this rule were designed to reflect the benefit categories in the actuarial value calculator (AVC), along with the addition of the “Urgent Care” benefit category. The cost sharing values for “Mental/Behavioral Health Inpatient Services” and “Substance Abuse Disorder Inpatient Services” benefits were not included in the proposed rule. However, we clarify that the “Mental/Behavioral Health Inpatient Services” and “Substance Abuse Disorder Inpatient Services” cost sharing values are populated based on the “Inpatient Hospital Services (for example, Hospital Stay)” cost sharing values since this benefit

³⁰⁶ In general, MHPAEA and its implementing regulations apply to group health plans and health insurance issuers in the group and individual markets, and require 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.

correlates to admission in a hospital or mental health facility. We further clarify that for the “Inpatient Hospital Services” benefit category in Tables 12 and 13, the “(Including Mental Health and Substance Use Disorder)” portion of the benefit category name was mistakenly excluded in the proposed rule. We therefore amended the name of this benefit category to more closely align with the corresponding benefit category in the AVC.

We also clarify that the AVs for several of the plans in each set differ slightly from the AVs of the corresponding plans in the proposed rule, due to a miscalculation with the AVC. We clarify that when a prescription drug formulary tier has copay after deductible as the form of cost sharing, both the “Subject to Deductible?” and “Copay only applies after deductible?” boxes must be selected in the AVC for that particular tier, or an incorrect AV will be calculated.

In both sets of standardized plan options, expanded bronze, standard silver, the silver 73 CSR variant, and the silver 87 CSR variant were affected by this miscalculation. After resolving this miscalculation, in the first set of standardized plan options, the AV for expanded bronze changed from 64.06 percent to 64.18 percent; the AV for standard silver changed from 70.04 percent to 70.06 percent; the AV for the silver 73 CSR variant changed from 73.10 percent to 73.11 percent; and the AV for the silver 87 CSR variant changed from 87.04 percent to 87.05 percent. In the second set of standardized plan options, the AV for expanded bronze changed from 64.07 percent to 64.18 percent; the AV for standard silver changed from 70.05 percent to 70.06 percent; the AV for the silver 73 CSR variant changed from 73.01 percent to 73.03 percent; and the AV for the silver 87 variant changed from 87.05 percent to 87.06 percent. The AVs for other metal levels were not affected by this miscalculation since these plans did not have copay after deductible as the cost sharing type for any benefits.

We also note that one asterisk (*) was mistakenly excluded in the plan designs in the proposed rule. Specifically, in the second set of standardized plan options, the gold plan’s specialty drug tier should be exempt from the deductible and should thus have an asterisk next to

its cost sharing amount. All other cost sharing parameters in both of the below sets of standardized plan options remain unchanged from the original plans in the proposed rule.

HHS also finalizes, as proposed, that we will exercise our existing authority under § 155.205(b)(1) to resume the differential display of standardized plan option plans on HealthCare.gov beginning with the PY 2023 open enrollment period.³⁰⁷ Similarly, also beginning with the PY 2023 open enrollment period, HHS finalizes, as proposed, that we will resume enforcement of the existing standardized plan options display requirements under §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv) for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE-FP – including those using the Classic DE and EDE Pathways – meaning that these entities are required to differentially display standardized plan options in a manner consistent with how standardized plan options are displayed on HealthCare.gov, unless HHS approves a deviation.

HHS also finalizes, as proposed, that any requests from web-brokers or QHP issuers that seek approval for an alternate differentiation format will be reviewed based on whether the same or similar level of differentiation and clarity would be provided under the requested deviation as is provided on HealthCare.gov. We also 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 – only needs to differentially display those standardized plan options it offers.³⁰⁸ To minimize the burden of complying with these display requirements, HHS will provide access to information on standardized plan options to web-brokers and QHP issuers through the Health Insurance Exchange Public Use Files (PUFs) and QHP Landscape file.

³⁰⁷ The PY 2023 OEP is scheduled from November 1, 2022 to January 15, 2023. See 45 CFR 155.410(e)(3).

³⁰⁸ See 81 FR 94118.

TABLE 12: 2023 Final Standardized Plan Options Set One (For All FFE and SBE-FP Issuers, Excluding Issuers in Delaware, Louisiana, and Oregon)

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	59.86%	64.18%	70.06%	73.11%	87.05%	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 (Including Mental Health and Substance Use Disorder)	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 and 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*
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 13: 2023 Final Standardized Plan Options Set Two (For Issuers in Delaware and Louisiana)

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	59.86%	64.18%	70.06%	73.03%	87.06%	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 (Including Mental Health and Substance Use Disorder)	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 and 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

We summarize and respond to public comments received on the proposals related to the standardized plan options.³⁰⁹ We also offer several points of clarification.

³⁰⁹ In connection with HHS' proposal to require FFE and SBE-FP issuers to offer standardized plan options, HHS sought comment on: (1) requiring FFE and SBE-FP issuers to offer standardized plan options at every product network type, metal level, and throughout every service area that they offer non-standardized plan options; (2) not limiting the number of non-standardized plan 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 plan 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

Comment: Many commenters supported requiring issuers offering QHPs through FFEs and SBE-FPs to offer standardized plan options at every product network type, at every metal level, and throughout every service area that they offer non-standardized plan options, explaining that standardized plan options could play an important role in simplifying the plan selection process. These commenters explained this approach will enable consumers to more easily compare plans by standardizing cost sharing parameters, thereby allowing individuals to focus on other factors crucial to their health, such as premiums, networks, quality, and customer satisfaction.

Many commenters also explained that requiring issuers to offer standardized plan options could improve affordability by requiring pre-deductible coverage of key services. These commenters explained that lowering cost barriers to services and supplies that address health conditions that disproportionately affect historically underserved communities aligns with broader Federal efforts intended to reduce health disparities. These commenters also explained that consumers frequently choose plans based only on premiums—without a clear understanding of additional out-of-pocket costs they might experience. These commenters thus explained that requiring issuers to offer standardized plan options with enhanced pre-deductible coverage could reduce the risk of consumers experiencing unexpected financial costs for receiving care.

Several commenters explained that the effectiveness of plan standardization in improving access to care and enhancing affordability is evinced by the experience of the nine States that have already adopted standardized plan option requirements in their respective State Exchanges.

remain subject to differential display requirements; (6) the continuation of an exceptions process that allows these entities to deviate from the display of standardized plan 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 plan options; (9) exempting FFE and SBE-FP issuers that are subject to existing state standardized plan options requirements under state action taking place on or before January 1, 2020 from being required to offer the standardized plan options in this proposal; (10) the methodology used to design these standardized plan options; (11) if the proposed standardized plan 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 plan 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 PY 2023 and beyond; and (15) having two sets of standardized plan options (that is, a separate set for Delaware and Louisiana). See 87 FR 671 through 680.

These commenters explained that several of these State Exchanges have required issuers to offer standardized plan options since their inception in 2014. These commenters also explained that standardized plan option requirements have played an important role in achieving some of the lowest rates of premium growth in the country in these State Exchanges.

Response: We agree that consumers will benefit from tools that further streamline the decision-making process, especially given that there has been a proliferation of plan offerings on the Exchanges in the last several years. We also agree that standardized plan options can play an important role in that simplification by allowing consumers to compare offerings based on other meaningful features, such as premiums, networks, formularies, and quality ratings. We believe that employing standardized plan option requirements while simultaneously narrowing the *AV de minimis* ranges will allow consumers to more easily and more meaningfully differentiate between choices and select a plan that meets their unique needs.

We believe the approach to standardized plan options finalized in this rule strikes an appropriate balance between simplifying the plan selection process, making it easier for consumers to more meaningfully compare available plan options, combatting potentially discriminatory benefit designs, reducing health disparities, and advancing health equity, while simultaneously preserving a sufficient range of consumer choice, minimizing the degree of disruption arising from the implementation of these requirements, and continuing to foster competition in the Exchanges.

We also agree that implementing the standardized plan option requirements finalized in this rule will improve access to care, enhance affordability, and advance health equity. The standardized plan options finalized in this rule include several important plan design features that we believe will provide additional consumer protections and mitigate health disparities, aligning with several of HHS' top priorities. Several of these design features include enhanced pre-deductible coverage for many EHB services, greater consumer certainty from having copays

instead of coinsurance as the form of cost sharing for as many benefits as possible, and having copays for all prescription drug tiers, including for the specialty drug tier.

Comment: Several commenters disagreed that HHS is legally obligated to resume standardized plan options, explaining that the *City of Columbus, et al. v. Cochran* ruling simply stated that the prior administration provided insufficient justification for discontinuing standardized plan options, but not that doing so was unlawful. These commenters noted that instead of resuming standardized plan options, HHS should issue a new rule with a more thorough explanation than what was provided in the 2019 Payment Notice final rule explaining why standardized plan options should remain discontinued.

Response: As we discussed in the proposed rule, we first introduced standardized plan options in the 2017 Payment Notice. We then discontinued standardized plan options 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*.³¹⁰ The court specifically vacated the portion of the 2019 Payment Notice that ceased HHS' practice of designating some plans in the FFEs as "standardized plan options," a policy that the 2019 Payment Notice (83 FR 16930, 16974 through 16975) described as seeking to maximize innovation by issuers in designing and offering a wide range of plans to consumers. As such, we announced our intent to engage in rulemaking under which we would propose to resume standardized plan options in time for PY 2023.³¹¹ More recently, President Biden's Executive Order on Promoting Competition in the American Economy directed HHS to implement standardized plan options to facilitate the plan selection process for consumers on the Exchanges.³¹²

³¹⁰ 523 F. Supp. 3d 731 (D. Md. 2021).

³¹¹ 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 plan 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.

³¹² Executive Order 14036 on Promoting Competition in the American Economy. (2021, July 9). 86 FR 36987.

Although we agree with commenters that the *City of Columbus* ruling did not require HHS to resume standardized plan options, it did cause HHS to reevaluate its prior decision to discontinue the designation of standardized plan options in the 2019 Payment Notice. As we explained in the proposed rule (87 FR 672), we believe that the conditions that currently define the individual market differ significantly from the conditions that defined the market when standardized plan options were discontinued in 2019, when the market was considered to be at risk of destabilization. We believe that the risk of market destabilization has subsided, as is demonstrated by the proliferation of plan offerings, increased issuer participation in the Exchanges, and record high enrollment. We believe that resuming standardized plan options at this time can play a constructive role in enhancing the consumer experience, increasing consumer understanding, and simplifying the decision-making process for consumers on the Exchanges despite the fact that the *City of Columbus* ruling does not legally obligate HHS to do so.

Comment: Several commenters who opposed these standardized plan option requirements noted that the current degree of standardization enabled by plan AV, different metal tiers of coverage, and mandatory coverage of EHB is sufficient to allow for easier plan comparison.

Response: We disagree that the current degree of standardization enabled by AV, different metal tiers of coverage, and mandatory coverage of EHB is adequate to enable sufficiently easy plan comparison, especially given the proliferation of plan offerings in recent years. As discussed later in the Choice Architecture and Preventing Plan Choice Overload Comment Solicitation, the proliferation of plan offerings available to consumers increases the risk of choice overload, coverage disruption, and suboptimal plan selection. We believe that given this proliferation of plan offerings, additional standardization is needed, and that consumers will benefit from additional tools that facilitate decision-making, including from the standardized plan option requirements finalized in this rule.

Comment: Some commenters stated that HHS should not require issuers to offer standardized plan options since consumer uptake of standardized plan options was low in previous years.

Response: We believe it is appropriate to require FFE and SBE-FP issuers to offer standardized plan options despite the comparatively low uptake of these plans in PY 2017 and PY 2018 for several reasons. As previously discussed, there has been a considerable proliferation of plan offerings available to consumers on the Exchanges over the last several years, and we believe that requiring issuers to offer these standardized plan options will play an important role in mitigating the risk of plan choice overload associated with the proliferation of plan offerings.

We also believe that these standardized plan options contain several plan design features, such as enhanced pre-deductible coverage, copays for as many benefit categories as possible, and copays for all tiers of prescription drug coverage, that provide important consumer protections. We believe these design attributes can play a significant role in decreasing barriers to access for several important health services, reducing the risk of unexpected costs and the associated financial harm, mitigating the risk of health disparities, combatting potentially discriminatory benefit designs, and advancing health equity. Altogether, we believe the advantages of standardized plan options outweigh the fact that consumer uptake of these options was comparatively low in previous plan years.

Comment: Many commenters opposed to requiring issuers to offer standardized plan options generally noted that these requirements would impede innovative plan designs that are tailored to meet the unique needs of enrollees. These commenters explained that when issuers develop plan offerings, they conduct extensive research to develop innovative plans that meet the needs of the populations and communities within their service areas. These commenters also expressed concerns that standardized plan options would not be able to keep pace with the innovation in the market.

Response: We disagree that requiring issuers to offer these standardized plan options will impede innovative plan designs tailored to meet the unique needs of enrollees. After considering comments received in response to the proposed rule, and based on our experience with reviewing plan cost-sharing structures during QHP certification, we are not of the view that non-standardized plans have sufficiently innovated with cost-sharing structures to justify not requiring issuers to offer standardized plans. We believe these standardized plan options requirements will increase enrollment and improve health outcomes without impeding issuers' ability to innovate in plan designs in their non-standardized offerings. We also note that we will continue to investigate whether there are lessons that we can draw from non-standardized plan options in terms of innovative plan designs that can apply to standardized plan options in future plan years.

Comment: Many commenters opposed to requiring standardized plan options stated that these requirements would unnecessarily constrain consumer choice. These commenters pointed out that some consumers choose less generous plans while others choose more generous plans, suggesting that there is not a one-size-fits-all plan design capable of satisfying all enrollees' unique health needs.

Response: We disagree that requiring issuers to offer standardized plan options would unnecessarily constrain consumer choice. First, the standardized plan options finalized in this rule reflect the most popular plan design attributes that consumers are already accustomed to. Second, as discussed elsewhere in this section, there has been a proliferation of plan choices available to consumers on the Exchanges. This proliferation significantly complicates the plan selection process, and increases the risk of choice overload, coverage disruption, and suboptimal plan selection. Contrary to the claim that these standardized plan option requirements will constrain consumer choice, we believe they will facilitate consumer choice by allowing consumers to more meaningfully compare between plans. Finally, if consumers believe that their

unique health needs are not met with the standardized plan options finalized in this rule, they retain the ability to choose from non-standardized plan options.

Comment: Several commenters stated that requiring issuers to offer standardized plans at every product network type, at every metal level, and throughout every service area in which they offer non-standard plans could increase the total number of plan offerings on Exchanges that rely on the Federal platform, exacerbating consumer confusion and increasing the risk of choice overload.

To circumvent this problem, some of these commenters recommended that HHS simply not require issuers to offer standardized plans, while others recommended requiring issuers to offer standardized plan options while also simultaneously limiting the number of non-standardized plan options that issuers can offer. The commenters who supported limiting the number of non-standardized plan options issuers can offer cited the increased number of plans that HHS described in the proposed rule as evidence that the number of plan choices on the Exchanges has increased to a point where it is difficult for consumers to make informed decisions, which can result in decreased enrollment. Several of the commenters who supported limiting the number of non-standardized plan options issuers can offer also cited the success of State Exchanges that limit the number of plan offerings in order to facilitate consumer decision-making.

Response: We are aware that these standardized plan option requirements could potentially increase the total number of plan offerings on the Exchanges. We also agree that the number of plan offerings on the Exchanges has increased to a point that is detrimental to consumers. That said, we chose to require issuers to offer standardized plan options while not also simultaneously limiting the number of non-standardized plan options issuers can offer in order to strike the greatest balance between simplifying the plan selection process and not causing an excessive amount of disruption in too condensed a timeframe. Considering that the QHP certification cycle for PY 2023 will have begun by the time this rule has been published,

we do not believe it feasible to limit the number of non-standardized plan options that issuers can offer without causing significant disruption to issuers' portfolios of plan offerings, which would also increase the risk of enrollment disruption.

In addition, we believe it would be important to first conduct extensive stakeholder engagement in order to determine whether limiting the number of non-standardized plan options that issuers can offer would be appropriate before proposing adoption of such an approach. We anticipate initiating this stakeholder engagement in the coming months and applying the lessons learned from this stakeholder engagement to our approach to standardized plan options in the 2024 Payment Notice.

Furthermore, we encourage issuers to modify their existing non-standardized plan offerings—in accordance with uniform modification requirements at 45 CFR 147.106(e)—to conform with the cost-sharing parameters of the standardized plan options finalized in this rule, if possible and so desired. This would significantly reduce the number of total new plan offerings on the Exchanges, which would also reduce the risk of choice overload, while allowing issuers to easily crosswalk enrollees from their current non-standardized plan offering to the standardized plan option equivalent.

Comment: Some commenters explained that requiring issuers to offer standardized plan options would increase issuer burden by increasing the total number of plan offerings in their portfolios. Several of these commenters stated that this increased burden could discourage issuers from entering new markets, thus reducing competition.

Response: We believe that requiring issuers to offer the standardized plan options finalized in this rule will not significantly increase issuer burden. As previously discussed, we encourage issuers to modify their existing non-standardized offerings to conform with the cost sharing parameters for the standardized plan options finalized in this rule so they do not have to offer both their non-standardized plan offerings and standardized plan option equivalents side by side in order to minimize issuer burden, if so desired. We also believe that issuers will be able to

utilize the same provider networks and formularies for these standardized plan options as they do for their current non-standardized offerings, which we believe will further minimize issuer burden. Given these considerations, we do not expect these requirements to impose an excessive amount of issuer burden that will discourage issuers from entering new markets, and we therefore do not expect these requirements to reduce competition in this regard.

Comment: Several commenters recommended that HHS narrow the scope of the proposed rule and require issuers to offer only one standardized plan option at the silver metal level if it requires issuers to offer them at all. These commenters generally noted that HHS should only expand standardized plan options gradually, if at all, to minimize disruptions.

Response: We disagree that we should narrow the scope of the rule and require issuers to offer only one standardized plan option at the silver metal level, and that we should only expand standardized plan options gradually to minimize disruption. We believe that our approach of requiring issuers to offer standardized plan options at every product network type, at every metal level, and throughout every service area (but not at product network types, metal levels, or service areas where issuers do not offer non-standardized plan options) while also not limiting the number of non-standardized plan options that issuers can offer strikes an appropriate balance between simplifying the plan selection process while also minimizing the risk of disruption.

Comment: Many commenters explained that resuming the meaningful difference standard (previously codified at 45 CFR 156.298) would be an effective and targeted method to prevent duplicative plan offerings while simultaneously ensuring that issuers continue to have the flexibility necessary to innovate. Several of these commenters supported resuming the meaningful difference standard in conjunction with requiring issuers to offer standardized plan options, while several of these commenters supported resuming the meaningful difference standard in place of the standardized plan option requirements finalized in this rule. Many of the commenters who supported resuming the meaningful difference standard recommended that

HHS adopt a more stringent approach than that previously taken, explaining that the standard in its previous iteration failed to prevent duplicative plan offerings.

Several commenters cited States' role in regulating individual market health insurance plans, requesting that HHS coordinate with State regulators in the event of HHS implementing a meaningful difference standard.

Response: Although we do agree that resuming the meaningful difference standard in conjunction with the standardized plan option requirements finalized in this rule could be an effective and targeted method to prevent duplicative plan offerings, we do not believe it is appropriate to resume the meaningful difference standard for PY 2023. We believe that additional research is needed to build upon and refine the previous version of the meaningful difference standard. We also believe that resuming the meaningful difference standard for PY 2023 would not grant issuers and States sufficient time to modify their portfolio of plan offerings prior to the PY 2023 QHP certification cycle.

Comment: Several commenters requested that HHS clarify if issuers are required to offer these standardized plan options off-Exchange.

Response: We clarify that issuers are generally required to offer standardized plan options off-Exchange pursuant to guaranteed availability requirements at 45 CFR 147.104. That said, issuers are not required to actively market these plans off-Exchange.

Comment: Several commenters requested that HHS clarify if issuers are required to offer the standardized plan options finalized in this rule in the small group market.

Response: We clarify that FFE and SBE-FP issuers are only required to offer the standardized plan options finalized in this rule in the individual market, but not the small group market.

Comment: Several commenters requested that HHS clarify whether issuers are required to offer standardized plan options for family plans, and if so, if HHS has designed standardized plan options for family plans.

Response: HHS affirms that issuers are required to offer standardized plan options for family plans. HHS also clarifies that issuers are able to offer standardized plan options as family plans by applying a family (other than self-only) MOOP and a family (other than self-only) deductible that is double the self-only MOOP and the self-only deductible, respectively, provided for in the standardized plan options finalized in this rule. We note that this approach is consistent with the approach taken in the 2017 Payment Notice (81 FR 12204, 12292).

Comment: Several commenters supported exempting FFE and SBE-FP issuers that are already subject to State standardized plan option requirements from the standardized plan option requirements finalized in this rule.

Response: We agree that it is appropriate to exempt FFE and SBE-FP issuers that are already required to offer standardized plan options under State action taking place on or before January 1, 2020 from the standardized plan option requirements finalized in this rule. We believe imposing duplicative Federal standards on these issuers would yield no benefit to consumers or issuers and that it would unnecessarily increase issuer burden. We further believe that FFE and SBE-FP States that have enacted standardized plan option requirements and implemented specific plan designs are positioned to best understand the unique needs and conditions in their respective markets.

Comment: Several commenters requested that HHS clarify whether the requirement for FFE and SBE-FP issuers to offer standardized plan options applies to issuers in States that are transitioning to a State Exchange model type in a future plan year.

Response: We clarify that all FFE and SBE-FP issuers are subject to these requirements, even if they anticipate that their State will transition from having an FFE or SBE-FP to a State Exchange in a future plan year (such as issuers in the State of Virginia). We reiterate that the only FFE and SBE-FP issuers exempt from the requirement to offer standardized plan options at every product network type, at every metal level, and throughout every service area they offer

non-standardized plan options are those that are already subject to State requirements enacted prior to January 1, 2020, such as issuers in the State of Oregon.

Comment: Several commenters recommended applying these standardized plan options requirements to State Exchange issuers that are not already required to offer standardized plan options per existing State requirements, while many were opposed to this approach, citing that State Exchanges are most familiar with the nuances and demands of their respective markets and should therefore be allowed to determine if issuers should be required to offer standardized plan options in these markets.

Response: We do not believe it is appropriate to apply the standardized plan option requirements finalized in this rule to State Exchange issuers, including issuers that are not already required to offer standardized plan options per existing State requirements, because we believe State Exchanges are best positioned to understand both the nuances of their respective markets and consumer needs within those markets. We also believe that State Exchanges are best positioned to determine whether standardized plan options would be beneficial to consumers in their respective States. However, because the SBE-FPs use the same platform as the FFEs, we are finalizing 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.

Comment: Several commenters requested that HHS clarify whether pediatric dental benefits can be included in standardized plan options.

Response: We affirm that pediatric dental benefits can be included in these standardized plan options if so desired, but note that the cost sharing parameters for these benefits are not standardized.

Comment: Several commenters requested that HHS clarify if telehealth services can be offered at a lower cost sharing amount than in-person services.

Response: Telehealth services cannot be offered at a lower cost sharing amount than in-person services, primarily due to limitations in the AVC. We intend to consider whether this flexibility should be afforded for future plan years.

Comment: Several commenters asked HHS to clarify how they should assign cost sharing to benefits not included in the AVC or the standardized plan options finalized in this rule.

Response: We note that when offering the standardized plan options finalized in this rule, issuers only have to match the cost sharing parameters for the benefits specified in the plan designs for the standardized plan options finalized in this rule. Issuers retain the ability to determine the cost sharing for benefits not included in the standardized plan options finalized in this rule, subject to State and Federal law.

Comment: Many commenters made recommendations regarding specific features of the plan designs. Several commenters disagreed with the methodology used in designing these standardized plan options, stating that designing standardized plan options to reflect popular plan design features (in the form of enrollee-weighted medians) would fail to meet the unique health needs of consumers. Commenters also stated that health care markets vary dramatically between States, as do the most popular plan design features in each of these markets, and therefore, that these plan designs would not resonate with consumers in every State.

Response: We designed the standardized plan options in this proposal by mirroring the most popular plan design features of QHPs offered through the FFEs and SBE-FPs in PY 2021 (in the form of enrollee-weighted medians), meaning that these plan designs are similar to those that millions of consumers are already currently enrolled in. Furthermore, though we do agree that there are some differences between the health care markets of different States, as well as between the most popular plan design features in these States, there are many similarities between different States and plan design features, as well.

For example, in the FFEs and SBE-FPs in PY 2021, 90 percent of non-CSR silver plan enrollees had plans with copays exempt from the deductible as the form of cost sharing for

primary care visits. The 30th percentile copay amount for this benefit category was \$30 per visit, while the 70th percentile was \$40 per visit. Thus, the range between the 30th and 70th percentiles for copay amounts for primary care visits for non-CSR silver plan enrollees in all FFEs and SBE-FPs in PY 2021 was only \$10, meaning the standardized plan options finalized in this rule have design features that are largely compatible with plan design features that millions of enrollees are already accustomed to. The fact that there is little variation in many of the most frequently utilized benefit categories across FFEs and SBE-FPs supports the decision to employ an enrollee-weighted median methodology in designing these plans.

To ensure these standardized plan options are able to meet the unique health needs of all consumers, we reiterate that we intend to conduct extensive stakeholder engagement (including with State regulators, issuers, provider groups, health advocacy groups, and consumer groups) over the next year. We anticipate incorporating the feedback we receive during this stakeholder engagement when designing standardized plan options for future plan years so that we can design plans that meet the unique health needs of all consumers. In the meantime, we believe the fact that consumers can still select from an unlimited number of non-standardized plan options in PY 2023 means that all consumers can select plans that meet their unique health needs.

Comment: Several commenters expressed concern with having one set of standardized plan options apply to all FFE and SBE-FP States. These commenters stated that a uniform national set of plan designs is unlikely to be attractive to consumers since health care markets vary dramatically between States, as do the most popular plan design features in these States. These commenters also stated that having State-specific plan designs could help mitigate the degree of disruption to local markets and increase consumer uptake of standardized plan options. These commenters also requested clarification on how these standardized plan options would interact with State cost sharing laws.

Response: We designed two sets of standardized plan options to apply to different sets of States in order to more precisely tailor these plan designs to the unique market conditions in

different States and to comply with the unique cost sharing laws in these different States. We also conducted extensive stakeholder engagement with more than 30 State departments of insurance to ensure that these plan designs comply with unique cost sharing laws. We also solicited comments on potentially relevant State cost sharing laws that could affect plan designs in the proposed rule. We also note that we intend to assess the feasibility and utility of designing State-specific standardized plan options to further mitigate the risk of disruption and to increase consumer uptake of these plans in future plan years.

Comment: Several commenters requested clarification regarding how these standardized plan options interact with State-mandated benefits.

Response: Nothing in the design of these standardized plan options supersedes the obligation to cover State-mandated benefits, as applicable. Similar to other benefits not included in these standardized plan options, issuers retain the ability to set the cost sharing parameters for these benefits, subject to State and Federal law.

Comment: Several commenters requested that HHS confirm that the standardized plan options finalized in this rule are compliant with MHPAEA and its implementing regulations.

Response: We affirm that the cost sharing parameters for these plan designs are designed so that issuers can design standardized plan options that are compliant with the MHPAEA and its implementing regulations. For example, copays for mental health or substance use disorder benefits in the outpatient, in-network office visit sub-classification in each plan design are equal to the least restrictive level for copays that apply to substantially all medical and surgical benefits in that sub-classification. Since standardized plan options do not include standardized treatment limitations on any of these benefits, issuers will be responsible for ensuring that the plan features they design outside of these standardized cost sharing parameters are compliant with MHPAEA and its implementing regulations.

Comment: Several commenters suggested that HHS incorporate VBID principles into future iterations of standardized plan options, explaining that doing so could further reduce

barriers to necessary services and promote health equity among consumers. Similarly, many commenters supported including low deductibles and pre-deductible coverage for as many benefits as possible in plan designs, explaining that doing so would improve accessibility to important services. Some commenters requested that HHS modify the plan designs to include more pre-deductible coverage for particular benefits, including for preventive services beyond those mandated by Federal requirements, maternity care, laboratory and radiologic services, and some or all tiers of prescription drug coverage. Several commenters added that by improving the affordability of basic services that underserved populations typically lack access to, standardized plan options could also help address health disparities.

Response: We affirm that VBID principles were incorporated into these plan designs by exempting particular services from the deductible, decreasing barriers to access for particular services and prescriptions drug tiers, and having copays as the form of cost sharing instead of coinsurance rates for particular benefit categories. We also intend to explore the utility of incorporating additional VBID principles into future iterations of standardized plan options.

We attempted to exempt as many benefits as possible from the deductible while also maintaining the lowest deductible possible, designing a plan that has an AV within the permissible *de minimis* range of the metal level AVs, and ensuring the competitiveness of these plans' premiums by having AVs near the floor of these *de minimis* ranges. Given these constraints, we are not able to exempt other benefits, such as laboratory and radiologic services, from the deductible without also raising the deductible or increasing the AV and therefore the expected premiums of these plans. We are also unable to decrease the deductibles for these plans without offsetting the change to AV by subjecting additional benefits to the deductible or increasing these plans' AV or premiums.

Comment: Several commenters requested that HHS clarify the specific types of specialist visits that are exempt from the deductible in these standardized plan options and if there are any limits on the number of visits exempt from the deductible. One commenter requested that HHS

clarify that deductible exemptions apply to the full range of pediatric preventive services, including those provided by a pediatric specialist.

Response: We clarify that we defer to issuers in how they classify which benefits belong to which benefit category, including how issuers classify “specialist visits” and therefore which specialist visits are exempt from the deductible per the cost sharing parameters in these plan designs. We also clarify that there are no visit limits for any of the benefit categories, including specialist visits, for any metal level in either of the two sets of standardized plan options finalized in this rule. We also reiterate that nothing in the design of these standardized plan 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 plan option.

Comment: Several commenters recommended including separate medical and drug deductibles in the plan designs to allow those who rely on prescription drugs to manage a particular health condition to more quickly meet their drug deductible.

Response: We chose integrated medical and drug MOOPs and deductibles for these plan designs because this was the most popular plan design feature in the FFEs and SBE-FPs in PY 2021. Since the majority of enrollees have a plan with this design feature, and since we wish to minimize the risk of disruption, we included this feature in these standardized plan options. We also note that we intend to consider the utility of splitting medical and drug MOOPs and deductibles in future iterations of standardized plan options for future plan years.

Comment: Several commenters requested that HHS clarify how deductibles and cost sharing should be applied to the specific benefit categories included in the standardized plan options finalized in this rule.

Response: We clarify that in both sets of the standardized plan options above in Tables 12 and 13, if a cost sharing amount for a particular metal level is accompanied by a (*), this benefit category’s cost sharing is exempt from the deductible.

Comment: Many commenters supported including copays instead of coinsurance for as many benefits as possible. These commenters explained that coinsurance disproportionately burdens persons with chronic illness and disabilities and that by improving affordability for basic services that underserved populations typically lack access to, these plan designs would help address health disparities. Some commenters further explained that copays are more transparent than coinsurance and that copays make it easier to predict out-of-pocket costs.

Several commenters recommended applying copays to more benefit categories, including for the emergency room, hospital inpatient, imaging, and lab work benefit categories. Several other commenters recommended eliminating coinsurance from the plan designs altogether. Several other commenters expressed concern that copays were too high for certain services.

Response: We affirm that we applied copays instead of coinsurance rates for as many benefits as possible in order to enhance consumer certainty and decrease barriers that obstruct access to these services. We agree this design feature will play an important role in improving affordability and transparency for important services, and that this design feature will also address health disparities. That said, since we designed these standardized plan options to reflect the most popular design features of QHPs in the FFEs and SBE-FPs in PY 2021, and since the majority or plurality of consumers did not have copays for particular benefit categories (such as for hospital inpatient), we chose coinsurance rates for these particular benefit categories. For this reason, we are unable to eliminate coinsurance from the plan designs altogether. We also note that we are unable to decrease copays for certain services without concurrently offsetting these changes with increases to deductibles, MOOPs, or subjecting additional benefits to the deductible.

Comment: Many commenters supported including copays as opposed to coinsurance specifically for prescription drugs, including for the non-preferred and specialty tiers, explaining that doing so would alleviate the burden for persons with chronic illnesses and disabilities. Commenters who supported the use of copays rather than coinsurance for prescription drugs

explained that high cost sharing on prescription drugs negatively affects medication adherence, leading to increased health care costs overall. Several commenters requested that HHS exempt all drugs from the deductible, lower copays for the different drug tiers, and cap all specialty drug copays at \$150 (as was done in the second set of standardized plan options).

