

DEPARTMENT OF THE TREASURY**31 CFR Part 33****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Part 600****Office of the Secretary****45 CFR Parts 153, 155, and 156****[CMS–9895–F]****RIN 0938–AV22****Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO–OP) Program; and Basic Health Program**

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

ACTION: Final rule.

SUMMARY: This final rule includes payment parameters and provisions related to the HHS-operated risk adjustment program, as well as 2025 user fee rates for issuers offering qualified health plans (QHPs) through federally facilitated Exchanges (FFE) and State-based Exchanges on the Federal platform (SBE–FPs). This final rule also includes requirements related to the auto re-enrollment hierarchy; essential health benefits; failure to file Federal income taxes to reconcile advance payments of the premium tax credit (APTC); non-standardized plan option limits in the FFEs and SBE–FPs and a related exceptions process; standardized plan options in the FFEs and SBE–FPs; special enrollment periods (SEPs); direct enrollment (DE) entities supporting Exchange applications and enrollments; the Insurance Affordability Program enrollment eligibility verification process; requirements for agents, brokers, web-brokers, and DE entities assisting Exchange consumers; network adequacy; public notice procedures for section 1332 waivers; prescription drug benefits; updates to the Consumer Operated and Oriented Plan (CO–OP) Program; and State flexibility on the effective date of coverage in the Basic Health Program (BHP).

DATES: These regulations are effective on June 4, 2024.

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I. Executive Summary

We are finalizing changes to the provisions and parameters implemented through prior rulemaking to implement the Patient Protection and Affordable Care Act (ACA).¹ These proposals are published under the authority granted to the Secretary by the ACA and the Public Health Service (PHS) Act.² In this final rule, we are finalizing changes related to some of the ACA provisions and parameters we previously implemented and are implementing new provisions. Our goal with these requirements is to provide consumers access to quality, affordable coverage, while minimizing administrative burden and ensuring program integrity. The changes finalized in this rule are also intended to help increase

transparency, advance health equity, and mitigate health disparities.

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

These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.

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

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

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

rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. Section 1302(d) of the ACA describes the various levels of coverage based on AV. Consistent with section 1302(d)(2)(A) of the ACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the ACA directs the Secretary of HHS to develop guidelines that allow for *de minimis* variation in AV calculations. Sections 1302(b)(4)(A) through (D) of the ACA establish that the Secretary must define EHB in a manner that: (1) reflects appropriate balance among the 10 categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHBs based on age, life expectancy, disability, degree of medical dependency, or quality of life.

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

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

Section 1312(c) of the ACA generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of

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

² See sections 1311, 1312, 1313, 1321, 1332, and 1343 of the ACA and section 2792 of the PHS Act.

a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the ACA.

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

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

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

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

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

prevent the application of regulations issued by the Secretary.

Section 1322 of the ACA establishes the Consumer Operated and Oriented Plan (CO-OP) program, which is a loan program that funds the establishment of private, non-profit, consumer-operated, consumer-oriented health plan issuers of QHPs. The ACA requires, among other requirements, that substantially all of a CO-OP's activities consist of issuing QHPs in the individual and small group markets, and that a CO-OP be governed by a board of directors where a majority is elected by members covered by policies issued by the CO-OP.

Section 1331 of the ACA provides States with the option to operate a Basic Health Program (BHP).

Section 1332 of the ACA provides the Secretary of HHS and the Secretary of the Treasury (collectively, the Secretaries) with the discretion to approve a State's proposal to waive specific provisions of the ACA, provided the State's section 1332 waiver plan meets certain requirements. Section 1332(a)(4)(B) of the ACA requires the Secretaries to issue regulations regarding procedures for the application and approval of section 1332 waivers.

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

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

Section 1402 of the ACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver

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

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

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

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

Section 5000A of the Code, as added by section 1501(b) of the ACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to \$0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals aged 30 and above qualify to enroll in catastrophic coverage under §§ 155.305(h) and 156.155(a)(5).

Section 1902(r)(2)(A) of the Social Security Act (the Act), which permits

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

States to apply less restrictive methodologies than cash assistance program methodologies in determining eligibility for certain eligibility groups.

1. Premium Stabilization Programs

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

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

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

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

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

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

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

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

- In the March 8, 2016 **Federal Register** (81 FR 12203) (2017 Payment Notice), we finalized the benefit and payment parameters for the 2017 benefit year to expand the provisions related to

the premium stabilization programs, set forth certain oversight provisions, and establish the payment parameters in those programs.

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

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

- In the May 11, 2018 **Federal Register** (83 FR 21925), we published a correction to the 2019 HHS risk adjustment coefficients in the 2019 Payment Notice.

- On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final HHS risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level EDGE data set.⁵

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

- In the December 10, 2018 **Federal Register** (83 FR 63419), we adopted the 2018 benefit year HHS risk adjustment

methodology as established in the final rules 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 State payment transfer formula for the 2018 benefit year, including the reasons why the program is operated by HHS in a budget-neutral manner.

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

- On May 12, 2020, consistent with § 153.320(b)(1)(i), we published the 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website.⁶

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

- In the December 1, 2020 **Federal Register** (85 FR 76979) (Amendments to the HHS-Operated Risk Adjustment Data Validation Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program (2020 HHS–RADV Amendments Rule)), we adopted the creation and application of Super HCCs in the sorting step that assigns HCCs to failure rate groups, finalized a sliding scale adjustment in HHS–RADV error rate calculation, and added a constraint 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

⁴ See ACA section 1341 (transitional reinsurance program), ACA section 1342 (risk corridors program), and ACA section 1343 (HHS risk adjustment program).

⁵ CMS. (2018, July 27). *Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients*. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf>.

⁶ CMS. (2020, May 12). *Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients*. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>.

scores from the same benefit year as that being audited.

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

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

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

- In the May 6, 2022 **Federal Register** (87 FR 27208) (2023 Payment Notice), we finalized revisions related to the HHS-operated risk adjustment program, including the benefit and payment parameters for the 2023 benefit year, HHS risk adjustment model recalibration, and policies related to the collection and extraction of enrollee-level EDGE data. We also finalized the adoption of the interacted HCC count specification for the adult and child models, along with modified enrollment duration factors for the adult model models, beginning with the 2023 benefit year.⁸ We also repealed the ability for States, other than prior participants, to request a reduction in HHS risk adjustment State transfers starting with the 2024 benefit year. In addition, we

approved a 25 percent reduction to 2023 benefit year HHS risk adjustment transfers in Alabama's individual market and a 10 percent reduction to 2023 benefit year HHS risk adjustment transfers in Alabama's small group market. We also finalized further refinements to the HHS-RADV error rate calculation methodology beginning with the 2021 benefit year.

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

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 final rule (2019 Program Integrity Rule) published in the December 27, 2019 **Federal Register** (84 FR 71674).

In the April 27, 2023 **Federal Register** (88 FR 25740) (2024 Payment Notice), we finalized a policy to implement improper payment pre-testing and assessment (IPPTA) requirements for State Exchanges to ensure adherence to the Payment Integrity Information Act of 2019. In addition, we finalized allowing additional time for HHS to review evidence submitted by agents and brokers to rebut allegations pertaining to Exchange agreement suspensions or

terminations. We also introduced consent and eligibility documentation requirements for agents and brokers.

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 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 April 17, 2018 **Federal Register** (83 FR 17058) (2019 Payment Notice), 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, 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), which was published by HHS and the Department of the Treasury, we finalized additional amendments to the guaranteed availability regulations regarding special enrollment periods.

- In the May 6, 2022 **Federal Register** (87 FR 27208), we finalized a revision

⁷ See CMS. (2021, July 19). 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients. <https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf>.

⁸ On May 6, 2022, we also published the 2023 Benefit Year Final HHS Risk Adjustment Model Coefficients at <https://www.cms.gov/files/document/2023-benefit-year-final-hhs-risk-adjustment-model-coefficients.pdf>.

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.

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 18310) (Exchange Establishment Rule), we implemented the Affordable Insurance Exchanges (Exchanges), consistent with title I of the ACA, to provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. This included implementation of components of the Exchanges and standards for eligibility for Exchanges, as well as network adequacy and essential community provider (ECP) certification standards.

In the August 17, 2011, **Federal Register** (76 FR 51201) we published a proposed rule regarding eligibility determinations, including the regulatory requirement to verify incarceration status. In the March 27, 2012, **Federal Register** (77 FR 18309) we finalized the regulatory requirement to verify incarceration attestation using an approved electronic data source that is current and accurate, and when attestations are not reasonably compatible with information in an approved data source, to resolve the inconsistency.

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, published in the December 22, 2016 **Federal Register** (81 FR 94058).

In the Market Stabilization final rule, published in the April 18, 2017 **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice, 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 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) (part 1 of the 2022 Payment Notice), we finalized only a subset of the proposals in the 2022 Payment Notice proposed rule. In the May 5, 2021 **Federal Register** (86 FR 24140), we published part 2 of the 2022 Payment Notice. In the September 27, 2021 **Federal Register** (86 FR 53412) (part 3 of the 2022 Payment Notice), in conjunction with the Department of the Treasury, we finalized amendments to certain policies in part 1 of the 2022 Payment Notice.

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

In the April 27, 2023 **Federal Register** (88 FR 25740) (2024 Payment Notice), we revised Exchange Blueprint approval timelines, lowered the user rate fee for QHPs in the FFEs and SBE-FPs, and amended re-enrollment hierarchies for enrollees. We also finalized policies to update FFE and SBE-FP standardized plan options; further reduce the risk of plan choice overload on the FFEs and SBE-FPs by lowering the limit on non-standardized plan options that issuers may offer from four to two; introduce an exceptions process to the limitation on non-standardized plan options in FFEs and SBE-FPs; and ensure correct QHP information. In addition, to prevent gaps in coverage, we amended coverage effective date rules, lengthened the special enrollment period from 60 to 90 days to those who lose Medicaid

coverage, and prohibited QHPs on FFEs and SBE-FPs from terminating coverage mid-year for dependent children who reach the applicable maximum age. We also finalized policies on verifying consumer income and permitting door-to-door assisters to solicit consumers. To ensure provider network adequacy, we finalized provider network and ECP policies for QHPs.

5. Essential Health Benefits

We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12834) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide States with additional options from which to select an EHB-benchmark plan for plan year (PY) 2020 and subsequent plan years. In the 2023 Payment Notice, published in the May 6, 2022 **Federal Register** (87 FR 27208), we revised § 156.111 to require States to 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, otherwise the State's EHB-benchmark plan for the applicable plan year will be that State's EHB-benchmark plan applicable for the prior year. We displayed the Request for Information; Essential Health Benefits (EHB RFI), published in the December 2, 2022 **Federal Register** (87 FR 74097) to solicit public comment on a variety of topics related to the coverage of benefits in health plans subject to the EHB requirements of the ACA.

6. State Innovation Waivers

In the March 14, 2011 **Federal Register** (76 FR 13553), HHS and the Department of the Treasury (collectively, the Departments) published the "Application, Review, and Reporting Process for Waivers for State Innovation" proposed rule to implement section 1332(a)(4)(B) of the ACA.

In the February 27, 2012 **Federal Register** (77 FR 11700), the Departments published the "Application, Review, and Reporting Process for Waivers for State Innovation" final rule (2012 Final Rule).

In the October 24, 2018 **Federal Register** (83 FR 53575), the Departments issued the 2018 Guidance, which superseded the previous guidance published in the December 16, 2015 **Federal Register** (80 FR 78131) (2015 Guidance) and set forth requirements that States must meet for waivers,

application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations.

In the November 6, 2020 **Federal Register** (85 FR 71142), the Departments issued an interim final rule (November 2020 IFC), which set forth flexibilities for waivers under section 1332 during the COVID-19 Public Health Emergency.

In the December 4, 2020 **Federal Register** (85 FR 78572), the Departments published the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations” proposed rule (2022 Payment Notice proposed rule) which proposed to codify certain policies and interpretations of the 2018 Guidance.

In the January 19, 2021 **Federal Register** (86 FR 6138), the Departments published the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations” final rule (part 1 of the 2022 Payment Notice) which codified many of the policies and interpretations of the 2018 Guidance.

In the September 27, 2021 **Federal Register** (86 FR 53412), part 3 of the 2022 Payment Notice, the Departments published the “Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond” final rule (September 2021 Final Rule), which superseded and rescinded the policies and interpretations outlined in the 2018 Guidance and repealed the previous codification of the interpretations of statutory guidelines in part 1 of the 2022 Payment Notice. The Departments also finalized flexibilities in the public notice requirements and post-award public participation requirements for section 1332 waivers under certain emergent situations and processes and procedures for amendments and extensions for approved waiver plans.

7. Consumer Operated and Oriented Plans (CO-OPs)

In the December 13, 2011 **Federal Register** (76 FR 77392), we published the “Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program” final rule (2011 CO-OP Rule), which established the rules governing the CO-OP program to make loans to

capitalize eligible prospective CO-OPs. In the May 11, 2016 **Federal Register** (81 FR 29146), we amended several CO-OP standards related to governance requirements to provide greater flexibility, and to facilitate private market transactions that would assist efforts of CO-OPs to arrange access to new sources of needed capital.

8. Basic Health Program (BHP)

In the March 12, 2014, **Federal Register** (79 FR 14111), we published a final rule entitled “Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity,” implementing section 1331 of the ACA, which governs the establishment of BHPs.

9. State Flexibility in the Use of Income and Resource Disregards in Medicaid Eligibility

In the January 19, 1993 **Federal Register** (58 FR 4929), we published a final rule with comment period entitled “Medicaid Program; Eligibility and Coverage Requirements,” in which we prescribed, at 42 CFR 435.601, the financial methodologies States Medicaid agencies must apply in determining eligibility for Medicaid, with options to apply less restrictive income and resource methodologies for the eligibility groups specified in section 1902(r)(2) of the Act.

In the August 22, 1994 **Federal Register** (59 FR 43052), we published a final rule entitled “Medicaid Program; Eligibility and Coverage Requirements,” in which we amended 42 CFR 435.601(f)(1) to delete cross-references to other regulatory provisions that had been removed from the CFR.

In the November 30, 2016 **Federal Register** (81 FR 86456), we published a final rule entitled “Medicaid and Children’s Health Insurance Programs: Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP,” in which we amended 42 CFR 435.601(b) to confirm that its provisions govern only individuals who are excepted from application of modified adjusted gross income financial methodologies (MAGI) in accordance with 42 CFR 435.603(j) (relating to “Eligibility Groups for which MAGI-based methods do not apply”). We also established in 42 CFR 435.601(d)(1) the authority for States to apply less

restrictive methodologies for medically needy individuals whose income eligibility is determined under 42 CFR 435.831(b)(1) (including medically needy individuals whose eligibility is determined under MAGI-based methodologies that comply with certain rules relating to the financial responsibility of relatives and other individuals described in 42 CFR 435.602).

B. Summary of Major Provisions

The regulations outlined in this final rule will be codified in 31 CFR part 33, 42 CFR part 600, and 45 CFR parts 153, 155, and 156.

1. 31 CFR Part 33 and 45 CFR Part 155

This final rule amends section 1332 Waivers for State Innovation (referred to throughout this final rule as section 1332 waivers) implementing regulations regarding State public notice and comment procedures. The Departments are finalizing changes in 31 CFR part 33 and 45 CFR part 155 to allow States the flexibility to hold a State public hearing or post-award forum in a virtual format, or hybrid format, which would be considered as the equivalent of holding an in-person meeting. Specifically, the Departments are finalizing changes to 31 CFR 33.112(c) and 45 CFR 155.1312(c) and 31 CFR 33.120(c) and 45 CFR 155.1320(c). These changes are effective immediately upon publication of this final rule.

2. 42 CFR Part 435

We are not finalizing the proposed amendment to 42 CFR 435.601(d) to remove paragraph (d)(4) at this time. The removal of this paragraph would have provided States with greater flexibility to adopt income and/or resource disregards in determining Medicaid financial eligibility for individuals excepted from the application of financial methodologies based on MAGI (“non-MAGI” methodologies). States are already permitted to expand eligibility for individuals who are subject to non-MAGI methodologies by disregarding income and resources that would otherwise be required to be considered in determining an individual’s eligibility. However, under current rules, States must apply such income and resource disregards to all individuals within each Medicaid eligibility group. Removing paragraph (d)(4) would have allowed States, when considering expanding eligibility for non-MAGI individuals, to target disregards at discrete individuals within an eligibility group. As described more fully below, many commenters raised

concerns about this proposal and recommended that we impose “safeguards,” “guardrails,” or “no-harm” requirements in expanding the States’ disregard-related flexibility. These commenters asserted that such requirements are necessary to ensure that States do not use the flexibility to reduce eligibility or harm beneficiaries. We are not finalizing this proposal at this time to allow for further consideration of commenter concerns.