Conversely, some commenters were opposed to both incorporating copays instead of coinsurance for all tiers of prescription drugs as well as exempting non-preferred and specialty tier prescription drugs from the deductible. These commenters expressed concern that these plan design features would increase the risk of adverse selection and could therefore contribute to an increase in premiums that would undermine access to affordable health coverage. These commenters also explained that these plan designs are more generous than existing plan offerings, demonstrating that plan designs with these features are not sustainable within current market conditions. One commenter requested that HHS clarify whether the plan designs allow prescription drugs associated with preventive services to be covered with zero cost sharing.

Response: We agree that having copays for all prescription drug tiers (including the non-preferred brand and specialty tiers) will enhance predictability, increase medication adherence, and decrease overall health care costs. We note that we were unable to exempt all drugs from the deductible and lower the cost sharing for all tiers due to constraints with AV. Exempting additional tiers from the deductible and lowering the cost sharing amounts for these tiers would require subjecting other medical benefits to the deductible, increasing the cost sharing for other medical benefit categories, or increasing the AV, and therefore increasing the premiums of these plans. We also note that we decided not to apply the \$150 copay cap to both sets of standardized plan options because only Delaware and Louisiana had State cost sharing laws that necessitated this design feature.

We understand that these design features may increase the risk of adverse selection, but we believe this risk is sufficiently mitigated by the fact that all FFE and SBE-FP issuers are required to offer these plans at every product network type, at every metal level, and throughout

every service area they offer non-standardized plan options. Therefore, we believe this risk to be distributed evenly among issuers. Furthermore, we reiterate that we designed these plans to have AVs near the floor of the *de minimis* range for each AV metal level to ensure these plans' premiums are competitive.

HHS reiterates once more that nothing in the design of these standardized plan 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 plan option. We clarify that these plan designs allow prescription drugs associated with preventive services to be covered with zero cost sharing.

Comment: Several commenters expressed concern with the plan design including only four tiers of prescription drug cost sharing, stating that this plan design feature would be difficult for issuers to implement and disruptive for consumers. These commenters explained that having six tiers of formulary cost sharing is becoming increasingly common among commercial issuers and that this design feature is permitted under Medicare Part D. These commenters therefore recommended that HHS include six tiers of prescription drug cost sharing in the plan designs to allow issuers the flexibility to develop formularies in a way that is most effective in promoting affordability. Conversely, several commenters supported including only four tiers of prescription drug cost sharing in the plan designs, explaining that doing so would offer more affordable, predictable, understandable prescription drug coverage.

Response: We agree that including only four tiers of prescription drug cost sharing in these plan designs offers more affordable, predictable, and understandable drug coverage, and that this design feature will play an important role in facilitating the consumer decision-making process by allowing consumers to more easily compare formularies between plans. That said, we intend to explore the feasibility and utility of including more than four tiers of prescription drug cost sharing in future iterations of standardized plan options in future plan years.

Comment: Several commenters requested that HHS clarify if standardized plan options are permitted to have more than one tier of provider networks.

Response: We clarify that we designed the standardized plan options finalized in this rule to have only one cost sharing tier such that no standardized plan option may have a tiered provider network. This approach aligns with the goals of simplifying the consumer decision-making process and making health insurance more understandable for consumers on the Exchanges. Furthermore, considering that the vast majority of plans offered through the Exchanges (nearly 90 percent) do not have tiered provider networks, we believe this plan design feature reflects current market realities and minimizes the risk of disruption for both issuers and enrollees.

Comment: Several commenters requested that HHS include health savings account (HSA)-eligible HDHPs in these sets of standardized plan options.

Response: We have not included HSA-eligible HDHPs in these sets of standardized plan options because enrollees still have the opportunity to enroll in non-standardized HSA-eligible HDHPs, if they so desire.

Comment: Many commenters supported differentially displaying standardized plan options on HealthCare.gov. Most of these commenters also supported extending standardized plan options differential display requirements to web-brokers and issuers' direct enrollment websites. Citing the overwhelming number of plan offerings available for consumers, these commenters urged HHS to improve and simplify the shopping experience by allowing consumers to easily identify standardized plan options. Many of these commenters noted that differentially displaying standardized plan options assumes even greater importance if issuers are permitted to offer an unlimited number of non-standardized plan options. These commenters also noted that extending these display requirements to web-brokers' and issuers' direct enrollment websites would promote consistent messaging across platforms. Several commenters also

explained that several State Exchanges have had success in differentially displaying standardized plan options and that HHS should draw from this experience.

In contrast, many commenters opposed differentially displaying standardized plan options, explaining that doing so could direct consumers to more expensive plans that may not be best suited for their needs. Several of these commenters urged HHS to give web-brokers and issuers that utilize alternative enrollment pathways – including Classic DE and EDE – flexibility in how to display standardized plan offerings to consumers utilizing their platforms due to concerns over technical and platform limitations.

Response: We agree that differentially displaying standardized plan options on HealthCare.gov and direct enrollment websites will improve and simplify the shopping experience by allowing consumers to more easily identify the standardized plan options. We also disagree that differentially displaying standardized plan options could direct consumers to more expensive plans that may not be best suited for their needs. We first note that we designed these standardized plan options to have AVs near the floor of the AV *de minimis* range for each metal level to ensure the competitiveness of these plans' premiums. We also note that we designed these plans to reflect the most popular plan design features throughout the FFEs and SBE-FPs in PY 2021 and we therefore do not believe these plans' premiums will differ significantly from the premiums of non-standardized plan options.

Further, since we are differentially and not preferentially displaying these standardized plan options, we believe that we can structure choice architecture in a way that allows consumers to meaningfully evaluate other non-standardized plan options and select these plans, if they so desire. A comment summary regarding specific recommendations for the differential display of standardized plan options is discussed in the Comment Solicitation on Choice Architecture and Preventing Choice Overload section later in this rule.

We also note that we will continue to provide web-brokers and issuers that utilize alternative enrollment pathways – including Classic DE and EDE – the ability to request to

deviate from how standardized plan options are differentially displayed on HealthCare.gov due to concerns over technical and platform limitations. We will provide additional technical guidance on how to submit this request to deviate in the future.

Comment: Several commenters expressed concern about the timing of the implementation of these requirements. These commenters explained that complying with these requirements would impose a significant burden on issuers as they try to meet filing deadlines for PY 2023, with several commenters requesting that HHS delay the implementation of these requirements until the plan year 2024, if they are implemented at all.

Response: We are finalizing our proposal to require issuers to offer standardized plan options for PY 2023 and beyond, as proposed. We first announced in part 2 of the 2022 Payment Notice final rule (86 FR 24140, 24265) our intent to resume standardized plan options and to propose specific plan designs in the 2023 Payment Notice. We also sought comment on the best method to resume standardized plan options in part 3 of the 2022 Payment Notice proposed rule (86 FR 35156, 35162 through 25163). We then affirmed our intent to resume standardized plan options in PY 2023 and explained our rationale for doing so in part 3 of the 2022 Payment Notice final rule (86 FR 53412, 53419 through 23420). We believe these announcements provided ample notice of our intent to propose standardized plan option requirements in the 2023 Payment Notice proposed rule such that States, issuers, and other affected stakeholders should have sufficient time to prepare for compliance with the requirements we finalize in this rule.

Additionally, since the cost sharing parameters for the EHBs covered under these plans are already specified, issuers will be able to utilize existing networks and formularies they already utilize in connection with other plans in their portfolios, and since issuers are not required to offer standardized plan options at product network types, metal levels, or services areas in which they do not already offer non-standardized plan options, we do not anticipate that issuers will be unable to meet the filing deadlines.

11. Network Adequacy (§ 156.230)

We proposed 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 engaged and received feedback from numerous stakeholders representing diverse perspectives in developing the proposed policies. We are finalizing the following provisions as proposed, with two exceptions: 1) we are not finalizing the proposal on network tiering; 2) for appointment wait time standards, we are finalizing and delaying implementation until PY 2024. We are also finalizing the following updates to § 156.230: substituting the phrase “substance use disorder” in place of “substance abuse”; and retaining paragraph (f), which was deleted in error.

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 final rule (77 FR 18309) and codified at § 156.230. HHS seeks to ensure that quantitative, prospective network adequacy reviews 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 2017 Market Stabilization final rule (82 FR 18346) 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 (83 FR 16930.) 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*.³¹³ 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 (86 FR 24140; 86 FR 53412) our intent to undertake rulemaking to establish network adequacy standards, beginning in this rulemaking for PY 2023.

b. FFE Network Adequacy Reviews

In the 2023 Payment Notice proposed rule (87 FR 584), HHS proposed 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 beginning with the QHP certification cycle for PY 2023. HHS proposed not to evaluate QHP network adequacy in FFE States performing plan management functions that elect to perform their 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 before QHP certification. States performing plan management functions are States served by an FFE where the State has agreed to assume primary responsibility for reviewing issuer-submitted QHP certification material and making certification recommendations to HHS.

We are finalizing this policy as proposed.

We summarize and respond to public comments received on this proposal below.

³¹³ 523 F. Supp. 3d 731 (D. Md. 2021).

Comment: Many commenters expressed strong support for HHS' proposal to conduct network adequacy reviews of the provider networks of QHPs offered through the FFEs. Key reasons for this support included ensuring consistency of network adequacy standards and reviews across States; providing a minimum set of network adequacy standards that States can meet or exceed; and addressing various issues related to consumer access.

Response: We concur that conducting robust network adequacy reviews of QHPs on the FFEs will have numerous benefits, including strengthening QHP enrollees' access to a variety of health care providers.

Comment: Some commenters stated that HHS should defer to States' reviews as they believe States are the most appropriate regulators of network adequacy. These commenters expressed that States understand and can tailor network adequacy reviews based on unique market conditions and that HHS network adequacy reviews could be duplicative and burdensome.

Response: We understand that some States, issuers, and other stakeholders believe that States are best positioned to regulate network adequacy. Given that States have unique knowledge and experience that are beneficial to assessing QHPs' provider networks, HHS will continue to partner with and learn from States as we conduct network adequacy reviews and pursue future network adequacy rulemaking. In recognition of this viewpoint, and as proposed, HHS will allow States performing plan management functions to choose to conduct their reviews, as long as they adhere to standards as stringent as HHS' standards and conduct prospective reviews. For all other FFEs, HHS will conduct network adequacy reviews to assure that QHP enrollees across States have reasonable access to a variety of health care providers to meet their needs.

Comment: Some commenters urged HHS to allow States performing plan management functions to conduct their network adequacy reviews if they have an approach that is

“comparable to” Federal network adequacy standards, rather than “as stringent as” Federal standards.

Response: HHS believes it is important for States performing plan management functions to conduct network adequacy reviews that are at least as stringent as Federal reviews for two main reasons. First, HHS seeks to ensure QHP enrollees in all FFEs have a minimum standard of consumer protections regarding reasonable access to providers. We believe the Federal standards set a strong floor from which States performing plan management functions can implement even more robust standards if desired. If HHS were to allow States performing plan management to conduct network adequacy reviews that are comparable to Federal reviews, rather than as stringent, this could lead to reviews of a smaller provider specialty list or reviews that have less stringent parameters, for example. Second, whether a network adequacy review is “comparable” is a less concrete determination than whether it is “as stringent.”

HHS is defining “as stringent as” to mean that the reviews include assessing compliance with time and distance standards and appointment wait time standards using the same specialty list and parameters. Time and distance reviews must be based on quantitative data collected from the issuer (not attestation) and supported by a justification requirement if an issuer does not meet one or more of the standards. We believe assessing quantitative data for time and distance reviews, rather than using qualitative measures, gives a fuller and more accurate picture of how a QHP assures reasonable access to providers. Assessing time and distance using quantitative data also allows us to make comparisons year-over-year and across issuers. We are codifying in § 156.230 that time and distance reviews must be based on quantitative issuer-submitted data.

Appointment wait time reviews, which will begin in PY 2024, must be based on methods as stringent as HHS’ methods (as a minimum standard) and supported by a justification requirement if an issuer does not meet one or more of the standards. HHS will propose the method for assessing compliance with appointment wait time standards in future rulemaking. States can implement network adequacy standards and reviews that are more stringent than

HHS' standards, described here. For example, we consider shorter time and distance or appointment wait time standards to be more stringent than longer ones.

We also acknowledge that State-specific challenges (for example, provider supply shortages, topographic barriers, etc.) may necessitate justification allowances, such as mitigating measures (for example, in-network cost sharing for out-of-network providers) that ensure access to a provider specialty type that would otherwise be unavailable to enrollees, while the States partner with issuers and providers to reach a more permanent solution. We believe the justification process for network adequacy will sufficiently accommodate such challenges and allowances.

Comment: Several commenters requested that HHS closely assess the network adequacy reviews of States performing plan management that elect to perform their reviews to ensure they review and enforce standards at least as stringent as HHS' standards.

Response: We will closely partner with these States to ensure they understand HHS' standards, that the States have adequate State authority to conduct such reviews, and that their reviews will appropriately assess network adequacy for QHPs in their State before plan confirmation to support timely QHP certification.

Comment: Some commenters expressed concern that the additional contracting required to achieve the new network adequacy standards could increase costs to consumers, while other commenters believe that the standards are unlikely to raise consumer costs.

Response: We acknowledge that commenters shared mixed feedback about whether the new network adequacy standards would raise consumer costs. We do not anticipate that the updated network adequacy requirements will substantially raise costs to consumers. We acknowledge that there may be some additional burden for QHP issuers and States to comply with the new network adequacy requirements. We will work to minimize the burden to the extent feasible by increasing transparency of the network adequacy review process, offering technical assistance resources and consultations, and collaborating with issuers and States to address

questions and issues that arise during the PY 2023 network adequacy review process. We believe the benefits to consumer protection resulting from strengthened network adequacy standards strike a reasonable balance with the potential for increased issuer burden and cost, given the strategies described above that HHS will undertake to mitigate the burden.

Comment: Some commenters expressed concern regarding the implementation timeline for network adequacy reviews and requested that reviews be delayed until PY 2024 due to the time needed by issuers and States to prepare for the reviews and given the continued impacts of the COVID-19 pandemic on the health care system.

Response: We understand the desire expressed by some commenters to delay the implementation of network adequacy reviews given the time needed to collect information from providers on appointment wait times in the COVID-19 context. We acknowledge these concerns and, as discussed in the Appointment Wait Times section of this preamble, we will finalize the appointment wait time standards, but delay their implementation until PY 2024. We believe it is reasonable to implement the other finalized elements of the network adequacy proposal in PY 2023 for reasons described in the Time and Distance and Telehealth sections of this preamble.

Comment: Some commenters requested that HHS further align Federal network adequacy standards with the National Committee for Quality Assurance (NCQA) accreditation standards.

Response: We have reviewed the NCQA standards regarding network adequacy. We believe it is appropriate to align with NCQA in its use of business days to measure appointment wait time standards, which will be finalized in the final PY 2023 Letter to Issuers. We will also finalize that the appointment wait time standard for the behavioral health category will align with NCQA's standards; NCQA does not have quantitative parameters for the other categories we are finalizing for appointment wait times. NCQA does not currently have quantitative standards for time and distance so we cannot consider alignment.

Comment: One commenter requested HHS retain the provision in the network adequacy regulation text that clarifies that QHPs do not have to use provider networks.

Response: HHS will retain this provision that clarifies that QHPs do not have to use provider networks. In the proposed rule, the deletion was an error, and we appreciate the commenter bringing it to our attention.

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 the 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 (77 FR 18309), 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 assure that all services will be accessible to enrollees without unreasonable delay. In the 2016 Payment Notice final rule (80 FR 10749), 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.

In section c, parts ii, ii, and iv of this preamble, we proposed 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 proposed 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 were 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 to evaluate Medicare Advantage plans. 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 proposed 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 populations. The additional specialties proposed are emergency medicine, outpatient clinical behavioral health, pediatric primary care, and urgent care.

HHS proposed that time and distance standards be calculated at the county level and vary by county designation. We 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 14 and 15. To count towards meeting the time and distance standards, individual and facility providers listed in Tables 14 and 15 must be appropriately licensed, accredited, or certified to provide services in their State, as applicable, and must have in-person services available.

TABLE 14: 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 15: 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 proposed to 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 proposed to codify the network adequacy justification process in regulation at § 156.230(a)(2)(ii).

HHS sought 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 sought comment on the parameters that should apply with respect to behavioral health providers to ensure adequate access to these services. HHS also sought 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.

We are finalizing this policy as proposed.

We summarize and respond to public comments received on this policy below.

Comment: Many commenters, across a range of stakeholder types, supported the proposed quantitative time and distance standards. Key reasons for this support included appreciation for instituting a quantitative assessment of consumer access; concurrence with the inclusion of a variety of individual and facility provider types, including QHP-specific additions to the Medicare Advantage provider specialty list; and varying time and distance standards by county type since provider availability can be influenced by local population density.

Response: HHS agrees that stringent quantitative time and distance standards for the expanded provider specialty lists that vary by county designation will help strengthen QHP enrollees' access to a variety of providers to meet their health care needs.

Comment: There was mixed feedback on the inclusion of emergency medicine physicians: some commenters stated that the addition would be duplicative of required facility types and No Surprises Act protections, while others agreed with HHS' contention that including emergency medicine physicians would provide proactive consumer protections and increase enrollee access to in-network providers.

Response: HHS understands that some stakeholders have differing opinions about the inclusion of emergency medicine physicians on the provider specialty list for time and distance reviews. We believe that the anticipated benefits to consumer access and protections outweigh the concerns about duplication, and we will include emergency medicine physicians as proposed.

Comment: Numerous commenters requested that HHS consider additional provider specialties (for example, anesthesiologists, audiologists, and providers offering gender-affirming care, among others) for inclusion in future time and distance standards.

Many commenters specifically requested additions to or refinement of the Outpatient Clinical Behavioral Health category, such as separate categories for mental health and substance use disorder services, and delineating between pediatric and adult behavioral health providers. Some commenters requested refining certain provider specialty types, including allowing OB/GYNs to count as primary care providers; aligning OB/GYN parameters with the parameters

for specialists rather than for primary care; considering how safety-net family planning and sexual health services are delivered by a range of non-OB/GYN providers; dividing requirements for oncology providers into separate categories for medical and surgical oncology; allowing mid-level practitioners to count as specialty care providers for time and distance standards; and allowing family medicine physicians to count towards pediatric primary care.

Response: HHS is finalizing the individual and facility provider specialty lists for time and distance as proposed. We believe the current specialty list builds on and strengthens the specialty list that HHS used for assessing time and distance when we previously did so in PYs 2015-2017, which will help increase access to a variety of provider types and strengthen consumer protections. HHS appreciates the feedback suggesting additions to and refinement of the provider specialty list for time and distance standards. Prior to considering the adoption of these suggestions in future rulemaking, HHS will need to conduct further assessment and research as they may also have unintended consequences.

We appreciate the suggestion from commenters that OB/GYNs count towards time and distance standards for primary care providers. We believe there could be potential unintended consequences if we were to allow OB/GYNs to count as primary care providers for time and distance standards. For example, since OB/GYNs most commonly care for female patients, including OB/GYNs as primary care providers for time and distance standards could hamper access to primary care for male patients. We will further assess this suggestion and its potential implications and will consider this for future rulemaking.

For PY 2023, while we will not have separate adult and pediatric standards for Outpatient Clinical Behavioral Health, we have unique specialty codes in the Essential Community Provider/Network Adequacy (ECP/NA) template that distinguish the two age categories (adult and pediatric) for some behavioral health specialty types, allowing for data collection and analysis, and consideration of further refinement in the future.

Though we do not have a time and distance standard specifically for gender-affirming care and surgery providers, the provider specialty list does include many providers who offer services that may be useful for individuals seeking gender-affirming care, like endocrinologists, urologists, and behavioral health clinicians.

Comment: Some commenters expressed concerns that Federal time and distance standards cannot adequately account for geographic variations, like provider supply and population density. One commenter expressed concerns that many issuers in their state might fail the new standards, that the network adequacy standards could disincentivize new issuers from entering the market, and that counties would be left without available Exchange health insurance options. Several commenters shared suggestions for less stringent time and distance reviews, like broader qualitative standards, or separate time and distance standards for rural areas, geographies with provider shortages, and narrower networks.

Response: We understand that some stakeholders have concerns about HHS assessing QHPs for compliance with quantitative time and distance standards. We believe that quantitative time and distance standards, when varied by county type, provide a useful assessment of whether QHPs provide reasonable access to care, and when combined with appointment wait time standards, will offer a more comprehensive evaluation of the adequacy of QHPs' networks. HHS believes that less stringent time and distance standards (like qualitative standards or separate standards for rural areas, geographies with provider shortages, and narrower networks) would not sufficiently assure reasonable access to providers.

Where QHPs cannot comply with these standards due to provider shortages and other factors that affect issuers of given service areas similarly (like topographic challenges, such as a lake in the middle of a county), issuers can include such explanations in their justifications. HHS will take such considerations into account in determining whether the justification is sufficient to satisfy this QHP certification standard.

HHS is aware of the potential risks related to implementing time and distance standards, such as standards being too stringent, not accounting for geographic variations, and leading to fewer QHPs. We believe these risks can be managed with increased transparency, updates to network adequacy QHP application documents, and coordination and partnership with States and issuers. We have made several changes to increase transparency, which we anticipate will make it easier for issuers to understand and comply with network adequacy standards. The ECP/NA template will include the Taxonomy Codes tab that shows which taxonomy codes crosswalk into which individual provider and facility specialty types. The Instructions and FAQs will provide more detail on the network adequacy review process and what issuers need to submit to HHS to demonstrate satisfaction of network adequacy standards. The Network Adequacy Justification Form is a streamlined tool that will enable issuers to show HHS how they are making progress toward compliance with network adequacy standards. Coordination with States will allow for a two-way exchange of information so HHS can better understand local patterns of care and how they may relate to Federal network adequacy standards. This information helps us give issuers as much credit for their networks as possible.

Comment: Other commenters expressed that due to the differences between QHPs and Medicare Advantage plans – in terms of consumers, provider reimbursements, and contracting dynamics – network adequacy standards applying to Medicare Advantage plans may not be appropriate to apply to QHPs.

Response: HHS acknowledges that QHPs and Medicare Advantage plans serve different enrollee populations. HHS has tailored the provider specialty list accordingly to better align with the provider access needs of QHP enrollees. HHS has added the following provider specialties for time and distance: emergency medicine, outpatient clinical behavioral health, pediatric primary care, and urgent care. Details on why each of these specialties was added are included in the proposed rule (87 FR 584, 681). When HHS conducted Federal network adequacy reviews during PYs 2015-2017, our time and distance standards for network adequacy were also

foundationally based on Medicare Advantage standards. Based on that prior experience, our research on network adequacy standards, and the public comments received on this rule supporting this approach, we believe it is reasonable to resume using time and distance network adequacy standards that are based on Medicare Advantage standards.

Comment: Some commenters expressed that time and distance metrics are not appropriate for SADPs and that a network breadth measure might be more appropriate. However, while some commenters noted that time and distance standards are not appropriate for SADPs, most commenters supported the inclusion of dental providers.

Response: Based on prior rates of SADPs' compliance with time and distance standards and our assessment of the availability of dental providers against the time and distance parameters finalized in the 2023 Letter to Issuers, HHS anticipates most SADPs and medical QHPs with embedded dental benefits will be able to meet the standards for dental providers. If a plan is still working to come into compliance with network adequacy standards, they will be able to use the justification process as needed. Consequently, as proposed, HHS will include dental as a specialty for which compliance with time and distance standards is assessed.

Comment: Several commenters stated that facility-based providers, such as physical, occupational, speech, and behavioral health therapists, should not be included in the individual provider specialty list for time and distance since some issuers may contract at the facility level for those services.

Response: For rehabilitation and behavioral health therapists, we understand that some issuers contract at the facility level rather than with individual providers. We have decided to include these providers on the individual provider list because many of these providers offer services in varied locations and may not be contracted with a single facility.

Comment: Several commenters made requests related to the justification process for issuers that do not meet network adequacy standards, including requests for greater clarity on the process; requested that HHS adopt a justification process that mirrors Medicare Advantage's

approach to justifications; and requested that HHS ensure that justifications are not used in lieu of issuers contracting with additional providers.

Response: Issuers with network adequacy deficiencies will receive a partially pre-populated Network Adequacy Justification Form via the Plan Management (PM) Community and will need to submit the completed form to the PM Community by the required deadline. The justification process will require issuers that do not yet meet network adequacy standards detail: the reasons that one or more standards were not met; the mitigating measures the issuer is taking to ensure enrollee access to respective provider specialty types; information regarding enrollee complaints regarding network adequacy; and the issuer's efforts to recruit additional providers. HHS will use any updated provider data submitted on its ECP/NA template and the completed Network Adequacy Justification Form submitted as part of the certification process to assess whether the issuer meets the regulatory requirement, prior to making the certification decision.

HHS reviewed the Medicare Advantage exception process and made the QHP network adequacy justification process align where it made sense to do so. HHS has made some distinctions, like using a partially pre-populated Excel form with information on all needed corrections, rather than issuers having to complete a separate justification request for each county/specialty/network combination for which deficiencies are required. The justification process for QHP network adequacy is designed to help an issuer demonstrate its progress toward greater compliance with the standards. HHS will partner with issuers and States to ensure that the justification process is not used in place of contracting with additional providers.

Comment: Some commenters also requested that HHS clarify what provider and facility types count towards certain provider specialty categories, including dental providers and urgent care. Several commenters requested greater transparency regarding how compliance with time and distance standards would be calculated.

Response: In response to requests for additional clarity, further details on which provider specialty types count towards each time and distance category; and how compliance with time

and distance standards are calculated, such information will be made available through materials such as the QHP Application Instructions, the ECP/NA template, Frequently Asked Questions and the final PY 2023 Letter to Issuers.

Comment: Several commenters expressed concern about county type designations. They requested that HHS develop parameters for updating county type designations; requested that HHS ensure that county type designations can accurately reflect counties with both rural and metropolitan areas; and encouraged HHS to monitor the functionality of county type designations across various types of States, to ensure meaningful provider availability.

Some commenters shared other suggestions regarding potential additions to time and distance standards, including requiring issuers to contract with all ECPs in the service area when provider shortages prevent the issuer from meeting time and distance standards. A commenter also suggested HHS consider possible interventions like provider incentives or transportation programs to assist areas experiencing provider shortages. One commenter requested that HHS systematically test network adequacy data submission and require issuers to provide additional information, like out-of-network claims data, to enhance HHS' understanding of how consumers are experiencing QHP networks in practice.

Response: HHS thanks commenters for their feedback regarding county type designations and possible additions to the time and distance requirements. HHS will need to further research these suggestions and their implications before considering them for future rulemaking.

Comment: A commenter encouraged HHS to require issuers to make telehealth psychiatry services available when Advanced Practice Registered Nurses (APRNs) are counted towards the Outpatient Clinical Behavioral Health category regardless of whether they are psychiatric APRNs.

Response: In the ECP/NA template, HHS will detail which taxonomy codes will crosswalk into each individual provider and facility specialty type. For Outpatient Clinical

Behavioral Health, only psychiatric APRNs would count towards this provider type; other APRNs are not included.

iii. Appointment Wait Times

For the certification cycle for PYs beginning in 2023, HHS proposed 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 proposed 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.

HHS proposed that 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 16 must be appropriately licensed, accredited, or certified to practice in their State, as applicable, and must have in-person services available.

TABLE 16: Final Provider Specialty List for Appointment Wait Time Standards

Provider/Facility Type
Behavioral Health
Primary Care (Routine)
Specialty Care (Non-Urgent)

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 proposed 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 proposed to codify the network adequacy justification process in regulation at § 156.230.

HHS sought 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 sought 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.

We are finalizing this policy as proposed and delaying the implementation of network adequacy reviews for appointment wait time standards until PY 2024.

We summarize and respond to public comments received on this policy below.

Comment: Many commenters from a variety of stakeholders supported the proposal to institute appointment wait time standards to assess the adequacy of provider networks. Other commenters suggested additions to and refinement of the list of categories for appointment wait time standards. Some commenters requested that the Primary Care (Routine) category apply to routine dental services, such as cleanings. Several commenters requested that HHS create separate appointment wait time standards for different levels of urgency, such as routine, urgent, and emergent, as well as discharge follow-up. One commenter requested that HHS apply appointment wait time standards to all individual providers and facility types. Other commenters

suggested separate appointment wait time categories for substance use disorder treatment services, oncology specialties, urgent care, family planning providers, and sexual health care providers. One commenter encouraged HHS to partner with patient groups to further refine appointment wait time standards.

Response: HHS agrees that implementing quantitative appointment wait time standards for network adequacy has multiple benefits, including helping ensure that QHP enrollees have timely access to care. We appreciate the feedback suggesting additions to and refinement of the list of categories for appointment wait time standards. HHS may pursue additional strategies to evaluate the appropriateness of appointment wait time standards for a variety of provider types. HHS also may engage with consumer groups on this topic as suggested in public comment for future policymaking. HHS will further assess these suggestions and consider them for future rulemaking.

Comment: Many commenters encouraged HHS to conduct additional oversight of provider networks throughout the year (outside of QHP certification), using strategies such as direct testing and monitoring of appointment wait times, to ensure enrollees have reasonable access to providers. One commenter requested that HHS consider providing funding for one entity in each State to conduct ongoing monitoring of appointment wait times.

Response: HHS is investigating approaches to monitor network adequacy outside of the QHP certification process. We appreciate commenters' suggestions on possible methods for additional oversight and will assess further prior to future rulemaking.

Comment: Some commenters suggested that appointment wait time standards be calculated using business days instead of calendar days to align with NCQA standards, some State network adequacy standards, and common business practices.

Response: Draft parameters for appointment wait time standards were detailed in the draft PY 2023 Letter to Issuers.³¹⁴ HHS agrees that aligning appointment standards with NCQA and some State network adequacy standards by using business days instead of calendar days will help minimize the burden and is reasonable given that many providers operate using business days. This change will be finalized in the final PY 2023 Letter to Issuers.

Comment: Some commenters opposed the implementation of the proposed appointment wait time standards, stating that the standards may be too dynamic, non-standardized, and beyond the control of issuers (and sometimes providers, particularly given the context of the COVID-19 pandemic). Some commenters expressed concern that the data collection required for the appointment wait time standards would be burdensome for issuers and providers, and they suggested possibly delaying the implementation of such standards to PY 2024 or beyond.

Response: HHS acknowledges that some stakeholders have concerns about the appointment wait time standards and the timeline for their implementation, including that appointment wait time requirements are not standardized, can be challenging for issuers to improve, and that data collection would be too burdensome. In recognition of those concerns, we have made several accommodations to the implementation of this new provision to ease the transition to this new standard. As noted above, HHS is finalizing appointment wait time standards, but delaying their implementation until PY 2024. HHS will also align the appointment wait time standards with appointment wait time standards used by NCQA and some States by using business days instead of calendar days.

Regarding concerns that appointment wait time requirements are not standardized, specific draft parameters for appointment wait times are described in the draft PY 2023 Letter to Issuers³¹⁵ and will be finalized in the final PY 2023 Letter to Issuers. The ECP/NA template³¹⁶

³¹⁴ 2023 Letter to Issuers in the Federally-facilitated Exchanges. CMS. (2022, January 7). <https://www.cms.gov/files/document/2023-draft-letter-issuers-508.pdf>.

³¹⁵ 2023 Letter to Issuers in the Federally-facilitated Exchanges. CMS. (2022, January 7). <https://www.cms.gov/files/document/2023-draft-letter-issuers-508.pdf>.

³¹⁶ Draft ECP/NA template: *Essential Community Providers and Network Adequacy*. CMS. <https://www.qhpcertification.cms.gov/s/ECP%20and%20Network%20Adequacy> .

shows which provider types crosswalk into which appointment wait time categories. We believe that the appointment wait time parameters are reasonable based on existing industry standards, such as those from NCQA and some States.

Issuers that do not yet meet the appointment wait time standards, once implemented in PY 2024, can use the justification process to update HHS on the progress of their contracting efforts for the respective plan year. HHS will review such justifications to determine whether the variance(s) described 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. HHS understands that some issuers may not already collect appointment wait time data, which is one of the reasons we are delaying the implementation of this requirement until PY 2024. Issuers that are unable to meet the specified standards would be able to submit a justification to account for variances.

Comment: Some commenters requested that SADPs either be exempt from compliance with appointment wait time standards or held to a lower compliance threshold than the threshold to which medical QHPs are held.

Response: We appreciate the feedback suggesting that SADPs be exempt from appointment wait time standards or held to a lower compliance threshold. We do not agree that SADPs should be exempt from compliance with appointment wait time standards or have a lower threshold applied than for medical QHPs. HHS believes it is important that timely access to care is ensured, regardless of plan type. Additionally, medical QHPs that have embedded dental benefits will be held to the same appointment wait standards for dental providers as SADPs. The compliance threshold is detailed in the draft PY 2023 Letter to Issuers³¹⁷ and will be finalized in the final PY 2023 Letter to Issuers.