3. 42 CFR Part 600

We are finalizing the amendment, with modifications, to 42 CFR 600.320(c) to allow States a third option when choosing the effective date of eligibility for enrollment for BHP applicants. Under current rules, States have the option to choose between following: either the Medicaid rules at 42 CFR 435.915 or the Exchange rules at 45 CFR 155.420(b)(1). We are finalizing to add an option to the effective date of coverage rules that would allow States to start coverage on the first day of the month following the date of application. In addition, we are adding another option under 42 CFR 600.320(c) that, subject to HHS approval, a State may establish its own effective date of eligibility for enrollment policy.

4. 45 CFR Part 153

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2024, the HHS-operated risk adjustment program is subject to the fiscal year 2024 sequestration.⁹ Therefore, the HHS-operated risk adjustment program will sequester payments made from fiscal year 2024 resources (that is, funds collected during the 2024 fiscal year) at a rate of 5.7 percent.

We are finalizing the recalibration of the 2025 benefit year HHS risk adjustment models using the 2019, 2020, and 2021 benefit year enrollee-level EDGE data. For the 2025 benefit year, we are finalizing the continued application of a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models (see, for example, 84 FR 17463 through 17466). We are finalizing a modification to the adjustment factors for the receipt of CSRs in the HHS risk adjustment models to improve predictive accuracy for the American Indian and Alaska Native (AI/AN) subpopulation who are

enrolled in zero and limited cost-sharing plans and retaining the other CSR adjustment factors in HHS risk adjustment. We are also finalizing a risk adjustment user fee for the 2025 benefit year of \$0.18 per member per month (PMPM). Additionally, we are finalizing that in certain cases, we may require a corrective action plan to address an observation identified in an HHS risk adjustment audit.

5. 45 CFR Part 155

In part 155, we are finalizing the amendment to § 155.105(b) to require that a State seeking to operate a State Exchange must first operate an SBE-FP for at least one plan year, including its open enrollment period. We believe this requirement will give States sufficient time to create, staff, and structure a State Exchange that could transition to operating its own platform and establish relationships with interested parties critical to a State Exchange’s success in operating a Navigator and consumer outreach program, assuming plan management responsibilities, and communicating effectively with consumers to support enrollment and avoid health care coverage gaps.

We are finalizing the revision to § 155.106(a)(2) as it pertains to Exchange Blueprint requirements for States transitioning to a State Exchange. Specifically, we are finalizing the addition that we may require that a State submitting a Blueprint application seeking to operate a State Exchange provide, upon request, supplemental documentation to HHS detailing the State’s implementation of its State Exchange functionality, including information regarding the State’s ability to implement and comply with Federal requirements for operating an Exchange, as laid out in the State Exchange Blueprint. This could include a State submitting detailed plans regarding its State Exchange consumer assistance programs and activities, such as information on its direct outreach plans. Further, we are finalizing a requirement that a State applying to transition to a State Exchange must provide the public with a notice and copy of its State Exchange Blueprint application, as well as conduct periodic public engagements whereby interested parties can learn about the status of a State’s transition to a State Exchange and provide input on that transition.

We are finalizing the amendment to § 155.170(a)(2) to codify that benefits covered in a State’s EHB benchmark plan will not be considered in addition to EHB, even if they had been required by State action taking place after December 31, 2011, other than for

purposes of compliance with Federal requirements. Under this policy, there would be no obligation for the State to defray the cost of a State mandate enacted after December 31, 2011, that requires coverage of a benefit if that benefit is included in the State’s EHB-benchmark plan. Benefits that are covered in a State’s EHB-benchmark plan will not be considered in addition to EHB and will remain subject to the various rules applicable to the EHB, including the prohibition on discrimination in accordance with § 156.125, limitations on cost sharing in accordance with § 156.130, and restrictions on annual or lifetime dollar limits in accordance with § 147.126. We believe that this change would promote consumer protections and facilitate compliance with the defrayal requirement by making the identification of benefits in addition to EHB more intuitive.

At § 155.205(a), we are finalizing, with modifications, the establishment of additional minimum standards for Exchange call center operations. Specifically, we are finalizing the requirement that all Exchange call centers, other than those of SBE-FPs and Small Business Health Options Program (SHOP) Exchanges that do not provide for enrollment in SHOP coverage through an online SHOP enrollment platform, provide consumer access to a live call center representative during an Exchange’s published hours of operation to assist with submitting their Exchange application. We believe speaking to a live representative will help troubleshoot consumer Exchange application issues, provide a real time opportunity for a live representative to explain Exchange application terminology to a consumer, ensure the consumer provides the most correct information for the Exchange application, alleviate unnecessary follow-up, and provide greater overall consumer satisfaction.

We are finalizing the amendment to § 155.205(b)(4) to require that an Exchange operate a centralized eligibility and enrollment platform on the Exchange’s website (or, for an SBE-FP, the Federal eligibility and enrollment platform) such that the Exchange allows for the submission of the single, streamlined application for enrollment in a QHP and insurance affordability programs through the Exchange’s website and performs eligibility determinations for all consumers based on submissions of the single, streamlined application. Further, we are finalizing the amendment to § 155.302(a)(1) to clarify that the Exchange, through the centralized

⁹ OMB. (2023, March 13). OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2024. https://www.whitehouse.gov/wp-content/uploads/2023/03/BBEDCA_Sequestration_Report_and_Letter_3-13-2024.pdf.

eligibility and enrollment platform operated on the Exchange's website (or, for an SBE-FP, the Federal eligibility and enrollment platform), is the entity that is responsible for making all determinations regarding the eligibility for QHP coverage and insurance affordability programs regardless of whether an individual files an application for enrollment in a QHP on the Exchange's website (or, for SBE-FPs, on the Federal eligibility and enrollment platform), or on a website operated by a non-Exchange website allowed for under § 155.220 or § 155.221. We are also clarifying that only entities that an Exchange elects to contract with to operate its centralized eligibility and enrollment platform can perform this function on behalf of an Exchange, such that Exchanges will not be able to solely rely on non-Exchange entities, including a web-broker (defined at § 155.20) or other entities under § 155.220 or § 155.221, to make such eligibility determinations on behalf of the Exchanges.

We are also finalizing the amendment to § 155.205(b)(5) to require that an Exchange operate a centralized eligibility and enrollment platform on the Exchange's website (or, for an SBE-FP, the Federal eligibility and enrollment platform) so that the Exchange (or, for an SBE-FP, the Federal eligibility and enrollment platform) meets the requirement under § 155.400(c) to maintain record of all effectuated enrollments in QHPs, including changes in effectuated QHP enrollments.

We are finalizing the amendment to § 155.220(h) specifying that the CMS Administrator, who is a principal officer, is the entity responsible for handling requests by agents, brokers, and web-brokers for reconsideration of HHS' decision to terminate their Exchange agreement(s) for cause. This amendment will improve transparency by specifying who would review reconsideration requests under § 155.220(h).

We are finalizing changes to §§ 155.220 and 155.221 to apply certain standards to web-brokers and Direct Enrollment (DE) entities assisting consumers and applicants across all Exchanges, including State Exchanges, for both the State Exchange's Individual Exchange and SHOP. We seek to ensure that certain current minimum HHS standards applicable in the FFEs and SBE-FPs, related to web-broker website display of standardized QHP comparative information, disclaimer language, information on eligibility for APTC/CSRs, operational readiness, and access by downstream agents and

brokers, also apply to web-brokers in State Exchanges. Similarly, we are finalizing the extension of certain DE entity requirements applicable in the FFEs and SBE-FPs related to marketing and display of QHPs, providing consumers with correct information and refraining from certain conduct, marketing of non-QHPs, website disclaimer language, and operational readiness to DE entities across all Exchanges, to newly apply to DE entities in State Exchanges. These policies will help establish greater general uniformity with respect to these requirements for web-brokers and DE entities operating in the Exchanges and establish minimum Federal consumer protections in all States, regardless of the Exchange model.

We are finalizing updates to § 155.221(b) to require that *HealthCare.gov* changes be reflected and prominently displayed on DE entity non-Exchange websites assisting consumers in FFEs and SBE-FPs within a notice period¹⁰ set by HHS. We are also finalizing the requirement that DE entities make these display changes in a manner consistent with display changes made by HHS to *HealthCare.gov* by meeting standards communicated and defined by HHS within a time period set by HHS, unless HHS approves a deviation from those standards. This approach codifies our existing practice of communicating important changes to the *HealthCare.gov* display to EDE entities to ensure their EDE websites conform to those changes and provide the same vital information to consumers, expands our existing change request processes to permit entities to request deviations from the required display changes, and requires DE entities that do not participate in EDE to also comply with this practice. Additionally, this approach will also require that all display changes which affect the visual aspects of the website that users see and interact with must be prominently displayed on the non-Exchange websites. Finally, we are also finalizing the extension of this policy to require State Exchanges that choose to implement a DE program to require their DE entities to implement and prominently display website changes in a manner that is consistent with display changes made by State Exchanges to State Exchanges' websites on their non-Exchange websites, unless the State Exchange approves a deviation from

those standards should the State Exchange elect to permit deviation requests.

We are finalizing, in connection with the failure to file and reconcile process at § 155.305(f)(4), that Exchanges be required to send notices to tax filers for the first year in which they have been determined to have failed to reconcile APTC as an initial warning to inform and educate tax filers that they need to file and reconcile, or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive year. We clarify in the rule that an Exchange must either send a direct notice to a tax filer as described above or send a more general notice to an enrollee or their tax filer explaining that they are at risk of losing APTC. Currently, the regulation does not detail notification procedures for tax filers who have failed to reconcile for 1 year. We intend to provide implementation guidance and sample notices prior to the restart of FTR processes. We are finalizing the requirement that all Exchanges be required to send informative notices for the first year in which tax filers have been identified as failing to file and reconcile.

We are finalizing the amendment to § 155.315(e) to provide that all Exchanges can accept applicant incarceration status attestations without further verification, and Exchanges may verify applicant incarceration status using an HHS-approved verification data source. HHS would approve an alternative electronic data source for State Exchanges to use for incarceration verification if it provides data that are current and accurate, and if its use minimizes administrative costs and burdens.

We are finalizing the proposal to reinterpret State Exchange and State Medicaid and Children's Health Insurance Program (CHIP) agency use of the Federal Data Services Hub to access and use the income data provided by the Verify Current Income (VCI) Hub service as a State Exchange or a State Medicaid and CHIP agency function because these State entities use this optional service to implement eligibility verification requirements applicable to them. More specifically, State Exchanges and State Medicaid and CHIP agencies have the option to use this information to verify a tax household's annual income attestation for Exchange QHP eligibility and the Medicaid applicant's current household income as required to make insurance affordability program eligibility determinations. We are also finalizing that these State agencies must pay for their use of the VCI Hub Service, and HHS will invoice

¹⁰ "Notice period" refers to the time period that DE entities have to reflect and prominently display *HealthCare.gov* changes communicated to them by HHS pursuant to this proposal.

them monthly for the amount they must pay to reimburse HHS for the costs of their access and actual utilization of CSI income data from the prior month, including an administrative fee amount. In accordance with these policies, we are finalizing the amendment to § 155.320(c) to reflect this reinterpretation for the Exchanges but did not propose to amend the Medicaid regulations as the Medicaid regulations already address Medicaid agency verification requirements and are not typically used to delineate Medicaid agency operations in this manner.

We are finalizing the revision to § 155.330(d) to require Exchanges to conduct periodic checks for deceased enrollees twice yearly and subsequently end deceased enrollees' QHP coverage. Additionally, we are finalizing the revision to § 155.330(d)(3) to grant the Secretary the authority to temporarily suspend the periodic data matching (PDM) requirement during certain situations or circumstances that lead to the limited availability of data needed to conduct PDM or of documentation needed for an enrollee to notify the Exchange that the result of PDM is inaccurate, as described in § 155.330(e)(2)(i)(C). These policies will align § 155.330(d) with current Federal Exchange policy and operations, prevent overpayment of QHP premiums, and accurately capture household QHP eligibility based on household size.

We are finalizing, as proposed, the amendment to § 155.335(j)(1) and (2) to require Exchanges to re-enroll individuals who are enrolled in catastrophic coverage, as defined in section 1302(e) of the ACA, into a new QHP for the coming plan year, except that we are amending the new language that we proposed at § 155.335(j)(1)(v) and (j)(2)(iv) to incorporate the phrase, "to the extent permitted by applicable State law." Incorporating these individuals enrolled in catastrophic coverage into the auto re-enrollment hierarchy rules at § 155.335(j) will help ensure continuity of coverage in cases where the issuer does not continue to offer a catastrophic plan for the new plan year, or these individuals are no longer eligible for enrollment in a catastrophic plan for the new year, and these individuals do not actively select a different QHP. We are also finalizing the addition of a new paragraph (j)(5) to § 155.335 to establish that an Exchange may not newly auto re-enroll into catastrophic coverage an enrollee who is currently enrolled in coverage of a metal level as defined in section 1302(d) of the ACA. This change reflects our current practice for Exchanges on the Federal platform.

We are finalizing the amendment to § 155.400(e)(2) to codify that the flexibility for issuers experiencing billing or enrollment problems due to high volume or technical errors is not limited to extensions of the binder payment.

We are finalizing, with modifications, the amendment to § 155.410(e)(4)(ii) to revise parameters around the adoption of an alternative open enrollment period by a State Exchange. Specifically, we are finalizing that for benefit years beginning on or after January 1, 2025, State Exchanges must adopt an open enrollment period that begins on November 1 of the calendar year preceding the benefit year and ends January 15 of the applicable benefit year or later. Additionally, as a modification, we are finalizing new paragraph (e)(4)(iii), which provides flexibility for any State Exchange that held an open enrollment period that began before November 1, 2023, and ended before January 15, 2024, for the 2024 benefit year to continue to begin open enrollment before November 1 for consecutive future benefit years, so long as the open enrollment period continues uninterrupted for at least 11 weeks. If the State Exchange changes the dates of the annual open enrollment period after the effective date of this rule, it must comply with paragraphs (e)(4)(i) and (ii) for all future annual open enrollment periods. Finally, we have also finalized a modification to amend § 155.410(e)(4)(i) to reference new paragraph (e)(4)(iii). We believe these policies will give consumers ample time to enroll in coverage; provide Navigators, certified application counselors, and agents and brokers ample time to assist all interested applicants; balance consistency against providing State Exchanges with additional flexibility; reduce disruption to current Exchange operations; reduce consumer confusion; and improve access to health coverage.

At § 155.420(b), we are finalizing aligning the effective dates of coverage after selecting a plan during certain special enrollment periods across all Exchanges, including State Exchanges. We are requiring all State Exchanges to provide coverage that is effective on the first day of the month following plan selection, or an earlier date, if a consumer enrolls in a QHP during special enrollment periods that follow the regular effective dates of coverage in 45 CFR 155.420(b). This policy will prevent coverage gaps, particularly for consumers transitioning between different Exchanges or from other insurance coverage.

We are finalizing the amendment to paragraph § 155.420(d)(16) to revise the parameters around the availability of a special enrollment period for APTC-eligible qualified individuals with a projected annual household income no greater than 150 percent of the Federal Poverty Level (FPL). Specifically, we are finalizing to remove the limitation that this special enrollment period is only available to a consumer whose applicable taxpayer's applicable percentage, which is used to determine the amount of the consumer's premium not covered by APTC, is 0 percent, and to give Exchanges the option to permanently provide this special enrollment period. We believe this policy will provide affordable coverage to more uninsured people and additional enrollment opportunities to low-income consumers.

We are finalizing the addition of § 155.430(b)(1)(iv)(D) to permit an enrollee to retroactively terminate the enrollee's enrollment in a QHP through an Exchange on the Federal platform when the enrollee enrolls in Medicare Parts A or B (including enrollment in Parts A and B through a Medicare Advantage plan). The effective date of the retroactive termination must be no earlier than the later of (1) the day before the first day of coverage under Medicare Parts A or B or a Medicare Advantage plan, and (2) the day is 6 months before retroactive termination of QHP coverage is requested. Enrollees must request retroactive termination of coverage within 60 days of the date they retroactively enroll in Medicare (the date the enrollment occurs, not the Medicare coverage effective date). We are also finalizing that retroactive terminations are not permitted for stand-alone dental plans (SADPs). This policy will allow consumers to avoid overlapping coverage and paying unnecessary premiums. HHS has the option to elect whether to implement this provision for Exchanges on the Federal platform, and State Exchanges will have the option of implementing this policy.

Under § 155.1050(a)(2)(i)(A), we are finalizing that for plans years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must establish and impose quantitative time and distance network adequacy standards for QHPs that are at least as stringent as standards for QHPs participating on the FFEs under § 156.230(a)(2)(i)(A). Additionally, we are finalizing that, for plans years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must conduct quantitative network adequacy reviews prior to certifying any plan as a QHP, consistent

with the reviews conducted by the FFEs under § 156.230. Specifically, we are finalizing at § 155.1050(a)(2)(i)(B) that, for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must conduct network adequacy reviews to evaluate a plan's compliance with network adequacy standards under § 156.230(a)(1)(ii), (a)(1)(iii), and (a)(2)(i)(A) prior to certifying any plan as a QHP, while providing QHP certification applicants the flexibilities described under § 156.230(a)(2)(ii) and (a)(3) and (4). We are also finalizing § 155.1050(a)(2)(ii) to provide that, for plan years beginning on or after January 1, 2026, HHS may grant an exception to the requirements described under § 155.1050(a)(2)(i) to a State Exchange or SBE-FP that demonstrates with evidence-based data, in a form and manner specified by HHS, that (1) the Exchange applies and enforces alternate quantitative network adequacy standards that are reasonably calculated to ensure a level of access to providers that is as great as that ensured by the Federal network adequacy standards established for QHPs under § 156.230(a)(1)(iii), (a)(2)(i)(A), and (a)(4); and (2) the Exchange evaluates whether plans comply with applicable network adequacy standards prior to certifying any plan as a QHP. Lastly, we are finalizing § 155.1050(a)(2)(i)(C) to provide that, for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must require that all issuers seeking certification of a plan as a QHP submit information to the Exchange reporting whether or not network providers offer telehealth services.

6. 45 CFR Part 156

In part 156, after reviewing the public comments and revising our projections based on newly available data that impacted our enrollment projections, we are finalizing an FFE user fee rate of 1.5 percent of total monthly premiums and an SBE-FP user fee rate of 1.2 percent of total monthly premiums. On November 15, 2023, we issued the 2025 benefit year premium adjustment percentage index and related payment parameters in guidance, consistent with the policy finalized in part 2 of the 2022 Payment Notice.¹¹

For benefit years beginning on or after January 1, 2026, we are finalizing three revisions to the standards for State selection of EHB-benchmark plans at § 156.111. First, we are finalizing our proposal to consolidate the options for States to change EHB-benchmark plans

at § 156.111(a) to reduce the burden on States to decide between three functionally identical choices. Second, we are finalizing revisions to the typicality standard at § 156.111(b)(2) so that, in demonstrating that a State's new EHB-benchmark plan provides a scope of benefits that is equal to the scope of benefits of a typical employer plan in the State, the scope of benefits of a typical employer plan in the State will be defined as any scope of benefits that is as or more generous than the scope of benefits in the State's least generous typical employer plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), and as or less generous than the scope of benefits in the State's most generous typical employer plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), among the typical employer plans currently defined at § 156.111(b)(2)(i)(A) and (B). We are also finalizing the removal of the generosity standard at § 156.111(b)(2)(ii) and a technical revision to the language regarding supplementation at § 156.111(b)(2)(i). Third, we are finalizing revisions to § 156.111(e)(3) to require States to submit a formulary drug list as part of their application to change EHB-benchmark plans only if the State is seeking to change its prescription drug EHB.

We are finalizing the removal of the regulatory prohibition at § 156.115(d) on issuers from including routine non-pediatric dental services as an EHB beginning with PY 2027, which would provide States the option to add routine adult dental services as an EHB by updating their EHB-benchmark plans pursuant to § 156.111.

We are finalizing the amendment to § 156.122 to codify that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB. As a result, they would be subject to requirements including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits, unless the coverage of the drug is mandated by State action and is in addition to EHB pursuant to § 155.170, in which case the drug will not be considered EHB. In addition, for plan years beginning on or after January 1, 2026, we are finalizing the amendment to § 156.122 to provide that the Pharmacy & Therapeutics (P&T) committee must include a patient representative. We also sought and received comments on a possible future policy proposal to replace the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) with the USP Drug Classification system (DC) to

classify the prescription drugs required to be covered as EHB under § 156.122(a)(1).

For PY 2025, we are finalizing the proposal to follow the approach finalized in the 2024 Payment Notice concerning standardized plan option metal levels, and to otherwise maintain continuity with our approach to standardized plan options finalized in the 2023 and 2024 Payment Notices.¹² We are finalizing only minor updates to the plan designs for PY 2025 to ensure these plans have AVs within the permissible *de minimis* range for each metal level. Our updates to plan designs for PY 2025 are detailed in the discussion of § 156.201 in the preamble of this final rule, specifically in Tables 12 and 13.

We are finalizing an exceptions process at § 156.202 that will allow issuers in the FFEs and SBE-FPs to offer additional non-standardized plan options per product network type, metal level, inclusion of dental and vision benefit coverage, and service area for PY 2025 and subsequent plan years, if the issuer can demonstrate that these additional non-standardized plans have specific design features that will substantially benefit consumers with chronic and high-cost conditions and meet other requirements.

We are finalizing a new regulatory provision that would permit us to allow a CO-OP loan recipient to voluntarily terminate its loan agreement with us and cease to constitute a qualified non-profit health insurance issuer (QNHI), for the purpose of pursuing innovative business plans that are not otherwise consistent with the governance requirements and business standards applicable to a CO-OP borrower. Under the new regulatory provision, we will be able to consider a request by a CO-OP to voluntarily terminate its loan agreement for reasons other than financial viability, provided all outstanding CO-OP loans issued to the loan recipient are repaid in full prior to termination, and we believe granting the request would meaningfully enhance consumer access to quality, affordable, member-focused, non-profit health care options in affected markets.

We are finalizing conforming amendments to the payment and collections process set forth at

¹² This includes continuation of the differential display of standardized plan options on [HealthCare.gov](https://www.healthcare.gov) and enforcement of the 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 (Classic DE) and Enhanced Direct Enrollment (EDE) Pathways.

¹¹ <https://www.cms.gov/files/document/2025-papi-parameters-guidance-2023-11-15.pdf>.

§ 156.1215 to align with the policies and regulations proposed in the Federal Independent Dispute Resolution Operations proposed rule (88 FR 75744) and that are contingent on their finalization. This provision will provide that administrative fees for utilizing the No Surprises Act Federal independent dispute resolution (IDR) process for health insurance issuers that participate in financial programs under the ACA would be subject to netting as part of HHS' integrated monthly payment and collections cycle. Additionally, we are finalizing the amendment to § 156.1215 to provide that any amount owed to the Federal Government by an issuer and its affiliates for unpaid administrative fees due to the Federal Government from these issuers and their affiliates for utilizing the Federal IDR process in accordance with § 149.510(d)(2), after HHS nets amounts owed by the Federal Government under these programs, would be the basis for calculating a debt owed to the Federal Government.

III. Summary of the Provisions of the Proposed Regulations

A. 31 CFR Part 33 and 45 CFR Part 155—Section 1332 Waivers

1. Background

Section 1332 of the ACA permits States to apply for a section 1332 waiver to pursue innovative strategies for providing their residents with access to higher value, more affordable health insurance coverage. To allow for greater flexibility in communicating with the public, we are finalizing updates to the public hearing process requirements for section 1332 waivers.

Under section 1332(b) of the ACA, the Secretary of HHS and the Secretary of the Treasury (collectively, the Secretaries) may exercise their discretion to approve a request for a section 1332 waiver only if the Secretaries determine that the proposal for the section 1332 waiver meets the following four requirements, referred to as the statutory guardrails: (1) the proposal provides coverage that is at least as comprehensive as coverage defined in section 1302(b) of the ACA and offered through Exchanges established under title I of the ACA, as certified by the Office of the Actuary of CMS, based on sufficient data from the State and from comparable States about their experience with programs created by the ACA and the provisions of the ACA that would be waived; (2) the proposal provides coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the State's residents as would be provided under title I of the

ACA; (3) the proposal provides coverage to at least a comparable number of the State's residents as would be provided under title I of the ACA; and (4) the proposal does not increase the Federal deficit. The Secretaries retain their discretionary authority to deny requested section 1332 waivers when appropriate given consideration of the application, as a whole, even if a proposal for a section 1332 waiver meets the four statutory guardrails.

The Departments are responsible for monitoring an approved section 1332 waiver's compliance with the statutory guardrails and for conducting evaluations to determine the impact of the section 1332 waiver. Specifically, section 1332(a)(4)(B)(v) of the ACA requires the Secretaries to promulgate regulations that provide for a process for the periodic evaluation of approved section 1332 waivers. The Secretaries must also promulgate regulations that provide for a process under which States with approved section 1332 waivers submit to the Secretaries periodic reports concerning the implementation of the State's waiver program.¹³

2. Finalized Amendments to Normal Public Notice Requirements (31 CFR 33.112, 31 CFR 33.120, 45 CFR 155.1312, and 45 CFR 155.1320)

Sections 1332(a)(4)(B)(i) and (iii) of the ACA provide that the Secretaries shall promulgate regulations that provide for a process for public notice and comment at the State level, including public hearings, and a process for providing public notice and comment at the Federal level after the section 1332 waiver application is received by the Secretaries, respectively, that are both sufficient to ensure a meaningful level of public input. Current regulations at 31 CFR 33.112 and 45 CFR 155.1312 specify State public notice and comment period and participation requirements for proposed section 1332 waiver requests, and 31 CFR 33.116(b) and 45 CFR 155.1316(b) specify the public notice and comment period and approval requirements under the accompanying Federal process.

In the November 2020 IFC (85 FR 71142), the Departments revised regulations to set forth flexibilities in the public notice requirements and post-award public participation requirements for section 1332 waivers during the COVID-19 PHE. In the September 2021 Final Rule (86 FR 53502), the Departments extended those changes beyond the COVID-19 PHE to allow similar flexibilities in the event of future

natural disasters; PHEs; or other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life. Currently, in such an event, States may submit a request to the Departments to modify, in part, the State public notice requirements specified in 31 CFR 33.112(a)(1), (b), (c), and (d) and 45 CFR 155.1312(a)(1), (b), (c), and (d), and the Federal public notice requirement specified in 31 CFR 33.116(b) and 45 CFR 155.1316(b), pursuant to 31 CFR 33.118(a) and 45 CFR 155.1318(a).

The criteria to request a modification from the normal public notice requirements during an emergent situation are set forth in 31 CFR 33.118(b)(1) through (5) and 45 CFR 155.1318(b)(1) through (5). Pursuant to 31 CFR 33.118(b)(3) and 45 CFR 155.1318(b)(3), the State's request to modify normal public notice procedures is required to include: the justification for the requested modification from the State public notice procedures as it relates to the emergent situation and the alternative public notice procedures, including public hearings, that it proposes to implement at the State level and that are designed to provide the greatest opportunity for and level of meaningful public input from impacted interested parties that is practicable given the emergent circumstances motivating the State's request for a modification.

Since the finalization of the flexibilities in 31 CFR 33.118(b)(1) through (5) and 45 CFR 155.1318(b)(1) through (5), almost all States with approved section 1332 waivers ("section 1332 waiver States") submitted requests that were granted by the Departments to conduct their annual post-award forums virtually instead of in-person during the COVID-19 PHE to reduce the risk of transmission of COVID-19. Similarly, during the COVID-19 PHE, States submitting new section 1332 waiver applications, waiver extension requests, or waiver amendment requests also requested to host their State public hearings virtually and these requests were also granted by the Departments. However, with the recent expiration of the Federal COVID-19 PHE¹⁴ (and many State COVID-19 PHEs)¹⁵ and in

¹⁴ The Federal COVID-19 PHE ended on May 11, 2023. <https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html#:~:text=That%20means%20with%20the%20COVID,the%20expiration%20of%20the%20PHE.>

¹⁵ For example, in Alaska the State's PHE ended on July 1, 2022 (<https://health.alaska.gov/PHE/Pages/default.aspx>); in Colorado the Disaster

¹³ See ACA section 1332(a)(4)(B)(iv).

line with the requirements of 31 CFR 33.120(c) and 45 CFR 155.1320(c) and 31 CFR 33.112(c) and 45 CFR 155.1312(c), the Departments have ceased granting States' requests to hold public hearings or post-award forums virtually instead of in-person on the basis of the Federal COVID-19 PHE.

Upon review and consideration of the lessons learned during the COVID-19 PHE, the Departments have determined that some current provisions regarding normal State public notice procedures are outdated given the increased accessibility that technology has provided for virtual and telephonic meetings. States have shared that their residents benefitted from the States' opportunity to host public hearings and post-award forums virtually, and that they would like to continue doing so to facilitate attendance. States have also reported to the Departments that hosting meetings virtually during the COVID-19 PHE did not decrease the amount or quality of meaningful input received. States' experiences during this time demonstrated that interested parties were able to virtually attend meetings and submit public comments verbally or in-writing, and States did not report any significant issues relating to virtual platforms that impeded public attendance or participation. States continued to share with the Departments summaries of their post-award forums, as well as all public comments received and actions taken in response to concerns or comments, in accordance with section 1332 waiver annual reporting requirements. In States' new waiver applications, waiver extension requests, and waiver amendment requests, States also shared with the Departments summaries of virtually conducted hearings from their State public comment periods and addressed public comments or concerns received.

Beyond mitigating the spread of COVID-19, information shared by section 1332 waiver States has demonstrated that the opportunity to host post-award forums and public hearings on virtual platforms facilitated comparable or higher levels of public attendance when compared to previously held in-person meetings. For example, at Maryland's annual post-award forums held in 2019 (in-person)

and 2020–2022 (virtual), the State saw comparable participation across the years from interested parties. Minnesota also reported comparable attendance at its post-award forums across the years: 4 attendees in 2018 (in-person), 1 in 2019 (in-person), 4 in 2020 (virtual), 9 in 2021 (virtual),¹⁶ and 2 in 2022 (virtual). Likewise, Wisconsin had 6 attendees at its post-award forum in 2019 (in-person), 24 in 2020 (virtual),¹⁷ 11 in 2021 (virtual), and 7 in 2022 (virtual). Wisconsin noted that using a virtual format has allowed individuals who would otherwise not be able to attend in-person to view the State's presentation and that this has proven to be a convenient means for individuals to attend the forum.

States that began waiver implementation after the start of the COVID-19 PHE have also reported successfully hosting virtual post-award forums. For example, Colorado conducted its first post-award forum entirely virtually in 2020 and reported 79 attendees.¹⁸ Pennsylvania had 2 attendees at its first post-award forum in 2021 (virtual) and 4 in 2022 (virtual). Pennsylvania noted that due to the expansiveness of the State's geography, there has historically been low in-person attendance, as observed at its in-person public hearings in 2019 for its waiver application, where no members of the public attended the first meeting, and two members of the public attended the second meeting.

States submitting new waiver applications, waiver extension requests, or waiver amendment requests during the COVID-19 PHE also reported successfully conducting their public hearings on virtual platforms. For example, in January 2022, Alaska held a combined post-award forum and State public hearing for its waiver extension application both in-person and with a telephonic option, which 3 members of the public attended either in-person or virtually. In April 2022, Washington held two State public hearings virtually, in which 9 representatives from organizations attended and shared public comments.

There are other Federal programs and agencies that permitted a virtual option in place of in-person public hearings prior to the COVID-19 PHE or that have

more recently amended their policies for public input to continue virtual and telephonic options that were first implemented during the COVID-19 PHE. For example, States that are applying for Medicaid section 1115 demonstrations are permitted to use telephonic and web-based conference capabilities for public meetings. In fact, per 42 CFR 431.408(a)(3), a State must use telephonic and/or web conference capabilities for at least one of the two required public hearings to ensure Statewide accessibility to the public hearing, unless it can document it has afforded the public throughout the State the opportunity to provide comment, such as holding the two public hearings in geographically distinct areas of the State.

As another example, during the COVID-19 PHE, the Internal Revenue Service (IRS) began holding public hearings on notices of proposed rulemaking telephonically instead of in-person. Following the end of the Federal COVID-19 PHE, the IRS recently announced that, for proposed regulations published in the **Federal Register** after May 11, 2023,¹⁹ public hearings would be conducted in-person but that a telephonic option would remain available for those who prefer to attend or testify by telephone.