³¹⁷ 2023 Letter to Issuers in the Federally-facilitated Exchanges. CMS. (2022, January 7). <https://www.cms.gov/files/document/2023-draft-letter-issuers-508.pdf>.

Comment: One commenter requested that HHS consider removing the requirement that providers have in-person services available to count towards these standards since some behavioral health providers only offer services via telehealth.

Response: We are aware that some providers only offer services via telehealth. We acknowledge the growing importance of telehealth, and we want to ensure that telehealth services do not displace the availability of in-person care. Consequently, we are finalizing that, to count towards the standards, providers must have in-person services available. Providers that do not have in-person services available will not be counted when assessing appointment wait times.

Comment: A commenter requested that appointment wait time standards should be overridden by provider assessment of when it would be appropriate for the enrollee to access care.

Response: We appreciate the suggestion that appointment wait time standards should be overridden by provider assessment of when it would be appropriate for the enrollee to access care. We will further assess this idea prior to considering it for future rulemaking.

Comment: A commenter requested that HHS allow issuers the opportunity to conduct outreach to providers and reassess appointment wait time measurement when they are not meeting the appointment wait time standards before any enforcement action would occur.

Response: We acknowledge the commenter's concern that issuers might be subject to enforcement action for not meeting appointment wait time standards without having the opportunity to come into compliance. HHS will work in partnership with issuers who are not yet meeting network adequacy standards and support their efforts to come into compliance as part of issuer compliance monitoring and workplans.

Comment: Some commenters requested more clarity, such as what provider types are included in the behavioral health category for appointment wait time standards, and how appointment wait time standards apply to dental providers. Commenters also inquired as to

whether the standards apply to appointments for existing patients, new patients, or both. Some commenters requested additional insight regarding methodological ambiguities related to the appointment wait time standards, including what period of time the standards will be based on, how the parameters of appointment wait time are defined, how to account for seasonality, and how to best validate this data.

Response: The provider types that filter into the Behavioral Health category for appointment wait time standards will be detailed in the Taxonomy Codes tab of the ECP/NA template.³¹⁸ For clarification on how appointment wait time standards apply to dental providers, all dental providers – general dentists and specialists – would be included in the Specialty Care category. Appointment wait time standards apply to both new and existing patients. In response to all other requests for additional clarity on the appointment wait time standards, including information on methodology, we will provide further information in the QHP Application Instructions, the ECP/NA template, Frequently Asked Questions, and the final PY 2023 Letter to Issuers.

In the proposed rule, HHS solicited comments on other ideas to strengthen network adequacy policy in future years and other aspects of QHP certification that impact health equity.

Comment: Several commenters suggested other ideas to strengthen and expand network adequacy policy in future years. Many commenters shared requests related to access to providers with certain competencies, skills, or specializations. Several commenters requested HHS consider standards that ensure a network provides an adequate supply of culturally and linguistically competent providers, and they requested that HHS have QHPs collect and display languages spoken by providers and their staff. Some commenters requested that HHS require that QHPs ensure access to providers who serve enrollees with rare, complex, or chronic health conditions, and providers who are culturally competent to serve LGBTQ+ individuals.

³¹⁸ Draft ECP/NA template: *Essential Community Providers and Network Adequacy*. CMS. <https://www.qhpcertification.cms.gov/s/ECP%20and%20Network%20Adequacy>.

We received several comments requesting that we consider a requirement for QHPs to track the number of providers accepting new patients throughout the year, and one request to have QHPs collect information on provider hours of operation. Some commenters requested that HHS collect and share data on provider demographics and report provider accessibility by public transit.

Some commenters suggested provider-enrollee ratios as an additional network adequacy standard to consider for future rulemaking. Several commenters were in favor of HHS developing unique standards for pediatric specialty providers and implementing enrollee ratios by specialty, geographic accessibility, and population density. Some commenters also requested that HHS define minimum appropriate provider standards to meet the needs of children with special health care needs as well as of diverse cultural, ethnic, and linguistic backgrounds. One commenter suggested HHS consider requiring issuers to report on the number of psychiatric providers and outpatient clinical behavioral health providers who have billed for services within a certain timeframe. Other commenters requested HHS measure the availability of integrated behavioral health in primary care.

Commenters encouraged the consideration of requiring issuers to report data by race and ethnicity on the population living in geographic areas that do not have access to providers within travel time and distance standards. Another commenter requested that HHS include auxiliary aids and services for people with disabilities, as well as data on the accessibility of all providers and facilities, in future network adequacy standards. One commenter requested that quality rating system measures be tied to network adequacy standards. Another commenter requested that provider non-discrimination policies be included in future rulemaking.

Response: HHS appreciates the suggestions on potential ways to enhance and grow network adequacy standards in the future. We will further assess these ideas prior to considering them for future rulemaking.

Comment: HHS also received numerous comments regarding suggestions for future rulemaking related to consumer protections. Many commenters requested further clarity on how QHPs can ensure enrollees can access care when not available in-network for their specific needs, which would include covering out-of-network providers at in-network cost sharing rates if a qualified provider is not available within the network or at the lowest cost-sharing tier. Some commenters also requested a clear complaint process for enrollees to report network adequacy issues. HHS received a comment requesting that QHP issuers be required to pay for interpretation services and auxiliary aids for contracted providers. Another commenter requested that HHS detail the actions that are taken when QHPs fail to meet network adequacy standards. Some comments received requested HHS consider the implications of MHPAEA on network adequacy standards.

Response: HHS appreciates the suggestions on potential ways to strengthen consumer protection through enhanced network adequacy standards in the future. We will further assess these ideas prior to considering them for future rulemaking.

Comment: HHS received some suggestions related to provider availability, such as requirements for issuers to provide reasonable notice of terminations of a provider's in-network status and allowing the ability for enrollees to change plans when provider availability in a network changes significantly.

Response: We acknowledge the suggestions related to provider availability, such as requirements for the issuer to provide reasonable notice of provider terminations. These recommendations also implicate provisions enacted in sections 113 and 116 of the No Surprises Act.³¹⁹ These provisions of No Surprises Act establish continuity of care protections³²⁰ in

³¹⁹ The Consolidated Appropriations Act, 2021 (CAA) was enacted on December 27, 2020 and includes Title I (No Surprises Act) in Division BB.

³²⁰ Section 9818 of the Code, section 718 of ERISA, and sections 2799A-3 and 2799B-8 of the PHS Act, as added by section 113 of division BB of the Consolidated Appropriations Act, 2021 (CAA) establish continuity of care protections in instances when terminations of certain contractual relationships result in changes in provider or facility network status. The Departments of HHS, Labor and Treasury have announced that until rulemaking is completed to fully implement these provisions, plans, issuers, providers, and facilities are expected to implement the

instances when terminations of certain contractual relationships result in changes in provider or facility network status and establish standards intended to protect participants, beneficiaries, and enrollees, such as a protocol for responding to requests about a provider's network participation status. HHS, along with the Departments of Labor and the Treasury, intends to issue future rulemaking or guidance to further implement those provisions, and will take these comments into account in developing such materials.

Comment: Some commenters shared feedback regarding the network breadth pilot, including both concern and support. HHS received some comments expressing that the network breadth pilot should not be continued in its current State. One commenter shared that the network breadth pilot is made more useful to consumers by using the actual percent participation value, prohibiting issuers from marketing plans based on the breadth categories, and allowing issuers to submit network adequacy data on machine-readable files. Some comments suggested that the network breadth methodology and labels be clarified as they can be confusing to consumers. HHS received one comment asking that the methodology be modified so that providers are not excluded based on taxonomies in the National Plan & Provider Enumeration System (NPPES) and that special types of PCPs are more appropriately documented. Some comments expressed support for the continuation of the network breadth pilot with its current labels.

Response: Although these comments were not within the scope of HHS' proposals on network adequacy presented in the proposed rule, HHS appreciates the comments received regarding the network breadth pilot. We will consider the above suggestions for future rulemaking after further assessment.

iv. Tiered Networks

HHS proposed 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

requirements using a good faith, reasonable interpretation of the statute. See FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49, <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf>.

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 the use of PPO network providers would result in higher cost-sharing obligations for the 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 proposed 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 sought 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.

After considering commenter concerns that the policy could unduly restrict plan network designs and innovation, we have decided not to finalize this policy. While we continue to believe this proposal has potential consumer protection benefits and would promote greater cost-sharing affordability, further research is warranted to evaluate the potential benefits and drawbacks of requiring providers to be contracted within the network tier that results in the lowest cost-sharing obligation in order for those providers to be counted towards satisfaction of the network adequacy standards.

We summarize and respond to public comments received on this policy below.

Comment: HHS received numerous comments in support of the proposal that for plans that use tiered networks, to count towards network adequacy standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. However, several commenters broadly opposed or cautioned against the lowest cost-sharing tier requirement, citing concerns that it would restrict the success of network innovation strategies,

such as value-based steering and contracting arrangements, or encourage issuers to remove the lowest cost-sharing tier entirely.

Response: We agree with commenters who supported the proposal as we concur that the proposal could help ensure that network adequacy standards provide reasonable access to care and help enhance health equity by enabling enrollees to access care at the lowest cost-sharing rate. Notwithstanding, we understand commenters' concerns that finalization of this policy could inadvertently restrict innovation and the issuers' ability to design and implement plan networks across all Exchange plans, which may result in decreased cost sharing for enrollees and decreases in overall health care costs. While we believe this proposal has potential benefits to consumer protection and affordability for cost sharing, we believe further research on the potential benefits and drawbacks is warranted prior to finalizing such a proposal.

Comment: One commenter suggested that a lower-cost virtual primary care option should not be considered a "lowest tier."

Response: While we are not finalizing this proposal regarding network tiering, we will consider this suggestion for future rulemaking.

Comment: Another commenter expressed that the network tiering requirement would not be appropriate for SADPs as tiered networks are uncommon for this plan type.

Response: We acknowledge that network tiers may be less common among SADPs. While we are not finalizing this proposal, we do not agree that any future network tiering requirements should not apply to SADPs – they simply would not be relevant for the particular QHPs (medical or SADPs) that do not use network tiers.

v. Telehealth Services

HHS proposed 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 proposed 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 the 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.

HHS sought comment on this proposal, including comments on how HHS might incorporate telehealth availability into network adequacy standards in future PYs. We specifically sought 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 for meeting time and distance standards.

We are finalizing this policy as proposed.

We summarize and respond to public comments received on this policy below.

Comment: Commenters expressed widespread support regarding the proposal to require issuers to identify which of their in-network providers offer telehealth services. Commenters also suggested additional telehealth information to consider collecting, like the availability of telemental health services and audio-only services, as well as tracking prescription digital therapeutics.

Response: HHS appreciates the comments received in support of the requirement for QHPs to report whether their in-network providers offer telehealth services. We agree that this data collection will be relevant to HHS' analysis of whether a QHP meets network adequacy standards and will help inform the future development of telehealth standards. We appreciate the suggestions regarding additional telehealth-related information that HHS could collect and will consider this for future rulemaking.

Comment: Some commenters requested that HHS either not require issuers to report telehealth service availability or delay the implementation of this requirement. These commenters expressed concern that collecting and reporting telehealth capability would be

overly burdensome for issuers and premature given the evolving nature of telehealth. One commenter suggested that telehealth data collection be delayed until a Federal database of provider telehealth availability is created. Several commenters requested that HHS minimize the burden related to telehealth data collection as much as possible, including one who suggested that State-level efforts might be able to be repurposed to gather this information. Some commenters stated that telehealth data collection and reporting is not appropriate for SADPs since telehealth is a newer modality for dental providers and the data collection and reporting may not lead to helpful insights at this time. One commenter suggested that HHS should incentivize QHPs to increase telehealth availability among their contracted providers as a benefit design rather than through network adequacy requirements.

Response: We understand some commenters are concerned about the implementation of telehealth data collection, including the timeline, due to the increased burden for issuers and that telehealth services are still evolving. HHS acknowledges that some commenters believe telehealth data collection is not appropriate for SADPs at this time due to the newness of tele-dentistry. We recognize that some QHPs may not have data available on whether their contracted providers offer telehealth and that for those QHPs, this data collection may result in an increased burden. Simultaneously, we understand that some QHPs may already have this information available through sources like provider surveys or claims data. While telehealth services continue to evolve for many specialties, including dental providers, we believe that collecting telehealth availability data at this point in time will provide key insights that can influence future policy development, and that these benefits outweigh the associated potential burden for some QHPs. We will work to minimize the burden where possible, like by providing technical assistance to issuers and allowing issuers flexibility with what methods they use to collect telehealth data.

Comment: Many commenters expressed that more research is needed to understand whether and how to count telehealth providers towards network adequacy standards. Numerous

commenters identified additional considerations for incorporating telehealth into network adequacy standards, such as inequities for rural and low-income providers, health plan location, broadband access, and variation in types and requirements of telehealth between providers and States. These commenters also emphasized that the appropriateness of telehealth should be a decision made between the patient and provider and that telehealth should not expand at the expense of available in-person care.

Several commenters shared suggestions with HHS regarding possible additional requirements related to telehealth services. Some commenters requested that we consider offering a telehealth credit for network adequacy standards, similar to Medicare Advantage. Some commenters stated telehealth standards and policies should ensure access to culturally, linguistically competent providers who can serve consumers with disabilities and should also increase access in low-income and geographically remote regions. One commenter encouraged HHS to adopt a separate national network adequacy standard for telehealth providers. Some commenters requested that HHS ensure telehealth information is reported promptly and that telehealth information is included in provider directories. One commenter suggested that HHS consider requiring QHPs to contract with telehealth services in areas where there are shortages of in-person providers.

Response: We concur with the recommendations from commenters that more research is needed before HHS could consider incorporating the availability of telehealth services into network adequacy policy for QHPs, such as a telehealth credit like Medicare Advantage. We also agree that telehealth services should be made available in addition to, rather than instead of, in-person care. HHS appreciates the suggestions received regarding additional requirements for telehealth services and other telehealth-related information that HHS could collect from QHPs. We will consider this information for future rulemaking. We thank commenters for their ideas about other ways to collect telehealth data, like a partnership with States, through a Federal

database on telehealth or encouraging telehealth services through other means. We will consider these ideas for future rulemaking.

vi. Solicitation of Comments – Unintended Impacts of Stronger Network Adequacy Standards

HHS is of the view that the network adequacy standards we included in the proposed 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.

We sought comment 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.

We summarize and respond to the comments received below.

Comment: Numerous commenters expressed diverse viewpoints regarding potential unintended impacts of stronger network adequacy standards. Several commenters expressed their belief that stronger network adequacy standards would not impact contracting negotiations between issuers and providers. Two commenters shared concerns that the proposed network adequacy standards could disproportionately harm smaller QHP issuers and reduce market competition. A commenter expressed apprehension that appointment wait time standards could be codified in provider contracting agreements and particularly harm providers that are in highest demand. Another commenter stated that the stronger network adequacy standards could help

mitigate declining provider reimbursement rates. One commenter encouraged consideration of a requirement for issuers to offer at least one QHP Statewide for each metal level at which they offer coverage to mitigate the risk of network adequacy standards disincentivizing QHP issuers from offering plans in rural counties. HHS received another comment asking us to consider potential cost implications of including specialized cancer providers in network adequacy requirements.

Some commenters requested that HHS not enact prohibitions against all-or-nothing contract clauses or steerage prohibitions, sharing concerns that such policies could limit enrollee access to providers. Another commenter encouraged HHS to consider regulation to eliminate all-or-nothing contract clauses, while a separate commenter expressed that they did not anticipate prohibition of all-or-nothing contract clauses would sufficiently protect plans from unintended consequences of network adequacy standards. One commenter suggested that any future regulation regarding restrictions on contracting terms should only be applied to provider types that would benefit from the network adequacy standards. One commenter shared that they had experienced regional struggles with all-or-nothing contract clauses in the context of QHPs and offered a further discussion on what they learned.

Response: HHS understands that stakeholders have a variety of opinions regarding the impact of stronger network adequacy standards, as well as all-or-nothing contracting clauses. We appreciate the feedback received and will consider it in future rulemaking.

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 was not 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 considered whether there is a need for greater alignment in FFE and State Exchange network adequacy standards.

HHS sought comment on whether a more coordinated, national approach to network adequacy rules across all Exchanges that is suited to address contemporary conditions in the health care markets is needed. For example, we sought 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 sought 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 sought 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.

We summarize and respond to the comments received below.

Comment: Commenters had mixed feedback on whether HHS should regulate network adequacy for all Exchanges, including setting standards and conducting reviews for QHPs in State Exchanges. Many commenters requested that regulators of State Exchanges be allowed to continue using their network adequacy standards and conducting their reviews. Some commenters suggested that HHS direct State network adequacy reviews, rather than conducting separate Federal reviews, to avoid duplication since some States have mandates to review network adequacy. Some commenters emphasized the importance of having only one applicable set of network adequacy standards per State. One commenter suggested that Federal network adequacy standards are not needed, as they stated was evidenced by high consumer satisfaction and consumer selection of narrow network plans. Many commenters requested that HHS extend Federal network adequacy standards to State Exchanges in future rulemaking. Several

commenters suggested that State alignment with Federal standards would be ideal, and that Federal standards should offer a strong floor that all States must meet.

Response: We appreciate the comments received and understand that there are diverse opinions regarding the appropriate regulator for network adequacy standards in State Exchanges. HHS will monitor existing network adequacy standards in State Exchanges relative to the Federal standards finalized in this rule and will consider whether application to State Exchanges in future PYs is warranted.

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 the inclusion of ECPs in QHP provider networks and provides an alternate standard for issuers that provide a majority of their covered professional 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 proposed 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, of available ECPs in the plan's service area. HHS proposed 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, in addition to satisfying the contract offering requirements described in § 156.235(a)(2)(ii) that require a plan to offer a contract to at least one ECP in each of the available ECP categories in each county in the plan's service area and offer a contract to all available Indian health care providers in the plan's service area. 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.

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. 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 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 proposed 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 the 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 proposed to codify the network tiering requirement for satisfying the ECP standard in regulation at § 156.235.

Additionally, for PY 2023 and beyond, HHS proposed that issuers could comply with the requirement at § 156.235(a)(2)(ii)(B) to offer 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 also considered 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 solicited 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 sought 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 sought 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 EO 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 sought comment on these proposals, including from ECPs and issuers serving low-income and medically underserved populations. HHS also sought comment on ideas for further strengthening ECP policy.

After reviewing the public comments, we are finalizing all provisions as proposed. Additionally, in response to comments we solicited on whether and how to clarify the “Other ECP Providers” requirement, we have amended the regulatory text at § 156.235(a)(2)(ii)(B) to clearly define the “Other ECP Providers” category, as follows:

At least one ECP in each of the six (6) ECP categories in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. The ECP categories are Federally Qualified Health Centers, Ryan White Program Providers, Family Planning Providers, Indian Health Care Providers, Inpatient Hospitals, and Other ECP Providers. The Other ECP Providers category includes the following types of providers: Substance Use Disorder Treatment Centers, Community Mental Health Centers, Rural Health Clinics, Black Lung Clinics, Hemophilia Treatment Centers, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics.

We summarize and respond to public comments received on essential community providers (§ 156.235) below.

Comment: The majority of commenters supported increasing the required ECP participation standard from 20 percent to 35 percent of available ECPs in the plan’s service area that are included within the applicable plan year HHS ECP list, citing expanded access to health care for vulnerable populations and improved health equity. Several of these commenters indicated that HHS should require QHPs to demonstrate that they can meet the 35 percent participation threshold in all ECP categories, or in specific categories such as Substance Use

Disorder Treatment Centers, Ryan White providers, hospitals, and each subcategory of “Other ECP Providers”; while other commenters suggested that HHS implement an “any willing provider” standard.

Response: We are finalizing the required ECP participation standard at 35 percent as proposed. Many commenters, including providers, provider associations, and consumer advocacy groups, supported the proposal to raise the ECP participation standard from 20 percent to 35 percent. In response to suggestions that HHS require QHPs to contract with 35 percent of the ECPs as applied to each of the specific categories of ECPs, HHS continues to require QHPs to contract with at least one ECP within each of the six ECP categories in each county in the issuer’s service area and believes the current approach better ensures geographic distribution of such ECPs in each of the six ECP categories across the issuer’s service area than applying the 35 percent threshold to each of the six ECP categories would achieve. Regarding commenters’ recommendations that HHS apply a 35 percent threshold standard to each of the six ECP categories and/or implement an “any willing provider” standard, HHS recognizes that issuer network participation negotiations are a tool that issuers use to manage costs, which are generally reflected in lower premium rates. Reducing issuers’ ability to limit the scope of their networks could eliminate that cost management tool and potentially cause premiums to increase substantially; therefore, we do not support these recommendations at this time.

Comment: While agreeing with the proposed increase to 35 percent, numerous commenters cautioned against a one-size-fits-all approach to ensure there are enough ECPs in all networks. Some commenters stated that a fixed percentage for all QHPs may not be sufficient to achieve the desired goal due to geographic areas varying in demographic composition, including the difficulty of meeting the 35 percent participation standard in rural areas. Some commenters stated that this standard could deter issuers from entering service areas with few ECPs.

Response: In response to concerns raised about potential difficulties meeting the increased standard in rural areas and other geographic areas that vary in demographic

composition that can lead to the presence of few ECPs, section 1311(c)(1)(C) of the Affordable Care Act requires that a QHP's network include ECPs, *where available*, that serve predominantly low income and medically-underserved populations. We reflect this in our regulations by permitting issuers that cannot meet the contracting standards to satisfy the QHP certification standard by submitting a justification. Therefore, the standard does not penalize issuers that cannot meet the ECP standard because of a lack of certain types of ECPs within a service area.

Comment: Several commenters opposed the increase of the required ECP provider participation standard from 20 percent to 35 percent of available ECPs in the plan's service area included within the applicable plan year HHS ECP list. These commenters expressed concern about the increased administrative burden and cost that the raised threshold would place on issuers and providers. A few commenters pointed out unintended negative consequences that could arise from the increased standard, including price increases for consumers. Some commenters recommended delaying any threshold increase until the 2024 plan year or implementing a more moderate increase for the 2023 plan year, from 20 to 25 percent, to account for this increased burden.

Response: Regarding commenters' concerns about the increase of the ECP threshold to 35 percent, we do not anticipate the majority of issuers having difficulty meeting the increased standard. For the plan year 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 contracting percentage across all FFE issuers was 55 percent and 54 percent, respectively. Given that during the 2015-2017 plan years, all issuers satisfied the 30 percent standard when permitted to supplement their QHP applications with ECP write-ins and justifications, CMS anticipates that any issuers falling shy of the 35 percent threshold for the 2023 plan year could satisfy the standard by relying on these same methods of compliance. Given issuers' success with meeting the 30 percent standard in previous plan years, HHS

believes that the 35 percent standard will provide both issuers and providers with sufficient flexibility to negotiate contract terms that do not lead to increased prices for consumers.

Accordingly, as we do not anticipate that compliance with this increased threshold will be too large a burden for issuers to meet for plan year 2023, we decline to delay implementation.

Comment: The majority of commenters supported the proposal to require QHPs with tiered networks to meet the ECP threshold in the lowest cost-sharing tier. One commenter noted that plans' preferred tiers often have providers that agree to accept more favorable rates and provide additional services such as coordinating care. The commenter stated that such plans should not be placed at a disadvantage for placing ECPs on a second general tier with providers that do not offer additional services.

Response: We are finalizing this provision as proposed. We intend to monitor consumer complaints regarding any potential disadvantages that could result from this requirement; however, we anticipate the benefit of the lowest cost-sharing tier requirement for low-income, medically underserved consumers, such as ensuring that these consumers can access an ECP provider offering essential health benefits through more affordable cost-sharing, to outweigh any disadvantages incurred by plans due to their choice of tiering structure.

Comment: In response to HHS' solicitation for comments on clarifying which providers may fit the category of "Other ECP Providers" in the regulatory text, two commenters recommended that HHS define the ECP category of "Other ECP Providers" in the regulatory text. Numerous commenters supported the addition of "Substance Use Disorder Treatment Centers" to the "Other ECP Providers" ECP category, including provider associations and advocacy groups. One commenter opposed the addition of Substance Use Disorder Treatment Centers to the "Other ECP Providers" ECP category, citing variability in the quality, oversight and services provided at such centers; another commenter noted HHS should explore how it will define "substance use treatment centers" and allow stakeholders additional time to comment prior to adding to the "Other ECP Providers" ECP category.

Response: In response to these comments recommending that we clarify the meaning of the ECP category of “Other ECP Providers,” we are amending § 156.235(a)(2)(ii)(B), as referenced in the preamble. The provider types that we have included in the ECP category of “Other ECP Providers” reflect, for the most part, those that have been listed within this ECP category in the Letter to Issuers in previous years and with whom many issuers have already been including in their provider networks. The only new provider type that we are adding to this ECP category of “Other ECP Providers” is Substance Use Disorder Treatment Centers. We are adding Substance Use Disorder Treatment Centers to the ECP category of “Other ECP Providers” as proposed. HHS will rely on the Substance Use Treatment Locator (<https://findtreatment.gov/>) made available by the Substance Abuse and Mental Health Services Administration (SAMHSA) to identify such treatment centers providing quality care to the consumers that they serve. This addition of Substance Use Disorder Treatment Centers effectively gives issuers an additional provider type by which they can satisfy the contract offering requirement for the ECP category of “Other ECP Providers” in each county in their service area. In some counties or service areas, depending on which types of ECPs are available, HHS acknowledges that this addition could decrease the chance that an issuer would choose to contract with another provider type grouped under the “Other ECP Providers” ECP category, but it is our opinion that adding this new category outweighs that potential effect because it is critically important to ensure access to SUD treatment to all consumers who require such treatment. Additionally, we note that issuers may increase access to a variety of providers by contracting with more than one available ECP per ECP category, including “Other ECP Providers,” in each county in their service area if they choose to do so.

Comment: Several commenters suggested that we disaggregate hemophilia treatment centers and behavioral health providers from the “Other ECP Providers” category and create new ECP categories for freestanding birth centers and for providers that are essential to specialized cancers such as brain tumors.

Response: In previous years, we have considered such recommendations to disaggregate provider types included in the “Other ECP Providers” ECP category and creating a separate ECP category for each, in addition to creating a separate ECP category for freestanding birth centers; however, because our analysis of the available ECPs in each of these ECP subcategories continues to indicate that there are too few ECPs within each of these provider types appearing on our ECP list to afford issuers sufficient flexibility in their contracting, we will not be disaggregating these subcategories of providers or creating new ECP categories at this time. While we may revisit this consideration in the future, we encourage QHP issuers to include in their networks these additional providers to best meet the needs of the populations they serve.

Comment: Two commenters recommended that HHS should improve the overall accuracy of the HHS ECP List.

Response: HHS has recently launched a monthly provider outreach initiative that automatically notifies providers on the HHS ECP List that they should revisit the online ECP petition to verify the accuracy of their data if they have not refreshed their provider data in over 12 months. Additionally, HHS has recently programmed additional validation checks within its online ECP petition to better ensure that only qualified providers can petition for inclusion on the HHS ECP List. Furthermore, HHS, through its operating divisions HRSA, SAMHSA, and along with other entities, continues to verify the operating status and qualifications of providers for inclusion on the HHS ECP List to help ensure that the number and types of providers to which issuers are held to contracting to satisfy the ECP standard reflect an accurate universe of qualified ECPs that are available within the issuer’s respective service area.

Comment: One commenter suggested that HHS should require QHPs to comply with ECP standards throughout the coverage year and report any material change in their ECP contracts to ensure that at no time their network falls below the ECP participation standard. Several commenters suggested HRSA’s HIV/AIDS Bureau monitor and enforce contracting requirements for Ryan White HIV/AIDS Program Providers.

Response: We appreciate commenters' suggestions on how to better monitor issuers' compliance with the ECP standard throughout the plan year and will consider different methods of enforcing compliance with the ECP standard in future plan years.

Comment: One commenter suggested that HHS include regulatory language specifying that good faith contract terms must include all of the services the plan covers and that the provider offers and include reimbursement at generally applicable payment rates; another suggested that HHS require QHPs to contract with ECPs at a reimbursement level no lower than the established rate at which they are compensated under Medicaid or Medicare to ensure that ECPs have a financial incentive to participate. Another commenter requested that HHS include in guidance that health systems contract with ECPs separately.

Response: Comments on good faith contract terms and reimbursement rates are out of the scope of this rule. However, we expect issuers to comply with existing regulatory provisions³²¹ and sub-regulatory guidance³²² that may apply to these topics.

Comment: One commenter recommended that HHS eliminate QHP issuers' option to submit a narrative justification that describes why they could not meet the standard but still have a network that is sufficient to meet the needs of low-income and underserved enrollees.

Response: We appreciate the commenter's recommendation to eliminate the option for issuers to submit a narrative justification to satisfy the ECP standard. More information on changes to the ECP justification process for the plan year 2023, including the format of the justification and how and where it will be submitted, will be made available through forthcoming materials, including the QHP Application Instructions, the ECP/NA template, the ECP Tools, Frequently Asked Questions, and the Final Plan Year 2023 Letter to Issuers.

³²¹ 45 CFR 156.235(d) and (e).

³²² 2018 Letter to Issuers in the Federally-facilitated Marketplaces (2017, February 17). CMS. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-marketplaces-and-February-17-Addendum.pdf>.

Comment: Several commenters recommended that HHS should include information on which ECPs have telemedicine services available on the HHS ECP List. One State expressed support for ECPs offering telehealth services because consumers seeking care in their first language could benefit from telehealth services provided by ECPs. Several commenters urged that HHS monitor the use of telehealth services to ensure that they do not undermine access to care protections. Commenters cautioned that allowing issuers to meet the ECP participation standard with telehealth services in lieu of in-person care could improve health care access in some areas while jeopardizing care quality and exacerbating health inequities in other areas.

Response: We appreciate commenters' recommendations for integrating telehealth services into the ECP list. We acknowledge concerns that telehealth should not be used as a substitute for in-person care. We will consider these recommendations for adding telehealth services information to the ECP list in future rulemaking.

13. Standards for Downstream and Delegated Entities (§ 156.340)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 686), we proposed 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. We proposed 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. We refer readers to the proposed rule for a more detailed discussion of the proposal and its supporting rationale (87 FR 686 through 687).

After reviewing the public comments, and based on the rationale provided in the proposed rule and in this rule, we are finalizing the amendments to § 156.340, as proposed, to clarify and strengthen requirements holding 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 are also finalizing the proposal 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."

We summarize and respond to public comments received on standards for QHP issuer downstream and delegated entities (§ 156.340).

Comment: The commenters expressed support for the proposed amendments to § 156.340 and lauded its clarification and its strengthening of oversight standards for QHP issuers toward their downstream and delegated entities with regard to relevant Exchange regulations. One commenter stated that they supported the changes proposed because they clarify that QHP issuers and their downstream and delegated entities remain responsible for complying with all Federal requirements, including QHP certification standards, Exchange processes and procedures, the maintenance of records, and enrollment rules for agents, brokers, and web-brokers. Another commenter stated the increased requirements for QHP issuers to hold their downstream and delegated entities accountable, including the increased record-keeping requirements, are essential to hold QHP issuers accountable for meeting applicable federally-defined performance standards and without that accountability, issuers could evade those standards by delegating duties to other entities which could avoid accountability by "neither maintaining records, nor reporting data showing compliance".

Response: We appreciate the support for the proposed amendments to § 156.340 and the accompanying clarification of the standards applicable to QHP issuers and their downstream and delegated entities in all Exchange models. These comments articulate the reasons behind the decision to make the amendments and clarifications to the 156.340. Moreover, these supportive commenters describe the scenario the changes are intended to prevent or mitigate: evasion by issuers of applicable Exchange requirements by the delegation of duties to entities otherwise capable of avoiding accountability. By codifying a regulatory requirement that holds QHP issuers in all Exchange models responsible for compliance with Exchange requirements by their downstream and delegated entities, the appropriate Exchange authority can ensure compliance with applicable requirements and hold issuers accountable for their actions and the actions of their downstream and delegated entities in situations of non-compliance.