The Departments considered whether to propose requiring States to hold at least one of the required public hearings for waiver applications in-person. However, as explained above, States have successfully hosted post-award forums and public hearings for section 1332 waiver applications virtually to allow for meaningful public input over the last several years. Furthermore, by allowing States the ability to hold all of their meetings virtually, States may better allow for input across different geographies, communities, and populations. We also considered proposing the standard under section 1115 demonstrations where one hearing is required to be done virtually. However, given the successful hosting of virtual meetings with public participation by States for section 1332 waivers, it does not seem necessary to continue to require in-person meetings to solicit public input on section 1332 waivers.

The Departments believe that by allowing States the opportunity to hold post-award forums and public hearings virtually and through digital platforms, States would be able to continue

Recovery Order ended on April 27, 2023 (<https://hcpf.colorado.gov/covid-19-phe-planning>); in Georgia the State of Emergency ended on May 11, 2023 (<https://dph.georgia.gov/press-releases/2023-05-11/dph-news-release-end-public-health-emergency-declaration>); and in Rhode Island the State's COVID-19 Disaster Emergency ended on May 11, 2023 (<https://governor.ri.gov/executive-orders/executive-order-23-05>).

¹⁶ Note that this post-award hearing was also a hearing for the State's waiver extension application, which likely increased attendance.

¹⁷ Note that attendance was relatively higher in 2020 likely due to the forum following the State's first full year of implementing its reinsurance program.

¹⁸ Note that this post-award forum was also a hearing for the State's waiver extension application, which likely increased attendance.

¹⁹ Internal Revenue Service, Public Hearings on Proposed Regulations to Be Conducted in Person with Telephone Options Available, Announcement 2023-16. Accessed at <https://www.irs.gov/pub/irs-drop/a-23-16.pdf>.

facilitating attendance and participation from interested parties and the public to provide meaningful input. As such, the Departments are of the view that updating the State public notice procedures would enhance public participation in the section 1332 waiver review and monitoring process. This approach would help remove barriers to participation and increase opportunities for engagement in policymaking for communities and local partners who may face barriers to in-person participation (for example, those in rural areas). This approach is also consistent with Executive Order 14094, Executive Order on Modernizing Regulatory Review, as it would affirm States' abilities to be inclusive in seeking public input from interested or affected parties, including members of underserved communities, and promote best practices for information accessibility and engagement with interested or affected parties through the use of alternative platforms and media for engaging the public.²⁰ Further, this approach may improve States' abilities to understand and eliminate barriers experienced by underserved or under-represented communities, and identify opportunities to advance health equity, while diminishing administrative burden related to the integration of in-person and virtual formats.

Therefore, in this final rule, the Departments are finalizing as proposed that a virtual (that is, one that uses telephonic, digital, and/or web-based platforms) or hybrid (that is, one that provides for both in-person and virtual attendance) public hearing or forum be considered as the equivalent of holding an in-person meeting. In the 2012 Final Rule (77 FR 11700), the Departments noted that as set forth in 31 CFR 33.112(c)(1) and (2) and 45 CFR 155.1312(c)(1) and (2), a State must hold at least two public hearings in distinct locations. Under this policy, States would still need to hold at least two public hearings in distinct locations. For example, the Departments clarify that under this final rule, a State would not be permitted to count a public hearing in which there is simultaneously an in-person location and virtual platform as two hearings (or two locations). Instead, one virtual or hybrid meeting would still count as one public hearing, and two virtual or hybrid meetings would count as two public hearings.

In this final rule, we are finalizing as proposed in the 2025 Payment Notice proposed rule (88 FR 82510, 82520), to amend 31 CFR 33.112(c) and 45 CFR

155.1312(c) and 31 CFR 33.120(c) and 45 CFR 155.1320(c). More specifically, the Departments are finalizing modifications to 31 CFR 33.112(c) and 45 CFR 155.1312(c) to permit States to conduct public hearings in a virtual or hybrid format in lieu of conducting an in-person meeting. The Departments also finalize as proposed amending 31 CFR 33.120(c) and 45 CFR 155.1320(c) to provide that for a State's annual post-award forum, the public forum shall be conducted in an in-person, virtual (that is, one that uses telephonic, digital, and/or web-based platforms), or hybrid (that is, one that provides for both in-person and virtual attendance) format. These changes will go into effect upon publication of this final rule.

This policy is limited to allowing flexibility to host required meetings virtually. States would still be required to continue to abide by all other public notice requirements, including public notice procedural requirements for waiver applications, waiver extension and waiver amendment requests, and post-award forums. For example, States would still be required to have a process to consult and collaborate with Federally-recognized tribes,²¹ as applicable, as well as take reasonable steps to provide meaningful access for individuals with limited English proficiency (LEP) (for example, language assistance services that may include interpretation in non-English languages provided in-person or remotely by a qualified interpreter, translated written content in paper or electronic form into or from languages other than English, and written notice of availability of language assistance services), and appropriate steps to ensure effective access for and communication with individuals with disabilities (for example, accessibility of information and communication technology).²² States should recognize that virtual meetings may present additional accessibility challenges for people with communications and other disabilities, as well as to those who lack broadband access. Complying with the requirement to ensure effective communication may entail providing American Sign Language interpretation and real-time captioning, as well as ensuring that the virtual platform is interoperable with

assistive technology for people with disabilities.

Finally, the Departments clarify that under this final rule, States shall have a process by which members of the public can request in-person meetings for the annual post-award forum or State public hearings on waiver applications, waiver extension requests, or waiver amendments requests, and that States shall accommodate those requests whenever possible. In addition, States with approved section 1332 waivers and States seeking approval for proposed waivers would continue to have flexibility to submit requests to the Departments during emergent situations to modify certain public participation requirements as set forth in 31 CFR 33.118(b)(1) through (5) and 45 CFR 155.1318(b)(1) through (5).

The Departments sought comment on these proposals and received 29 comments on the section 1332 waiver proposals from various interested parties, including States, health and disease advocacy organizations, general advocacy organizations, health care provider organizations, and research organizations. All comments generally expressed support for the proposed changes, though some raised additional considerations related to accessibility.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these provisions as proposed. We summarize and respond to public comments received on the proposed amendments to normal public notice requirements (31 CFR 33.112, 31 CFR 33.120, 45 CFR 155.1312, and 45 CFR 155.1320) below.

Comment: The Departments received comments supporting the additional flexibilities for States to conduct public hearings and post-award forums in a virtual or hybrid format. Commenters agreed that these updates would facilitate public participation on section 1332 waivers by increasing access to meetings for people who would otherwise face barriers to attending in-person meetings (for example, due to geographic distance, transportation, childcare, limited mobility, chronic health conditions). Commenters also agreed with the Departments' clarification that one meeting held in a hybrid format does not meet the existing requirement that States hold at least two such events in separate locations, and that States would still need to hold at least two public hearings in distinct locations (for example, one virtual or hybrid meeting counts as one meeting, and two virtual or hybrid meetings count as two meetings).

²¹ See 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2).

²² See Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d, 45 CFR part 80), Section 1557 of the ACA (42 U.S.C. 18116, 45 CFR part 92), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794, 45 CFR part 84), and Title II of the Americans with Disabilities Act (42 U.S.C. 12131 *et seq.*, 28 CFR part 35).

²⁰ 88 FR 21879, <https://www.govinfo.gov/content/pkg/FR-2023-04-11/pdf/2023-07760.pdf>.

Several comments from States shared their own positive experiences with hosting public hearings and post-award forums virtually during the COVID-19 pandemic. They explained that public participation did not suffer because the meetings were held virtually. These States also noted that the ability to hold virtual public hearings and post-award forums without needing to request a modification from the normal public notice requirements due to an emergent situation (as they would have done under previous guidance) would reduce administrative hurdles. However, one State asserted that there is no benefit from requiring States to hold public forums in-person and that it is an inefficient use of State resources.

Response: The Departments appreciate the support and have finalized the rule as proposed.

Comment: We received several comments expressing concern that virtual or hybrid meetings may simultaneously pose additional challenges for States to comply with Federal civil rights protections and requirements for accessibility. These commenters voiced concern that people with disabilities, people with LEP, and people with limited broadband access may experience barriers to participation. These commenters encouraged the Departments to issue additional subregulatory guidance to States that clarify related Federal civil rights protections and requirements and to provide examples of compliance strategies to ensure that people with accessibility needs can meaningfully participate in the public comment process. Similarly, one commenter recommended that CMS include in the final rule accessibility standards for virtual and hybrid meetings, such as practices related to pre-event information, live captioning, assistive technology, and document and platform accessibility; and another commenter proposed that the Departments codify essential accessibility practices in the final rule, such as closed captioning, simultaneous interpretation, option to dial in to meetings, and ensuring that the technology used is compatible with assistive technologies used by people with disabilities. Finally, one commenter recommended that the Departments require States to include a virtual option when public hearings are held in-person, which would allow for participation from people who cannot safely attend in-person (for example, people who are immunocompromised). This commenter also requested that States posting public notice for these meetings should ensure the notices are

easily accessible and prominently displayed on their websites.

Response: The Departments agree with commenters that despite the additional flexibilities for States to host meetings in a virtual or hybrid format, it continues to be important for States to comply with applicable Federal civil rights law and ensure accessibility in the public notice and comment process. Regarding commenters' suggestion that the Departments issue additional subregulatory guidance and provide examples of compliance strategies, or to codify accessibility standards and practices into the final rule, we emphasize that the finalization of these provisions does not change requirements for States to ensure Federal civil rights protections and meet applicable accessibility needs. Indeed, in the 2021 Final Rule, the Departments reiterated that any public participation processes must comply with applicable Federal civil rights laws.²³ The Departments expect that States will continue to take accessibility considerations into account to ensure a meaningful level of public input during State notice and comment periods and post-award forums. States may reference the HHS Office for Civil Rights for information on Federal civil rights laws and protections.²⁴ Additionally, comments on issuing subregulatory guidance and codifying accessibility standards and practices are not directly in response to the proposed rule and are out-of-scope. As such we have finalized this rule as proposed.

Finally, the Departments remind States that they must publish the date, time, and location of the public forum in a prominent location on the State's public website, at least 30 days prior to the date of the planned public forum. Consistent with Federal civil rights law, including section 1557 of the ACA, section 504 of the Rehabilitation Act of 1973, and Title II of the Americans with Disabilities Act, section 1332 waiver applications must be accessible to individuals with disabilities, including when such applications are posted online. To assist with ensuring website accessibility, States may look to national standards issued by the Architectural and Transportation Barriers Compliance Board (often referred to as "section 508

standards"),²⁵ or alternatively, to standards issued by the World Wide Web Consortium's (W3C).²⁶

Comment: One commenter who supported the proposed provisions also encouraged the Departments to consider the benefits of in-person meetings by gathering feedback from States to provide guidance on best practices, as in-person meetings may offer a greater level of participant engagement compared to virtual meetings (for example, in-person public testimonies during the State legislative process can have more meaningful impact than virtual testimonies).

Response: As noted in the proposed rule, the Departments considered whether to propose requiring States to hold at least one of the required public hearings for waiver applications in-person. Some States had previously expressed to the Departments and in public comments on this proposed rule that they appreciated the flexibility to virtually conduct public hearings and forums. As demonstrated over the last several years, States have successfully hosted post-award forums and public hearings for section 1332 waiver applications virtually to allow for meaningful public input. Furthermore, States continue to have the option to conduct all public hearings or post-award forums in-person. We encourage States to consider where other opportunities for consumer involvement exist. We believe that the proposed State and Federal public notice and comment processes, along with the post-award public forum provision, ensure meaningful opportunities for participation.

Comment: One commenter suggested that the Departments provide flexibility on whether or not to conduct post-award forums due to what the commenter asserts is a lack of statutory authority, a history of low attendance at post-award forums, the belief that this input could be gathered at a much lower cost with written comments, and the view that the forums are duplicative of other State evaluation processes.

Response: The Departments require post-award forums under their authority under section 1332 (a)(4)(B)(iv) and (v), 31 CFR 33.120, and 45 CFR 155.1320 to require States to submit periodic reports and conduct periodic evaluations to monitor States' compliance with Federal and regulatory requirements for section 1332 waivers. Further, we believe that the public should have an opportunity

²³ Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond (86 FR 53412, 53457) <https://www.govinfo.gov/content/pkg/FR-2021-09-27/pdf/2021-20509.pdf>.

²⁴ <https://www.hhs.gov/civil-rights/for-individuals/index.html>.

²⁵ For more information on section 508 standards, see <https://www.section508.gov/develop/web-content/>.

²⁶ For more information, see <https://www.w3.org>.

to comment at a post-award public forum as reflected in 31 CFR 33.120(c) and 45 CFR 155.1320(c) and note that the requirement for a post-award forum is part of the periodic monitoring and evaluation of waivers. This comment is outside the scope of this rulemaking.

B. 42 CFR Parts 435 and 600

1. Increase State Flexibility in the Use of Income and Resource Disregards for Non-MAGI Populations (42 CFR 435.601)

In the proposed rule, we proposed to provide States with greater flexibility to adopt income and/or resource disregards in determining financial eligibility under section 1902(r)(2) of the Act for individuals excepted from application of modified adjusted gross income financial methodologies (“MAGI-based methodologies”).

Specifically, we proposed to remove the current 42 CFR 435.601(d)(4), which was first adopted in 1993. As explained in the preamble to the proposed rule, the current rule describes the eligibility groups to which States may apply less restrictive methodologies and requires that any less restrictive methodologies elected by a State be “comparable for all persons within each category of assistance within an eligibility group.” As further explained in 42 CFR 435.601(d)(4), for example, if the agency chooses to apply a less restrictive income or resource methodology to an eligibility group of aged individuals, it must apply that methodology to all aged individuals within the selected group.

In the preamble to the proposed rule, we noted that, upon further review, we recognize that section 1902(r)(2)(A) of the Act does not expressly impose a comparability mandate, and that we did not identify a specific legal rationale for the mandate when we originally proposed and finalized 42 CFR 435.601(d)(4), 54 FR 39421, 39433 (September 26, 1989); 58 FR 4908, 4919 (January 19, 1993). We thus concluded that the inclusion of the mandate was a policy choice. We further considered that section (3)(b) of the Sustaining Excellence in Medicaid Act of 2019, Public Law 116–39, permits States to target income and/or resource disregards to people who need home and community-based services (HCBS).²⁷ In light of this analysis, and given that States over the years have expressed interest in targeting income

and/or resource disregards to subpopulations within eligibility groups, we proposed to eliminate paragraph (4) from 42 CFR 435.601(d).

We explained that we believed that eliminating this provision would: increase State flexibility; provide States more options to extend eligibility to specific populations based on a State’s circumstances; and enable States to achieve targeted expansions of coverage that best meet their needs, in contrast to the all-or-nothing approach for income and resource disregards that is effectively required by 42 CFR 435.601(d)(4). We acknowledged, however, that it was possible that eliminating the comparability requirement from 42 CFR 435.601(d)(4) might enable a State to narrow an existing disregard that is broadly available to an eligibility group at present to discrete members of the group instead. We indicated that we had not received inquiries from States on the permissibility of such an approach, and that we believed States would utilize the elimination of 42 CFR 435.601(d)(4) to expand eligibility. We invited comment on our proposal.

Comment: We received many comments on our proposal. A majority of the commenters expressed either conditional or outright support for the proposal. Commenters agreed that the proposal would increase State flexibility and facilitate targeted expansions of Medicaid coverage. Commenters also indicated that the proposal would foster State development of innovative pathways to Medicaid eligibility and help low-income and vulnerable populations. Many commenters also agreed that States would most likely use the flexibility to increase Medicaid eligibility.

However, many commenters who expressed support for the proposal (and some who opposed it) emphasized that, as the proposal leaves open the possibility that States could use the offered flexibility to narrow existing disregards, CMS should impose “safeguards,” “guardrails,” or “no-harm” requirements that would effectively prohibit the States’ use of the flexibility in this manner. Some of these commenters noted that the proposal should not be finalized without these requirements. A number of commenters suggested that States’ exercise of the flexibility be closely monitored, with one recommending that the proposal, if finalized, should be reexamined if States use it in a manner that adversely affects beneficiaries. A few commenters suggested that we were underestimating the likelihood of States using the additional flexibility to reduce

eligibility, and that, as an example, such a course of action might be attractive for States facing budget pressure.

Response: We appreciate the support we received for the general concept of providing States with additional flexibility in this area. However, given the significant concerns and comments that we received, we have decided that we should consider this proposal further and any necessary beneficiary protections, and we are not finalizing it at this time. As we indicated in the preamble to the proposed rule, we believe the proposal would provide States more options to extend eligibility. It is not our intent, however, to offer methods by which States may be likely to reduce it in practice or otherwise harm beneficiaries. We therefore intend to further evaluate the comments regarding the additional flexibility we proposed for States. We will consider the commenters’ recommendations regarding the use of “guardrails,” or other beneficiary protections as well as the need for other modifications to our proposal that would address these commenters’ concerns regarding adequate beneficiary protections in a proposal in the future.