Comment: Several commenters were not supportive of the proposal and objected to the language as it pertains to the record retention requirement in the new paragraph (b)(5) as overly broad. These commenters expressed concern that the proposed new record retention requirement in § 156.340(b)(5) appeared to give HHS access to “virtually all data and information,” including consumer data maintained by the downstream and delegated entities, and that it would enable HHS to go on a “fishing expedition” for information unrelated to Exchange activity. One commenter suggested the proposed requirement in new paragraph (b)(5) would place “undue burden” on downstream and delegated entities and also echoed the perception that it provides HHS with “unyielding authority” to request information from them, but did not otherwise quantify or further define these concerns. Some commenters also requested additional guidance about the types of information downstream and delegated entities would have to provide, and generally requested modification of the regulatory language in new paragraph (b)(5) to be more specific and limited in scope. Several commenters made general requests that the documents and systems to which the relevant authority may request access pursuant to the downstream and delegated entity’s Exchange activities be limited without

providing examples. One commenter requested an exception to permit downstream and delegated entities to challenge requests that would be “commercially impracticable.” The commenter also requested the language in paragraph (b)(5) be limited to requests and information that are of such vital importance to Exchange operations that the Exchange could not operate without the disclosure. The commenter did not include data or information to support these assertions, describe what constituted “commercially impracticable” requests, or provide examples of what would constitute an instance that might be of such vital importance to Exchange operations.

Response: We respectfully disagree with the comments suggesting the language required in Exchange agreements between QHP issuers and downstream and delegated entities by new paragraph (b)(5) expands HHS’ authority to demand information, making it unlimited in scope and imposing new risk and undue burden on both QHP issuers and their downstream and delegated entities. The amendments to § 156.340(b)(5) make clear and explicit in regulation downstream and delegated entity obligations to maintain Exchange-related records and comply with the relevant Exchange authority’s demand to receive the entity’s books, contracts, computers or other electronic systems relating to the QHP issuer’s obligations in accordance with applicable Federal Exchange standards. Because the provision applies to all types of Exchange, including State Exchanges, HHS is not inclined to be overly prescriptive with regard to provision of more specific guidance. More descriptive details will be provided by the relevant Exchange authority. With regard to information that could be requested by HHS, as administrator of the FFE, more specificity is provided in § 156.715, which describes the records and information requested of FFE and SBE-FP issuers during compliance reviews. By way of a further illustrative example, documents that are typically requested as part of compliance reviews under § 156.715 include, but are not limited to; issuers’ contracts with all downstream and delegated entities for Exchange-specific language, records of agent and broker registration and training, and records of the handling of complaints concerning affiliated agents, brokers, and

web-brokers. While we generally anticipate requesting similar information from downstream and delegated entities under § 156.340(b)(5), we emphasize that the exact information, data, records, books, contracts, computers, and electronic systems that could be requested as part of a review under § 156.340(b)(5) will vary depending on the facts and circumstances at hand. We also affirm that, like the existing authority in § 156.340(b)(4), the authority captured in § 156.340(b)(5) is specific to Exchange operations.

We also disagree that the record retention requirement in new paragraph (b)(5) is overly broad or that it would allow HHS to request or access information unrelated to Exchange activity. This regulatory provision is narrowly drafted and codifies the relevant Exchange authority's – that is, the State Exchange, the FFE, or the SBE-FP – right to access records that are related to the QHP issuer's participation in the relevant Exchange to confirm compliance with applicable Federal Exchange standards. As such, under § 156.340(b)(5), the relevant Exchange authority can demand and receive information on consumers enrolled in the Exchange from a downstream or delegated entity of a QHP issuer participating on its Exchange to ensure or otherwise confirm compliance with applicable Federal Exchange standards. Additionally, HHS has authority to access the records of downstream and delegated entities of QHP issuers participating in FFEs and Exchanges using the Federal platform under the existing requirements in § 156.340(b)(4).³²³ Affirming HHS' authority to access this information, as the relevant Exchange authority for FFEs, while codifying similar rights for State Exchanges when they are the relevant Exchange authority, in new paragraph (b)(5) does not represent an expansion of HHS authority or access to records. To that end, by affirming the relevant Exchange authority's right to access information for purposes of ensuring all entities participating in or supporting another entity's participation in the Exchange are compliant with applicable Federal Exchange

³²³ As noted above, the existing text at § 156.340(b)(4) requires downstream and delegated entities of QHP issuers participating in FFEs or SBE-FPs to provide HHS access to the entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations with applicable Exchange standards.

standards, HHS declines to incorporate language in the regulation that would limit this authority to situations concerning issues of vital importance to the Exchange. We did not propose such a limitation and further note that the establishment of such a restriction would require further notice with comment rulemaking to define the phrase and identify parameters for what could constitute issuers of “vital importance” to the Exchange. The suggested limitation could also create unnecessary barriers to the relevant Exchange authority accessing information relevant to Exchange operations and compliance of regulated entities with applicable Federal Exchange standards. Finally, we note the adoption of a 10-year standard in § 156.340(b)(5) aligns with other Exchange record retention requirements. Therefore, it too, does not represent an expansion of record retention obligations for QHP issuers participating in Exchanges or their downstream and delegated entities pertaining to Exchange related records, data, information, or systems. We also did not propose and decline to adopt in this rule an exception or carve-out. The adoption of these amendments is intended to make clear the obligations and responsibilities of all QHP issuers participating in all Exchanges models, and all of their downstream and delegated entities with no exceptions. However, as the relevant Exchange authority for the FFEs, we welcome an open dialogue with QHP issuers and their downstream and delegated entities about the burdens and time associated with complying with any particular request for records under § 156.340(b)(5). We encourage State Exchanges to similarly be open to such conversations.

Comment: Additionally, several commenters expressed concern about the impact the changes could have on agreements and contract negotiations between issuers and potential and existing downstream or delegated entities. One commenter suggested the language required by new paragraph (b)(5) could bring contract negotiations to a “stalemate” or considerably slow them down, because it requires both downstream and delegated entities and QHP issuers submit to the Exchange’s authority to “request any information they desire under the pretext of Federal standards.” The commenter did not provide further information or evidence to support the claim that the Federal standards have been used as a pretext to demand information unrelated to

Exchange activity.³²⁴ Another commenter suggested the language in new paragraph (b)(5) would increase downstream and delegated entities' responsibility and risk, potentially causing them to raise their rates, but did not specify what additional responsibility or risk the downstream and delegated entities would assume. That commenter also recommended that responses to inquiries pursuant to paragraph (b)(4) and new paragraph (b)(5) from the relevant Exchange authority come directly from the downstream or delegated entity, when applicable, and not flow through the QHP issuer. The commenter did not provide the rationale for this recommendation.

Two commenters also expressed concern with respect to the proposed applicability date and the timing for implementation of any necessary change(s) to contract language. They indicated contracts will have to be modified, and 60 days from rule publication is not sufficient to come into compliance with the requirement. Additionally, a commenter requested a burden estimate for modification of contracts, pursuant to the comment, summarized above, that the inclusion of the contract language constitutes a significant change that would impose an "undue burden" on QHP issuers and downstream and delegated entities. The commenters did not provide an explanation for why the contract modifications required more time, or describe the nature of the "undue burden" beyond the suggestion of HHS overreach due to language that it asserted was not sufficiently narrow or specific. No data or information beyond these general assertions was presented to substantiate the request for a new implementation date.

One commenter indicated that while it agreed QHP issuers should retain full oversight over downstream and delegated entities, it objected to what it characterized as the imposition of required contract terms by new paragraph (b)(5), on the grounds that each organization should be free to contract in a manner governed by their own risk tolerance. The commenter offered

³²⁴ As noted above, we disagree with this assertion. Affirming HHS' authority to access this information, as the relevant Exchange authority for FFEs, in new paragraph (b)(5) while codifying similar rights for State Exchanges when they are the relevant Exchange authority does not represent an expansion of HHS authority or access to records or otherwise allow HHS to request or access information unrelated to Exchange activity.

several alternative options, including “required written delegation agreements with performance report expectations for content and frequency” and “documented and recorded annual audits of each delegated entity’s performance, which the issuer properly distributes for review and approval by the issuer’s governing body.” However, the commenter did not provide an explanation as to why these recommendations were preferable to inclusion of the issuer’s oversight obligations in its agreements with downstream and delegated entities. A different commenter expressed support for clarifying that the general obligations and requirements regarding downstream and delegated entities of QHP issuers are applicable across all Exchanges types, but requested an explanation as to the reason for the clarification. The commenter noted that if the reason for requiring explicit contract language in agreements between QHP issuers and their downstream and delegated entities is to align with MA requirements, such alignment would be inappropriate, given the “significant differences” between the two programs. The commenter further explained that the Federal government has financial obligations to MA programs and assumes some of the enrollees’ risk with regard to claims, whereas the QHP issuers on the Exchanges assume all risk with regard to enrollees’ claims.

Response: As explained above and in the proposed rule, the proposed amendments to § 156.340 were drafted so QHP issuers on all Exchange types are subject to the same minimum downstream and delegated entity standards. HHS is finalizing these amendments as proposed to 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. HHS appreciates the comments about the burdens associated with implementation of the amendments; however, we are finalizing the implementation date and burden estimates as proposed and without changes, as we disagree that there is a significant or “undue” burden associated with these amendments. No evidence has been provided substantiating any added

burden is placed on the downstream and delegated entities or on the QHP issuers, and while HHS appreciates the entities' desire to contract with respect to their own risk tolerance, the requirement that issuers maintain oversight and accountability for their downstream and delegated entities' actions is not a new requirement. The alternative methods proposed by the commenter, such as required written delegation agreements with performance report expectations for content and frequency, would likely be more onerous and inflexible for both the issuer and its downstream or delegated entity than modification of existing contracts to include language describing risk the issuer has already assumed by engaging the downstream or delegated entity's assistance with Exchange related activities, because the suggested alternatives would also require drafting entirely new documents, follow-up, and evaluation of performance metrics. In addition, the commenters did not provide any evidence or information to support their general assertions about the "undue burden" and additional time needed to modify contracts. As explained in the proposed rule, we anticipate the amendments to § 156.340 will impose minimal burden on QHP issuers and Exchange authorities. We recognize that some QHP issuers may need to make changes to existing record retention policies and their agreements with delegated and downstream entities. But since issuers participating in FFEs and SBE-FPs were already subject to the existing downstream and delegated entity standards in § 156.340, and to HHS' existing authority to request records under § 156.715, and commenters did not provide analysis or other information to substantiate the request for a new implementation date, that record requests should flow through the downstream or delegated entity and not the issuer, or support the claims of "undue burden," HHS will finalize the amendments to § 156.340 as proposed.

We recognize there are differences between the Medicare Advantage program and the Exchanges. For example, the populations served are different. Also, as noted in the comment submitted, HHS subsidizes premiums for qualified individuals enrolled in Exchange coverage, but it is not responsible for or at risk for claims incurred by Exchange enrollee the way it does

for Medicare Advantage coverage. Notwithstanding these differences, there are also similarities and the use of downstream and delegated entities by the regulated entity is one example of a similarity. As such, our intention is to learn from and leverage the experience from the Medicare Advantage program, where appropriate. As explained when we first established the QHP issuer downstream and delegated entity standards in § 156.340, we believe the most legally effective way to ensure that a QHP issuer retains the necessary control and oversight over its downstream or delegated entities is to require that all agreements governing the relationships among a QHP issuer and its delegated and downstream entities contain provisions specifically describing each of the downstream and delegated entity's obligations.³²⁵ We looked to the existing standards for entities that contract with Medicare Advantage organizations at 42 CFR 422.504(i)(3)-(4) as a guide because it was a framework familiar to HHS, regulated entities, other stakeholders, as well as the general public. It also met the goals of protecting consumers from harm and holding QHP issuers and their downstream and delegated entities accountable for compliance with applicable Federal Exchange requirements.

In this final rule, we clarify and extend the requirements in § 156.340 to 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.

14. Payment for Cost-Sharing Reductions – Clarification of CSR Payment and Data Collection Processes (§ 156.430)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 687 through 688), we proposed 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

³²⁵ See 78 FR 37056. Also see 78 FR 54120.

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.³²⁶ As a result, CSR payments ceased as of October 12, 2017. 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 proposed to amend § 156.430 to state 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 proposed several modifications to § 156.430. First, we proposed 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 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 proposed 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 proposed 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

³²⁶ *Payments to Issuers for Cost-Sharing Reductions (CSRs)*. (2017, October 12). HHS. <https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf>.

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 proposed 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 it would be voluntary for issuers that did not receive CSR 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 proposed 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 proposed 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 noted that, regardless of whether HHS makes CSR payments, issuers are required to provide CSRs to enrollees as specified at § 155.1030. We sought comment on these proposals.

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

We summarize and respond to public comments received on payment for cost-sharing reductions – clarification of CSR payment and data collection processes (§ 156.430) below.

Comment: One commenter supported the proposals.

Response: We appreciate the support and are finalizing, as proposed, that CSR 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.

Comment: Another commenter requested additional clarification on how the proposals would impact the existing CSR reconciliation data submission process and schedule before HHS implements any changes.

Response: These amendments are not intended to change the existing CSR data submission process or schedule. In October 2017, the Attorney General declared that the government could not make CSR payments in the absence of an appropriation, and that because there was no appropriation, CSR payments must stop.³²⁷ HHS then announced that CSR payments would be discontinued until an appropriation exists.³²⁸ HHS has not made advance CSR payments for any period since October 2017 due to a lack of an appropriation. Also, in the absence of an appropriation, HHS cannot make CSR reconciliation payments for any past period. Because of this, since the 2018 benefit year, HHS has made the CSR data submission process optional. To this effect, HHS has periodically provided issuers an annual optional window to submit CSR data and restatements in light of ongoing litigation. Under the amendments finalized in this rule, the CSR data submission process would continue in the same manner as it has been operated since the 2018 benefit year CSR data submission, and these amendments are merely

³²⁷ Ibid.

³²⁸ Ibid.

aligning our regulations with existing operations. If HHS makes CSR payments to QHP issuers in the future, HHS will notify QHP issuers that a CSR data submission will be mandatory for any issuers receiving CSR payments for any part of the benefit year.

Additionally, these amendments do not impact the CSR data submission schedule. Consistent with past benefit years, the timing of the CSR data submission process will continue to be announced annually in guidance.

15. 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 five health care topic areas identified 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 (80 FR 10750), HHS established a phase-in approach for QIS implementation standards and reporting requirements to provide QHP issuers time to understand the populations enrolling in a QHP offered through the Exchange and to build quality performance data on their respective QHP enrollees.³²⁹ 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

³²⁹ 80 FR 10750, 10844 (2015, February 27).

improvement, and provide increased reimbursement to their providers or other market-based incentives to reward achievement of those goals.³³⁰

In line with this approach and under the same authorities, in the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 688), HHS proposed 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 proposed 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 proposed this expansion of the QIS standards, which aligns with health equity efforts across Federal government policies and programs; however, we did not propose 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 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.^{331, 332, 333, 334, 335, 336, 337} 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

³³⁰ Ibid.

³³¹ Lindenauer, P. K., Lagu, T., Rothberg, M. B., Avrunin, J., Pekow, P. S., Wang, Y., Krumholz, H., & Hines, H. (2013). Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *British Medical Journal*.

³³² Trivedi, A. N., Nsa, W., Hausmann, L. R. M., Lee, J., Ma, A., Bratzler, D., Mor, M., Baus, K., Larbi, F., & Fine, M. (2014). Quality and Equity of Care in U.S. Hospitals. *New England Journal of Medicine*. 371(24):2298-2308.

³³³ Polyakova, M., Udalova, V., Kocks, G., Genadek, K., Finlay, K., & Finkelstein, A. N. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. *Health affairs (Project Hope)*, 40(2), 307–316. <https://doi.org/10.1377/hlthaff.2020.02142>.

³³⁴ *Rural Communities: Age, Income, and Health Status. Rural Health Research Recap*. (2018). Rural Health Research Gateway. <https://www.ruralhealthresearch.org/recaps/5>.

³³⁵ *2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities*. (2020). HHS Office of Minority Health. https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.

³³⁶ *Sexual Orientation Disparities in Risk Factors for Adverse COVID-19-Related Outcomes, by Race/Ethnicity*. (2021, February 5). CDC. www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.

³³⁷ Poteat, T. C., Reisner, S. L., Miller, M., & Wirtz, A. L. (2020). COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. *medRxiv: the preprint server for health sciences*, 2020.07.21.20159327. <https://doi.org/10.1101/2020.07.21.20159327>.

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.³³⁸

We are specifically committed to achieving equity in health care outcomes for QHP enrollees by supporting QHP issuer 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 final 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.”³³⁹ 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, we are strengthening efforts across all programs to address disparities and advance health equity. In addition, this is a topic area that QHP issuers across the Exchanges have increasingly been focusing on in their QIS submissions.

A CMS evaluation of QHP issuer QIS submissions in the FFEs in PY 2020 found that an estimated 60 percent of QIS submissions addressed health care disparities. Building on the phase-in approach established in the 2016 Payment Notice and our experiences evaluating QIS submissions over the years and during the COVID-19 PHE, we proposed to update the QIS

³³⁸ Guth, M., Garfield, R., & Rudowitz, R. (2020). The Effects of Medicaid Expansion Under the ACA: Studies from January 2014 to January 2020. *Kaiser Family Foundation*. <https://www.kff.org/medicaid/report/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review/>.

³³⁹ 86 FR 7009 (2021, January 25).

standards. We proposed 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. However, we did not propose amendments to the regulatory text outlined in § 156.1130. We sought comment on this proposal.

We summarize and respond to public comments received on the quality improvement strategy (§ 156.1130) proposal. After reviewing commenter responses, we are finalizing as proposed.

Comment: Many commenters supported the proposal to expand QIS standards to require issuers to address health and health care disparities in addition to one other topic area identified in section 1311(g)(1) of the ACA as part of their QIS beginning in 2023. Specifically, commenters expressed strong support for the increased focus on health and health care disparities within the QIS standards and achieving equity in health outcomes for QHP enrollees, as well as driving accountability for advancing health equity.

Response: We appreciate commenters' support to expand QIS standards to require QHP issuers address health and health care disparities which aligns with health equity efforts across Federal government policies and programs. QHP issuers in all Exchange model types will be required to address health and health care disparities in addition to one other topic area identified in section 1311(g)(1) of the ACA as part of their QIS beginning in 2023. This new guideline will apply for the first time to the QIS submissions QHP issuers provide to Exchanges in the 2023 calendar year, which would describe the issuer's strategy for addressing health and health care disparities for the 2024 Plan Year, beginning on January 1, 2024.

Comment: Several commenters stated that although the proposed QIS policy ties effective performance on reducing health and health care inequities to financial reward, the current proposal does not go far enough to advance health equity. Some commenters urged CMS to require more public transparency and accountability about the process of selecting, implementing, evaluating, and reporting the outcomes of QIS interventions to ensure QHPs

prioritize health equity work. These commenters noted that currently there are no public reporting requirements for QIS activities (for example no list of QIS topics selected, no public report on progress or successful outcomes).

Response: We appreciate the comments on the proposals to expand QIS standards to address health and health care disparities and clarify that the QIS statutory provisions do not tie performance within a QIS to a financial reward for issuers. Instead, section 1311(g)(1) of the ACA defines a QIS as a payment structure developed by issuers that provides increased reimbursement or other market-based incentives for improving health outcomes of plan enrollees (for example, through provider incentives such as increased reimbursement or bonus payments, or through enrollee financial incentives such as a monetary reduction of enrollee premiums and other out-of-pocket costs). Thus, consistent with the requirement in section 1311(c)(1)(E) of the ACA, QHP issuers must implement a QIS and they are required to incorporate market-based incentives within their respective QIS programs. We also acknowledge commenters' requests for greater public transparency and interest in greater accountability regarding the process QHP issuers undertake to select, implement, evaluate, and report the outcomes of disparity-related QIS programs. Unlike other Exchange quality programs, section 1311(c)(1)(E) and (g) of the ACA do not provide for the public reporting of data on QHP issuer QIS programs.³⁴⁰ Instead, the QIS requirements focus on collection of information by Exchanges from issuers within QIS forms to demonstrate compliance with the QHP certification requirements in section 1311(c)(1)(E) of the ACA. The collection of this information also facilitates the Exchange's understanding of its QHP issuers' payment structure frameworks that provide increased reimbursement or other market-based incentives for the implementation of activities related to the topics specified in section 1311(g) of the ACA. We recognize issuers use proprietary information in their QIS submissions they may not want published, and that their strategies may contain confidential information about

³⁴⁰ Compare, for example, the statutory provisions that established the Quality Rating System and Enrollee Satisfaction Survey, which require Exchanges to publish information on their respective websites. See sections 1311(c)(3) and (c)(4) of the ACA. Also see 45 CFR 155.1400 and 155.1405.

their enrollee populations. Additionally, QIS requirements provide issuers flexibility in meeting this certification requirement by allowing diverse, qualitative, non-standardized information that would not be easily and clearly shared publicly.

We further note that the policy adopted in this final rule seeks to align the QIS with other Federal quality standards related to data collection efforts and disclosure of information focused on quality improvement and advancing health equity, which includes balancing the desire to encourage transparency with the need to safeguard confidential and proprietary information. Some types of confidential and proprietary information include the tools, resources, and data sets issuers use in describing their quality improvement strategies within their QIS forms. For example, an issuer may have concerns disseminating a patient data collection tool they consider proprietary that is described within their QIS to a wider audience. Furthermore, some issuers choose to report on their internal quality improvement progress using measures that are included within other performance programs, and that may not be fully validated at the time they submit their QIS during the applicable benefit year's QHP Application Period. Finally, some issuers use internally developed measures they consider proprietary that are not intended for public reporting. At the same time, however, we understand the interest in the public reporting of QIS information, and HHS will continue to consider if there are ways or subsets of QIS information could be publicly released.

Comment: Several commenters noted that QHPs should have to seek input from underserved enrollees or stakeholders who represent underserved communities to guide their QIS activity selection.

Response: We appreciate the feedback related to QHP issuers seeking input from underserved enrollees or stakeholders who represent underserved communities to guide their QIS activity selection and to shape which activities they prioritize when addressing health or health care equity. HHS agrees that such feedback would help guide issuer development of QIS programs that target the needs of their specific populations, including those in underserved

communities. HHS will consider including language further encouraging these outreach activities in the 2024 Plan Year Technical Guidance, which will inform submissions in the 2023 calendar year. However, we did not propose and decline to adopt a requirement mandating such outreach in this final rule.

Comment: A few commenters noted that QHP issuers may face barriers when collecting race, ethnicity, language and other data on certain sub-populations, including consumers in underserved communities. Commenters expressed that these barriers may be due to a lack of standardization across State and Federal data collection requirements. Commenters also recommended HHS consider approaches to standardize data collection that includes collection of information that may be used to develop tailored quality improvement strategies. Two commenters urged HHS to address data collection barriers and delay finalizing the QIS proposal until issuers have more robust data to identify disparities. The commenters noted that when race and ethnicity or social determinant of health (SDOH) data is collected, relatively few individuals voluntarily provide this information to their health plans due to concerns about how the data will be used, and that the data available to issuers to identify health care disparities is limited and may vary by issuer due to State laws limiting the data issuers can collect. One commenter recommended that, for QIS standards, HHS should define disparities more broadly, beyond race, ethnicity, and language, which may not apply to every health plan, and reiterated that HHS should use a broad definition that encompasses other factors such as LGBTQI+ status, location (rural/urban), and physical and mental disabilities.

Response: We recognize QHP issuers may experience barriers or other challenges when collecting certain data and that State and Federal data collection requirements for race, ethnicity, language, and other data on certain populations are currently not standardized. There are many reasons why the data collection requirements may not be standardized, including different statutory authorities and mandated data elements. The proposals being finalized in this rule are limited and specific to the QIS requirements under section 1311(c)(1)(E) of the ACA applicable

to QHP issuers participating in Exchanges. The QIS statutory provisions do not provide HHS authority to standardize State and Federal data collection requirements or remove barriers that may exist with respect to collection of race, ethnicity, language and other data on certain sub-populations, including consumers in underserved communities. However, the QIS statute and the HHS implementing regulations provide a mechanism to encourage QHP issuers participating in Exchanges to focus more efforts on addressing health and health disparities. Section 1311(g)(1) of the ACA explicitly identifies the implementation of activities to reduce health and health care disparities, including through the use of language services, community outreach, and cultural competency trainings, as one of the topic areas for QHP issuer QIS programs. Issuers operating in States that have laws that limit the collection of certain data may have to rely on other data sources or indirect estimation (for example, geographic assignment, Bayesian indirect surname and geocoding) to incorporate activities to reduce health and health care disparities in their QIS programs. Similarly, issuers who do not have access to this type of data through existing data sources (for example, if enrollees decline to provide this information) will also have to identify other resources that can be used for this purpose. We are also aware of and intend to continue to monitor the development of industry standards, as well as State law activity, applicable to the collection and use of race and ethnicity data elements. As industry standards and state laws applicable to the collection and use of race and ethnicity data elements evolve, HHS will consider whether any changes to the QIS program requirements would be appropriate.

Flexibility is one of the key foundational principles of the QIS, and we intend to continue to offer flexibility to encourage issuer innovation and to promote a culture of continuous quality improvement. This will include taking into consideration steps issuers take to expand their data collection efforts to support QIS activities that address health and health care disparities (along with the other QIS topics identified in section 1311(g)(1) of the ACA). With respect to the new QIS guideline finalized in this rule, as noted above, we anticipate that indirect estimation (for example, geographic assignment, Bayesian indirect surname and geocoding) may be used by

issuers until such time in which issuers are able to directly collect data, such as race, ethnicity, and language, to analyze and address potential health and health care disparities. For example, NCQA introduced race and ethnicity stratifications for select Healthcare Effectiveness Data and Information Set (HEDIS®) measures,³⁴¹ which allows an organization to report the stratification using their own directly collected member data as well as report directly collected data supplemented with indirect race and ethnicity data. QHP issuers would be permitted to take a similar approach for the development of their QIS programs and the incorporation of activities to reduce health and health care disparities. For this reason, we do not believe it is necessary to delay finalization of the QIS proposal until HHS has addressed data collection barriers or until issuers have more robust data to identify disparities.

Additionally, we emphasize that the requirement adopted in this final rule that requires QHP issuers to address health and health care disparities as a specific topic area within their QIS beginning in 2023 is not limited to implementing strategies that solely focus on race and ethnicity health and health care disparities. Nor does it mandate the collection and submission of individual enrollee's race and ethnicity data to HHS. QHP issuers will have flexibility in how they elect to address and define health and health care disparities in their QIS. For example, QHP issuers could focus on enrollee populations that belong to a racial or ethnic minority group, live with a disability, identify as a member of the LGBTQI+ community, have limited English proficiency, live in a rural area, or earn near or below the poverty level, which they have identified may be associated with worse health outcomes. Additionally, we affirm that QIS initiatives to address health and health care disparities may include a broad range of activities such as language services, community outreach, cultural competency trainings, social needs-sensitive self-management recommendations, and increased collection and use of demographic and disparities-related data that will be used to develop QIS program activities designed to

³⁴¹ More information about NCQA's approach and timeline for stratification of select HEDIS measures can be found here: *Data, Measurement and Equity*. National Committee for Quality Assurance. <https://www.ncqa.org/about-ncqa/health-equity/data-and-measurement/>.

identify and reduce disparities.

Comment: One commenter requested that CMS delay the implementation of the proposed expansion of the QIS standards until January 1, 2024, at the earliest, as this would align with the NCQA changes and the introduction of race and ethnicity stratification reporting requirements for certain select HEDIS® measures, which are lagging. The commenter stated that many health plans base their QIS on their HEDIS® measurements, and noted that aligning applicability of the QIS update with the NCQA change would ease administrative burden and ensure continuity for health plans. Another commenter noted that given the diversity of QIS requirements across Federal and State-based Exchanges, HHS should create a standardized approach to advancing equity and incorporating reducing health and health care disparities into existing QIS requirements by adding stratification by race/ethnicity for any associated quality measures.

Response: We clarify that we are finalizing the proposal to require QHP issuers to address health and health care disparities in addition to one other topic identified in section 1311(g)(1) of the ACA in the QIS submissions they provide to Exchanges beginning in the 2023 calendar year, which would apply to the 2024 Plan Year. As such, issuers will be required to describe their strategy for addressing health and health care disparities beginning on January 1, 2024. This aligns with the NCQA introduction and implementation of race and ethnicity stratification for select HEDIS® measures for the 2022 Measurement Year, that will be collected in the 2023 calendar year. We appreciate and share the commenter's commitment to advancing health equity by requiring QHP issuers to address potential disparities in their quality improvement strategies, but we also recognize the limitations issuers may face when collecting certain data in support of conducting their QIS activities. We further clarify and affirm that QHP issuers across all Exchange types must adhere to the same minimum QIS Federal standards established by HHS, but State Exchanges (both State Exchanges and SBE-FPs) have the flexibility to change certain details, such as the timeframe and format for submission of QIS information by their respective issuers, and they can establish standards that go beyond Federal

QIS requirements.³⁴² However, they cannot reduce a QHP issuer's QIS obligations below the minimum QIS Federal standards established by HHS.

We understand the request from some commenters to create a standardized approach to advance health equity which includes stratification of race and ethnicity data in relation to QIS requirements. We generally support and strive for standardized and coordinated approaches across HHS to advance health equity. We also support flexibility to ensure that QHP issuers can develop various strategies across their populations and across their provider contracts. Although we have established Federal minimum standards for QHP issuers to follow and address in their quality improvement strategies, the QIS program is intended to provide QHP issuers with flexibility in the design and implementation of their respective QIS initiatives and activities. For example, QHP issuers have flexibility in how they elect to address health and health care disparities in their QIS, such that their data collection efforts do not need to be limited to race and ethnicity information. In addition, and based on public comment, HHS believes that imposing specific performance measures on QHP issuers would limit their ability to target their strategies to their specific populations and possibly limit innovation. We further recognize that State laws may impact the ability to collect certain data, which could limit the ability to develop standardized collection standards. Finally, as we noted previously, the QIS statutory provisions do not provide HHS authority to standardize State and Federal data collection requirements or remove barriers that may exist with respect to collection of race, ethnicity, language and other data on certain sub-populations, including consumers in underserved communities.

Comment: One commenter encouraged HHS to revise its proposal and allow issuers to embed a health equity strategy into their selected QIS topics instead of requiring QHP issuers to establish a separate QIS focused on addressing disparities. The commenter also urged HHS to provide detailed criteria to help issuers develop meaningful projects that fulfill the intent of

³⁴² See 45 CFR 156.1130 and 80 FR 10844 through 10848. Also see, for example, Section 4.2, *QIS Technical Guidance and User Guide for the 2022 Plan Year* (2021) CMS.<https://www.cms.gov/files/document/qis-technical-guidance-and-user-guide-2022-plan-year.pdf>.

addressing the health care needs of underserved populations, while also allowing issuers flexibilities to establish goals and metrics for success that accommodate the more limited data and longer timeframes to successfully address disparities, and in particular, the limitations for collecting data related to race and ethnicity. The commenter also requested HHS evaluate potential requirements to address disparities for populations other than the underserved communities and work to create QIS requirements that align with a more global population health approach to addressing disparities.

Response: We agree QHP issuers should advance equity as a foundational aspect of quality rather than consider equity as a siloed aspect of performance, and we encourage QHP issuers to incorporate health equity into each of their quality improvement strategies. We further clarify that under the QIS guideline, as proposed and as finalized, QHP issuers have flexibility in the design and implementation of their respective QIS initiatives and activities. This includes the flexibility to establish two separate QIS initiatives – one that focuses only on addressing health and health care disparities and a second one that focuses only on wellness and health promotion (or another topic identified in section 1311(g)(1) of the ACA) – or the flexibility to establish one QIS initiative that focuses on addressing health and health care disparities in addition to wellness and health promotion (or another topic identified in section 1311(g)(1) of the ACA). Both approaches would be compliant with the new QIS guideline finalized in this rule. In other words, QHP issuers will not need to develop de novo strategies or create and submit multiple QIS programs, but can address health and health care disparities within an existing QIS. If an issuer elects this approach, they should select “reduce health and health care disparities” as a topic area in addition to at least one other topic area when submitting its plan year 2024 QIS submission in the 2023 calendar year. We intend to address this, and other operational details related to this new guideline, as part of the Plan Year 2024 QIS Technical Guidance. We did not propose and generally decline to adopt detailed criteria to direct QHP issuer QIS programs that address health and health care disparities.

As detailed above, QHP issuers have flexibility in how they elect to address health and health care disparities in their QIS, such that their data collection efforts do not need to be limited to race and ethnicity information. For example, QHP issuers could focus on enrollee populations that belong to a racial or ethnic minority group, or those that live with a disability, identify as a member of the LGBTQI+ community, have limited English proficiency, live in a rural area, or earn near or below the poverty level, which may be associated with worse health outcomes. QHP issuers also have broad flexibility in terms of the goals they have identified, the activities they've employed to advance their QIS, and the measures they use. Within their QIS, issuers must report their initial baseline assessment results, and then must subsequently report their progress in relation to the baseline results they've provided. Since the QIS program promotes continuous quality improvement, issuers are asked to analyze their progress using their baseline data, but at this time they are not penalized for not meeting their progress targets or milestones. Additionally, QIS initiatives to address health and health care disparities may include a broad range of activities such as language services, community outreach, cultural competency trainings, social needs-sensitive self-management recommendations, and increased demographic and disparities-related data collection.