Comment: Many commenters who supported the proposal specifically noted its potential to benefit “at-risk” or “vulnerable” populations, people 65 years old and older, people with blindness or disabilities, “dually eligible” individuals, and prospective medically needy individuals. Commenters also indicated that the proposal could: allow States to develop innovative pathways to Medicaid eligibility; potentially ease the application process for applicants and thereby allow access to coverage more quickly; stabilize coverage for individuals who may experience minor changes in income and/or resources that might otherwise render them ineligible; and possibly produce important information about current eligibility barriers that could lead to broader reforms. One commenter suggested that the flexibility offered by the proposal would be a “commonsense change” that would allow States both to improve care for non-MAGI populations and address “nonsensical, unintended situations that have resulted from different eligibility groups having different income and resource limits.”

Response: We agree that the proposal could benefit the various populations described in these comments. We also agree that the proposal could facilitate State innovation in expanding Medicaid eligibility pathways and support more seamless transitions between eligibility groups. As explained above, however,

²⁷ For further information, see CMS State Medicaid Director Letter 21–004, “State Flexibilities to Determine Financial Eligibility for Individuals in Need of Home and Community-Based Services,” https://www.medicaid.gov/sites/default/files/2021-12/smd21004_0.pdf.

we are continuing to consider the comments we received and are not finalizing the proposal at this time.

Comment: We received many comments that raised concerns with States using the additional flexibility offered by the proposal to reduce existing disregards. Nearly all commenters who raised these concerns recommended that, if we finalized the proposal, we should prohibit States from reducing or narrowing existing disregards for portions of eligibility groups. Some commenters also suggested that the regulatory text, if the proposal is finalized, should require that any targeting criteria be both grounded on a sound rationale and not discriminate based on race, gender, sexual orientation, disability, age, or health condition. A few other commenters recommended that, at the very least, we should include in the regulation a requirement that individuals who may lose eligibility due to a State reducing or narrowing existing disregards be offered a “transitional period” so that they are not immediately terminated and instead have time to potentially conform to new eligibility rules. A few commenters questioned the legal basis for our proposed change.

Response: We appreciate this input. As we noted in the preamble to the proposed rule, State inquiries on the scope of the comparability rule in 42 CFR 435.601(d)(4) have generally centered on ideas on how to expand eligibility instead of reducing it. However, as we explained above, we are not finalizing our proposal at this time in order to further consider our proposal in light of these comments.

Comment: A few commenters raised operational concerns about implementation of our proposal. A few others expressed concern that we should obtain additional input from interested parties before moving forward with our proposal. We also received comments not directly related to the proposal, such as comments asserting a need for periodic adjustments in resource standards and for working with States to identify the most appropriate resource standards for different Medicaid populations.

Response: We appreciate this input. As explained above, we are not finalizing our proposal at this time to further consider our proposal considering the comments received on the proposal.

2. Changes to the Basic Health Program Regulations (42 CFR 600.320)

Section 1331 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education

Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010), provides States with the option to operate a Basic Health Program (BHP). In the States that elect to operate a BHP, the State’s BHP makes affordable health benefits coverage available for lawfully present individuals under age 65 with household incomes between 133 and 200 percent of the Federal poverty level (FPL) (or in the case of a lawfully present non-citizen, ineligible for Medicaid or the Children’s Health Insurance Program (CHIP) due to immigration status, with household incomes between zero and 200 percent of the FPL) who are not eligible for Medicaid, CHIP, or other minimum essential coverage. As of the date of this final rule, only Minnesota is implementing a BHP. Oregon has submitted a Blueprint with a proposed BHP implementation date of July 1, 2024.

Under current 42 CFR 600.320(c), States must establish a uniform method of determining the effective date of eligibility for enrollment in a standard health plan following either the Medicaid process at 42 CFR 435.915 exclusive of 42 CFR 435.915(a) or the Exchange standards at 45 CFR 155.420(b)(1).

Although the current BHP regulation provides States with some flexibility in establishing an effective eligibility date for enrollment, it does not permit a State to select an effective date of coverage standard for eligible individuals as of the first day of the month following the month of application or eligibility determination regardless of when they apply or are found eligible to enroll in a standard health plan in the BHP. We believe eligible individuals should have access to coverage as soon as feasible.

While the Medicaid process at 42 CFR 435.915, exclusive of paragraph (a), allows for a State operating a BHP to have the earliest possible effective date for its enrollees, we understand that some States may have operational or regulatory constraints that do not allow them to follow the Medicaid process, but may be able to implement an effective date for all eligible applicants the first day of the month after the month in which the eligibility determination is made, regardless of which day of the month such determination occurs.

We are finalizing the proposed rule to revise § 600.320(c) to add a third option at paragraph (c)(3) that would allow a State operating a BHP to establish an effective date of eligibility for enrollment for all enrollees on the first day of the month following the month in which BHP eligibility is determined. Under § 600.320(c)(1), States would

continue to have the option to follow the Exchange standards at 45 CFR 155.420(b)(1), and under 42 CFR 600.320(c)(2), a State may follow Medicaid standards at 42 CFR 435.915 exclusive of paragraph (a).

We sought comment on the proposed additional option for determining the effective date of eligibility for enrollment in a standard health plan as well as an alternative option of allowing a State to establish its own uniform effective date policy.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision with the following modifications: we are adding § 600.320(c)(4) to specify that subject to HHS approval, a State may establish its own effective date of eligibility for enrollment policy as long as it is (1) no later than the first day of the second month following the date that an individual has been determined BHP-eligible; and (2) no more restrictive than § 600.320(c)(1) through (3). We summarize and respond to public comments received on the proposed BHP effective date policy below.

Comment: Many comments supported the additional flexibility for States operating a BHP to follow an effective date of eligibility for enrollment on the first day of the month following the month in which BHP eligibility is determined.

Response: We appreciate the comments supporting our proposal, and for reasons discussed below, we are finalizing the regulation changes as proposed with only minor modifications.

Comment: A few commenters supported an option to allow a State to establish its own effective date of eligibility policy, which we had sought comment on.

Response: We appreciate the comments and agree that individual States’ needs should be taken into account. Therefore, we are adding an option that allows a State to establish its own effective date of eligibility for enrollment policy. We have added § 600.320(c)(4), which specifies that subject to HHS approval, a State may establish its own effective date of eligibility policy. We specify that a State-developed effective date must be no later than the first date of the second month following the date that an individual has been determined BHP-eligible. In addition, the effective date of eligibility for enrollment must be no more restrictive than § 600.320(c)(1) through (3). This effective date policy should provide greater flexibility for a State to meet its own population’s needs

and not cause delays in coverage. We expect this request to be submitted via a Blueprint revision.

Comment: One commenter questioned our discussion of the intersection of premium payments and enrollment in a BHP. The commenter was concerned that we were suggesting that the proposed option at § 600.320(c)(3) would require enrollment after an eligibility determination was made, regardless of whether a premium payment was received.

Response: This regulation sets out the allowable effective dates of coverage but does not describe all of the processes surrounding enrollment of an individual into coverage. The lack of mention of premium payment was not intended to preclude a State from requiring premium payments prior to enrollment. States may require payment of premiums prior to enrolling an individual into BHP. A State that wishes to be particularly clear about its enrollment policies may adopt the option under § 600.320(c)(4) and specify in the BHP Blueprint that it is providing additional time to account for a BHP-individual to pay a premium.

C. 45 CFR Part 153—Standards Related to Reinsurance, Risk Corridors, and HHS Risk Adjustment

In subparts A, B, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the ACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual, small group markets, or merged markets, inside and outside the Exchanges. In accordance with § 153.310(a), a State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program or have HHS do so on its behalf.²⁸ HHS did not receive any requests from States to establish and operate a risk adjustment program for the 2025 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2025 benefit year.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2024, the HHS-operated risk adjustment program is subject to the fiscal year 2024

sequestration.²⁹ The Federal Government's 2024 fiscal year began on October 1, 2023. Therefore, the HHS-operated risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from fiscal year 2024 resources (that is, funds collected during the 2024 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 1985,³⁰ as amended, and the underlying authority for the HHS-operated risk adjustment program, the funds that are sequestered in fiscal year 2024 from the HHS-operated risk adjustment program will become available for payment to issuers in fiscal year 2025 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, the program would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

Additionally, we note that the Infrastructure Investment and Jobs Act³¹ amended section 251A(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 and extended sequestration for the HHS-operated risk adjustment program through fiscal year 2031 at a rate of 5.7 percent per fiscal year.³²

After consideration of the comment and for the reasons outlined in the proposed rule, the HHS-operated risk adjustment program will sequester payments made from fiscal year 2024 resources at a rate of 5.7 percent. We summarize and respond to the public comment received on the fiscal year 2024 sequestration rate below.

Comment: One commenter acknowledged the sequestration rate for the HHS-operated risk adjustment program.

Response: The HHS-operated risk adjustment program will sequester payments made from fiscal year 2024 resources at a rate of 5.7 percent.

2. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories

(HCCs)), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year,³³ and prescription drug categories (RXC) beginning with the 2018 benefit year.³⁴ Starting with the 2023 benefit year, we removed the severity illness factors in the adult models and added interacted HCC count factors (that is, additional factors that express the presence of a severity or transplant HCC in combination with a specified number of total payment HCCs or HCC groups on the enrollee's record) to the adult and child models³⁵ applicable to certain severity and transplant HCCs.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 cost sharing reduction (CSR) adjustment factor. The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score (PLRS)) within a geographic rating area is one of the inputs into the State payment transfer formula,³⁷ which determines the State transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable State market risk pool for a given benefit year. Thus, the HHS risk

³³ For the 2017 through 2022 benefit years, there is a set of 11 binary enrollment duration factors in the adult models that decrease monotonically from one to 11 months, reflecting the increased annualized costs associated with fewer months of enrollments. See, for example, 81 FR 94071 through 94074. These enrollment duration factors were replaced beginning with the 2023 benefit year with HCC-contingent enrollment duration factors for up to 6 months in the adult models. See, for example, 87 FR 27228 through 27230.

³⁴ For the 2018 benefit year, there were 12 RXCs, but starting with the 2019 benefit year, the two severity-only RXCs were removed from the adult models. See, for example, 83 FR 16941.

³⁵ See Table 1 for a list of factors in the adult models, and Table 2 for a list of factors in the child models.

³⁶ See 87 FR 27224 through 27228.

³⁷ The State payment transfer formula refers to the part of the Federally certified risk adjustment methodology that applies in States where HHS is responsible for operating the program. The formula calculates payments and charges at the State market risk pool level (prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year). See, for example, 81 FR 94080.

²⁹ Office of Management and Budget. (2023, March 13). OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2024. https://www.whitehouse.gov/wp-content/uploads/2023/03/BBEDCA_Sequestration_Report_and_Letter_3-13-2024.pdf.

³⁰ Public Law 99–177 (1985).

³¹ Public Law 117–58, 135 Stat. 429 (2021).

³² 2 U.S.C. 901a.

²⁸ See also 42 U.S.C. 18041(c)(1).

adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

a. Data for HHS Risk Adjustment Model Recalibration for the 2025 Benefit Year

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82527), we proposed to recalibrate the 2025 benefit year HHS risk adjustment models with the 2019, 2020, and 2021 enrollee-level EDGE data. In the proposed rule, we explained the history of recalibrating the risk adjustment models with enrollee-level EDGE data and why we use three years of blended data for recalibration.³⁸ Given this history and reasoning, we proposed to determine coefficients for the 2025 benefit year based on a blend of separately solved coefficients from the 2019, 2020, and 2021 benefit years' enrollee-level EDGE data, with the costs of services identified from the data trended between the relevant year of data and the 2025 benefit year.³⁹ The coefficients listed in Tables 1 through 6 reflect the use of trended 2019, 2020, and 2021 benefit year enrollee-level EDGE data, as well as other HHS risk adjustment model updates finalized in this final rule (including, for example, the pricing adjustment for Hepatitis C drugs).

We sought comment on the proposal to determine 2025 benefit year coefficients for the HHS risk adjustment models based on a blend of separately solved coefficients from the 2019, 2020, and 2021 enrollee-level EDGE data.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this approach as proposed. We summarize and respond to public comments received on the proposed enrollee-level EDGE data to be used for

HHS risk adjustment model recalibration for the 2025 benefit year below.

Comment: A few commenters supported utilizing the 2019, 2020, and 2021 enrollee-level EDGE data to recalibrate the risk adjustment models for the 2025 benefit year as proposed. Other commenters opposed using these years of enrollee-level EDGE data due to concerns about the impact of the COVID-19 PHE on 2020 and 2021 benefit year enrollee-level EDGE data.

Response: We are finalizing the use of the 2019, 2020, and 2021 enrollee-level EDGE data to recalibrate the 2025 risk adjustment models as proposed. As detailed further below, our analyses found the 2020 and 2021 benefit year enrollee-level EDGE data is sufficiently similar to prior years of enrollee-level EDGE data such that exclusion of these data years from the risk adjustment model recalibration is not warranted.

We recognize that if a benefit year of enrollee-level EDGE data has significant changes that differentially impact certain conditions or populations relative to others or is sufficiently anomalous relative to expected future patterns of care, we should carefully consider what impact that benefit year of data could have if it is used in the annual model recalibration for the HHS-operated risk adjustment program.⁴⁰ This includes consideration of whether to exclude or adjust that benefit year of data to increase the models' predictive validity or otherwise limit the impact of anomalous trends. For this reason, we conducted extensive analysis on the 2020 benefit year enrollee-level EDGE data to consider its inclusion in the recalibration of the 2024 benefit year risk adjustment models. In the 2024 Payment Notice proposed rule⁴¹ and final rule⁴² we discussed our analysis of the 2020 benefit year data to identify possible impacts of the COVID-19 PHE.⁴³ Likewise, when we were developing the proposal for recalibration of the 2025 benefit year risk adjustment models, we conducted similar analyses on the 2021 benefit year enrollee-level EDGE data as we did to the 2020 benefit year enrollee-level EDGE data to examine the potential impact of the COVID-19 PHE. We did

not find any notable anomalous trends, especially when considering that every year of data can be unique, and therefore, some level of deviation from year to year is expected. Specifically, our analysis found:

- The total sample size in the recalibration data set was similar between the 2019, 2020, and 2021 benefit years, with the individual market at the national level seeing an increase in enrollment in the 2021 benefit year and the small group market at the national level seeing a slight decrease in enrollment in the 2021 benefit year.

- In the 2021 EDGE enrollee-level recalibration data set, PMPM spending increased substantially relative to the 2020 benefit year. The increased percentage was similar for institutional and professional services, preventive services, and drugs. While the year-over-year increase was larger than usual, the 2-year increase in spending between 2019 and 2021 was more consistent with historical trends. For both 2020 and 2021, year-over-year spending changes were consistent across enrollee risk factors and thus did not skew the relative factors used in the HHS risk adjustment models.

- Across all data submitted through issuer's EDGE servers between 2019 to 2020 benefit years for enrollees in our recalibration sample, there was a 3,681 percent increase in claims with telehealth services, whereas between the 2020 and 2021 benefit years, we observed a 1.25 percent increase in claims with telehealth services. Thus, use of telehealth services remained much higher in the 2021 benefit year than in the 2019 benefit year. While it is likely the continued higher use of telehealth services in 2021 was in part a response to the ongoing COVID pandemic in 2021, it is also at least in part due to changes in patterns of care that can be expected to continue into future benefit years. We therefore expect that the use of telehealth services may continue at a level somewhere between the higher levels observed in the 2020 and 2021 benefit years and the lower 2019 benefit year levels in the 2025 benefit year, as would be appropriately reflected by including all three data years in the 2025 EDGE data recalibration.

- The percentage of enrollees with one or more HCCs was similar between the 2019 and 2020 benefit year enrollee-level EDGE recalibration data. The percentage of enrollees with one or more HCC increased slightly between the 2020 and 2021 benefit year enrollee-level EDGE recalibration data sets in

³⁸ 88 FR 82510 at 82527 through 82528.