16. Disbursement of Recouped High-Cost Risk Pool Funds – Administrative Appeals of Issuers of Risk Adjustment Covered Plans (§ 156.1220)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 689), we proposed 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 proposed 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).

In the proposed rule, we also clarified 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 administrative appeal, issuers whose charge amounts are reduced would report the high-cost risk pool charges paid for that benefit year net of recouped funds as a result of an administrative appeal in the next MLR reporting cycle consistent with 45 CFR 153.710(h). This same framework would also apply to high-cost risk pool funds recouped as a result of audits under § 153.620(c)(5)(ii) and actionable discrepancies under § 153.710(d).

We sought comment on this proposal.

After consideration of relevant comments, we are finalizing these policies, as proposed.

We respond to the comments received on these policies.

Comment: Several commenters expressed general support for these proposals.

Response: After consideration of relevant comments, we are finalizing, as proposed, the policies related to disbursement of high-cost risk pool funds recouped as a result of audits of risk adjustment covered plans under § 153.620(c), actionable high-cost risk pool-related discrepancies filed pursuant to § 153.710(d), and successful high-cost risk pool administrative appeals filed pursuant to § 156.1220.

17. Direct enrollment with the QHP issuer in a manner considered to be through the Exchange (§ 156.1230)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 689), we proposed to amend § 156.1230 such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. As we explain in the Supplemental Information section earlier in the preamble, HHS will address this policy, as well as public comments submitted in response to the proposal, in a future rulemaking.

18. 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 build Exchanges that 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 that 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.³⁴³

Earlier in this section E of the preamble, we finalized the provision to require FFE and SBE-FP issuers to offer the standardized plan options finalized in this rule. Standardized plan options offer one solution to the problem of choice overload through standardizing cost-sharing structures and increasing plan comparability by allowing consumers to focus on plan premiums,

³⁴³ Taylor EA, Carman KG, Lopez A, Muchow AN, Roshan P, & Eibner C. (2016) Consumer *Decision-making* in the Health Care Marketplace. RAND Corporation. https://www.rand.org/pubs/research_reports/RR1567.html

provider networks, formularies, and quality ratings.³⁴⁴ In light of the proliferation of seemingly similar plans offered through the Exchanges over the last several years, HHS solicited comment regarding 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' 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 during the open enrollment period for PY 2022, there was 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, several rating areas have more than 50 silver plans, excluding CSR variations, available to consumers – a number we believe makes 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 during the open enrollment period for PY 2022, consumers were 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 plan years 2019 and 2022 suggests consideration of the need to limit the proliferation of seemingly

³⁴⁴ Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces. (2021, December 28). Office of the Assistant Secretary for Planning and Evaluation. <https://aspe.hhs.gov/sites/default/files/documents/222751d8ae7f56738f2f4128d819846b/Standardized-Plans-in-Health-Insurance-Marketplaces.pdf>.

similar plans in order to further streamline and optimize the plan selection process for consumers on the Exchanges.

HHS remains 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.³⁴⁵ These conclusions are supported by the comments received during both this rulemaking and 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' 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.”³⁴⁶ Thus, in order to streamline and optimize the plan selection process for consumers on the Exchanges, HHS expressed interest in exploring possible methods of improving choice architecture and solicited comments on doing so. Several provisions finalized within this rule complement this goal, including the standardized plan options provision at § 156.201 and the provisions that modify the applicable *AV de minimis* ranges at §§ 156.140, 156.200, and 156.400.

Specifically, the standardized plan options provision at § 156.201 requires FFE and SBE-FP issuers to offer plans with standardized cost sharing parameters at every product network type, at every metal level, and throughout every service area that they offer non-standardized plan options. Though this provision does not limit the number of non-standardized plan options

³⁴⁵ Zhou, C. & Zhang, Y. (2012). “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: 2259–2265.

³⁴⁶ 80 FR 75,488, 75,542 (2015, December 2).

for PY 2023, HHS stated that it intends to consider and propose future rulemaking, as appropriate, to determine whether to limit the number of non-standardized plan options that FFE and SBE-FP issuers may offer through the Exchanges in PYs beginning on or after January 1, 2024.

Additionally, the provisions at §§ 156.140, 156.200, and 156.400 finalized modifications to the applicable AV *de minimis* ranges. HHS modified 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 finalized a *de minimis* range of +5/-2. Under § 156.200, HHS finalized, 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 finalized under § 156.400 to specify *de minimis* ranges of +1/0 percentage points for income-based silver CSR plan variations. HHS explained that it anticipates that these provisions would have the effect of decreasing the number of plan offerings due to more restricted AV *de minimis* ranges.

HHS also solicited comment on resuming the meaningful difference standard (previously codified at 45 CFR 156.298) and the best approach for doing so. 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 number of plans offered through the Exchanges has increased sharply over the last several years, HHS explained that it continues to believe 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 acknowledged 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 plan options exclusively, and exclude plans that have not demonstrated the administrative capability, prices, networks or product designs that improve consumer value. HHS explained that it 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 and solicited comments accordingly.

Altogether, we sought 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 sought 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 sought comments on other evidence-based approaches to improve choice architecture within the Exchanges.

We summarize public comments on these topics below, but note that comments related to standardized plan options, changes to the *AV de minimis* ranges, and the meaningful difference standard are summarized and addressed in more detail earlier in their respective sections in the preamble: §§ 156.201, 156.140, 156.200, and 156.400. We also acknowledge and appreciate comments on improving choice architecture within the Exchanges and on the benefits and potential drawbacks of adopting an active purchaser model and will take these comments into account as part of future research and decision-making processes.

Comment: In response to a comment solicitation regarding how HHS might address choice overload in the Exchanges, many commenters supported improving choice architecture on HealthCare.gov to enhance the consumer shopping experience, in addition to requiring issuers to

offer standardized plan options. Many commenters suggested that HHS provide educational resources and accessibility support for consumers, such as interactive graphics and videos explaining relevant health care and insurance terminology. These commenters noted that modifying choice architecture on HealthCare.gov to make it more intuitive and educational could greatly benefit consumers with low health literacy.

Similarly, some commenters stated that Exchanges should prioritize decision support tools that direct consumers to consider total out-of-pocket costs instead of premiums. These commenters suggested using more plain language, utilizing hover text to define key terms and distinguishing features, improving accessibility for consumers with vision impairments, and developing tutorials. One commenter urged HHS to engage with issuers and stakeholders to identify tools and features that would be most meaningful for consumers. This commenter also suggested seeking consumer feedback to better identify, test, and launch changes to the HealthCare.gov shopping and plan selection user interface.

Response: HHS shares commenters' position that it is extremely important to make plan information accessible and actionable for all consumers, including those with visual, auditory or speech disabilities, those for whom English is a second language, or those who otherwise may have challenges with incorporating important but complex health insurance plan benefit design information into their decision-making process. HHS appreciates these comments and recommendations on additional educational resources to maximize consumers' ability to select the best plan for themselves and their families, and we note that we will take these recommendations into consideration as we continue to work towards this goal.

Comment: Many commenters also advocated for improving choice architecture and decision-support tools as an alternative to requiring standardized plan options or limiting plan offerings. These choice architecture suggestions included mandating decision-support tools, having shoppers "opt-out" rather than "opt-in" to provide their expected health care service utilization, actively redirecting consumers to plans with higher AVs and lower total costs,

displaying estimated out-of-pocket costs, and highlighting patient-friendly cost sharing parameters such as fixed-dollar copayments and pre-deductible services on plan cards.

One commenter urged HHS to include pop-up alerts and to require consumers to click to confirm that they would like to enroll in plans with higher costs and lower actuarial values. These commenters also suggested improving the functionality of features such as filters and sort options by providers, facilities, formularies, quality ratings, and networks. One commenter encouraged HHS to collect consumer preferences and anticipated health care service utilization prior to displaying plans in order to ensure that plans are initially filtered and sorted for consumers. This commenter further recommended that HHS display the highest metal level plans first if the net premiums are \$0 for multiple metal levels within a product.

Some commenters suggested that HHS employ choice architecture improvements to direct eligible shoppers to CSR plan variations so they can utilize the savings available to them. Specifically, these commenters suggested that an out-of-pocket cost sort option could help customers understand the concept of total costs and show CSR-eligible consumers that the most generous CSR plan variations are guaranteed to have lower total out-of-pocket costs than those of plans at higher metal levels. Similarly, some commenters recommended preferentially displaying silver cost-sharing reduction variants while continuing to display plans from low to high total cost.

Finally, one commenter stated that HHS should reform the choice architecture on the Exchanges. This commenter explained that both Federal and State Exchanges should be required to implement decision-support tools that direct consumers to contemplate total costs instead of just premiums. This commenter added that Exchanges should be required to actively redirect consumers to plans that provide the lowest cost for the highest actuarial value, such as a bronze to a silver plan with cost sharing reductions. This commenter cited several examples of State Exchanges that have implemented similar changes.

Response: HHS appreciates the variety and detail of comments on methods of enhancing choice architecture to further streamline consumers' decision-making process and empower individuals to select the best plan for themselves and their families. We note that we will take these comments into consideration as we continue to explore advancements in choice architecture on HealthCare.gov.

Comment: A few commenters supported HHS adopting an active purchaser model in future years. Several commenters supported it as part of a larger strategy that they stated should also include both standardized plan options and a meaningful difference standard. Some of these commenters also stated that the State of California's use of this approach illustrates the benefits of limiting the number of plan offerings, lowering costs for consumers, setting standards for plan quality, and fostering robust competition among plans seeking entry into the Exchange.

However, multiple commenters opposed HHS adopting an active purchaser model for the Federal Exchanges, mainly due to concerns that doing so would put too much control over plan offerings in the hands of the Exchange, as opposed to allowing issuers the flexibility to design plans based on consumer preferences and needs. These commenters were also concerned that an active purchaser model could reduce the number of issuers willing to participate in Exchanges on the Federal platform by requiring issuers who are not selected for a given year to pause their individual market operations and later expend time and resources to apply in a future year.

Response: As noted in the proposed rule, HHS acknowledges that a number of State Exchanges have successfully employed an active purchaser model and that we intend to consider whether such a model would be appropriate in future PYs to further streamline the plan selection process for consumers on the Exchanges. HHS appreciates comments considering the advantages and disadvantages of such a model, and we will take this feedback into consideration as part of future decision-making processes.

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

1. Reimbursement for clinical services provided to enrollees (§ 158.140)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 691), we proposed to amend § 158.140(b)(2)(iii) to clarify that only 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 are finalizing this proposal as proposed.

Section 2718(a) of the PHS Act requires health insurance issuers offering group or individual health insurance coverage (including a grandfathered health plan) to separately report the percentage of total premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees for activities that improve health care quality, as well as all other non-claim (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. Section 158.140 sets forth the MLR reporting requirements related to reimbursement for clinical services provided to enrollees, including a requirement in § 158.140(b)(2)(iii) that issuers must include the amount of incentive and bonus payments made to providers with incurred claims. Due to the lack of clarity and specificity in the regulations, some issuers include an overly broad variety of incentive and bonus payments made to providers. The inclusion of many types of provider incentives and bonuses in incurred claims is appropriate and consistent with the purpose of the statute, but only to the extent that such bonuses incentivize providers to deliver objectively measurable higher-quality care and value for enrollees.

In the course of conducting MLR examinations pursuant to §§ 158.401 and 158.402, we 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. 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.

We summarize and respond to public comments received on the proposal to clarify the inclusion of provider incentives and bonuses in incurred claims (§ 158.140) below.

Comment: The overwhelming majority of commenters supported the proposed clarification and accompanying regulatory amendment. Commenters stated that this regulatory provision needs to be clarified and tightened to ensure the faithful execution of the MLR requirements. Commenters further stated that the proposed clarification is necessary to prevent issuers from evading compliance by inappropriately using the MLR standard itself to trigger “incentive” or “bonus” payments and to prevent issuers from inflating their MLRs by including any such payments that are not based on quality or performance metrics.

Response: We appreciate the supportive comments and agree that it is important to look beyond the labels used (for example, provider “incentive” or “bonus” payments) to confirm that the provider payments meet the applicable standards for inclusion in incurred claims for MLR reporting purposes. After considering public comments, we are finalizing the amendment to § 158.140(b)(2)(iii), as proposed, to explicitly clarify in regulation that to be included in incurred claims “incentive” or “bonus” payments to providers must be tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers. Any provider payment that is based on the financial condition or actions of the issuer may not be reported as incurred claims. For example, we generally believe that payment arrangements between issuers and providers that result in there being no scenario in which an MLR rebate would ever be paid to consumers or that are tied to the financial condition or actions of the issuer would violate both the letter and the spirit of the law. It is inappropriate to include such provider payments – even if labeled as “incentive” or “bonus” payments – as incurred claims in issuers’ MLR calculations. This includes arrangements where the MLR standard itself is used as the threshold to determine whether such a payment is due, or because some other

metric, such as issuer profit or surplus, is used, or if the arrangement is otherwise designed to substantially avoid compliance with the MLR rebate requirements.

Comment: One commenter that supported the proposal recommended that HHS also clarify that provider incentives and bonuses are not required to be excluded from incurred claims solely because they incorporate shared savings elements or cost efficiency requirements in addition to clinical quality requirements. This commenter further recommended a safe harbor for provider incentives that do not exceed a specified cap (such as 20 percent), make the incentive contingent on meeting objective clinical measurements, and require disclosure to any beneficiary that requests it.

Response: We confirm that under the proposal, the fact that a provider incentive or bonus program has a shared saving or other cost efficiency element does not disqualify the entire incentive or bonus from being classified as incurred claims, as long as the incentive or bonus is tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers. We do not believe that a safe harbor proposed by the commenter is necessary and decline to adopt one at this time.

Comment: Several commenters requested that HHS distinguish alternative payment models such as Accountable Care Organization (ACO) initiatives, arrangements where the issuer shares savings with providers, and value-based contracting (VBC) from the types of arrangements that were the cause for concern, and requested that HHS allow all bonuses and incentives paid under such alternative payment models to be reported as incurred claims. These commenters expressed concern that the proposal would inhibit issuers' ability to pursue such cost containment strategies and suggested that the proposal is inconsistent with HHS' support of value-based payment models. Some of these commenters asserted that purely financial savings that reduce the total cost of care are an appropriate basis for provider bonuses or incentives. Other commenters suggested that such alternative payment models reduce utilization needs and lead to better health outcomes, or at least lower costs while continuing to provide quality care.

Response: HHS continues to support innovative alternative payment models that deliver efficient and high-quality care. We further note that the MLR statute and HHS implementing regulations in 45 CFR part 158 do not prohibit issuers from adopting a wide range of value-based payment models, including ones that may not be tied to clinical or quality standards. The clarification and accompanying amendment to § 158.140(b)(2)(iii), which we are finalizing as proposed, is instead limited in applicability to the treatment and reporting of these amounts for MLR purposes. As explained in the proposed rule (87 FR 691), in the course of conducting MLR audits, we uncovered several instances where provider payments labeled as “incentive” or “bonus” that were triggered based on the financial condition or actions of the issuer³⁴⁷ were included in the issuer’s incurred claims. This violates the spirit of the statute by artificially inflating the issuer’s MLR and depriving consumers of the rebates they would otherwise be owed under section 2718(b) of the PHS Act. It is also inconsistent with the requirements that dictate separate reporting and treatment of the percentage of total premium review (after certain adjustments) expended on reimbursement for clinical services and activities that improve health care quality, and on all other non-claims (administrative) costs.³⁴⁸ In order to increase compliance and improve program integrity, we are finalizing as proposed, the regulatory amendment to codify the agency’s existing policy and interpretation of the statute regarding the treatment of provider “incentives” and “bonuses” that are not tied to clinical or quality standards for MLR reporting and rebate purposes. This will further ensure that consumers receive value for their premium payments and the rebates they are owed under the statute.

We agree with the commenter who suggested that value-based payment models can reduce utilization and lead to better outcomes, or lower costs, without compromising the quality of care. Issuers employing such models or arrangements should be able to demonstrate this

³⁴⁷ This included arrangements under which payments were made to providers any time the issuer’s MLR fell below a specified threshold, such as the applicable standard established in section 2718(b)(1)(A)(i) and (ii) of the PHS Act. Other arrangements of this nature used a metric tied to when the issuer’s profitability exceeded a specified threshold. Payments were sometimes made to clinical providers or hospitals and other times were made to non-clinical parent holding companies.

³⁴⁸ See section 2718(a) of the PHS Act and 45 CFR 158.110, et. seq.

through the use and documentation of appropriate clinical or quality metrics and thus such incentive or bonus payments would be eligible for inclusion in incurred claims. Further, we are not aware of any CMS value-based payment initiatives (such as Medicare shared savings initiatives and alternative payment models) that do not include clinical or quality standard requirements and generally disagree the adoption of the amendment to § 158.140(b)(2)(iii) is inconsistent HHS' support of innovative, value-based payment models.

Comment: One commenter expressed concern that the proposed clarification could potentially place (unspecified) burdens on physicians to earn the incentive and bonus money.

Response: While we acknowledge the comment, as the commenter did not provide any specifics regarding potential burdens, the substance of the commenter's concern is not clear. We note that this provision will not impact every provider incentive and bonus arrangement since, for example, it is unlikely to impact the majority of issuers that exceed MLR standards or existing arrangements, the majority of which are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards applicable to providers. In addition, as discussed above, this provision does not prohibit issuers from adopting value-based payment models that may not be tied to clinical or quality standards. Nor does this provision require issuers to add clinical or quality documentation requirements on providers to existing value-based payment models.³⁴⁹ Rather, the amendment to § 158.140(b)(2)(iii), which we are finalizing as proposed, is limited in applicability to the treatment and reporting of these amounts for MLR purposes. As explained above, the inclusion of provider incentives and bonuses in incurred claims when the incentives and bonuses fail to incorporate clinical or quality standards could create incentives to inappropriately reduce or even withhold medical care and would reduce the value consumers receive for their premium dollars.

³⁴⁹ We further note that to the extent the issuer elects to impose documentation requirements on its providers under a value-based payment model or other arrangements, those types of requirements would fall outside of the MLR calculation and rebate framework under section 2718 of the PHS Act and the implementing regulations at 45 CFR part 158.

Comment: One commenter recommended that we adopt a narrow exception to the reporting requirement under § 158.140(b)(2)(iii) for issuer payments to providers at risk of becoming insolvent due to extraordinary circumstances, such as the COVID pandemic, subject to prior approval of the applicable State regulator. According to this commenter, such payments in extraordinary circumstances may be necessary to enable providers to continue providing medical care and to ensure that issuers were able to comply with network adequacy requirements.

Response: We understand and commend issuers that made cash payments to help prevent at-risk providers from becoming insolvent due to the COVID pandemic in order to ensure that consumers had access to medical care. However, we did not propose and are not finalizing the exception suggested by the commenter. We intend to further consider the treatment of such payments in extraordinary circumstances under the MLR framework codified in 45 CFR part 158, and would address any policies in this regard in future guidance or rulemaking, as applicable.

Comment: One commenter urged HHS to exercise greater oversight of insurance companies that own or are owned by companies that also own networks of providers and other health care services. The commenter described a number of reporting or business practices made possible by vertical integration in health care that have the potential to erode the PHS Act MLR protections. According to the commenter, these include issuers channeling more health care dollars to their own provider groups, encouraging enrollment in an HDHP and contributing to an HSA offered by an affiliate, and reporting as QIA the expenses for utilization management programs that may not actually benefit enrollees or improve their health. Another commenter agreed that the examples of provider incentives described in the proposed rule are troubling but recommended that the more appropriate remedy is stronger enforcement rather than clarifying the regulations.

Response: We understand the commenter's concern regarding issuers that are integrated with health care providers and agree with the suggestions and will continue to focus our

oversight and enforcement on ensuring issuer compliance with MLR reporting requirements for all of the different types of provider arrangements or payment models issuers may employ. As part of this effort, we intend to consider the impact of vertical integration on the reporting and treatment of provider payments under the MLR framework codified in 45 CFR part 158, including the impact on rebates owed to consumers. However, we note that our ability to identify non-compliant reporting of provider incentives and bonuses for targeted enforcement is limited as the MLR rules require issuers to aggregate by State and market the amounts they incurred for any such incentives and bonuses. Additionally, the MLR reporting requirements require issuers to report only the amounts incurred for provider incentives and bonuses and do not require them to describe or provide details about the incentive or bonus program itself. Thus, the level of detail that is available does not support easily identifying errant practices. In addition, we believe that clarification of the requirements in regulation is necessary and appropriate to increase awareness and ensure broad and uniform compliance. We also emphasize our intention to combine this regulatory clarification with heightened oversight and monitoring of compliance with MLR reporting and rebate requirements with respect to these types of arrangements to ensure consumers receive value for their premium payments, consistent with the statute.

Comment: A few commenters requested that the clarification be prospective to give issuers sufficient time to come into compliance.

Response: As explained above and in the proposed rule, the clarification and amendment to § 158.140(b)(2)(iii), which we are finalizing as proposed, codifies the Department's existing policy and interpretation of the statute. Including provider "incentive" or "bonus" payments that are not based on clearly defined, objectively measurable, and well-documented clinical or quality improvement standards in incurred claims artificially inflates the issuer's MLR and deprives consumers of the rebates they would otherwise be owed. This practice is also inconsistent with the statutory requirements that dictate separate reporting and treatment of the percentage of total premium review (after certain adjustments) expended on reimbursement for clinical services and

activities that improve health care quality, and on all other non-claims (administrative) costs. We further note that the MLR requirements established under section 2718 of the PHS Act have generally been effective since 2011. Finally, as noted above, the adoption of this regulatory amendment does not require issuers to modify existing arrangements with providers. Instead, it is limited in applicability to the treatment and reporting of these amounts for MLR purposes. The next annual MLR report is not due until July 31, 2022.³⁵⁰ For all of these reasons, we disagree that additional time is needed or should be provided for issuers to come into compliance.

After consideration of the comments received on this proposal, we are finalizing the regulatory amendment to § 158.140(b)(2)(iii) as proposed.

2. Activities that improve health care quality (§ 158.150)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 691 through 692), we proposed 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. In order to ensure reporting consistency among issuers and ensure that QIA expenses included in the MLR numerator represent the actual value provided for consumers' premium dollars, consistent with the purpose of section 2718 of the PHS Act, we are finalizing the proposal 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.

As discussed in the proposed rule (87 FR 691 through 692), section 2718(a) of the PHS Act requires health insurance issuers offering group or individual health insurance coverage (including a grandfathered health plan) to 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, as well as all other non-claims costs. Section 158.221 defines the numerator of an issuer's MLR to include the issuer's incurred

³⁵⁰ See 45 CFR 158.110(b).

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. For example, some issuers allocate to QIA fixed costs – such as office space or IT infrastructure – that would, for the most part, exist even if the issuer did not engage in any QIA. Some issuers include in QIA expenses amounts exceeding the cost of providing the actual QIA service. 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. 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 reporting or apportioning indirect expenses without adequate documentation or support.

We sought comment on this proposal.

We summarize and respond to public comments received on the activities that improve health care quality proposal (§ 158.150). We note that we received a few comments and suggestions that were outside the scope of the proposed rule, which are not addressed in this final rule.

Comment: The majority of commenters supported the proposal 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. These commenters agreed that it is reasonable, appropriate, and necessary to prevent issuer MLRs from being inflated.

Most commenters generally agreed that overhead costs should not be allowed to be reported as QIA. A few commenters requested that certain non-salary expenses associated with employees performing QIA functions be allowed in QIA expenses. These commenters noted that employee benefits are part of compensation, and that expenses related to office space, equipment, and IT infrastructure are necessary for such employees to perform QIA. Several of these commenters stated that issuers should be allowed to allocate a portion of indirect costs to QIA on a pro rata basis. Several commenters requested that we provide a specific list of examples of expenses that are or are not permitted as direct expenses. Another commenter suggested that HHS should convene stakeholders to discuss an appropriate methodology for allocating indirect costs to QIA expenses rather than adopting the proposed amendment to § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses.

Response: We appreciate the supportive comments on this proposal. We agree with commenters that non-salary benefits of employees performing QIA functions that are part of compensation packages are directly tied to QIA, and we clarify that we consider the cost of such employee benefits to be a direct QIA expense. Thus, the issuer's cost of health coverage, retirement contributions, life insurance, or similar benefits provided to employees actually performing QIA may be included in QIA expenses under § 158.150(a), as amended. However, similar to salary costs, such costs may only be included up to the percentage that reflects the percentage of the employees' time actually spent on QIA. Issuers that report such costs as QIA

should take care to both document and retain records supporting the amount(s) reported and the determination of what portion of these costs are a direct QIA expense.³⁵¹

However, as explained in the proposed rule, many of the other indirect expenses identified by these commenters³⁵² would be incurred even if issuers did not engage in QIA. For example, it is unlikely that an issuer's cost of purchasing, renting, and maintaining an office building or equipment is meaningfully impacted by the engagement of some of its employees in QIA. Therefore, we disagree that expenses for items such as office space, equipment, and IT infrastructure are directly or in some cases even indirectly related to QIA, or that they are incurred in the furtherance of quality improvement. As such, for MLR reporting and rebate purposes, these expenses are classified as non-claims, administrative costs and should not be included in the MLR numerator. Allowing issuers to report these same expenses as expenditures on QIA is inappropriate. It would undermine the purpose and intent of section 2718 of the PHS Act and would allow issuers to inflate QIA costs (and the MLR numerator) by including fixed costs that would be incurred regardless of whether the issuer engages in QIA. We also do not believe that there is a compelling policy rationale to allow issuers to automatically shift a *pro rata* portion of such costs to consumers. For the same reasons, we do not believe that convening stakeholders to discuss an appropriate methodology for allocating such expenses is necessary.

We provided multiple examples of the types of expenses that we consider to be indirect expense that should not be reported as QIA in both the proposed rule and this rule. Examples include: office space (including rent or depreciation, facility maintenance, janitorial, utilities, property taxes, insurance, wall art), human resources, salaries of counsel and executives, computer and telephone usage, travel and entertainment, company parties and retreats, IT systems, and marketing of issuers' products. This list, however, is not intended to be exhaustive or all-inclusive. As a general matter, expenses for items or services that have no direct or

³⁵¹ See 45 CFR 158.502.

³⁵² Examples of other indirect expenses identified by commenters include costs related to office space, equipment, and IT infrastructure.

quantifiable relationship to health care quality cannot reported as QIA and will not be considered direct QIA expenses. Conversely, expenses for items or services that primarily or exclusively support QIA as opposed to regular business or other functions, when reasonable and quantifiable³⁵³, are likely to constitute direct expenses that are properly included in QIA expenses. We intend to continue to monitor issuer QIA reporting and will issue further guidance, as may be necessary, and welcome stakeholder feedback on which other types of expenses they would like us to address in technical guidance on direct versus indirect expenses.

Comment: Two commenters expressed concern that, under the proposal, HHS appears to take the position that health information technology (HIT) expenses, which are specifically allowed by §§ 158.150 and 158.151, cannot be reported as QIA if they are determined to be indirect.

Response: We do not believe that the amendment to § 158.150(a) to specify that only direct expenses related to activities that improve health care quality can be included in QIA expenses for MLR reporting and rebate purposes conflicts with the definition of HIT at § 158.151. Section 158.151 defines HIT as specifically being “designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, as well as those consistent with Medicare and/or Medicaid meaningful use requirements.” This definition recognizes that some information technology is HIT; while also recognizing that not all information technology is HIT. We affirm and clarify that HIT expenses that meet the applicable requirements in §§ 158.150 and 158.151 are permissible costs that can be included as QIA expenses. For example, the cost of software designed and used primarily for QIA purposes, such as HEDIS reporting, constitutes a direct expense related to activities that improve health care quality and can be included in QIA expenses for MLR reporting and rebate purposes. In contrast, as explained above and in the proposed rule, the costs of IT infrastructure

³⁵³ Consistent with 45 CFR 158.502, issuers must maintain all documents and other evidence necessary to enable HHS to verify that the data reported complied with the applicable definitions and criteria.

that primarily supports regular business functions such as billing, enrollment, claims processing, financial analysis, and cost containment, even when the same IT infrastructure also happens to support QIA activities in addition to regular business functions, do not constitute a direct expense related to activities that improve health care quality and cannot be included in QIA expenses for MLR reporting and rebate purposes. As a simple example, the cost of the computer software license for an employee that works part of the time on QIA should not be allocated to QIA expenses for MLR reporting purposes. The fact that the employee uses this software to write QIA documents in addition to other documents does not convert this otherwise general non-claims, administrative cost into one of the types of expenses eligible to be included in the MLR numerator as QIA expenses.

Comment: A few commenters that opposed the proposal disagreed with the classification of the administrative expenses and profits of issuers' QIA vendors as indirect expenses. These commenters stated that this approach will disincentivize issuers from engaging vendors with appropriate expertise. Some commenters stated that vendors' administrative expenses and profits should be treated in the same manner regardless of whether vendors perform clinical services or QIA.

Response: We disagree that clinical providers' administrative costs and profits are analogous to non-clinical providers' administrative costs and profits. Clinical services are a provider function. QIA, on the other hand, is an issuer function. Where an issuer performs its own QIA without engaging a vendor, any "profit" that it makes on such QIA cannot be included in the MLR calculation. Accordingly, where an issuer chooses to outsource its QIA to a third party, rather than developing the necessary skills in-house, as it does for other issuer functions such as claims processing, network development, clinical policies, and case and utilization management, for example, for MLR reporting and rebate purposes that vendor stands in the shoes of the issuer. Consequently, the vendor's indirect costs, as well as any profit, cannot be

reported as a QIA expense that is included in the MLR calculation.³⁵⁴ We also disagree with the assertion that disallowing issuers to include QIA vendor administrative expenses and profits in QIA will disincentivize issuers from engaging with vendors with the appropriate expertise because, as noted, if the issuer were to perform the QIA itself, those same administrative expenses and profits would still not be a permissible inclusion in QIA. Further, many issuers have not been dissuaded from outsourcing claims processing, network development, clinical policies, and case and utilization management (UM) to vendors who have the respective, requisite expertise even though they cannot include the vendor's administrative expenses and profits in their MLR calculations.

Comment: A commenter urged us to review how insurers are categorizing their UM expenses and set clear guardrails around when, if ever, such activities can be categorized as QIA.

Response: We agree with the commenter that certain UM activities are designed to target cost-containment rather than quality improvement. To that end, under current regulations at § 158.150(c), issuers cannot include in QIA any prospective or concurrent UM costs or any retrospective UM costs that do not meet the definition of a QIA. Additionally, in the course of performing MLR examinations, HHS routinely reviews the UM program expenses that issuers report as QIA to ensure they comply with the regulatory requirements. We believe the current regulations provide sufficient guardrails on the reporting of UM expenses and therefore did not propose, and are not finalizing, any such changes at this time.

Comment: One commenter requested that we allow health equity accreditation costs in QIA.

Response: Issuers are currently permitted by § 158.150(b)(2)(i)(A)(5) to include in QIA expenses the costs associated with accreditation fees that are directly related to the quality of

³⁵⁴ See 45 CFR 158.140(3)(ii) and CCIIO Technical Guidance (CCIIO 2011-002): Questions and Answer Regarding the Medical Loss Ratio Interim Final Rule, May 13, 2011, Q&As 10-14, at <https://wayback.archive-it.org/2744/20200125161941/https://www.cms.gov/CCIIO/Resources/Files/Downloads/mlr-guidance-20110513.pdf>.

care activities. Therefore, to the extent, a health equity activity requiring accreditation meets the definition of a QIA at § 158.150, such accreditation fees can be reported as QIA expenses.

Comment: One commenter requested that the definition of QIA be revised to explicitly include issuer payments to providers for quality or clinical improvements directed at people with disabilities, such as the purchase of accessible medical and examination equipment.

Response: We did not propose and are not finalizing regulatory changes to address issuer payments to providers for quality or clinical improvements directed at people with disabilities. As such, modifying the regulation to specifically allow issuers to include expenses such as payments to clinical providers to purchase accessible medical office equipment for people with disabilities is out of the scope of this rulemaking. However, we note that to the extent such equipment purchases meet the requirements of § 158.150, § 158.151, or § 158.162(c), they may be included as QIA expenses in issuers' MLR calculations.

Comment: A few commenters requested that we clarify in which MLR reporting year the clarification is effective and requested that the effective date be prospective, suggesting that it should be effective beginning with the 2023 MLR reporting year to allow for contract renegotiation.