³⁹ As described in the 2016 Risk Adjustment White Paper (<https://www.cms.gov/ccio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf>) and the 2017 Payment Notice (81 FR 12218), we subdivide expenditures into traditional drugs, specialty drugs, medical services, and preventive services and determine trend factors separately for each category of expenditure. In determining these trend factors, we consult our actuarial experts, review relevant Unified Rate Review Template (URRT) submission data, analyze multiple years of enrollee-level EDGE data, and consult National Health Expenditure Accounts (NHEA) data as well as external reports and documents published by third parties. In this process, we aim to determine trends that reflect changes in cost of care rather than gross growth in expenditures. As such, we believe the trend factors we used for each expenditure category for the 2025 benefit year are appropriate for the most recent changes in cost of care that we have seen in the market.

⁴⁰ Since the start of model calibration for the HHS risk adjustment models in benefit year 2014, the COVID-19 PHE has been the only such situation to date. Other events and policy changes have not risen to the same level of uniqueness or impact.

⁴¹ 87 FR 78214 through 78218.

⁴² 88 FR 25749 through 25754.

⁴³ This analysis included assessing how the 2020 benefit year enrollee-level EDGE recalibration data compares to 2019 benefit year enrollee-level EDGE recalibration data.

both the recalibration and full data sets, as is the usual historical trend.

- Individual HCC frequencies and costs generally remained stable between the 2019, 2020, and 2021 benefit year enrollee-level EDGE recalibration data sets, even for the HCCs related to the severe manifestations of COVID-19. One exception was a notable increase in frequency for HCC 127 *Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes*, which was likely coded for cases in which acute respiratory distress syndrome (ARDS) was a manifestation of COVID-19, but relative allowed charges, and therefore, risk adjustment model coefficients, for HCC 127 (Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes) remained similar in 2021 compared to 2019 and 2020. We expect that as least some severe manifestations of COVID-19 are likely to continue to occur through the 2025 benefit year and those enrollees would continue to receive HCC 127 (Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes).

- RXC frequencies and costs were generally stable between the 2019, 2020, and 2021 benefit year enrollee-level EDGE recalibration data sets, with the exception of RXC 10 *Cystic Fibrosis Agents*, for which a new drug was introduced that increased costs in the 2020 and 2021 data compared to the 2019 data. We expect the continued use of this new drug to cause RXC 10 (Cystic Fibrosis Agents) costs to remain at the higher levels reflected in the 2020 and 2021 benefit years through the 2025 benefit year.

- The coefficients for the 2021 benefit year enrollee-level EDGE recalibration data are similar to the 2019 and 2020 benefit year's coefficients and are consistent with typical changes in coefficients for new years of data. A major benefit of blending separately solved models across three benefit years of data (that is, 2019, 2020, and 2021) is that unique features specific to one benefit year are captured but not over-emphasized.

Thus, after analyzing our results, we concluded there were no significant anomalies in the 2021 benefit year enrollee-level EDGE data to warrant precluding its inclusion from the 2025 benefit year HHS risk adjustment model recalibration. This is consistent with how we ultimately concluded there were no significant anomalies in the 2020 benefit year enrollee-level EDGE data to warrant precluding its inclusion from risk adjustment model

recalibration.⁴⁴ In fact, the analysis we conducted confirmed that its inclusion was within the range of previous year-to-year coefficient changes, and that many of the changes observed are likely to persist through the 2025 benefit year, as intended when transitioning to more recent years of data in model recalibration. Further, the blending of the coefficients from the separately solved models for benefit years 2020 and 2021, with benefit year 2019, also helps promote stability and we believe would sufficiently account for any differences resulting from the COVID-19 PHE.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments above, we are finalizing the approach for recalibrating the HHS risk adjustment models for the 2025 benefit year as proposed. The model coefficients for the 2025 benefit year listed in Tables 1 through 6 of this final rule are based on a blend of equally-weighted, separately solved coefficients from the 2019, 2020, and 2021 benefit years of enrollee-level EDGE data for all coefficients.

b. Pricing Adjustment for the Hepatitis C Drugs

For the 2025 benefit year, we proposed to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models.⁴⁵ Since the 2020 benefit year HHS risk adjustment models, we have been making a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the models.⁴⁶ The purpose of this market pricing adjustment is to account for significant pricing changes between the data years used for recalibrating the models and the applicable benefit year of risk adjustment as a result of the introduction of new and generic Hepatitis C drugs.⁴⁷

We sought comment on our proposal to apply a market pricing adjustment to the plan liability associated with

Hepatitis C drugs for the 2025 benefit year.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this adjustment as proposed. We summarize and respond to public comments received on the proposed pricing adjustment for Hepatitis C drugs below.

Comment: A few commenters supported the proposed Hepatitis C pricing adjustment in the risk adjustment models and noted that a pricing adjustment was still warranted for Hepatitis C drugs. Other commenters expressed concern about the Hepatitis C pricing adjustment and cautioned against reducing the Hepatitis C RXC coefficient more than the expected decrease in cost as reducing the coefficient in such a manner may incentivize issuers to reduce the availability of treatment.

Response: We agree with commenters that continuing to apply the Hepatitis C pricing adjustment in the 2025 benefit year HHS risk adjustment models remains appropriate and are finalizing the Hepatitis C pricing adjustment as proposed. As discussed in the proposed rule, as part of the 2025 benefit year model recalibration analysis, we reassessed the cost trend for Hepatitis C drugs using available enrollee-level EDGE data (including 2021 benefit year data) to consider whether the adjustment was still needed and if it is still needed, whether it should be modified. Specifically, although generic Hepatitis C drugs became available on the market in 2019, and therefore were available for all 3 years of data (2019–2021) used for the 2025 benefit year model recalibration, our analysis of the data continued to observe that costs for Hepatitis C drugs are not increasing at the same rate as other drug costs between the recalibration data years and the applicable benefit year of risk adjustment, likely due to continued increases in the proportion of Hepatitis C drug prescriptions for generic versions of the drugs. As such, we do not believe that the trends used to reflect growth in the prescription drug costs due to inflation and related factors for recalibrating the models would appropriately reflect the average cost of Hepatitis C treatments expected in the 2025 benefit year. Therefore, we believe a market pricing adjustment specific to Hepatitis C drugs in the HHS risk adjustment models for the 2025 benefit year is necessary to account for the lack of growth in Hepatitis C drug prices relative to other prescription drugs in the market between the data years used for recalibrating the models and the

⁴⁴ 87 FR 25749 through 25754.

⁴⁵ See, for example, 84 FR 17463 through 17466.

⁴⁶ The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking drugs mapped to RXC 2: Anti-Hepatitis C (HCV) Agents, Direct Acting Agents in the data used for recalibration.

⁴⁷ Silseth, S., & Shaw, H. (2021). Analysis of prescription drugs for the treatment of hepatitis C in the United States. Milliman White Paper. <https://www.milliman.com/-/media/milliman/pdfs/2021-articles/6-11-21-analysis-prescription-drugs-treatment-hepatitis-c-us.ashx>.

applicable benefit year of risk adjustment due to the introduction of new and generic Hepatitis C drugs in recent years. In making this determination, HHS consulted its actuarial experts and analyzed the most recent enrollee-level EDGE data available to further assess the changing costs associated with Hepatitis C enrollees. In developing the Hepatitis C RXC pricing adjustment for the 2025 benefit year, we considered that we had moved into the data years (2019–2021) under which the generic Hepatitis C drugs were available in the market for all of the data years used for model recalibration, and therefore, to avoid over-adjusting the Hepatitis C RXC, our pricing adjustment for the 2025 benefit year does not reduce the coefficient as much as prior benefit years. Instead, our pricing adjustment trends the Hepatitis C drugs at a lower rate than the other prescription drugs in the risk adjustment models to reflect the lack of

cost increases observed in the Hepatitis C drugs in 2021.

Thus, we believe that the Hepatitis C pricing adjustment we are finalizing accurately captures the anticipated costs of Hepatitis C drugs for the 2025 benefit year using the most recently available enrollee-level EDGE 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. 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 and plan to propose phasing out the market adjustment if and when appropriate.

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

The 2025 benefit year HHS risk adjustment model factors resulting from

the equally weighted (averaged) blended factors from separately solved models using the 2019, 2020, and 2021 enrollee-level EDGE data are shown in Tables 1 through 6. The adult, child, and infant models have been adjusted to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the \$1 million threshold.⁴⁸ Table 1 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, interacted HCC counts, and enrollment duration coefficients. Table 2 contains the factors for each child model, including the age-sex, HCCs, and interacted HCC counts coefficients. Table 3 lists the HCCs selected for the interacted HCC counts factors that would apply to the adult and child models. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant models' maturity and severity categories, respectively.

TABLE 1—ADULT HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR

| HCC or RXC No. | Factor | Platinum | Gold | Silver | Bronze | Catastrophic |
|----------------------------|---|----------|--------|--------|--------|--------------|
| Demographic Factors | | | | | | |
| | Age 21–24, Male | 0.189 | 0.128 | 0.086 | 0.057 | 0.056 |
| | Age 25–29, Male | 0.197 | 0.133 | 0.088 | 0.056 | 0.055 |
| | Age 30–34, Male | 0.230 | 0.160 | 0.110 | 0.073 | 0.072 |
| | Age 35–39, Male | 0.249 | 0.174 | 0.119 | 0.077 | 0.076 |
| | Age 40–44, Male | 0.282 | 0.203 | 0.143 | 0.095 | 0.094 |
| | Age 45–49, Male | 0.312 | 0.228 | 0.164 | 0.112 | 0.111 |
| | Age 50–54, Male | 0.381 | 0.290 | 0.218 | 0.161 | 0.160 |
| | Age 55–59, Male | 0.428 | 0.330 | 0.254 | 0.191 | 0.189 |
| | Age 60–64, Male | 0.472 | 0.365 | 0.282 | 0.212 | 0.210 |
| | Age 21–24, Female | 0.285 | 0.196 | 0.127 | 0.078 | 0.076 |
| | Age 25–29, Female | 0.308 | 0.212 | 0.137 | 0.082 | 0.081 |
| | Age 30–34, Female | 0.370 | 0.268 | 0.188 | 0.126 | 0.125 |
| | Age 35–39, Female | 0.428 | 0.323 | 0.239 | 0.174 | 0.172 |
| | Age 40–44, Female | 0.482 | 0.372 | 0.284 | 0.211 | 0.209 |
| | Age 45–49, Female | 0.481 | 0.369 | 0.277 | 0.200 | 0.198 |
| | Age 50–54, Female | 0.519 | 0.404 | 0.307 | 0.226 | 0.224 |
| | Age 55–59, Female | 0.482 | 0.368 | 0.271 | 0.191 | 0.189 |
| | Age 60–64, Female | 0.475 | 0.358 | 0.261 | 0.179 | 0.176 |
| HCC001 | HIV/AIDS | 0.342 | 0.265 | 0.234 | 0.197 | 0.196 |
| HCC002 | Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock | 9.075 | 8.875 | 8.830 | 8.740 | 8.739 |
| HCC003 | Central Nervous System Infections, Except Viral Meningitis | 8.379 | 8.276 | 8.229 | 8.151 | 8.149 |
| HCC004 | Viral or Unspecified Meningitis | 8.328 | 8.217 | 8.161 | 8.071 | 8.068 |
| HCC006 | Opportunistic Infections | 8.532 | 8.478 | 8.419 | 8.333 | 8.330 |
| HCC008 | Metastatic Cancer | 23.002 | 22.629 | 22.616 | 22.506 | 22.506 |
| HCC009 | Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia | 12.575 | 12.312 | 12.271 | 12.156 | 12.155 |
| HCC010 | Non-Hodgkin Lymphomas and Other Cancers and Tumors | 5.705 | 5.535 | 5.473 | 5.362 | 5.360 |
| HCC011 | Colorectal, Breast (Age < 50), Kidney, and Other Cancers | 3.651 | 3.476 | 3.405 | 3.283 | 3.280 |
| HCC012 | Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors | 2.424 | 2.295 | 2.230 | 2.129 | 2.127 |
| HCC013 | Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors | 0.967 | 0.875 | 0.785 | 0.677 | 0.674 |
| HCC018 | Pancreas Transplant Status | 6.320 | 6.253 | 6.239 | 6.228 | 6.219 |
| HCC019 | Diabetes with Acute Complications | 0.259 | 0.214 | 0.172 | 0.130 | 0.128 |
| HCC020 | Diabetes with Chronic Complications | 0.259 | 0.214 | 0.172 | 0.130 | 0.128 |
| HCC021 | Diabetes without Complication | 0.259 | 0.214 | 0.172 | 0.130 | 0.128 |
| HCC022 | Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19–21 | 0.311 | 0.282 | 0.244 | 0.180 | 0.178 |
| HCC023 | Protein-Calorie Malnutrition | 11.342 | 11.221 | 11.179 | 11.105 | 11.104 |
| HCC026 | Mucopolysaccharidosis | 23.821 | 23.642 | 23.619 | 23.556 | 23.556 |
| HCC027 | Lipidoses and Glycogenosis | 23.821 | 23.642 | 23.619 | 23.556 | 23.556 |
| HCC029 | Amyloidosis, Porphyria, and Other Metabolic Disorders | 6.512 | 6.413 | 6.373 | 6.305 | 6.303 |

⁴⁸ We did not propose any changes to the high-cost risk pool parameters for the 2025 benefit year.

Therefore, we are maintaining the \$1 million

attachment point and 60 percent coinsurance rate for the 2025 benefit year.