Response: We note that in the course of conducting MLR examinations, we have consistently disallowed some of the more egregious types of indirect expenses that issuers have reported and which we believe are unambiguously inconsistent with the spirit and intent of the law. Therefore, we are clarifying that this change is effective beginning with the 2021 MLR reporting year (reports due July 31, 2022). However, to allow issuers additional time to revise their reporting processes or undergo contract negotiations (and renegotiations), we intend to maintain the existing enforcement posture with respect to the MLR reports filed for the 2021 MLR reporting year, and will otherwise exercise enforcement discretion to not penalize issuers who make good faith efforts to comply and report QIA consistent with the clarifications in this rule until the 2022 MLR reporting year (reports due July 31, 2023). Issuers should not interpret

this enforcement approach to justify reporting any and all indirect QIA expenses on their 2021 Annual MLR Reporting Forms; instead it is intended to provide a transition in the limited situations, such as those identified by the commenter, that present barriers to adjusting the issuer's reporting practices for the 2021 MLR reporting year.

After consideration of the comments received on this proposal, we are finalizing the amendment to § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses, as proposed.

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 158.151.³⁵⁵ 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 § 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 the premium option described in § 158.221(b)(8), in which case the allocation method description should state so)," to each health insurance market

³⁵⁵ 86 FR 24140.

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 proposed to 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).

We summarize and respond to public comments received on the allocation of expenses proposed technical amendment (§ 158.170).

Comment: No commenters commented on this technical correction, but a commenter requested we reconsider and permit the previous allowance for plans to report 0.8 percent of earned premium as QIA in the MLR numerator to reduce the effort required of issuers to identify, track, and report QIA.

Response: While we appreciate the comment, as stated above, this change aligns § 158.170(b) with the vacatur of § 158.221(b)(8) by the United States District Court for the District of Maryland in *City of Columbus*. We are therefore finalizing this technical correction as proposed.

G. Solicitation of Comments on Health Equity, Climate Health, and Qualified Health Plans

To further HHS' 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, HHS is considering other ways to incorporate health equity standards through HHS' authority to enhance criteria for the certification of QHPs or by leveraging existing QHP requirements such as the Network Adequacy Standards at § 156.230 and Accreditation of QHP Issuers at § 156.275. We also sought 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.

We also sought comment on ways HHS might improve its understanding of the existing landscape of issuer collection of health equity data, including demographic information, as well as comment on how HHS might assess data sources that focus on population-level factors made available by governments, quasi-governmental entities, data vendors and other organizations. Specifically, we sought input on, among other things, health equity assessment tools, the challenges QHP issuers could face implementing a new accreditation product on health equity;³⁵⁶ and information on the demographic or SDOH data QHP issuers currently collect from enrollees. We summarize and respond to public comments received on HHS' solicitation of comments on health equity and climate health.

Comment: Commenters supported CMS' suggestion for QHP issuers to obtain a health equity accreditation, and some specified support for the National Committee for Quality Assurance (NCQA) Health Equity Accreditation to encourage issuers to take meaningful steps to advance health equity. Some commenters expressed concerns that the scope of the NCQA's Health Equity Accreditation was too narrow, noting that the NCQA does not explicitly discuss disability status in their accreditation language and that the accreditation is still new while other commenters found the NCQA's Health Equity Accreditation requirements too broad. In addition, commenters noted that NCQA may have not collaborated with the historically marginalized groups that are disproportionately impacted by health disparities when they developed the parameters of the accreditation. Furthermore, some commenters expressed concern with CMS sourcing a health equity accreditation from one accrediting body, suggesting that other organizations' accreditations may also provide useful parameters and requirements. A few commenters expressed that requiring any additional QHP accreditations would create significant cost and burdens for issuers.

³⁵⁶ *Health Equity*. National Committee for Quality Assurance. <https://store.ncqa.org/accreditation/health-equity-he.html>.

Response: We appreciate commenters' input on potentially requiring issuers to obtain a health equity accreditation and the challenges QHP issuers could face implementing a new accreditation product. We will consider the feedback as we continue to explore options for advancing health equity in the Exchanges.

Comment: Commenters supported the idea of collecting demographic or SDOH data, including information on enrollees' race, ethnicity, gender, sexual orientation, primary language, and disabilities, while also acknowledging the challenges of collecting data.

Commenters encouraged HHS to set standards for how issuers and other stakeholders should collect demographic data and suggested that recommendations from the Institute of Medicine, the Williams Institute at the University of California, Los Angeles, and forthcoming recommendations from the National Academies of Sciences, Engineering, and Medicine could offer foundational guidance. Commenters also suggested that HHS set an example for improving data collection.

While noting the importance of collecting accurate demographic data, some commenters identified data sharing and use agreements, Federal privacy and data protection laws, State laws, and a lack of formal standards for collecting data as barriers that may impede issuers' abilities to meaningfully collect and use SDOH and demographic data.

Response: We appreciate the commenters' insight into the current landscape of demographic data and SDOH. We will take these comments into consideration when considering ways to advance health equity through QHPs.

Comment: Commenters provided examples of datasets related to population factors that CMS could leverage to analyze whether QHP networks are providing adequate access to health care services for members within specific geographic areas, such as social vulnerability index scores, provider and consumer data, Provider Master Index/Shared Provider Profile (PMI/SPP), and census data.

Response: We will consider the use of these data sources to analyze and evaluate QHPs' performance related to providing equitable access to health care services.

Comment: Some commenters commented on the ability of QHP issuers to tailor provider networks based on the health needs of enrollees in specific geographic areas. Commenters were supportive of tailored provider networks, noting that issuers could contract with and develop networks based on the health needs of their enrollees, which issuers could identify through improved data collection. Commenters suggested QHP issuers could conduct this work in concert with CMS' ECP requirements.

Response: We appreciate the input and will consider the feedback as we continue to explore ways to promote health equity.

Comment: Commenters discussed health conditions and outcomes variables for which analysis and measurement may help CMS promote health equity. While many of these commenters encouraged CMS to use appropriate variables to promote health equity without providing specific feedback, some commenters identified populations that were vulnerable and may require target interventions to improve health outcomes. Some examples of the populations identified were minority mothers, individuals with diagnosed opioid use disorder or substance use disorders, individuals with special immigrant juvenile status, and individuals with behavioral health conditions.

Some commenters also suggested options that CMS could consider to effectively use outcome variables for analysis and measurement, which included relying on network adequacy standards to ensure that adequate health care services are available and provided, adding Value-Based Insurance Designs into the Exchanges, increasing the ratio of required Essential Community Provider contracts, and educating providers on the use of ICD-10 z-codes.

Response: We appreciate the suggestions for the use of health conditions and outcomes variables for which analysis and measurement may help CMS promote health equity. HHS

understands the importance of addressing vulnerable populations as it continues to explore ways to promote health equity.

Comment: Several commenters offered feedback on ways in which CMS could encourage QHP issuers to be accountable for improving health outcomes across all populations equitably. Commenters suggested that CMS encourage QHP issuers to engage with local organizations and become more integrated with providers and other community partners. Commenters also suggested that CMS could hold QHP issuers financially accountable for integrating with the communities they serve or for a small number of clinical measures.

Response: We will consider these suggestions as ways to advance health equity through QHPs.

Comment: Some commenters suggested that CMS could incentivize QHP issuers to advance health equity outside of the QHP certification requirement by considering activities that promote health equity as a QIA within MLR calculations or tie equity to plans' quality ratings. Several commenters recommended that we define QIA to explicitly include expenses related to coverage of SDOH and interventions that address social barriers to care or other health disparities. One commenter requested that we specify what types of SDOH expenses qualify as QIA.

Response: We appreciate these comments and supports issuers' efforts to design plans that improve health equity and address SDOH and will consider these suggestions as ways to promote health equity. While modifying the MLR regulation and framework to explicitly allow issuers to include investments in SDOH is outside the scope of this rulemaking, we will consider these comments for future rulemaking or guidance. We note that under the current MLR regulation at § 158.140, issuers can include SDOH costs in incurred claims if the SDOH expenses are for a covered policy benefit. Issuers can also include SDOH expenses that do not relate to covered benefits in QIA if the underlying activity meets the definition and applicable criteria for QIA at § 158.150. Additionally, issuers exempt from Federal income tax or not

subject to State premium taxes can, pursuant to §§ 158.162(b)(1)(vii) or 158.162(b)(1)(viii), respectively, deduct the expense from earned premium to the extent their SDOH expenses meet the regulatory definition of Community Benefit Expenditures under § 158.162(c).

Comment: Commenters discussed challenges that QHP issuers face in promoting and advancing health equity, but did not specify strategies that could overcome these challenges. Challenges included lack of Federal guidance and standardization for data collection.

Response: We appreciate the feedback and will consider these suggestions as we explore ways to promote health equity.

Comment: Commenters suggested several health equity tools that may help CMS address health disparities within QHPs, for example, Area Deprivation Index, Population Health Assessment, Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey, additional NCQA resources, and updated HEDIS health equity measures. In addition, commenters noted the Institute of Medicine, the Williams Institute at UCLA, and the National Academies on race, ethnicity, and language (REL) could offer models for health equity tools that CMS may want to consider.

Response: We will consider these health equity tools as a way to advance health equity through QHPs.

HHS also sought comment on how Exchanges and related health care system organizations can more readily prepare for the impacts of climate change. HHS believes that it is critical to study and prepare for these impacts given mounting evidence linking climate change to catastrophic natural events and chronic disease disproportionately harming at-risk populations including groups already suffering serious health disparities.

Comment: Of the 52 total comments received by HHS, all commenters acknowledged the threats climate change presents to human health and supported health care stakeholders considering the impact of climate change on their enrollees, providers, and employees. Twenty-five commenters supported the collection and public reporting of greenhouse gas emissions data

by providers and, in fewer cases, issuers. Thirteen commenters noted the importance of preparing health care systems for climate health threats by identifying at-risk enrollees prior to climate change events to better assist them with access to cooling and clean air resources. Twelve commenters suggested tying health care system and provider reimbursement to action on climate change and emissions reduction. Some commenters suggested incentives tied to action, and others suggested fines due to lack of commitment. Twelve commenters discussed the relationship between climate change and social determinants of health, noting the importance of anticipating and managing climate change's impact on the health of certain marginalized and high-risk populations. Nine commenters suggested that issuers or health care systems should further educate providers and enrollees about the health effects of climate change. Three commenters noted the importance of creating or updating measures sensitive to climate health impacts. Two commenters noted the strong connection between climate change and respiratory health problems. Additional commenters noted the impact of climate change on maternal and child health; women's health; skin cancers; and maintaining care quality. Commenters also mentioned the need to develop better forecasting tools to anticipate climate disasters and threats; maintaining care quality, and consider supply chain contributions to overall health care sector emissions.

Specific insight was shared on possible actions health care systems and issuers could take to better support preparedness for climate disasters and related impacts, especially for at-risk populations, and the opportunity for issuers to provide education and technical assistance on climate resilience and emissions reduction to providers and enrollees.

Response: These comments will inform HHS in determining how best to support the health care system and benefit delivery changes in response to climate change. These comments also will inform HHS through its Office of Climate Change and Health Equity, as well as other Federal agencies pursuing policies on climate change.

We will consider these comments as we consider ways QHPs can be more effective in addressing climate health.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-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 final 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 Tables 18 and 19. 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 solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

We summarize general comments on the Collection of Information Requirements (ICR) below:

Comment: A few commenters provided general comments regarding the ICR section of the proposed rule. These commenters urged HHS to consider the impact of the various data collection requirements on impacted entities. One commenter noted that the burden estimates contained in the ICR compound, and urged HHS to consider their total impact on the affected entities. Another commenter requested that HHS suspend new data collection on the proposed policies during the COVID-19 PHE to relieve the operational burden on impacted entities.

Response: We have carefully considered the burden of the information collection requirements associated with the proposed policies, including their combined impact, which is quantified in the Final Annual Recordkeeping and Reporting Requirements Tables, and the Accounting Table. While we appreciate the burden placed on all systems during the COVID-19 PHE, we believe that the new information collections for the finalized policies are necessary to carry out the proper functions of the agency.

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.³⁵⁷ Table 17 in this final rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 17: 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	\$48.33	\$48.33	\$96.66
Business Operations Specialist	13-1199	\$38.10	\$38.10	\$76.20
Operations Manager	11-1021	\$55.41	\$55.41	\$110.82
Computer and Information Systems Manager	11-3021	\$78.33	\$78.33	\$156.66
Eligibility Interviewers, Government Programs	43-4061	\$23.35	\$23.35	\$46.70
Computer System Analyst	15-1211	\$49.14	\$49.14	\$98.28
Computer Programmer	15-1251	\$46.46	\$46.46	\$92.92
Computer & Information Systems Manager	11-3021	\$78.33	\$78.33	\$156.66
Compliance Officer	13-1041	\$36.45	\$36.45	\$72.90
Web and Digital Interface Designer	15-1255	\$45.90	\$45.90	\$91.80

³⁵⁷ May 2021 National Occupational Employment and Wage Estimates. Available at *Occupational Employment Statistics*. (2022, March 31). Bureau of Labor Statistics. https://www.bls.gov/oes/current/oes_stru.htm.

B. ICRs Regarding State Flexibility for Risk Adjustment (§ 153.320)

We are finalizing the proposal to repeal the risk adjustment State flexibility to request reductions to risk adjustment State transfer payments for the 2024 benefit year and beyond, as proposed. We are also finalizing, as proposed, to provide an exception for the States that previously submitted State flexibility requests under § 153.320(d) to allow those States to continue to request this flexibility in the 2024 benefit year and beyond. As part of this policy, we are also finalizing, as proposed, the removal of the option for States applying under this exception in the 2024 benefit year and beyond 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 market risk pool as a justification for the State's request and the criteria for HHS approval. This retains the *de minimis* standard as the only option for prior participants to justify the reduction and for HHS to approve a request and is designed to 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. Further, we are finalizing this policy as proposed with the intention to propose in future rulemaking to repeal the exception for prior participants beginning with the 2025 benefit year to provide impacted stakeholders additional time to prepare for this proposed change and the potential elimination of this flexibility. Consistent with these policies, we finalized various amendments to the risk adjustment State flexibility regulations at § 153.320(d) to reflect the general repeal of this flexibility, with the exception of prior participants, and to remove one of the criteria for State justification and HHS approval beginning with the 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. Since publishing the proposed rule, we have updated the burden associated with this requirement based on the most recent available national occupational employment and wage estimates statistics. We estimate

that submitting the request and supporting evidence and analysis will take a business operations specialist 40 hours (at a rate of \$76.20 per hour) to prepare the request and 20 hours for a senior operations manager (at a rate of \$110.82 per hour) to review the request and transmit it electronically to HHS. We estimated that each State seeking a reduction will incur a burden of 60 hours at a cost of approximately \$5,264.40 per State to comply with this reporting requirement (40 hours for the insurance operations analyst and 20 hours for the senior manager). We have updated the estimated burden related to the submission of these requests because only one State, will continue to have this ability to make this request on the policy being finalized in this rule. In the 2019 Payment Notice,³⁵⁸ we estimated that 25 States would submit requests and provided a total burden of approximately 1,500 hours across all States, which would total \$131,610 based on current wage estimates. Since we estimate that only one State will continue to request reductions, we estimate that this burden will be reduced by \$126,345.60 to a total annual cost of \$5,264.40, reflecting the burden associated with one State's submission. We are finalizing this proposal to account for the burden associated with this revision, HHS submitted a reinstatement request to OMB for approval of the previously expired information collection request (OMB control number 0938-1155/CMS-10401). As noted in previous sections of this rule, HHS intends to propose in future rulemaking to fully repeal the State flexibility framework and eliminate the ability of prior participants to request reductions in risk adjustment transfers starting with the 2025 benefit year.

We did not receive any comments in response to the information collection requirements related to the proposed policy.

C. ICRs Regarding Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610, 153.700, and 153.710)

We are finalizing the proposal to collect and extract five new data elements from issuers' EDGE servers: ZIP Code, race, ethnicity, ICHRA indicator, and subsidy indicator beginning

³⁵⁸ 82 FR 51118.

with the 2023 benefit year. Specifically, we are finalizing that starting with the 2023 benefit year, issuers will be required to populate the ZIP Code data field, using the five-digit level based on the enrollee's mailing address, and the subsidy indicator data field, which is intended to indicate whether a particular enrollee is (or is not) receiving APTC. For the 2023 and 2024 benefit years, we are adopting a transitional period during which issuers are required to populate the fields for race and ethnicity using only data they already collect or have accessible regarding their enrollees.³⁵⁹ For example, for the 2023 and 2024 benefit years, for race and ethnicity data, issuers will be deemed in compliance if they submit these data elements using data they already have or collect through existing means, including, for example, through enrollee data captured and reported to the issuer by the FFE, SBE-FPs, and State Exchanges at the time of enrollment. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the fields using available sources and, in the absence of such an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the race and ethnicity data for these enrollees.

We are also finalizing, with slight modification, collection of the ICHRA indicator. For the 2023 and 2024 benefit year, similar to the transitional approach for race and ethnicity data, issuers are required to populate the field for the ICHRA indicator using only data they already collect or have accessible regarding their enrollees. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the field using available sources (for example, information from Exchanges and small employers, and requesting information directly from enrollees) and, in the absence of an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the ICHRA indicator for these enrollees. HHS will provide additional details on what constitutes a

³⁵⁹ HHS will collect these data elements in a format that is consistent with the 2011 HHS Data Standards. We also will provide a value for the race or ethnicity data elements that allows issuers to indicate that race or ethnicity are not known for a specific enrollee in recognition of situations where the enrollee declines to provide the information and situations where the issuer does not have an available data source to populate the fields.

good faith effort to ensure collection and submission of the race, ethnicity, and ICHRA indicator data elements beginning with 2025 benefit year data submissions in the future.³⁶⁰

In addition, as detailed earlier, we are finalizing the extraction of the three data elements that issuers already make accessible to HHS as part of the required risk adjustment data – plan ID, rating area, and subscriber indicator – but will extract plan ID and rating area beginning with the 2021 benefit year, and the subscriber indicator beginning with the 2022 benefit year. We concluded the proposals to extract these data elements will not pose an 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 did not propose to change the existing burden for the proposal to extract plan ID, rating area, and subscriber indicator.

For the five new data elements we proposed to collect beginning with the 2023 benefit year, we estimated that approximately 600 issuers would be subject to this new data collection. We proposed to collect these new data elements via issuers' ESES files and risk adjustment recalibration enrollment files. In the proposed rule (87 FR 584 and 695), we estimated 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 was \$225,168 for 600 issuers (2,400 total hours per year for all issuers). We explained the proposals to extract these data elements would not pose an additional operational burden to issuers, since the creation and storage of the extract are mainly handled by HHS. We are finalizing the proposed collection and extraction of ZIP Code, race, ethnicity, the ICHRA indicator, and the subsidy indicator. HHS submitted a reinstatement request to OMB for approval of the previously expired information collection request (OMB control number 0938-1155/CMS-10401). Once reinstated, HHS will revise the

³⁶⁰ After the transitional approach ends (beginning in the 2025 benefit year), the option to select the value to indicate race or ethnicity are not known for a specific enrollee will be available to issuers who comply with the good faith standard but are unable to populate the race or ethnicity EDGE data field for one or more enrollees.

information collection request to account for the burden associated with this policy, and will provide the applicable comment periods.

After a review of the comments received, and after incorporating the most recently updated wage estimate data, we are updating the burden estimates for this policy as described below.

We summarize and respond to public comments received on ICRs related to Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610, 153.700, and 153.710) below.

Comment: One commenter disagreed with the estimated 4 hours of work per issuer to collect and submit additional data elements estimated in this section of the proposed rule and reflected in the regulatory impact analysis of the proposed rule. The commenter stated that the cost associated with these collection and extraction proposals would be 500 hours of work per issuer. The commenter did not provide further detail regarding the methodology used to calculate its burden estimate of 500 hours.

Response: We are finalizing the proposal to require issuers of risk adjustment covered plans to submit and make accessible five new data elements (ZIP Code, race, ethnicity, the ICHRA indicator, and the subsidy indicator) as part of the enrollee-level EDGE data to HHS in States where HHS operates the risk adjustment program beginning with the 2023 benefit year. We are also finalizing the accompanying proposal for HHS to extract these data elements once available. To better reflect the most current agency estimates, we have modified the estimates from our proposed rule. Currently, all issuers that submit data to their EDGE servers³⁶¹ have automated the creation of data files that are submitted to their EDGE servers. For successful EDGE server data submission, each issuer will need to update their file creation process to

³⁶¹ Issuers that elect a risk adjustment default charge are not required to submit EDGE data. See 45 CFR 153.740(b) and 81 FR at 12237 -12238. Also see, for example, *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year* (2021, June 30). CMS. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf>.

include the five new data elements, which will require a one-time administrative cost. After incorporating the most recently updated wage estimate data, we estimate this cost at \$2,899.80 (reflecting 30 hours of work by a management analyst at an average hourly rate of \$96.66 per hour). In addition, rather than 4 hours of work, we now estimate, based on the most current agency estimates, that the new data collection will require 5 hours of work by a management analyst (one hour of work per new data element collected), at an average hourly rate of \$96.66 per hour. We have limited this estimate to the incremental information collection associated with the requirements of the new data collection. As such, although the new data collection requires that issuers transform and submit additional data elements, it does not require changes to the process or distributed data collection approach currently used by an issuer to submit and make risk adjustment data accessible to HHS, which is via issuers' ESES files and risk adjustment recalibration enrollment files on their EDGE servers. We also estimate that approximately 650 issuers, rather than 600 issuers as initially estimated, will be subject to this new data collection. Based on these modifications, we estimate approximately \$483.30 in total labor costs per year for each issuer. In addition, the cumulative one-time cost to update issuers' file creation process is \$1,884,870 for 650 issuers (19,500 total hours for all issuers). The cumulative additional annual cost estimate as a result of this proposal is \$314,145 for 650 issuers (3,250 total hours per year for all issuers).

In addition, we are finalizing the proposed extraction of the three data elements that issuers already make accessible to HHS as part of the required risk adjustment data – plan ID, rating area, and subscriber indicator – but will extract plan ID and rating area beginning with the 2021 benefit year, and the subscriber indicator beginning with the 2022 benefit year. As explained previously in this rule and in the proposed rule, extracting these data elements will not pose an additional operational burden to issuers since the creation and storage of the extract are not received by issuers and is primarily handled by HHS. Therefore, there is no additional issuer burden associated with extracting any of the new data elements that will be collected (ZIP Code,

race, ethnicity, the ICHRA indicator, and the subsidy indicator), or with extracting the data elements that are already being collected (plan ID, rating area, and subscriber indicator).

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)

In this final rule, we are finalizing the proposal to revise § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(I) through (6)³⁶² a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We are also finalizing the proposal 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. We are finalizing as proposed.

The revised disclaimer policy should result in a very limited new burden for web-brokers. The new standardized disclaimer requires 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 will be displaying a disclaimer much like the plan detail disclaimer that they have historically been required to display.

We estimated the revised disclaimer policy 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, we estimated a cost of \$411 in total labor costs

³⁶² While the preamble in the proposed rule referred to amendments to add new § 155.220(c)(3)(i)(A)(I) through (c)(3)(i)(A)(5), the discussion of the proposal and the proposed regulations made clear that the proposal would add new § 155.220(c)(3)(i)(A)(I) through (c)(3)(i)(A)(6). See, for example, 87 FR 641 through 642 and 721 through 722.

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 policy is \$8,220 for 20 web-brokers in the 2022 benefit year. We have updated these estimates based on the most recent available national occupational employment and wage estimates. We estimate a cost of \$459 in total labor costs for each web-broker, which reflects 5 hours of work by Web and Digital Interface Designers (15-1255) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of \$91.80. The cumulative additional cost estimate as a result of the revised disclaimer policy is \$9,180 for 20 web-brokers in the 2022 benefit year. We are finalizing this proposal and will revise the information collection under OMB control number 0938-1349 accordingly and provide the applicable comment periods.

We are also finalizing the proposal to amend § 155.220 to add a 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 the plan name, from lowest to highest premium, etc.). We are finalizing as proposed.

This policy should result in very limited new costs for web-brokers, since the information it requires they display on their websites is limited to text-based changes that are relatively easy to implement. Some web-brokers are already providing the information, and therefore, will not have to make any website updates. Other web-broker websites do not explicitly recommend QHPs, and therefore, the impact is 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. Furthermore, the extent of those textual updates should be relatively minor in most cases. We expect explanations to be short and easy for consumers to understand. Generally, we believe that a single phrase or a few sentences will suffice.

We estimated this policy 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 estimated 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 policy is \$8,220 for 20 web-brokers in the 2022 benefit year. We have updated these estimates based on the most recently available national occupational employment and wage estimates. We estimate a cost of \$459 in total labor costs for each web-broker, which reflects 5 hours of work by Web and Digital Interface Designers (15-1255) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of \$91.80. The cumulative additional cost estimate as a result of this policy is \$9,180 for 20 web-brokers in the 2022 benefit year. We are finalizing this proposal and will 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 proposed to amend § 155.420 to add a 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 the burden on consumers applying for special enrollment period types that no longer

require pre-enrollment verification. We expected 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 compared to a total of 970,000 individuals in 2019. We estimated 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. We have updated these estimates to reflect the most recent wage estimates based on the most recent national occupational employment and wage estimates. We anticipate that it will take an Eligibility Interviewer approximately 12 minutes (at an hourly cost of \$46.70) 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 \$5,306,600.³⁶³ 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 the annual burden for the Federal Government of 38,800 hours at a cost of \$1,811,960. It would also result in a decrease in the annual burden for consumers attesting to special enrollment period types that no longer require document verification of 194,000 hours.

We are finalizing this requirement 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

³⁶³ 82 FR 18346.

collection currently approved under OMB control number 0938-1207 (Expiration date: February 29, 2024).³⁶⁴

We did not receive any comments in response to the information collection requirements related to the proposed policy.

F. ICRs Regarding General Program Integrity and Oversight Requirements (§ 155.1200)

1. Programmatic Audit Requirement (§ 155.1200(c))

We proposed 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 proposed under part 155, subpart P. We estimated that there would be a burden reduction for State Exchanges related to the programmatic audit requirement under § 155.1200(c). Based on industry estimates of the average cost of contracting an auditor to conduct an independent external programmatic audit, HHS estimated 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 SMART. 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 estimated 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.

³⁶⁴ 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).

Based on these estimates, we expected 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

We requested comment on the reduction in burden proposed, and specifically sought feedback from State Exchanges regarding the annual cost of the programmatic audit process.

We did not receive any comments in response to the information collection requirements related to the proposed policy. We are not finalizing this provision at this time. Since we are not finalizing this provision, we have not provided updated burden estimates based on the most recently published wage estimate date. We provide further details in the preamble section of this final rule.

2. Reporting on APTC calculation methodology (§ 155.1200(b)(2))

We are finalizing to codify the proposed APTC proration methodology to be used by the Exchanges on the Federal platform, but we are not finalizing the requirement to prorate premium or APTC amounts for State Exchanges. Rather, beginning in PY 2024 we will require State Exchanges to implement a methodology to ensure that the total monthly APTC amount does not exceed an enrollee's monthly PTC eligibility to maintain compliance with HHS and IRS regulations. We are also finalizing the requirement that State Exchanges must prospectively report to HHS through existing State Exchange oversight mechanisms described at § 155.1200(b)(2) the methodology the State Exchange plans to use in PY 2024. The requirement to report this methodology to HHS will be fulfilled through the SMART and will impose minimal burden on State Exchanges, who already report on eligibility and enrollment and compliance with other Exchange program requirements through this tool. This information collection is currently approved under OMB control number: 0938-1244 (Expiration date July 31, 2022/CMS-10507).

G. ICRs Regarding State Exchange Improper Payment Measurement Program (§§ 155.1500 – 155.1540)

1. Data Collection (§ 155.1510)

As described in the preamble to § 155.1510, we explain the sampling process for each SEIPM review cycle. In § 155.1510(a)(1), we proposed 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 proposed 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 the 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 expected 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 did not expect reporting costs to vary considerably based on sample size. We sought comment on these assumptions.

We estimated 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 State Exchange into the burden estimates.

HHS estimated 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.

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 believed 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 proposed 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 estimated that it would take each selected State Exchange up to 1,000 hours to develop a CAP. We estimated 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 estimated 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.

After reviewing the public comments received for the SEIPM program proposal, we will not finalize this provision at this time. We have not provided updated burden estimates for any of the elements associated with the SEIPM program policy to reflect the most recent wage estimate data, as we are not finalizing this provision and the final estimated burden will not be included in the Accounting Table (Table 20). We summarize and respond to public comments received on ICRs Regarding State Exchange Improper Payment Measurement program (§§ 155.1500 through 155.1540) below.

Comment: One commenter stated their State Exchange currently expends approximately \$280,000 annually on other audit requirements. The commenter noted the SEIPM program will require significant changes to their reporting systems, as well as providing access to certain data. The commenter noted that CMS' estimated annual cost of the SEIPM program at \$3 million is over 10 times what their State Exchange spends on all of its current audits. Other commenters did not estimate the dollar amount of the burden cost to their State Exchanges but expressed concern about duplicative data collection and needed IT investments.

Response: After considering the public comments received, we will not finalize the SEIPM program proposal at this time. We will solicit public comments on the SEIPM program in future rulemaking.

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

We proposed 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.³⁶⁵

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

³⁶⁵ See 85 FR 29164, 29244.

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,³⁶⁶ repealing the annual reporting requirement will also remove the associated ICRs and the anticipated burden on States submitting such reports. Thus, as we are finalizing 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).

After reviewing the public comments, we are finalizing the repeal of the annual reporting policy at § 156.111(d) and (f), including revising the section heading to § 156.111 to instead read, “State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.”

I. ICRs Regarding Differential Display of Standardized Plan Options on the Web Sites of Web-Brokers (§ 155.220) and QHP Issuers (§ 156.265)

As detailed above, we are resuming enforcement of the standardized plan option 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, beginning with the PY 2023 open enrollment period.

We estimated 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 estimated 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

³⁶⁶ 86 FR 24140.

annual cost of \$164.40 per entity. Therefore, we estimated a total annual burden of 220 hours at a cost of \$18,804 for all applicable web-brokers and QHP issuers. Since the proposed rule, we have updated these estimates to reflect the most recently available national occupational employment and wage data. We estimated that it would take a web digital interface designer (OES occupational code 15-1255) 2 hours annually, at an average hourly cost of \$91.80 per hour, to implement these changes, at a total annual cost of \$183.60 per entity. Therefore, we estimated a total annual burden of 220 hours at a cost of \$20,196 for all applicable web-brokers and QHP issuers.

Consistent with the approach finalized in the 2018 Payment Notice,³⁶⁷ we continue to recognize that system constraints may prevent web-broker and QHP issuers from mirroring the HealthCare.gov display. We therefore will 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 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 estimated that 55 of the above web-brokers and QHP issuers would submit a request to deviate from the manner in which standardized plan options are differentially displayed on HealthCare.gov. We estimated 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. Therefore, we estimated 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. Since the proposed rule, we have updated these estimates to reflect the most recently available national occupational employment and wage estimates. We estimate it would

³⁶⁷ 81 FR 94118.

take a compliance officer (OES occupational code 13-1041) approximately 1 hour annually, at a rate of \$72.90 per hour, to complete the request to deviate from the display on HealthCare.gov, as well as the justification for the request. Therefore, we estimated a total annual burden for all web-brokers and issuers subject to the differential display requirements submitting a request to deviate of approximately \$4009.50 beginning in 2023.

To account for the burden associated with this ICR, (Non-Exchange Entities – OMB control number 0938-1329 (CMS-10666)) HHS submitted a reinstatement request to OMB for approval to restore the previously discontinued request.

We did not receive any comments in response to the information collection requirements related to the proposed policies.

J. ICRs Regarding Network Adequacy and Essential Community Providers (§§ 156.230 and 156.235)

We are finalizing amendments to § 156.230, including the 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 finalized raising the ECP provider participation standard 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. Reviews of appointment wait time standards will begin in the QHP

certification cycle for PY 2024. Lastly, an issuer must report the offering of telehealth services for each provider to help inform the future development of telehealth standards. We provided the definition of telehealth in the draft PY 2023 Letter to Issuers. Issuers will be required 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 can 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 final 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 the geographic location of ECPs in an issuer's provider network. Since we are finalizing raising 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.³⁶⁸ 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 increase in the ECP threshold would somewhat increase the 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 the 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

³⁶⁸ The ECP/NA template requires QHP issuers to report only that number of providers sufficient to demonstrate compliance with relevant requirements.

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 finalized a broader provider specialty list for time and distance standards than was evaluated for PYs 2015-2017. We also added appointment wait time standards and will begin implementing network adequacy reviews of appointment wait time standards in PY 2024. 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 4 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 estimated that the total annual burden associated with completing the additional requirements proposed within the ECP/NA template for medical QHPs for up to 215 issuers would be up to 4,300 hours. Assuming the compliance officer's average hourly rate of \$36.35 per hour, plus a 100% fringe benefit rate of \$36.45, we estimated 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 estimated that the total annual burden associated with this requirement for SADPs for up to 270 issuers would be up to 1,080 hours. Assuming the compliance officer's average hourly rate of \$36.35 per hour, plus a 100 percent fringe benefit rate of \$36.35, we estimated 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.