TABLE 1—ADULT HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR—Continued

| HCC or RXC No. | Factor | Platinum | Gold | Silver | Bronze | Catastrophic |
|------------------|---|----------|--------|--------|--------|--------------|
| HCC030 | Adrenal, Pituitary, and Other Significant Endocrine Disorders | 1.314 | 1.237 | 1.184 | 1.108 | 1.104 |
| HCC034 | Liver Transplant Status/Complications | 6.014 | 6.070 | 6.119 | 6.189 | 6.189 |
| HCC035_1 a | Acute Liver Failure/Disease, Including Neonatal Hepatitis | 7.464 | 7.288 | 7.254 | 7.181 | 7.184 |
| HCC035_2 | Chronic Liver Failure/End-Stage Liver Disorders | 2.319 | 2.160 | 2.125 | 2.042 | 2.041 |
| HCC036 | Cirrhosis of Liver | 0.613 | 0.534 | 0.490 | 0.417 | 0.416 |
| HCC037_1 | Chronic Viral Hepatitis C | 0.514 | 0.454 | 0.403 | 0.348 | 0.347 |
| HCC037_2 | Chronic Hepatitis, Except Chronic Viral Hepatitis C | 0.514 | 0.454 | 0.403 | 0.348 | 0.347 |
| HCC041 | Intestine Transplant Status/Complications | 6.014 | 6.070 | 6.119 | 6.189 | 6.189 |
| HCC042 | Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis | 11.053 | 10.907 | 10.903 | 10.857 | 10.857 |
| HCC045 | Intestinal Obstruction | 5.038 | 4.837 | 4.783 | 4.669 | 4.668 |
| HCC046 | Chronic Pancreatitis | 2.467 | 2.298 | 2.253 | 2.167 | 2.166 |
| HCC047 | Acute Pancreatitis | 2.467 | 2.298 | 2.251 | 2.147 | 2.146 |
| HCC048 | Inflammatory Bowel Disease | 1.108 | 1.023 | 0.944 | 0.820 | 0.816 |
| HCC054 | Necrotizing Fasciitis | 8.617 | 8.468 | 8.446 | 8.388 | 8.388 |
| HCC055 | Bone/Joint/Muscle Infections/Necrosis | 4.567 | 4.401 | 4.381 | 4.321 | 4.322 |
| HCC056 | Rheumatoid Arthritis and Specified Autoimmune Disorders | 1.082 | 0.993 | 0.930 | 0.845 | 0.843 |
| HCC057 | Systemic Lupus Erythematosus and Other Autoimmune Disorders. | 0.399 | 0.329 | 0.249 | 0.146 | 0.142 |
| HCC061 | Osteogenesis Imperfecta and Other Osteodystrophies | 1.924 | 1.801 | 1.740 | 1.639 | 1.637 |
| HCC062 | Congenital/Developmental Skeletal and Connective Tissue Disorders. | 1.924 | 1.801 | 1.740 | 1.639 | 1.637 |
| HCC063 | Cleft Lip/Cleft Palate | 0.922 | 0.819 | 0.759 | 0.678 | 0.676 |
| HCC066 | Hemophilia | 72.761 | 72.491 | 72.466 | 72.379 | 72.380 |
| HCC067 | Myelodysplastic Syndromes and Myelofibrosis | 11.237 | 11.118 | 11.090 | 11.024 | 11.020 |
| HCC068 | Aplastic Anemia | 11.237 | 11.118 | 11.090 | 11.024 | 11.020 |
| HCC069 | Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn. | 11.237 | 11.118 | 11.090 | 11.024 | 11.020 |
| HCC070 b | Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero | 1.690 | 1.607 | 1.553 | 1.479 | 1.477 |
| HCC071 b | Sickle-Cell Disorders, Except Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major. | 1.690 | 1.607 | 1.553 | 1.479 | 1.477 |
| HCC073 | Combined and Other Severe Immunodeficiencies | 4.065 | 3.975 | 3.947 | 3.887 | 3.885 |
| HCC074 | Disorders of the Immune Mechanism | 4.065 | 3.975 | 3.947 | 3.887 | 3.885 |
| HCC075 | Coagulation Defects and Other Specified Hematological Disorders. | 2.148 | 2.068 | 2.020 | 1.947 | 1.946 |
| HCC081 | Drug Use with Psychotic Complications | 1.602 | 1.472 | 1.377 | 1.233 | 1.229 |
| HCC082 | Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications. | 1.602 | 1.472 | 1.377 | 1.233 | 1.229 |
| HCC083 | Alcohol Use with Psychotic Complications | 0.902 | 0.788 | 0.716 | 0.612 | 0.610 |
| HCC084 | Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications. | 0.902 | 0.788 | 0.716 | 0.612 | 0.610 |
| HCC087_1 | Schizophrenia | 2.227 | 2.063 | 1.986 | 1.864 | 1.862 |
| HCC087_2 | Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis. | 2.190 | 2.030 | 1.951 | 1.820 | 1.818 |
| HCC088 | Major Depressive Disorder, Severe, and Bipolar Disorders | 0.969 | 0.871 | 0.786 | 0.672 | 0.669 |
| HCC090 | Personality Disorders | 0.663 | 0.586 | 0.492 | 0.379 | 0.376 |
| HCC094 | Anorexia/Bulimia Nervosa | 2.000 | 1.894 | 1.827 | 1.722 | 1.719 |
| HCC096 | Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes. | 8.590 | 8.557 | 8.527 | 8.484 | 8.481 |
| HCC097 | Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes. | 0.938 | 0.875 | 0.826 | 0.764 | 0.763 |
| HCC102 | Autistic Disorder | 0.718 | 0.641 | 0.553 | 0.455 | 0.452 |
| HCC103 | Pervasive Developmental Disorders, Except Autistic Disorder ... | 0.663 | 0.586 | 0.492 | 0.379 | 0.376 |
| HCC106 | Traumatic Complete Lesion Cervical Spinal Cord | 9.112 | 8.957 | 8.905 | 8.806 | 8.805 |
| HCC107 | Quadriplegia | 9.112 | 8.957 | 8.905 | 8.806 | 8.805 |
| HCC108 | Traumatic Complete Lesion Dorsal Spinal Cord | 6.380 | 6.241 | 6.187 | 6.089 | 6.087 |
| HCC109 | Paraplegia | 6.380 | 6.241 | 6.187 | 6.089 | 6.087 |
| HCC110 | Spinal Cord Disorders/Injuries | 5.153 | 4.975 | 4.928 | 4.826 | 4.824 |
| HCC111 | Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease. | 5.090 | 4.946 | 4.876 | 4.755 | 4.753 |
| HCC112 | Quadriplegic Cerebral Palsy | 0.730 | 0.629 | 0.565 | 0.467 | 0.465 |
| HCC113 | Cerebral Palsy, Except Quadriplegic | 0.424 | 0.355 | 0.299 | 0.219 | 0.217 |
| HCC114 | Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies. | 1.205 | 1.120 | 1.063 | 0.972 | 0.969 |
| HCC115 | Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy. | 5.216 | 5.134 | 5.117 | 5.076 | 5.076 |
| HCC117 | Muscular Dystrophy | 1.393 | 1.304 | 1.236 | 1.136 | 1.134 |
| HCC118 | Multiple Sclerosis | 2.218 | 2.101 | 2.042 | 1.944 | 1.941 |
| HCC119 | Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders. | 1.393 | 1.304 | 1.236 | 1.136 | 1.134 |
| HCC120 | Seizure Disorders and Convulsions | 1.040 | 0.948 | 0.884 | 0.792 | 0.789 |
| HCC121 | Hydrocephalus | 9.585 | 9.491 | 9.440 | 9.362 | 9.360 |
| HCC122 ° | Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage. | 10.181 | 10.044 | 9.986 | 9.886 | 9.884 |
| HCC123 | Narcolepsy and Cataplexy | 4.533 | 4.405 | 4.340 | 4.237 | 4.235 |
| HCC125 | Respirator Dependence/Tracheostomy Status | 21.869 | 21.665 | 21.623 | 21.532 | 21.534 |
| HCC126 | Respiratory Arrest | 8.558 | 8.341 | 8.300 | 8.210 | 8.209 |
| HCC127 | Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes. | 8.558 | 8.341 | 8.300 | 8.210 | 8.209 |
| HCC128 | Heart Assistive Device/Artificial Heart | 17.404 | 17.301 | 17.262 | 17.214 | 17.224 |
| HCC129 | Heart Transplant Status/Complications | 17.404 | 17.301 | 17.262 | 17.214 | 17.224 |

TABLE 1—ADULT HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR—Continued

| HCC or RXC No. | Factor | Platinum | Gold | Silver | Bronze | Catastrophic |
|--------------------------------------|---|----------|--------|--------|--------|--------------|
| HCC130 | Heart Failure | 1.896 | 1.809 | 1.773 | 1.707 | 1.705 |
| HCC131 | Acute Myocardial Infarction | 4.955 | 4.737 | 4.720 | 4.652 | 4.653 |
| HCC132 | Unstable Angina and Other Acute Ischemic Heart Disease | 3.690 | 3.489 | 3.452 | 3.355 | 3.355 |
| HCC135 | Heart Infection/Inflammation, Except Rheumatic | 8.848 | 8.756 | 8.695 | 8.602 | 8.599 |
| HCC137 | Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders | 2.122 | 2.033 | 1.975 | 1.895 | 1.893 |
| HCC138 | Major Congenital Heart/Circulatory Disorders | 2.122 | 2.033 | 1.975 | 1.895 | 1.893 |
| HCC139 | Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders | 2.122 | 2.033 | 1.975 | 1.895 | 1.893 |
| HCC142 | Specified Heart Arrhythmias | 1.921 | 1.819 | 1.752 | 1.645 | 1.645 |
| HCC145 | Intracranial Hemorrhage | 10.648 | 10.490 | 10.444 | 10.356 | 10.355 |
| HCC146 | Ischemic or Unspecified Stroke | 1.428 | 1.314 | 1.282 | 1.212 | 1.212 |
| HCC149 | Cerebral Aneurysm and Arteriovenous Malformation | 2.218 | 2.102 | 2.044 | 1.944 | 1.941 |
| HCC150 | Hemiplegia/Hemiparesis | 3.309 | 3.190 | 3.178 | 3.134 | 3.134 |
| HCC151 | Monoplegia, Other Paralytic Syndromes | 2.494 | 2.386 | 2.342 | 2.264 | 2.262 |
| HCC153 | Atherosclerosis of the Extremities with Ulceration or Gangrene | 7.988 | 7.837 | 7.849 | 7.827 | 7.828 |
| HCC154 | Vascular Disease with Complications | 5.128 | 4.989 | 4.949 | 4.869 | 4.868 |
| HCC156 | Pulmonary Embolism and Deep Vein Thrombosis | 7.621 | 7.535 | 7.461 | 7.345 | 7.341 |
| HCC158 | Lung Transplant Status/Complications | 11.099 | 10.994 | 10.963 | 10.924 | 10.930 |
| HCC159 | Cystic Fibrosis | 4.156 | 4.021 | 3.969 | 3.883 | 3.881 |
| HCC160 | Chronic Obstructive Pulmonary Disease, Including Bronchiectasis | 0.643 | 0.567 | 0.491 | 0.395 | 0.392 |
| HCC161_1 | Severe Asthma | 0.643 | 0.567 | 0.491 | 0.395 | 0.392 |
| HCC161_2 | Asthma, Except Severe | 0.643 | 0.567 | 0.491 | 0.395 | 0.392 |
| HCC162 | Fibrosis of Lung and Other Lung Disorders | 1.615 | 1.529 | 1.476 | 1.391 | 1.388 |
| HCC163 | Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections | 7.187 | 7.124 | 7.105 | 7.067 | 7.067 |
| HCC174 | Exudative Macular Degeneration | 1.224 | 1.097 | 1.010 | 0.878 | 0.874 |
| HCC183 | Kidney Transplant Status/Complications | 6.320 | 6.253 | 6.239 | 6.228 | 6.219 |
| HCC184 | End Stage Renal Disease | 20.669 | 20.237 | 20.330 | 20.158 | 20.046 |
| HCC187 | Chronic Kidney Disease, Stage 5 | 0.773 | 0.689 | 0.685 | 0.645 | 0.633 |
| HCC188 | Chronic Kidney Disease, Severe (Stage 4) | 0.773 | 0.689 | 0.685 | 0.645 | 0.633 |
| HCC203 | Ectopic and Molar Pregnancy | 1.850 | 1.673 | 1.534 | 1.319 | 1.314 |
| HCC204 | Miscarriage with Complications | 0.646 | 0.565 | 0.439 | 0.260 | 0.254 |
| HCC205 | Miscarriage with No or Minor Complications | 0.646 | 0.565 | 0.439 | 0.260 | 0.254 |
| HCC207 | Pregnancy with Delivery with Major Complications | 3.756 | 3.470 | 3.289 | 2.991 | 2.985 |
| HCC208 | Pregnancy with Delivery with Complications | 3.756 | 3.470 | 3.289 | 2.991 | 2.985 |
| HCC209 | Pregnancy with Delivery with No or Minor Complications | 2.769 | 2.554 | 2.335 | 1.972 | 1.962 |
| HCC210 | (Ongoing) Pregnancy without Delivery with Major Complications | 0.815 | 0.714 | 0.561 | 0.370 | 0.363 |
| HCC211 | (Ongoing) Pregnancy without Delivery with Complications | 0.530 | 0.454 | 0.318 | 0.170 | 0.166 |
| HCC212 | (Ongoing) Pregnancy without Delivery with No or Minor Complications | 0.018 | 0.005 | 0.000 | 0.000 | 0.000 |
| HCC217 | Chronic Ulcer of Skin, Except Pressure | 1.557 | 1.464 | 1.433 | 1.375 | 1.374 |
| HCC218 | Extensive Third-Degree Burns | 23.714 | 23.524 | 23.474 | 23.384 | 23.383 |
| HCC219 | Major Skin Burn or Condition | 2.604 | 2.484 | 2.428 | 2.345 | 2.344 |
| HCC223 | Severe Head Injury | 18.201 | 18.057 | 17.990 | 17.882 | 17.879 |
| HCC226 | Hip and Pelvic Fractures | 8.018 | 7.783 | 7.765 | 7.688 | 7.688 |
| HCC228 | Vertebral Fractures without Spinal Cord Injury | 4.277 | 4.116 | 4.047 | 3.925 | 3.922 |
| HCC234 | Traumatic Amputations and Amputation Complications | 4.861 | 4.706 | 4.682 | 4.619 | 4.618 |
| HCC251 | Stem Cell, Including Bone Marrow, Transplant Status/Complications | 18.571 | 18.584 | 18.547 | 18.531 | 18.535 |
| HCC253 | Artificial Openings for Feeding or Elimination | 5.697 | 5.584 | 5.563 | 5.511 | 5.511 |
| HCC254 | Amputation Status, Upper Limb or Lower Limb | 0.936 | 0.835 | 0.799 | 0.738 | 0.736 |
| Interacted HCC Counts Factors | | | | | | |
| | Severe illness, 1 payment HCC | -6.014 | -6.070 | -6.119 | -6.189 | -6.189 |
| | Severe illness, 2 payment HCCs | -5.733 | -5.806 | -5.833 | -5.886 | -5.886 |
| | Severe illness, 3 payment HCCs | -4.904 | -4.952 | -4.891 | -4.846 | -4.844 |
| | Severe illness, 4 payment HCCs | -4.190 | -4.178 | -4.033 | -3.871 | -3.865 |
| | Severe illness, 5 payment HCCs | -3.522 | -3.432 | -3.216 | -2.954 | -2.945 |
| | Severe illness, 6 payment HCCs | -3.024 | -2.835 | -2.557 | -2.202 | -2.192 |
| | Severe illness, 7 payment HCCs | -2.432 | -2.116 | -1.780 | -1.330 | -1.318 |
| | Severe illness, 8 payment HCCs | -2.179 | -1.784 | -1.416 | -0.910 | -0.896 |
| | Severe illness, 9 payment HCCs | -0.287 | 0.253 | 0.676 | 1.279 | 1.294 |
| | Severe illness, 10 or more payment HCCs | 7.398 | 8.299 | 8.836 | 9.657 | 9.679 |
| | Transplant severe illness, 4 payment HCCs | 3.792 | 3.704 | 3.651 | 3.531 | 3.516 |
| | Transplant severe illness, 5 payment HCCs | 7.054 | 6.949 | 6.906 | 6.792 | 6.775 |
| | Transplant severe illness, 6 payment HCCs | 12.584 | 12.463 | 12.431 | 12.324 | 12.304 |
| | Transplant severe illness, 7 payment HCCs | 15.636 | 15.506 | 15.473 | 15.364 | 15.346 |
| | Transplant severe illness, 8 or more payment HCCs | 31.955 | 31.916 | 31.908 | 31.845 | 31.825 |
| Enrollment Duration Factors | | | | | | |
| | Enrolled for 1 month, at least one payment HCC | 11.208 | 9.742 | 8.808 | 7.844 | 7.818 |
| | Enrolled for 2 months, at least one payment HCC | 5.197 | 4.458 | 3.958 | 3.479 | 3.466 |
| | Enrolled for 3 months, at least one payment HCC | 3.378 | 2.898 | 2.549 | 2.224 | 2.216 |
| | Enrolled for 4 months, at least one payment HCC | 2.129 | 1.799 | 1.545 | 1.313 | 1.307 |
| | Enrolled for 5 months, at least one payment HCC | 1.586 | 1.340 | 1.143 | 0.959 | 0.955 |
| | Enrolled for 6 months, at least one payment HCC | 1.039 | 0.857 | 0.705 | 0.560 | 0.556 |

TABLE 1—ADULT HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR—Continued

| HCC or RXC No. | Factor | Platinum | Gold | Silver | Bronze | Catastrophic |
|--|--|----------|--------|--------|--------|--------------|
| Prescription Drug Factors | | | | | | |
| RXC 01 | Anti-HIV Agents | 5.097 | 4.612 | 4.345 | 3.920 | 3.908 |
| RXC 02 | Anti-Hepatitis C (HCV) Agents, Direct Acting Agents | 8.273 | 7.809 | 7.812 | 7.711 | 7.714 |
| RXC 03 ^d | Antiarrhythmics | 0.080 | 0.072 | 0.064 | 0.051 | 0.036 |
| RXC 04 | Phosphate Binders | 0.901 | 1.115 | 1.007 | 1.206 | 1.390 |
| RXC 05 | Inflammatory Bowel Disease Agents | 1.324 | 1.227 | 1.105 | 0.941 | 0.936 |
| RXC 06 | Insulin | 1.366 | 1.193 | 1.018 | 0.844 | 0.838 |
| RXC 07 | Anti-Diabetic Agents, Except Insulin and Metformin Only | 0.800 | 0.702 | 0.582 | 0.409 | 0.403 |
| RXC 08 | Multiple Sclerosis Agents | 15.175 | 14.409 | 14.206 | 13.774 | 13.767 |
| RXC 09 ^e | Immune Suppressants and Immunomodulators | 12.005 | 11.495 | 11.478 | 11.335 | 11.337 |
| RXC 10 | Cystic Fibrosis Agents | 17.441 | 17.041 | 17.022 | 16.903 | 16.902 |
| RXC 01 x HCC001. | Additional effect for enrollees with RXC 01 and HCC 001 | 2.467 | 2.521 | 2.790 | 3.101 | 3.115 |
| RXC 02 x HCC037_1, 036, 035_2, 035_1, 034. | Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034). | -0.514 | -0.454 | -0.403 | -0.348 | -0.347 |
| RXC 03 x HCC142. | Additional effect for enrollees with RXC 03 and HCC 142 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| RXC 04 x HCC184, 183, 187, 188. | Additional effect for enrollees with RXC 04 and (HCC 184 or 183 or 187 or 188). | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| RXC 05 x HCC048, 041. | Additional effect for enrollees with RXC 05 and (HCC 048 or 041). | -0.688 | -0.631 | -0.570 | -0.471 | -0.468 |
| RXC 06 x HCC018, 019, 020, 021. | Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021). | 0.402 | 0.444 | 0.532 | 0.544 | 0.546 |
| RXC 07 x HCC018, 019, 020, 021. | Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021). | -0.258 | -0.213 | -0.172 | -0.130 | -0.128 |
| RXC 08 x HCC118. | Additional effect for enrollees with RXC 08 and HCC 118 | -0.132 | 0.227 | 0.497 | 0.902 | 0.914 |
| RXC 09 x HCC056 or 057 and 048 or 041. | Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057). | 0.343 | 0.396 | 0.433 | 0.492 | 0.494 |
| RXC 09 x HCC056. | Additional effect for enrollees with RXC 09 and HCC 056 | -1.082 | -0.993 | -0.930 | -0.845 | -0.843 |
| RXC 09 x HCC057. | Additional effect for enrollees with RXC 09 and HCC 057 | -0.399 | -0.329 | -0.249 | -0.146 | -0.142 |
| RXC 09 x HCC048, 041. | Additional effect for enrollees with RXC 09 and (HCC 048 or 041). | 1.315 | 1.406 | 1.499 | 1.634 | 1.638 |
| RXC 10 x HCC159, 158. | Additional effect for enrollees with RXC 10 and (HCC 159 or 158). | 42.562 | 42.609 | 42.695 | 42.807 | 42.812 |

^a HCC numbers that appear with an underscore in this document will appear without the underscore in the “Do It Yourself (DIY)” software. For example, HCC 35_1 in this table will appear as HCC 351 in the DIY software.