Since publishing the proposed rule, we have updated these estimates to reflect the most recently available national occupational employment and wage estimates. We currently estimate that the total annual burden associated with completing the additional requirements proposed within the ECP/NA template for medical QHPs for up to 215 issuers would be up to 4,300 hours. Assuming the compliance officer's average adjusted hourly rate of \$72.90 per hour, we estimate that the cost of completing the ECP/NA template for an individual medical QHP could be up to \$1,458 and for all 215 issuers, up to \$313,470. We estimate that the total annual burden associated with this requirement for SADPs for up to 270 issuers would be up to 1,080 hours. Assuming the compliance officer's average adjusted hourly rate of \$72.90 per hour, we estimate that the cost of completing the ECP/NA template for an individual SADP could be up to \$291.60, and for all 270 issuers, up to \$78,732. The total estimated cost for the annual burden associated with completing the ECP/NA template across both medical QHP and SADP issuers is \$392,202.

HHS submitted the Essential Community Provider-Network Adequacy (ECP/NA) Data Collection to Support QHP Certification information collection request (OMB control number 0938-NEW/CMS-10803) to OMB to request approval for data collections related to essential community provider and network adequacy requirements, which includes the changes finalized in this final rule. The existing information collection for QHP certification (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 in this rule.

We summarize and respond to public comments received on ICR regarding network adequacy and essential community providers (§§ 156.230 and 156.235) below.

Comment: Commenters submitted two remarks regarding the burden estimates associated with the addition of telehealth data collection reporting for SADPs. Commenters expressed concern that the burden was underestimated for SADPs and should be reassessed. The commenters shared that they believe the burden is underestimated because: SADPs do not currently collect data on telehealth; the estimate does not include costs for a second reviewer; and the hourly rate and total estimated hours are too low.

Response: We appreciate the feedback received on the burden estimates for SADPs. HHS is aware that the actual burden will vary for each QHP based on a variety of factors. We acknowledge that telehealth data collection may increase the burden for some QHPs, including SADPs. We are also aware that some QHPs already have telehealth data available, from sources like claims data or provider surveys. We have reflected the telehealth data collection requirement in our burden estimates and believe these estimates are reasonable. For issuers that have not yet received responses from providers regarding telehealth availability and do not have that information available from other sources, like claims data, they can select the response on the template that they are awaiting a response from that provider.

For QHP certification data collection and reporting, we use the mean hourly wages for a compliance officer to estimate costs. This data was retrieved from the Bureau of Labor Statistics

web site.³⁶⁹ HHS believes that this job title and associated hourly wage provide a reasonable basis for our estimates. We understand that multiple staff at different levels may be involved and the total number of anticipated hours reflects that. It is up to each issuer to determine their process for collecting and reporting ECP/NA data and how many staff are involved. We will collect user experience data regarding the information collection requirements related to network adequacy and will reassess burden estimates for future years as needed.

Comment: Two commenters expressed concern that the burden estimate was too low.

Response: HHS believes the burden estimates accurately reflect the time it takes for an issuer to complete the activities described in this package and bases its estimates on extrapolation from experience in prior plan years.

Comment: One commenter stated that updates made to ECP/NA data collection are necessary and should be approved.

Response: HHS agrees that the ECP/NA data collection is necessary to support the ECP/NA portions of the QHP certification review process.

Comment: Some commenters recommended that HHS defer to States that have similar network adequacy standards as the Federal network adequacy standards, and coordinate with States and NAIC where possible.

Response: As described in the preamble of this rule, HHS will defer to States performing plan management that elect to perform their own reviews during QHP certification, provided that the State applies and enforces network adequacy standards that are at least as stringent as the Federal standards. HHS will continue to coordinate with States and NAIC.

Comment: A commenter encouraged HHS to identify plans that use very narrow networks as a discriminatory enrollment selection process rather than to control costs.

³⁶⁹ *Occupational Employment and Wages, May 2021*. (2022, March 31). Bureau of Labor Statistics. <https://www.bls.gov/oes/current/oes131041.htm>.

Response: HHS appreciates this suggestion and will consider the possibility of identifying plans that use narrow networks as a method to deter consumers with greater health needs from enrollment.

Comment: Some commenters recommended that HHS align network adequacy standards with NCQA and Utilization Review Accreditation Commission (URAC) standards.

Response: HHS reviewed the NCQA and URAC standards regarding network adequacy. We believe it is appropriate to align with NCQA in its use of business days to measure appointment wait time standards, which will be finalized in the final PY 2023 Letter to Issuers. We will also finalize that the appointment wait time standard for the behavioral health category will align with NCQA's standards. NCQA and URAC do not have quantitative parameters for the other categories we are finalizing for appointment wait times nor do they have quantitative standards for time and distance.

Comment: One commenter requested HHS allow providers from multiple network tiers to be considered when assessing network adequacy.

Response: HHS is not finalizing the network tiering policy for network adequacy.

Comment: Some commenters requested that HHS defer network adequacy standards until PY 2024 and defer appointment wait time standards until COVID-related provider staffing issues are addressed.

Response: HHS is finalizing appointment wait time standards and delaying implementation until PY 2024.

Comment: Some commenters shared concerns that plans will not have enough time to implement changes required by the proposed network adequacy policies and that plans do not have sufficient details on the implementation plans for these policies. Some commenters offered feedback on specific provider types and requested more detail on how provider types are defined. One commenter requested clarification about aspects of the ECP/NA template, such as telehealth data collection, provider specialty codes, and time and distance parameters.

Response: HHS included details on the implementation of network adequacy policies in the draft 2023 Letter to Issuers and believes issuers will have sufficient time to comply with time and distance standards for PY 2023 and appointment wait time standards beginning in PY 2024. Further information, including detail on definitions of provider types and clarification requested regarding aspects of the ECP/NA template, will be included in the ECP/NA template, FAQs, QHP Application Instructions, and other related documents.

Comment: One commenter requested deferral of telehealth data collection.

Response: HHS will collect data from issuers on which providers offer telehealth as many issuers already have this information, can gather it during the required timeframe, or can select that they have requested information from the provider and are awaiting their response.

Comment: Two commenters recommended a clear network adequacy justification process.

Response: HHS has developed streamlined justification processes for network adequacy and ECP that are described in the preamble.

Comment: Some commenters requested that HHS use a phased-in approach to increasing the ECP threshold or that HHS defer raising the ECP threshold until PY 2024.

Response: HHS is finalizing the ECP threshold for PY 2023 as proposed as we anticipate the majority of issuers will be able to meet the standard and the justification process can be used by issuers that are working to come into compliance with the ECP standards.

Comment: One commenter requested HHS consider a different approach to assess network adequacy in rural areas.

Response: HHS believes the time and distance standards for rural areas are reasonable based on our review of industry standards. We will assess time and distance standards at the county level. Rural counties and counties with extreme access considerations will have time and distance parameters that are longer than more metropolitan areas.

Comment: A commenter asked HHS to exclude SADPs from appointment wait time standards requirement.

Response: HHS does not agree that SADPs should be exempt from compliance with appointment wait time standards. HHS believes it is important that timely access to care is ensured, regardless of plan type. HHS will evaluate all plans seeking QHP certification, including SADPs, for compliance with appointment wait times beginning in PY 2024.

Comment: One commenter recommended that HHS provide additional opportunities for stakeholder feedback on the implementation of network adequacy policies.

Response: HHS will continue seeking stakeholder feedback on network adequacy policies on an ongoing basis.

HHS received one out-of-scope comment to which we have not responded in this final rule.

K. ICRs Regarding Payment for Cost-Sharing Reductions (§ 156.430)

We proposed 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.³⁷⁰ We expected 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

³⁷⁰ OMB control number 0938-1266 (Cost-Sharing Reduction Reconciliation (CMS-10526)/Expiration date: July 31, 2024).

31, 2024) to account for this decreased burden when HHS is not making CSR payments to QHP issuers.

We did not receive any comments in response to the information collection requirements related to the proposed policy.

L. ICRs Regarding Quality Improvement Strategy (§ 156.1130)

We did not propose and are not finalizing any amendments to the regulatory text in 45 CFR 156.1130, which outlines QIS data collection and submission framework established in the 2016 Payment Notice.³⁷¹ The information collections associated with QIS data collection and submission requirements are currently 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 rule, we are finalizing, as proposed, that beginning with QIS submissions in calendar year 2023 (for the PY 2024 coverage), a QHP issuer would be required to address reducing health and health care disparities as one of the 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 did not estimate additional burden to be accounted for since the current QIS submission form already encompasses the estimated burden and costs associated with a QIS submission that may include several QIS topic areas.

We did not receive any comments in response to the information collection requirements related to the proposed policy.

M. ICRs Regarding Medical Loss Ratio (§§ 158.140, 158.150, 158.170)

We are finalizing the proposed amendments to § 158.140 to codify in regulation that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable,

³⁷¹ 80 FR 10750, 10844 through 10848.

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 are also finalizing amendments to § 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 are also finalizing the proposed 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.³⁷² We anticipate that implementing these provisions will require minor changes to the MLR Annual Reporting Form Instructions but will 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.

We did not receive any comments in response to the information collection requirements related to the proposed policies.

N. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 18: Final 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	650	650	30	19,500	\$1,884,870	\$1,884,870
§ 155.220	0938-1349	20	40	5	200	\$18,360	\$18,360
§§ 156.230 and 156.235	0938-NEW	270 (SADPs)	270	4	1,080	\$78,732	\$78,732
§§ 156.230 and 156.235	0938-NEW	215 (Medical QHPs)	215	20	4,300	\$313,470	\$313,470
§§ 155.220 and 156.265	0938-1329	55 (deviation request)	55	1	55	\$4,009.50	\$4,009.50
§§ 155.220 and 156.265	0938-1329	110 (differential display)	110	2	220	\$20,196	\$20,196
Total				62	25,355	\$2,259,858.50	\$2,259,858.50

³⁷² 86 FR 24261.

TABLE 19: Final 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	-\$126,345	-\$126,345
§ 155.420*	0938-1207	n>10		.2	-38,800	-\$1,811,960	-\$1,811,960
§156.111	0938-1174	41	0	13	-533	-\$45,817	-\$45,817
Total				73.2	-40,773	-\$1,984,122	-\$1,984,122

*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 final rule includes several policies with information collection requirements for which we use this rulemaking as the **Federal Register** notice through which to receive comment on their proposed revisions to or submissions of ICRs. These proposals include Verification of Eligibility for Special Enrollment Periods (§ 155.420), and the proposals on Network Adequacy and Essential Community Providers (§§ 156.230 and 156.235) and the proposal regarding Differential Display of Standardized Plan Options (§§ 155.220) and 156.265).

The following policies with associated information collection requests that require revision to align with policies in this rule, including State Flexibility for Risk Adjustment (§ 153.320), Risk Adjustment Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610, 153.700 and 153.710), and the 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) will be submitted for OMB approval outside of this rulemaking, through a separate **Federal Register** notice.

The policies for Quality Improvement Strategy (§ 156.1130), Medical Loss Ratio (§§ 158.140, 158.150, 158.170), Payment for Cost-Sharing Reductions (§ 156.430), and Reporting APTC Calculation Methodology (§ 155.1200(b)(2)) contain information collections which are currently approved by OMB that do not require revision. One policy, the State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111), as finalized, will discontinue the associated information collections and remove them from the ICRs, and the

information collected in the Determination of Error Findings Decision and Appeal Redetermination (§§ 155.1525 and 155.1530) policy is exempt from the PRA.

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

V. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes 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 finalizes 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 finalizes to remove the annual reporting requirement on States to report State-required benefits to HHS. The rule also finalizes refinements to the EHB nondiscrimination framework by including examples of presumptively discriminatory benefit designs. The rule also finalizes the requirement that issuers in FFEs and SBE-FPs offer standardized plan options. This rule finalizes to expand QIS standards and requires 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 final 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), and the Congressional Review Act (5 U.S.C. 804(2)).

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, reducing costs, 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, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). In accordance

with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The provisions in this final rule aim to ensure 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 anticipated that the provisions of this final 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 believed 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 20 depicts an accounting statement summarizing HHS' assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this final rule. The effects in Table 20 reflect the qualitative assessment of impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers. The annual monetized transfers described in Table 20 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 amendments to MLR requirements.

We are finalizing 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 estimated to cost

approximately \$60 million in the benefit year 2023.³⁷³ 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 20.

Additionally, for 2023, we are maintaining the FFE and the SBE-FP user fee rates at current levels, 2.75 and 2.25 percent of premiums, respectively.

TABLE 20: Accounting Table

Benefits:				
Qualitative:				
<ul style="list-style-type: none"> 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 the health insurance coverage due to the proposal to decrease the scope of special enrollment period verification. Greater consistency in protections based on EHB nondiscrimination. Increased access to more comprehensive provider networks and enhanced health equity³⁷⁴ due to the network adequacy and ECP finalized policies, which will 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 finalized policies. 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 finalized policies. 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)	-\$119.0 Million	2021	7 percent	2022-2026
	-\$120.3 Million	2021	3 percent	2022-2026
Quantitative:				
<ul style="list-style-type: none"> Reduction in costs for States related to annual reporting of State-required benefits, estimated to be one-time savings of \$100,829 in PY 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 \$63 million in 2022 and annual savings of \$134 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 \$5.3 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 \$126,345 in reporting costs to reflect the number of States participating in the State flexibility to request a reduction in risk adjustment State transfers in any market risk pool, which starting with the 2024 benefit year, will only be available to one prior participating State. Cumulative one-time implementation cost associated with the collection of five new data elements for risk adjustment is estimated to be approximately \$1,884,870 for 650 issuers, or \$2,899 per issuer in the 2023 benefit year. 				

³⁷³ As noted previously in this final 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.

³⁷⁴ Healthy People 2030 defines health equity as “the attainment of the highest level of health for all people.” *Healthy People 2030 Questions & Answers*. (2022, March 9). Office of Disease Prevention and Health Promotion. <https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/questions-answers>.

- Cumulative additional cost estimate for the collection of five new data elements for risk adjustment is estimated to be approximately \$314,145 for 650 issuers, or \$483.30 per issuer annually, beginning in the 2023 benefit year.
- Increased cost to web-brokers to implement minor text-based changes to their websites to add or modify a disclaimer. Estimated \$9,180 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 \$9,180 in one-time costs for 20 web-brokers in the 2022 benefit year.
- Increased annual cost of \$20,196 across all web-brokers and QHP issuers utilizing the Classic DE and EDE Pathways to comply with the standardized plan option differential display requirements in the 2023 benefit year.
- Increased annual cost of \$4,009.50 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 (beginning in PY 2024), 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 \$392,202 beginning in PY 2023.
- Increased costs to State Exchanges associated with one-time operational builds to comply with the APTC methodological requirements estimated at \$500,000 for each of 8 State Exchanges, or \$4 million in PY 2024.

Qualitative:

- Potential reduction in costs 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 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)	\$631.9 Million	2021	7 percent	2022-2026
	\$645.3 Million	2021	3 percent	2022-2026

Quantitative:

- Federal Transfers to Consumers: Increase in PTC payments due to changes in the AV *de minimis* range, estimated to be approximately \$0.73 billion in 2023, \$0.77 billion in 2024, \$0.77 billion in 2025, and \$0.76 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 2 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).

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 21 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 final rule discussed in this RIA. We did not expect the provisions of this final rule to significantly alter CBO’s estimates of the budget impact of the premium stabilization programs that are described in Table 21.

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 anticipated that, quantitatively, the effects of the provisions proposed in this rule are consistent with our previous estimates in the 2022 Payment Notice³⁷⁵ for the impacts associated with the APTC, the premium stabilization programs, and FFE (including SBE-FP) user fee requirements.

TABLE 21: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2023-2027, in billions of dollars³⁷⁶

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. The 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 rule finalizes amendments to § 147.104(i), which reverse the current 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 the current policy, individuals may have had to pay up to 3 months of past-due premiums plus a binder payment before enrolling in coverage.³⁷⁷ HHS lacks information on

³⁷⁵ 86 FR 6166 through 6173 and 24270 through 24282.

³⁷⁶ Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

³⁷⁷ 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

the frequency with which consumers miss payments or the frequency with which binder payments are made, and sought data or information related to past-due premiums in the proposed rule (87 FR 584 and 706). HHS was 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 2022 survey, 36 percent of insured adults reported being worried about being able to afford their monthly health insurance premium, with 12 percent being “very worried” and 23 percent being “somewhat worried.”³⁷⁸ In a 2021 survey, 27 percent of insured adults reported having a difficult time covering the cost of health insurance each month.³⁷⁹ In 2019, 73.7 percent of uninsured adults pointed to the high cost of coverage as the reason for being uninsured.³⁸⁰

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 2017.³⁸¹ 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 estimated 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

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.

³⁷⁸ Kirzinger, A., Kearney, A., Quasem, M., Stokes, M., Hamel, L., & Brodie, M. (2022). “KFF Health Tracking Poll – March 2022: Economic Concerns and Health Policy, The ACA, and Views of Long-term Care Facilities.” *KFF*, <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-march-2022/>

³⁷⁹ Data Note: Kearney, A., Hamel, L., Stokes, M., & Brodie, M. (2021). Americans’ Challenges with Health Care Costs. *KFF*, <https://www.kff.org/health-costs/issue-brief/data-note-americans-challenges-health-care-costs/>.

³⁸⁰ Tolbert, J., Orgera, K., & Damico, A. (2020). Key Facts about the Uninsured Population. *KFF*. <https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/>.

³⁸¹ 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.

in 2017.³⁸² 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.³⁸³ That figure was 13.5 percent in 2018 and 13.2 percent in 2017. Our analysis also suggested 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 final rule will 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 may lead to better health outcomes, if these individuals are able to maintain coverage.³⁸⁴ This final rule will also increase the ability for enrollees to access coverage with the same issuer or another issuer in the same controlled group in the next year. This will be of particular benefit to those Exchange enrollees living in counties with only one or two participating issuers.³⁸⁵ It may also

³⁸² As we reported in the April 18, 2017 **Federal Register** (82 FR 18346), that figure was approximately 16 percent in 2016.

³⁸³ 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.

³⁸⁴ We requested comment on whether there would be any impact on premiums, affordability, and access for the individuals who reliably pay. We solicited 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.

³⁸⁵ 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

reduce the costs and burden to enrollees related to searching for a new plan from another issuer or an issuer in a different controlled group when seeking to enroll in health care coverage. Being able to enroll with the same issuer will support access to the same network of services and providers, which could improve continuity of care.

This final rule may result in transfers from issuers who would have been able to recoup unpaid premiums from enrollees to those enrollees who will 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 will be minimal, as issuers generally are not permitted to waive past-due premiums and would be expected to pursue other means of collecting them.

We sought comment on the potential costs, benefits, and transfers associated with this provision. We also sought data related to past-due premiums, missed binder payments, and information on the population and characteristics of individuals with past-due premiums.

We summarize and respond to public comments received regarding the impact of the proposed change to the guaranteed availability of coverage (§ 147.104(i)) requirement below.

Comment: Many commenters stated that this provision will increase access to health insurance coverage and care for individuals who stop paying premiums and are currently unable to enroll in coverage because they cannot afford to pay past-due premiums. Commenters provided a number of reasons why individuals stop paying premiums, such as financial hardship or affordability, not receiving a notice of past-due premiums, or mistakenly forgetting to cancel coverage when becoming eligible for other forms of coverage. Commenters also provided various reasons for financial hardship such as periodic unemployment, chronic conditions, serious illnesses, addiction, domestic violence, crime, environmental disaster, and medical

counties. Source: McDermott, D. & Cox, C. (2020). *Insurer Participation on the ACA Marketplaces, 2014-2021*. KFF. <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 current interpretation of the guaranteed availability requirement. Source: Ahn, S. & Volk, J. (2017). *Relaxing the Affordable Care Act's Guaranteed Issue Protection: Issues for Consumers and State Options*. CHIRblog. <http://chirblog.org/relaxing-the-affordable-care-acts-guaranteed-issue-protection-issues-for-consumers-and-state-options/>.

emergencies. Commenters mentioned high rates of being uninsured among individuals in minority and underserved communities and women and children and the risks associated with being uninsured. One commenter cited studies that found a correlation between the lack of health insurance coverage and preventable deaths.

Many commenters stated that the current policy creates a barrier to coverage for and has a negative impact on low- or middle-income individuals and individuals experiencing financial hardship. Several commenters also stated that the current policy has a disproportionate impact on underserved populations, such as immigrants, people of color, disabled women, and the LGBTQI+ community, that continue to face cultural and financial barriers to coverage and care.

A few commenters also stated that if individuals are better able to maintain coverage because of this provision, it will improve continuity of care and lead to better health outcomes. One of these commenters noted in particular that enabling individuals to enroll with the same issuer the next plan year increases the likelihood that they will maintain relationships with their providers. Several commenters also highlighted the importance of continuous coverage during the COVID-19 pandemic.

Response: We agree with the commenters that this change improves health equity by removing a barrier to health insurance coverage and health care that disproportionately affects low-income, minority and underserved communities.

Comment: A few commenters stated that this provision will have a negative impact on consumers. Some commenters suggested that the provision will lead to higher costs for issuers and result in higher premiums for consumers. One commenter speculated that the increase in premiums could range from 0.3 percent to more than 3 percent. A few commenters also stated that the proposed rule will reduce access to coverage if issuers exit the market. A few commenters stated that the proposed rule could negatively affect risk pools. A commenter also expressed concern about the potential financial impact on providers who may not receive

payments when individuals fail to pay their premiums. One commenter also stated that it may negatively affect MLRs.

On the other hand, some commenters suggested that the proposed rule could improve the stability of risk pools, for instance, by reducing adverse selection. One of these commenters noted that the current policy may have deterred enrollment among younger, healthier individuals. A few commenters stated that the current policy worsened the risk pool and led to higher premiums, since individuals with significant health care costs are more likely to pay past-due premiums. One commenter noted that restrictions on enrollment outside of open enrollment periods limit adverse selection. In addition, one commenter stated that few issuers chose to implement the current policy because the implementation costs outweighed the premium losses. A commenter also speculated that the change would lead to reduced administrative costs for issuers. Several commenters stated that the amount of past-due premiums is minimal relative to issuers' profits. Several commenters also stated that issuers would be able to recoup past-due premiums by other means. One commenter noted that the financial risk to the individual from not having continuous coverage outweighs the cost to the risk pool from individuals not paying premiums (which could be recouped by issuers).

Response: We disagree that this rule is likely to result in an increase in premiums, have a negative financial impact on issuers or providers, or cause issuers to exit the market. There is no evidence that suggests that premiums would noticeably change because of a shift in how the guaranteed availability requirement is interpreted. As one commentator stated, few issuers have implemented the current policy of attributing payment made for new coverage to past-due premiums before effectuating new enrollment. In addition, as another commenter stated, issuers that did adopt the current policy are likely to experience a reduction in administrative costs due to this change. Issuers also have other means to recoup past-due premiums. We also agree with commenters that stated that this change may result in an improved risk pool by removing barriers to enrollment for young and relatively healthy individuals.

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)

In the 2023 Payment Notice proposed rule, HHS proposed amendments to certain regulations prohibiting discrimination in health insurance coverage, including discrimination in the design and implementation of health plan designs, under §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), 156.1230(b), and 156.125. HHS proposed to amend these regulations so that they explicitly identify and recognize sexual orientation and gender identity as prohibited forms of discrimination based on sex consistent with pre-2020 HHS discrimination policy. HHS also proposed refinements to its EHB nondiscrimination policy for health plan benefit designs through proposed amendments to § 156.125 regulation text that would require that a nondiscriminatory health plan design that provides EHB to be clinically based, incorporate evidence-based guidelines into coverage and programmatic decisions, and rely on a current and relevant peer-reviewed medical journal articles, practice guidelines, or recommendations from reputable governing bodies, or similar sources. We provided examples of presumptively discriminatory benefit designs to provide further clarity on our refined EHB nondiscrimination policy. HHS proposed that its refined EHB nondiscrimination policy under § 156.125, as reflected in the examples of presumptively discriminatory health plan designs, would be applicable starting on the earlier of PY 2023 or upon renewal of any plan subject to the EHB requirements.

We sought comment on the potential costs, benefits, and transfers associated with the proposals in these provisions.

As explained in the Supplementary Information section earlier in this preamble, HHS will address in future rulemaking the proposed amendments to §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) that would have explicitly identified and recognized sexual orientation and gender identity as prohibited forms of sex discrimination.

HHS is finalizing the proposed revisions to § 156.125(a) to state that a nondiscriminatory benefit design that provides EHB is one that is clinically based. However, HHS does not finalize the proposed revisions to § 156.125(a) that would have provided that a nondiscriminatory benefit design is one that incorporates evidence-based guidelines into coverage and programmatic decisions and relies on a current and relevant peer-reviewed medical journal articles, practice guidelines, or recommendations from reputable governing bodies, or similar sources.

HHS finalizes all but one of the examples of presumptively discriminatory benefit designs. Specifically, consistent with the explanation in the Supplementary Information section earlier in this preamble, HHS will address in future rulemaking the example related to gender-affirming care that illustrated a benefit design that presumptively discriminates against enrollees based on gender identity under § 156.125.

We summarize and respond to public comments received on the regulatory impact and burden analysis relevant to our proposals under § 156.125 that we finalize in this final rule. Accordingly, we do not respond to comments that relate to the proposal to specifically identify sexual orientation and gender identity as prohibited forms of sex discrimination, nor do we respond to comments that relate to the gender-affirming care example in the 2023 Payment Notice proposed rule.

Comment: One commenter questioned what the regulatory impact and burden would be on issuers and enrollees to declare a class of treatment based on “presumptive nondiscrimination.” Another commenter stated the policy refining the nondiscrimination standard would unintentionally impose costs that far exceed any benefits by limiting the ability of issuers to develop cost-effective formulary plan designs and by compelling plans to ignore the standard use of clinical evidence as a factor in determining the appropriate tier for drugs.

A commenter also asserted that the lack of a cost-benefit analysis makes the rule arbitrary and capricious (noting CMS does not cite how many plans already cover the procedures, how many individuals will seek them, their cost, and increased costs to issuers and insured). Other

commenters expressed concern that health plans may see increased utilization and higher costs due to an unintended adverse impact on issuers' ability to administer packages of benefits under the refined framework. Yet another commenter recommended that HHS should conduct and publish the results of a detailed cost study demonstrating premium impacts of refining the nondiscrimination standard for consumers prior to finalizing the proposal.

Response: With regards to the EHB nondiscrimination policy we are finalizing at § 156.125, we reiterate that the nondiscrimination requirements at § 156.125 apply only to benefit designs or implementation of a benefit designs to the extent that those benefits are EHB. The policy at § 156.125 does not apply to benefits that are not EHB. As mentioned in the proposed rule, the clarifications and changes we are finalizing to § 156.125 will most likely affect the vast majority of State EHB-benchmark plans. Because some current EHB-benchmark plans continue to be based on plan year 2014 plans, some of the EHB-benchmark plan designs may not comply with current Federal requirements such as nondiscrimination requirements at § 156.125. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers may need to further conform plan benefits covered as EHB, including coverage and limitations, to comply with current Federal requirements, such as the nondiscrimination requirement of § 156.125.

If a State EHB-benchmark plan has a discriminatory benefit design, the State may prohibit plans providing benefits that are substantially equal to the EHB-benchmark plan from replicating that discriminatory benefit design. However, we clarify that we will not consider State EHB-benchmark plan designs to be out of compliance with EHB-benchmark plan requirements at § 156.110(d) or § 156.111(b)(2)(v) if the State provides such guidance or otherwise directs issuers to comply with these refined nondiscrimination standards notwithstanding any aspects of the EHB-benchmark plan that are not otherwise consistent with these refined nondiscrimination standards. Therefore, under this approach, States are not required at this time to go through the formal process at § 156.111 to update their EHB-benchmark plans

solely for the purpose of removing any such discriminatory benefit designs on EHBs, but States that do elect to update their EHB-benchmark plans at any point going forward will be expected to ensure their new EHB-benchmark plans are compliant.

To the extent that States take actions necessary to come into compliance with the refined EHB nondiscrimination policy such actions may have a small impact on premiums. States making changes to their EHB-benchmark plans for plan years after 2020 have the flexibility to design their EHB-benchmark plans consistent with § 156.111, which provides more options in plan designs. 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 the scope of benefits requirements, under § 156.111(b).³⁸⁶

Plans subject to the EHB requirement have always been required to comply with the nondiscrimination requirements in § 156.125 regardless of the presence of any noncompliant discriminatory language in the relevant EHB-benchmark plan. We therefore further recognize that issuers subject to § 156.125 requirements may choose to carefully review the refined EHB nondiscrimination final rule to ensure compliance. We also recognize that such reviews may take time and that issuers may experience added burden to the extent that issuers make additional changes to their plans designs for benefits covered as EHB in response to those reviews. Although we expect that issuers are already compliant with current § 156.125 requirements, we also believe that finalizing the refined EHB nondiscrimination policy at § 156.125 to be

³⁸⁶ Section 156.111(b). <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-156>.

applicable on the earlier of PY 2023 or upon renewal of any plan subject to the EHB requirements will lessen any burden on issuers to make any necessary conforming changes than if we had finalized a mid-year effect date as proposed.

Further, we are declining to finalize that a nondiscriminatory benefit design that provides EHB must incorporate evidence-based guidelines into coverage and programmatic decisions, and rely on current and relevant peer-reviewed medical journal articles, practice guidelines, recommendations from reputable governing bodies, or similar sources. By instead finalizing only that plan designs providing EHB must be clinically based, we believe we are better balancing the need to protect consumers from discriminatory benefit designs without unreasonably limiting the sources that may be relied upon to assess whether a benefit design or its implementation are discriminatory. We will continually assess this policy to evaluate whether changes or further refinements are warranted.

3. Risk Adjustment (§§ 153.320, 153.610, 153.620, 153.700, 153.710, and 153.730)

We are finalizing two of the three proposed model specifications. Beginning with the 2023 benefit year, we are finalizing, as proposed, 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 to revise the enrollment duration factors for the adult models. However, we are not finalizing the proposed addition of a two-stage weighted model specification to the adult and child 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 an additional burden on State governments. The model specifications finalized in this rule result in limited changes to the number and type of risk adjustment model factors; therefore, we do not expect these changes to impact issuer burden beyond the current burden for the HHS-operated risk

adjustment program.³⁸⁷ To 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 the proposed changes using 2020 benefit year risk adjustment data.³⁸⁸

Additionally, we are finalizing, as proposed, the use of the 2017, 2018, and 2019 enrollee-level EDGE data to recalibrate the HHS risk adjustment models for the 2023 benefit year. 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 are also finalizing, as proposed, 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 are finalizing, as proposed, 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 will 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 2018.³⁸⁹ For the 2024 benefit year and beyond, we will 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 (except under the extenuating circumstances that are described previously in this rule). We removed the mapping

³⁸⁷ 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)), which is currently being updated. The previous version of the Supporting Statement is *Supporting Statement A*. (2017, December 22). OIRA. https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201712-0938-015.

³⁸⁸ See the *2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <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*. (2021, December 28). CMS. <https://www.cms.gov/files/document/report-summary-results-transfer-simulations.pdf>. Issuers that participated in the simulation also received detailed issuer-specific data, including risk score and transfer estimates for the simulated results.

³⁸⁹ See 81 FR 94075.

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.³⁹⁰ For the 2023 benefit year, we are finalizing, as proposed, to maintain the CSR adjustment factors finalized in the 2019-2022 Payment Notices.³⁹¹ Overall, we do not estimate that these policies 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. For the 2023 benefit year, we are finalizing, as proposed, to use the same methodology that we finalized in the 2022 Payment Notice to estimate our administrative expenses to operate the program. 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 2023 risk adjustment user fee will 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 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 will also repeal, as proposed, 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 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 removed, as proposed, as a criterion for State justification and HHS review and 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. We will retain as the sole requirement for State justification

³⁹⁰ 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.

³⁹¹ 83 FR 16953; 84 FR 17479; 85 FR 29190; and 86 FR 24181.

and criterion for HHS review and 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 changes to risk adjustment State flexibility request framework will 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 policy, Alabama would be considered a prior participant and could continue to request such reductions. However, we note that we intend to propose in future rulemaking to repeal the exception for prior participants beginning with the 2025 benefit year to provide impacted stakeholders additional time to prepare for this proposed change and the potential elimination of this flexibility. We did not anticipate any new burden or costs as a result of this policy.

We finalize the collection and extraction of five new data elements from issuers' EDGE servers through issuers' ESES files and risk adjustment recalibration enrollment files: ZIP Code, race, ethnicity, subsidy indicator, and ICHRA indicator beginning with the 2023 benefit year. Specifically, we are finalizing that starting with the 2023 benefit year, issuers will be required to populate the ZIP Code data field, using the five-digit level based on the enrollee's mailing address, and the subsidy indicator data field, which is intended to indicate whether a particular enrollee is (or is not) receiving APTC. For the 2023 and 2024 benefit years, we are adopting a transitional period during which issuers are required to populate the fields for race and ethnicity using only data they already collect or have accessible regarding their enrollees.³⁹² For example, for the 2023 and 2024 benefit years, for race and ethnicity data, issuers will be deemed in compliance if they submit these data elements using data they already have or collect through

³⁹² HHS will collect these data elements in a format that is consistent with the 2011 HHS Data Standards. We also will provide a value for the race or ethnicity data elements that allows issuers to indicate that race or ethnicity are not known for a specific enrollee in recognition of situations where the enrollee declines to provide the information and situations where the issuer does not have an available data source to populate the fields.

existing means, including, for example, through enrollee data captured and reported to the issuer by the FFE, SBE-FPs, and State Exchanges at the time of enrollment. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the fields using available sources and, in the absence of such an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the race and ethnicity data for these enrollees.

We are also finalizing, with slight modification, collection of the ICHRA indicator. For the 2023 and 2024 benefit year, similar to the transitional approach for race and ethnicity data, issuers are required to populate the field for the ICHRA indicator using only data they already collect or have accessible regarding their enrollees. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the field using available sources (for example, information from Exchanges and small employers, and requesting information directly from enrollees) and, in the absence of an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the ICHRA indicator for these enrollees. HHS will provide additional details on what constitutes a good faith effort to ensure collection and submission of the race, ethnicity, and ICHRA indicator data elements beginning with 2025 benefit year data submissions in the future.³⁹³

In addition, we will 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. We will extract plan ID and rating area beginning with the 2021 benefit year, and the subscriber indicator beginning with the 2022 benefit year. The extraction of plan ID, rating area, and subscriber indicator will pose a minimal burden on issuers (only the burden associated with the running of a command) since the creation and storage of the extract – which issuers do not receive – is mainly handled by HHS.

³⁹³ After the transitional approach ends (beginning in the 2025 benefit year), the option to select the value to indicate race or ethnicity are not known for a specific enrollee will be available to issuers who comply with the good faith standard but are unable to populate the race or ethnicity EDGE data field for one or more enrollees.

For the collection of the five new data elements, we estimated in the proposed rule that the cumulative additional cost estimate would be \$225,168 for 600 issuers (87 FR 584, 695). However, to reflect the most current agency estimates, we have modified the estimates from the proposed rule to reflect new wage data, and estimate that the cumulative additional cost estimate will be \$314,145 for 650 issuers, and that the addition of these five new data elements to the risk adjustment data submission requirements will be \$483.30 per issuer. In addition, we estimate a cumulative one-time administrative cost estimate to update the issuer's file creation process of \$1,884,870 for 650 issuers, reflecting a one-time cost of \$2,8992 per issuer, which is further explained in the Collection of Information section of this final rule. The extraction of these data elements will pose a minimal burden on issuers (only the burden associated with the running of a command) since the creation and storage of the extract – which issuers do not receive – is mainly handled by HHS. We expected minimal costs to HHS as a result of these new collections and extractions.

We are also finalizing, as proposed, 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 will not pose an 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 sought comment on estimated costs and transfers and potential benefits associated with these provisions.

We received one comment related to the burden associated with the requirement that issuers of risk adjustment covered plans to submit and make accessible the five new data elements as part of the enrollee-level EDGE data to HHS in States where HHS operates the risk adjustment program beginning with the 2023 benefit year, which we summarized and responded to in the Information Collection Requirements section of the rule.

4. Risk Adjustment Data Validation (§§ 153.350 and 153.630)

In this final rule, we finalize 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 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 policies 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 sought comment on these burden estimates. We did not receive any comments in response to the burden estimates for the HHS-RADV policies in this rule.

5. Agents, Brokers, and Web-brokers (§ 155.220)

a. Required QHP Comparative Information on Web-broker Websites and Related Disclaimer

In this final rule, we are finalizing the proposal 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)(6) a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We are also finalizing the proposal 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. We are finalizing as proposed.

This policy should result in very limited new burden for web-brokers. As we explained in the proposed rule (87 FR 584, 709), given CMS' current enforcement policies relative to these requirements, the QHP comparative information we are requiring web-broker websites to display is consistent with previously established requirements. As a result, these requirements would not present a new burden to web-brokers.

The new disclaimer will 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 will be displaying a standardized disclaimer much like the plan detail disclaimer that they have historically been required to display.

We estimated this policy will affect approximately 20 web-brokers. Given the minor modifications necessary to implement the revised disclaimer, we estimated 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 estimated as a result of this policy is \$8,220 for 20 web-brokers in the 2022 benefit year. We have updated these estimates based on the most recently available national occupational employment and wage estimates. We estimate a cost of \$459 in total labor costs for each web-broker, which reflects 5 hours of work by Web and Digital Interface Designers (15-1255) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of \$91.80. The cumulative additional cost estimate as a result of this policy is \$9,180 for 20 web-brokers in the 2022 benefit year.

We sought comment on the estimated burden associated with these proposals.

We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

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 are finalizing the proposal 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 are finalizing this proposal as proposed.

This policy 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 must update their websites to remove those advertisements and will lose any advertising revenue associated with such placements. Since advertisements on websites are inherently subject to change, even for those web-brokers that are required to make updates to their websites, the costs may be very limited, although we acknowledge that there may be loss of advertising revenue. We also realized, 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 sought comment on the potential costs, benefits, and transfers associated with this proposal. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

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

We are finalizing the proposal 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 are finalizing this proposal as proposed.

This policy should result in very limited new costs for web-brokers, since the information it requires they display on their websites is limited to text-based changes that are relatively easy to implement. Furthermore, the extent of those textual updates should be relatively minor in most cases. We expect explanations to be short and easy for consumers to understand. Generally, we believe that a single phrase or a few sentences will suffice. Some web-brokers are already providing the required information, and therefore, will not have to make any website updates. Other web-broker websites do not explicitly recommend QHPs, and therefore, the impact of this policy is 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 estimated this policy 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 estimated 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 policy is \$8,220 for 20 web-brokers in the 2022 benefit year. We have updated these estimates based on the most recently available national occupational employment and wage estimates. We estimate a cost of \$459 in total labor costs for each web-broker, which reflects 5 hours of work by Web and Digital Interface Designers (15-1255) per web-broker (100 hours

across all web-brokers annually) at an average hourly rate of \$91.80. The cumulative additional cost estimate as a result of this policy is \$9,180 for 20 web-brokers in the 2022 benefit year.

We sought comment on the potential costs and benefits associated with this proposal. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

d. Providing Correct Information to the FFEs and Prohibited Business Practices

The 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 believed 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 sought 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 sought comment on any potential costs or benefits associated with these proposals. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

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

We proposed 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 believed 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 (82 FR 51128), 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. 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 estimated 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 estimated 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 estimated 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 estimated 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 the 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 requested a comment on the estimated and potential costs and impacts of this proposal.

We summarize and respond to public comments received on the verification process related to eligibility for insurance affordability programs (§ 155.320) below.

HHS wishes to note that since the publication of the proposed rule, three States have transitioned from having State Exchanges using the Federal eligibility and enrollment platform to operating as State Exchanges that operate their own eligibility and enrollment platform, therefore, we are revising our previous estimated cost and saving estimates. We revise the 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 \$81 million for the 18 State Exchanges that operate their own eligibility and enrollment platform (operating in 17 States and the District of Columbia). We are still 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 \$63 million. The total annual cost to conduct sampling has been revised to \$126 million for the 18 State

Exchanges. Therefore, the total annual cost for the Exchanges using the Federal platform and the 18 State Exchanges that operate their own eligibility and enrollment platform has been revised to \$134 million in 2023 and onward. Finally, we revised the estimated cost to conduct research for Exchanges using the Federal platform to be approximately \$295,000 and for the 18 State Exchanges that operate their own eligibility and enrollment platform to be approximately \$5.3 million.

Comment: While not directly related to the cost estimates, one commenter expressed concern with the proposed risk-based approach for designing and developing processes for employer sponsored coverage verification as it could lead to increased APTC/CSR improper payments. The commenter noted that the Congressional Budget Office estimated that approximately \$83 billion will be spent on APTC/CSR in 2022. The commenter stated that based on HHS' own analysis that about two percent of consumers may have an incentive to enroll in Exchange coverage rather than coverage offered through an employer, this could result in about \$1.7 billion in APTC/CSR payments, which is larger than HHS' estimates to operationalize the random sampling requirement.

Response: HHS disagrees with the commenter's estimate because there are many other factors to take into consideration when estimating potential inappropriate payments of APTC/CSR, such as the average number of months an enrollee would have received APTC/CSR after HHS took action to end APTC/CSR. HHS believes using a flat estimate based on CBO projections, which doesn't take these factors into consideration, is misleading.

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

7. Proration of Advance Premium Tax Credit and Premium (§§ 155.240(e), 155.305(f)(5), and 155.340)

HHS proposed 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 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, using a specified methodology. This method of administering APTC would reduce instances of payments of APTC in excess of an applicable taxpayer's monthly PTC eligibility for a month in which an enrollee is enrolled in multiple policies within a month, each lasting less than the full calendar month, and thus would protect the applicable taxpayer from incurring income tax liability due to excess APTC.

HHS noted that this would benefit both issuers and enrollees by reducing instances of APTC over-payment and eliminating wasted resources dedicated to resolving over-payment issues. While the FFEs and SBE-FPs already prorate APTC and premium amounts, some State Exchanges do not currently prorate consistently the amount of applied APTC administered to issuers in their applicable States.

HHS acknowledged that those State Exchanges that do not currently prorate APTC or premium amounts would be financially impacted by the proposed requirement to implement this methodology, and this proposal would likely require operational systems builds to support this new proration requirement.

Based on historical cost data for State Exchanges 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 estimated 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 anticipated that each affected State 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 estimated that 8 State Exchanges currently prorate premium amounts but do not prorate APTC amounts. HHS anticipated that those State Exchanges which already prorate

premium amounts would have the operational and systems capacity to calculate the prorated premium and APTC amounts as required in the proposed policy.

Currently, State Exchanges vary in their approaches to implementing the proposed APTC and premium proration. In order to provide an upper bound estimate of this proposal's burden, HHS assumed that 10 State Exchanges, including State Exchanges that newly transitioned to being State Exchanges by the time of this rulemaking, would incur the highest level of implementation cost detailed earlier in this final 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 sought comment on the estimated costs and benefits described in this section.

We summarize and respond to public comments received on the proration of APTC and premium (§§ 155.240(e), 155.305(f)(5), and 155.340) below.

Comment: We received several comments on the estimated costs for a State Exchange to implement the proposed APTC and premium proration methodology. A few commenters stated that the estimated one-time implementation cost of \$1 million dollars per State Exchange was unreasonably burdensome, particularly considering competing programmatic demands and the ongoing COVID-19 PHE. Another commenter noted that HHS severely underestimated the implementation cost and estimated that it would cost approximately four times the burden estimate detailed in the proposed rule to implement the proposed proration methodology within their Exchange.

Response: HHS appreciates the comments on the estimated burden associated with the proposed policy. The estimates in the proposed rule were made using the best available information that HHS could access, and the comments received helped to clarify the impact that the proposed policy could have on State Exchanges. In an effort to be responsive to comments regarding implementation costs, HHS is finalizing this policy with modifications that will significantly reduce the burden on State Exchanges. We are not finalizing the requirement to

prorate premium or APTC amounts for State Exchanges. Rather, we are finalizing a requirement that, beginning in PY 2024, State Exchanges must implement a methodology to ensure that APTC calculations do not cause an enrollee's total monthly APTC amount from exceeding their PTC, in compliance with HHS and IRS regulations. Further, State Exchanges must prospectively report to HHS through existing State Exchange oversight mechanisms the methodology the State intends to use in PY 2024.

While many State Exchanges already have a methodology that meets the requirement of preventing an enrollee's monthly APTC amount from exceeding their monthly PTC eligibility, we note that some States will likely require operational IT systems changes to implement a compliant methodology. HHS estimates that 8 State Exchanges will require some form of operational investment to comply with this policy. The cost of a systems builds may vary among State Exchanges depending on their elected methodology, but we estimate \$500,000 in one-time contact labor cost per State Exchange. This cost estimate is lower than that in the proposed rule to reflect that State Exchanges will have the flexibility to implement any methodology that ensures an enrollee's monthly APTC does not exceed their PTC eligibility. We estimate that the one-time financial impact of this requirement to be approximately \$500,000 for 8 State Exchanges, or \$4 million in PY 2024.

The burden to report this information to HHS will be negligible, as State Exchanges will use existing oversight mechanisms. This reporting requirement will be included within the reporting requirements described at § 155.1200(b)(2) and the information collected will be addressed by the State Based Marketplace Annual Report Tool (SMART) PRA (OMB Control Number 0938-1244) which we explain earlier in the ICR section of this rule.

After reviewing the public comments, we are finalizing with modifications.

10. Special Enrollment Periods – Special enrollment period verification (§ 155.420)

We proposed to amend § 155.420 to add a 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 did 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 anticipated that this would result in 194,000 fewer individuals having their enrollment delayed or “pending” annually until eligibility verification is completed, which would result in a \$5,150,700 (or 20 percent) 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 did not anticipate that this would increase administrative costs on QHP issuers. Additionally, our data suggest 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 sought comment on the potential costs, benefits, and transfers associated with this proposal.

We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision. Therefore, we are finalizing these provisions as proposed.

11. General program integrity and oversight requirements (§ 155.1200)

As explained earlier in this preamble, we are not finalizing this provision related to general program integrity and oversight requirements at this time. We estimated that there would be a general reduction in reporting and contracting costs to State Exchanges related to meeting auditing requirements under § 155.1200. We anticipated 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 the benefit year 2024. The total cost annual reduction across 18 State Exchanges would be approximately \$1,631,243.16.

We sought comment on the potential costs, benefits, and transfers associated with this provision.

Comment: A few commenters expressed general concern regarding the estimated burden reduction associated with this proposal.

Response: We address these comments in the General Program Integrity and Oversight 155.1200 preamble discussion earlier in this rule. Based on public comments received, we are not finalizing this provision at this time.

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

As we explained earlier in section III. of the preamble, HHS is not finalizing the regulations we proposed to govern implementation of the SEIPM program could have the direct effect of reducing improper payments. We sought comment on the estimated costs and benefits and potential transfers associated with these provisions but did not receive any responsive comments.

13. FFE and SBE-FP User Fees (§ 156.50)

We are finalizing an FFE user fee rate of 2.75 percent of monthly premiums charged by the FFE issuer 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.³⁹⁴ We are finalizing an SBE-FP user fee rate of 2.25 percent of monthly premiums charged by the SBE-FP issuer 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.³⁹⁵ Therefore, we do not believe that these user fee rates will have any additional impact on premiums compared to the 2022 benefit year. We also finalize an amendment to § 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.³⁹⁶ We do not expect that it will have any additional regulatory impact

We sought comment on the potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to 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 proposed 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

³⁹⁴ 86 FR 53412, 53445.

³⁹⁵ Ibid.

³⁹⁶ Ibid.

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, any such burden experienced by States would be minimal.³⁹⁷ 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 final 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

³⁹⁷ 85 FR 29164, 29252.

still responsible for quantifying the cost of these benefits and reporting the cost to the State. We also noted 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 sought comment on the potential costs, benefits, and transfers associated with this provision.

After reviewing the public comments, we are finalizing repeal of the annual reporting policy at § 156.111(d) and (f), including revising the section heading to § 156.111 to instead read, “State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.”

We summarize and respond to public comments received repealing the annual reporting of State-required benefits below.

Comment: Many commenters supported the repeal of the annual reporting policy and noted that the policy is an unnecessary new administrative burden on States without adequate justification. One commenter explained that the reporting structure would have required State officials to either procure consultants or divert existing staff from other work to comply with an entirely new reporting process. Commenters stated that the elimination of this reporting requirement would remove a needless administrative burden while maintaining States’ responsibility to comply with the defrayal rule.

Other commenters objected to the repeal of the annual reporting policy and challenged the claims that the policy was overly burdensome. Such commenters noted that States should already have determined the status and cost of State-required benefits and that the reporting requirement should not place a burden on States of conducting new analyses. Commenters further noted that, after the initial reporting cycle, the administrative burden on States would be even more minimal.

Response: We maintain that the annual reporting policy would have imposed a minimal burden on States as the information that States would have been required to report to HHS

should already be readily accessible to States, as every State should already be identifying which State-required benefits are in addition to EHB and should be defraying any such costs. States should already have ready access to the information the annual reports would have required as States should already have in place a process for tracking and analyzing State-required benefits. However, even if the State burden would have been minimal, we still believe that taking a more targeted approach of engaging with individual States on questions of compliance with the defrayal requirement will yield similar results to the annual reporting policy without requiring all States, including even compliant States, to expend additional time and resources submitting a report with this detailed information.

15. Levels of Coverage (Actuarial Value) (§ 156.140, 156.200, 156.400)

We proposed 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 proposed 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 proposed 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 (82 FR 18346), 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 long 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 an 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 an 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 22.

TABLE 22: PTC Impact of +2/0 Silver *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.³⁹⁸

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 we do not have data to make an informed estimate.

We estimated 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 stated that 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 stated that 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.

³⁹⁸ There are no enrollees in bronze plans below 58% AV.

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.³⁹⁹ 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 estimated silver plans with an AV below 70 percent will see premiums increase by approximately 2 percent on average due to more generous benefits. We stated that we do not believe this would have a significant impact on the number of employers willing to offer ICHRAs or whether an ICHRA is considered affordable to most employees, but we invited comments to refute or refine this understanding on these issues in particular.

We sought comment on the estimated costs, benefits, and transfers associated with this provision. However, we did not receive comments that specifically addressed the accuracy of the burden estimates included in the proposed rule; instead, the comments received addressed the merits of the proposal itself, which we have addressed in the preamble. Thus, we are finalizing these burden estimates as proposed.

16. Standardized plan options (§ 156.201)

Section 156.201 finalizes the provision to require QHP issuers to offer standardized QHP options. Though these requirements necessitate the creation of new plans, HHS explained that it 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

³⁹⁹ See section 4980H of the Code; 26 CFR 54.4980H-1 – 26 CFR 54.4980H-6.

formularies of a majority of plans that issuers currently offer and because HHS designed the cost-sharing parameters, MOOPs, and deductibles for these new plans. Additionally, HHS designed these standardized plan options to resemble the most popular QHPs in the individual market FFEs and SBE-FPs in PY 2021, making these standardized plan options comparable to plans that the majority of issuers already offer. Furthermore, since HHS is requiring QHP issuers to offer standardized plan options at every product network type, at every metal level, and throughout every service area 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 are not required to extend plan offerings beyond their existing service areas.

Additionally, since HHS did not finalize any provision to limit the number of non-standardized QHP options that issuers can offer in PY 2023, HHS explained that it believes the majority of enrollees will remain enrolled in their current non-standardized plan options. Moreover, since HHS did not finalize any provisions 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 explained that it does not expect the total number of plans that issuers are offering to change substantially subsequent to the imposition of the requirement. Thus, though these new plans will have to be submitted for approval, certification, and display, we expected 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 non-standardized offerings.

As noted earlier in the preamble, HHS noted that it is resuming the differential display of standardized plan options per the existing authority at § 155.205(b)(1). HHS is assuming burden for the differential display of standardized plan options on HealthCare.gov, meaning FFE and SBE-FP issuers are not subject to this burden.

In addition, as noted in the preamble, HHS noted that it is resuming enforcement of the standardized plan option display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE-FP – including both the Classic DE and EDE Pathways – at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. HHS explained that it 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 is allowing these entities to submit requests to deviate from the manner in which standardized plan options are differentially displayed on HealthCare.gov, the potential burden for these for these entities is further reduced. HHS also noted that it intends to provide access to information on standardized plan options to web-brokers through the Health Insurance Marketplace PUFs and QHP Landscape file to further minimize the burden. The specific burden estimates for these requirements can be found in the corresponding ICR sections for §§ 155.220 and 156.265.

We sought comment on the potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision. We are finalizing these burden estimates as proposed.

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 final rule, HHS is finalizing that for PY 2023 and future PYs that all QHPs or QHP candidates that use a provider network must comply with network adequacy standards.

HHS finalized the proposal 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. HHS finalized 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 will be calculated at the county level using information from the ECP/NA template. HHS also proposed to adopt appointment wait time standards to assess whether FFE QHPs or QHP candidates fulfill network adequacy standards. HHS will begin implementation of reviews for appointment wait time standards in PY 2024. 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 did not finalize the proposal 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.

Finally, HHS finalized the proposal 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 the 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 sought comment on the potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to 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 noted 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 believed 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 expected that administrative cost changes would likely be minimal for most issuers.

HHS proposed 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 sought comment on the potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

19. Standards for Delegated and Downstream Entities (§ 156.340)

In this final rule, we are finalizing the proposal to amend and add language to § 156.340, to extend its applicability to QHP issuers on all Exchange models. We are finalizing changes to 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 is also finalizing the proposal 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 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 are also finalizing 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 anticipated these policies 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. 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 SHOs maintain oversight over downstream and delegated entities.

We sought comment on the potential costs, benefits, and transfers associated with this provision.

After reviewing the public comments and the general nature of the assertions that are unsupported by data, HHS will finalize our burden estimate and implementation date as proposed.

We summarize and respond to public comments received for standards for delegated and downstream entities.

Comment: A few commenters expressed concern that the addition of contract language proposed in paragraph (b)(5) would place a burden on downstream and delegated entities. Other commenters supported the benefits the proposed language in paragraph (b)(5) would confer by clarifying § 156.340 and its applicability.

Response: As acknowledged in our analysis, we anticipate this policy change will impose a minimal burden (that is, a limited additional burden). For example, some QHP issuers in State Exchanges may need to make changes to existing record retention policies and their agreements with delegated and downstream entities. Relatedly, some delegated and downstream entities may need to revise their record retention policies. However, we believe such changes will be relatively easy to make and implement (for example, changing a record retention policy and related agreements to retain records for 10 years instead of 7 years). We note that none of the commenters provided any data or specificity concerning the actual burdens, costs, or transfers they expected the changes to impose. We believe our analysis accounts for all burden.

20. Payment for Cost-Sharing Reductions (§ 156.430)

We are amending § 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 an appropriation to make CSR payments and voluntary for all 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 did not expect any of these provisions to increase the burden on issuers, as this amendment would codify existing practices.

We sought comment on any potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

21. Quality Improvement Strategy (§ 156.1130)

We proposed 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 did not propose any changes to the regulatory text. We did not estimate additional costs or burdens as a result of this proposal.

We sought comment on any potential costs, benefits, and transfers associated with this proposal. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

22. Medical Loss Ratio (§§ 158.140, 158.150, 158.170)

We are finalizing the proposal 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 are also finalizing the proposal 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. The 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 estimated 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 2019, 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 are also finalizing the proposal 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*,⁴⁰⁰ and thus deleted in part 2 of the 2022 Payment Notice final rule.⁴⁰¹ We did not anticipate any impact on rebates or premiums as a result of this change.

We sought comment on any potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

D. Regulatory Alternatives Considered

In developing the policies contained in this final 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.⁴⁰² 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,⁴⁰³ we found that non-linear model specifications often failed to converge. 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 aforementioned 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,

⁴⁰⁰523 F. Supp. 3d 731 (D. Md. 2021).

⁴⁰¹ 86 FR 24261.

⁴⁰² 85 FR 78572 at 78583-78586; See the *2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁴⁰³ *Ibid*.

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 of the proposed rule (87 FR 584, 620) (shown in Table 1 of this rule). We chose the list of HCCs in Table 3 of the proposed rule (shown in Table 1 of this rule) 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 overall predictive accuracy.

For the enrollment duration factors in the adult models, we are finalizing the replacement of the enrollment duration factors with monthly duration factors of up to 6 months for enrollees with HCCs. The purpose for changing the enrollment duration factors was to 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.⁴⁰⁴ We chose the 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.⁴⁰⁵

With respect to the changes to the recalibration of the RXC mappings for the adult risk adjustment models, we considered using the latest RXC mapping document available at the time that we recalibrate the adult risk adjustment models and applying it to all three underlying EDGE data years used to recalibrate the models for the benefit year. We chose the approach of recalibrating the adult risk adjustment models using each final, Q4 RXC mapping document that was developed using the benefit year of data corresponding to that benefit year. We believe that the benefits of this approach, which include limiting the volatility of some coefficients from year-to-year, ensuring that we are capturing the utilization and costs observed for the underlying drugs in use during the data year, and improving issuers' ability to plan for downstream implications of changes to RXC mapping, outweigh the benefits of the alternative approach of using the latest RXC mapping available at the time of recalibration, which would more closely align costs between recalibration data and current benefit year data.

With respect to the 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 EO 14009⁴⁰⁶ 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 EO 14009. In prior rulemakings, we received comments stating that risk adjustment State flexibility in any market

⁴⁰⁴ See, for example, 85 FR 78572 at 78585-78586 and Sections 3.3.1 and 3.3.2, *2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. (2021, October 26). CMS. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁴⁰⁵ As detailed above, these new factors, which we are finalizing as proposed, will only apply to partial-year adult enrollees with up to 6 months of enrollment and at least one payment HCC.

⁴⁰⁶ Executive Order 14009; 86 FR 7793 (2021, February 2).

may result in risk selection, market destabilization, increased premiums, smaller networks, and worse plan options. Therefore, we also considered whether to adopt a complete repeal of the flexibility to request reductions risk adjustment State transfers.

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 believed 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 believed 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 before which they may not be eligible, 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 final 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 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 plan options, we considered a range of options for the proposed policy approach at § 156.201. On one end of this range, we considered resuming standardized plan options as reflected in the 2017 and 2018 Payment Notices. This approach would have allowed issuers to voluntarily offer standardized plan 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 plan options per issuer, product network type, metal level, and service area over the course of several PYs. We also considered preferentially displaying standardized plan options over non-standardized plan options. We also considered requiring issuers to offer exclusively standardized plan options in FFEs and SBE-FPs. We explained that we believe that the approach we have chosen for standardized plan options in which we finalized the provision to require issuers to offer standardized plan options but did not finalize any provision 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 plan options.

For the 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.⁴⁰⁷ Under this alternative, HHS would assume responsibility for prorating the amount of APTC due to each State Exchange based on the methodology HHS proposed 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' Form 1095-A. HHS expected 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

⁴⁰⁷ 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.

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 sought 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 proposed 2024 benefit year implementation and request comments on the feasibility of 2023 benefit year implementation.

We did not receive any comments in response to the proposals in our general discussion regarding regulatory alternatives.

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 final rule, we finalize 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 believed that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for “small entities” established by the SBA, we did not believe that an initial regulatory flexibility analysis is required for such firms.

We believed 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.⁴⁰⁸ We believed 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.⁴⁰⁹ 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 final rule in part 158. Therefore, we do not expect the MLR provisions finalized in this rule to affect a substantial number of small entities.

The proposals related to SEIPM at §§ 155.1500-155.1540 were proposed to affect only State Exchanges, and HHS is not finalizing these proposals at this time.

In addition, section 1102(b) of the Social Security 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

⁴⁰⁸ *Table of Size Standards*. (2019, August 19). U.S. Small Business Administration. <https://www.sba.gov/document/support--table-size-standards>.

⁴⁰⁹ *Medical Loss Ratio Data and System Resources*. (2020). CMS. <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that this final rule will not affect small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately \$165 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 an 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 EO 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 EO 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 were elected previously to operate an Exchange, those States had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In our view, while this final rule will not impose substantial direct 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 (with an exception for prior participants) 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 believed this regulation has federalism implications due to the 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 are not being finalized. Accordingly, EO 13132 does not apply to this section of the final rule.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller for review. This final rule is a “major rule” as that term is defined in , because it is likely to result in an annual effect on the economy of \$100 million or more.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 26, 2022.

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

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, Aged, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Taxes, Technical assistance, Women, 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 amends 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. Redesignating paragraph (i) as paragraph (j); and
- b. Adding a new paragraph (i).

The addition reads as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(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 market risk pool 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 market risk pool 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 and risk adjustment data validation adjustments; 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 Corridors 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.

§ 155.206 [Amended]

10. 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”.

11. Amend § 155.220 by—

a. Revising paragraphs (c)(3)(i)(A) and (L);

b. Adding paragraph (c)(3)(i)(M);

c. Revising paragraph (j)(2)(ii);

d. In paragraph (j)(2)(iv), removing the phrase “described in § 155.260(b)(2); and” and adding in its place the phrase “described in § 155.260(b)(2);”; and

e. 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) Entering only 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 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 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 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

(2) The email address may not have domains that belong to the agent, broker, or web-broker or their business or agency.

(B) Entering only 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 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) Entering only 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 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), entering only 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 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.

* * * * *

12. Amend § 155.305 by revising paragraphs (f)(1)(i) and (5) 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

* * * * *

(5) *Calculation of advance payments of the premium tax credit.* The Exchange must calculate advance payments of the premium tax credit in accordance with 26 CFR 1.36B-3 and § 155.340(i) of this subpart.

13. 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 newly redesignated paragraph (d)(4)(i)(E); 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. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for the benefit year when 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) The Exchange must provide notice to the applicant 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;

* * * * *

(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.

* * * * *

14. 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 with 2024 and beyond, when an 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--

(i) In an Exchange using the Federal eligibility and enrollment platform, the amount of the advance payment of the premium tax credit paid to the issuer of the policy must equal the product of –

(A) 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

(B) 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.

(ii) [Reserved]

(2) For plan years beginning with 2024 and beyond, a State Exchange operating its own platform will be required to calculate advance payments of the premium tax credit in accordance with a methodology that does not cause the amount of advance payments of the premium tax credit applied to an enrollee’s monthly premium to exceed their expected monthly premium assistance credit amount when 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, and to prospectively report the methodology it intends to implement in the subsequent plan year to HHS under § 155.1200(b)(2).

15. 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 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 consistent with the non-discrimination requirements under § 155.120(c).

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.

PART 156 – HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

16. 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.

17. 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 29 CFR 2590.715-2713A(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:

* * * * *

18. 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 of the year 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 of the year 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 of the year that is 2 years before the effective date of the new EHB-benchmark plan. These must include:

* * * * *

19. 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.

* * * * *

20. 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 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. Beginning on the earlier of January 1, 2023 (the start of the 2023 plan year) or upon renewal of any plan subject to this rule, a non-discriminatory benefit design that provides EHB is one that is clinically-based.

* * * * *

21. 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.

22. Amend § 156.200 by revising paragraph (b)(3) to 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;

* * * * *

23. Add § 156.201 to read as follows:

§ 156.201 Standardized plan options.

For the 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 plan options under State action taking place on or before January 1, 2020, must offer in the individual market 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, at every 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).

24. Amend § 156.230 by revising paragraph (a) to read as follows:

§ 156.230 Network adequacy standards.

(a) *General requirement.* (1) Each QHP issuer that uses a provider network must ensure that the provider network consisting of in-network providers, 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 use disorder 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.* A QHP issuer on a Federally-facilitated Exchange must comply with the requirement in paragraph (a)(1)(ii) of this section by:

(A) For plan years beginning on or after January 1, 2023, 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.

Quantitative reviews of compliance with time and distance standards will be conducted using issuer-submitted data; and

(B) For plan years beginning on or after January 1, 2024, 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 Exchange does not satisfy the network adequacy standards described in paragraphs (a)(2)(i)(A) and (B) of this section, the issuer must include it 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 paragraphs (a)(2)(i)(A) and (B) 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.

* * * * *

25. Amend § 156.235 by revising paragraphs (a)(2)(i), (a)(2)(ii)(B), 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

(ii) * * *

(B) At least one ECP in each of the six (6) ECP categories in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. The ECP categories are: Federally Qualified Health Centers, Ryan White Program Providers, Family Planning Providers, Indian Health Care Providers, Inpatient Hospitals, and Other ECP Providers. The Other ECP Providers category includes the following types of providers: Substance Use Disorder Treatment Centers, Community Mental Health Centers, Rural Health Clinics, Black Lung Clinics, Hemophilia Treatment Centers, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics.

* * * * *

(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

26. Revise the subpart D heading to read as set forth above.

27. 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 paragraphs (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 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 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 an 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 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.

28. 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.

* * * * *

29. 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

* * * * *

PART 158 – ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

30. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg-18.

31. 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.

* * * * *

32. 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.

* * * * *

33. 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: April 28, 2022.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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