^b For the 2025 benefit year HHS risk adjustment models, we made the following changes to improve the prediction of sickle cell disease costs: (1) updated mappings for sickle cell disease so that additional diagnosis codes are included in the model (within HCC 71); (2) ungrouped HCCs 70 and 71 in the adult and child models; and (3) reassigned HCC 70 and 71 to a higher severity in the infant models. To reflect these changes, we also relabeled HCC 70 and HCC 71. These updated mapping and HCC label changes parallel the reclassified Medicare Part C V28 CMS-HCCs. See, for example, the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (February 1, 2023). <https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf>.

^c Consistent with fiscal year 2024 updates to ICD-10 codes (effective October 1, 2023; see <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>), we updated the label for HCC 122 from “Coma, Brain Compression/Anoxic Damage” to “Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Non-traumatic Brain Compression/Anoxic Damage.” The specific ICD-10 code update that prompted this label change was the addition of code R402A “Nontraumatic coma due to underlying condition”, which we have mapped to HCC 122. HCC 122 is only assigned to enrollees who do not also have a head injury code, because HCC 223 (Severe Head Injury) captures codes for head injury with loss of consciousness and supersedes HCC 122 in a hierarchy. As such, the scope of HCC 122 is better reflected by the updated label. Because this ICD-10 update is effective October 1, 2023, future releases of benefit year 2023 and benefit year 2024 DIY software will also reflect the updated label and diagnosis-to-HCC mapping.

^d We constrain RXC 03 to be equal to average plan liability for RXC 03 drugs, RXC 04 to be equal to the average plan liability for RXC 04 drugs, and we constrain RXC 03 x HCC142 and RXC 04 x HCC184, 183, 187, 188 to be equal to 0. See March 2016 Risk Adjustment Methodology Discussion Paper (March 24, 2016), available at: <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf> (where we previously discussed the use of constraints in the HHS risk adjustment models).

^e Similar to recalibration of the 2023 and 2024 benefit year HHS risk adjustment adult models and consistent with the policies adopted in the 2023 and 2024 Payment Notices, the 2025 benefit year factors in this rule reflect the removal of the mapping of 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 09x HCC048, 041) from the 2019 benefit year enrollee-level EDGE data sets for purposes of recalibrating the 2025 benefit year adult models. See 87 FR 27232 through 27235. Additionally, the factors for the adult models reflect the use of the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data included in the current year’s model recalibration (except under extenuating circumstances that can result in targeted changes to RXC mappings). See 87 FR 27231 through 27232.

TABLE 2—CHILD HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR

| Factor | Platinum | Gold | Silver | Bronze | Catastrophic |
|---|----------|--------|--------|--------|--------------|
| Demographic Factors | | | | | |
| Age 2–4, Male | 0.270 | 0.191 | 0.141 | 0.105 | 0.104 |
| Age 5–9, Male | 0.204 | 0.135 | 0.096 | 0.071 | 0.071 |
| Age 10–14, Male | 0.224 | 0.156 | 0.115 | 0.090 | 0.089 |
| Age 15–20, Male | 0.260 | 0.187 | 0.137 | 0.102 | 0.101 |
| Age 2–4, Female | 0.223 | 0.153 | 0.113 | 0.089 | 0.088 |
| Age 5–9, Female | 0.149 | 0.086 | 0.053 | 0.034 | 0.034 |
| Age 10–14, Female | 0.222 | 0.153 | 0.113 | 0.089 | 0.088 |
| Age 15–20, Female | 0.300 | 0.212 | 0.145 | 0.097 | 0.095 |
| Diagnosis Factors | | | | | |
| HIV/AIDS | 4.355 | 3.942 | 3.856 | 3.659 | 3.657 |
| Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock | 14.567 | 14.370 | 14.294 | 14.176 | 14.174 |
| Central Nervous System Infections, Except Viral Meningitis | 13.944 | 13.811 | 13.745 | 13.658 | 13.656 |
| Viral or Unspecified Meningitis | 12.972 | 12.833 | 12.741 | 12.617 | 12.614 |
| Opportunistic Infections | 18.957 | 18.895 | 18.813 | 18.719 | 18.716 |
| Metastatic Cancer | 30.530 | 30.304 | 30.243 | 30.137 | 30.136 |
| Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia | 8.962 | 8.738 | 8.640 | 8.486 | 8.484 |
| Non-Hodgkin Lymphomas and Other Cancers and Tumors | 7.708 | 7.523 | 7.421 | 7.266 | 7.263 |
| Colorectal, Breast (Age <50), Kidney, and Other Cancers | 4.194 | 4.057 | 3.972 | 3.844 | 3.841 |
| Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors | 4.194 | 4.057 | 3.972 | 3.844 | 3.841 |
| Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors | 1.265 | 1.155 | 1.058 | 0.937 | 0.933 |
| Pancreas Transplant Status | 11.660 | 11.580 | 11.544 | 11.505 | 11.503 |
| Diabetes with Acute Complications | 2.364 | 2.121 | 1.914 | 1.622 | 1.615 |
| Diabetes with Chronic Complications | 2.364 | 2.121 | 1.914 | 1.622 | 1.615 |
| Diabetes without Complication | 2.364 | 2.121 | 1.914 | 1.622 | 1.615 |
| Protein-Calorie Malnutrition | 19.614 | 19.505 | 19.457 | 19.397 | 19.396 |
| Mucopolysaccharidosis | 34.440 | 34.213 | 34.169 | 34.070 | 34.070 |
| Lipidoses and Glycogenosis | 34.440 | 34.213 | 34.169 | 34.070 | 34.070 |
| Congenital Metabolic Disorders, Not Elsewhere Classified | 4.690 | 4.583 | 4.523 | 4.442 | 4.439 |
| Amyloidosis, Porphyria, and Other Metabolic Disorders | 4.690 | 4.583 | 4.523 | 4.442 | 4.439 |
| Adrenal, Pituitary, and Other Significant Endocrine Disorders | 5.289 | 5.072 | 5.007 | 4.902 | 4.901 |
| Liver Transplant Status/Complications | 11.660 | 11.580 | 11.544 | 11.505 | 11.503 |
| Acute Liver Failure/Disease, Including Neonatal Hepatitis | 7.742 | 7.607 | 7.570 | 7.488 | 7.487 |
| Chronic Liver Failure/End-Stage Liver Disorders | 7.742 | 7.607 | 7.570 | 7.488 | 7.487 |
| Cirrhosis of Liver | 3.999 | 3.881 | 3.835 | 3.764 | 3.763 |
| Chronic Viral Hepatitis C | 1.257 | 1.152 | 1.093 | 1.027 | 1.025 |
| Chronic Hepatitis, Except Chronic Viral Hepatitis C | 0.294 | 0.249 | 0.198 | 0.140 | 0.138 |
| Intestine Transplant Status/Complications | 13.387 | 13.303 | 13.228 | 13.137 | 13.135 |
| Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis | 19.019 | 18.756 | 18.703 | 18.597 | 18.597 |
| Intestinal Obstruction | 4.601 | 4.431 | 4.343 | 4.208 | 4.205 |
| Chronic Pancreatitis | 10.235 | 10.115 | 10.085 | 10.007 | 10.007 |
| Acute Pancreatitis | 4.988 | 4.771 | 4.687 | 4.541 | 4.538 |
| Inflammatory Bowel Disease | 9.947 | 9.582 | 9.498 | 9.313 | 9.311 |
| Necrotizing Fasciitis | 4.144 | 3.957 | 3.872 | 3.746 | 3.745 |
| Bone/Joint/Muscle Infections/Necrosis | 4.144 | 3.957 | 3.872 | 3.746 | 3.745 |
| Rheumatoid Arthritis and Specified Autoimmune Disorders | 4.632 | 4.397 | 4.315 | 4.181 | 4.179 |
| Systemic Lupus Erythematosus and Other Autoimmune Disorders | 0.878 | 0.777 | 0.679 | 0.559 | 0.555 |
| Osteogenesis Imperfecta and Other Osteodystrophies | 1.241 | 1.140 | 1.069 | 0.981 | 0.979 |
| Congenital/Developmental Skeletal and Connective Tissue Disorders | 1.241 | 1.140 | 1.069 | 0.981 | 0.979 |
| Cleft Lip/Cleft Palate | 0.972 | 0.841 | 0.742 | 0.616 | 0.613 |
| Hemophilia | 64.093 | 63.672 | 63.604 | 63.429 | 63.427 |
| Myelodysplastic Syndromes and Myelofibrosis | 12.305 | 12.163 | 12.117 | 12.039 | 12.038 |
| Aplastic Anemia | 12.305 | 12.163 | 12.117 | 12.039 | 12.038 |
| Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn | 12.305 | 12.163 | 12.117 | 12.039 | 12.038 |
| Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero ^a | 3.564 | 3.400 | 3.303 | 3.173 | 3.170 |
| Sickle-Cell Disorders, Except Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major ^a | 3.369 | 3.233 | 3.160 | 3.055 | 3.053 |
| Combined and Other Severe Immunodeficiencies | 5.105 | 4.975 | 4.918 | 4.826 | 4.824 |
| Disorders of the Immune Mechanism | 5.105 | 4.975 | 4.918 | 4.826 | 4.824 |
| Coagulation Defects and Other Specified Hematological Disorders | 4.043 | 3.938 | 3.869 | 3.779 | 3.777 |
| Drug Use with Psychotic Complications | 2.350 | 2.204 | 2.111 | 1.972 | 1.969 |
| Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications | 2.350 | 2.204 | 2.111 | 1.972 | 1.969 |
| Alcohol Use with Psychotic Complications | 0.899 | 0.765 | 0.658 | 0.502 | 0.499 |
| Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications | 0.899 | 0.765 | 0.658 | 0.502 | 0.499 |
| Schizophrenia | 3.545 | 3.304 | 3.188 | 3.007 | 3.004 |
| Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis | 3.289 | 3.067 | 2.940 | 2.745 | 2.741 |
| Major Depressive Disorder, Severe, and Bipolar Disorders | 2.506 | 2.319 | 2.191 | 2.017 | 2.013 |
| Personality Disorders | 0.348 | 0.263 | 0.159 | 0.043 | 0.040 |
| Anorexia/Bulimia Nervosa | 2.207 | 2.070 | 1.977 | 1.846 | 1.843 |
| Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes | 12.082 | 12.007 | 11.947 | 11.870 | 11.868 |
| Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes | 0.867 | 0.758 | 0.686 | 0.583 | 0.581 |
| Autistic Disorder | 2.506 | 2.319 | 2.191 | 2.017 | 2.013 |

TABLE 2—CHILD HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR—Continued

| Factor | Platinum | Gold | Silver | Bronze | Catastrophic |
|--|----------|--------|--------|--------|--------------|
| Pervasive Developmental Disorders, Except Autistic Disorder | 0.374 | 0.303 | 0.222 | 0.140 | 0.139 |
| Traumatic Complete Lesion Cervical Spinal Cord | 10.147 | 9.959 | 9.908 | 9.810 | 9.809 |
| Quadriplegia | 10.147 | 9.959 | 9.908 | 9.810 | 9.809 |
| Traumatic Complete Lesion Dorsal Spinal Cord | 9.868 | 9.664 | 9.615 | 9.515 | 9.514 |
| Paraplegia | 9.868 | 9.664 | 9.615 | 9.515 | 9.514 |
| Spinal Cord Disorders/Injuries | 4.750 | 4.568 | 4.457 | 4.285 | 4.280 |
| Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease | 49.556 | 49.316 | 49.259 | 49.139 | 49.137 |
| Quadriplegic Cerebral Palsy | 0.638 | 0.454 | 0.383 | 0.266 | 0.265 |
| Cerebral Palsy, Except Quadriplegic | 0.254 | 0.134 | 0.073 | 0.029 | 0.028 |
| Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies | 1.624 | 1.514 | 1.448 | 1.345 | 1.342 |
| Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflam- matory and Toxic Neuropathy | 10.278 | 10.133 | 10.111 | 10.053 | 10.053 |
| Muscular Dystrophy | 5.546 | 5.399 | 5.326 | 5.206 | 5.203 |
| Multiple Sclerosis | 9.135 | 8.789 | 8.736 | 8.602 | 8.604 |
| Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders | 5.546 | 5.399 | 5.326 | 5.206 | 5.203 |
| Seizure Disorders and Convulsions | 1.556 | 1.429 | 1.316 | 1.169 | 1.165 |
| Hydrocephalus | 11.666 | 11.630 | 11.604 | 11.580 | 11.579 |
| Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage ^b | 11.216 | 11.250 | 11.261 | 11.287 | 11.287 |
| Narcolepsy and Cataplexy | 4.058 | 3.911 | 3.807 | 3.664 | 3.659 |
| Respirator Dependence/Tracheostomy Status | 24.720 | 24.506 | 24.442 | 24.337 | 24.336 |
| Respiratory Arrest | 15.720 | 15.472 | 15.398 | 15.267 | 15.266 |
| Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syn- dromes | 15.720 | 15.472 | 15.398 | 15.267 | 15.266 |
| Heart Assistive Device/Artificial Heart | 13.387 | 13.303 | 13.228 | 13.137 | 13.135 |
| Heart Transplant Status/Complications | 13.387 | 13.303 | 13.228 | 13.137 | 13.135 |
| Heart Failure | 4.067 | 3.968 | 3.914 | 3.830 | 3.828 |
| Acute Myocardial Infarction | 1.060 | 1.025 | 1.005 | 0.979 | 0.979 |
| Unstable Angina and Other Acute Ischemic Heart Disease | 1.060 | 1.025 | 1.005 | 0.979 | 0.979 |
| Heart Infection/Inflammation, Except Rheumatic | 17.077 | 16.964 | 16.888 | 16.786 | 16.783 |
| Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Dis- orders | 3.938 | 3.796 | 3.682 | 3.540 | 3.536 |
| Major Congenital Heart/Circulatory Disorders | 0.986 | 0.896 | 0.790 | 0.685 | 0.682 |
| Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders | 0.590 | 0.506 | 0.425 | 0.347 | 0.345 |
| Specified Heart Arrhythmias | 3.118 | 2.980 | 2.899 | 2.785 | 2.783 |
| Intracranial Hemorrhage | 12.686 | 12.611 | 12.565 | 12.497 | 12.495 |
| Ischemic or Unspecified Stroke | 1.470 | 1.362 | 1.304 | 1.210 | 1.208 |
| Cerebral Aneurysm and Arteriovenous Malformation | 1.049 | 0.952 | 0.899 | 0.807 | 0.804 |
| Hemiplegia/Hemiparesis | 5.471 | 5.353 | 5.295 | 5.207 | 5.205 |
| Monoplegia, Other Paralytic Syndromes | 1.374 | 1.253 | 1.183 | 1.072 | 1.070 |
| Atherosclerosis of the Extremities with Ulceration or Gangrene | 11.860 | 11.625 | 11.557 | 11.424 | 11.422 |
| Vascular Disease with Complications | 8.127 | 7.988 | 7.947 | 7.872 | 7.871 |
| Pulmonary Embolism and Deep Vein Thrombosis | 19.738 | 19.604 | 19.533 | 19.426 | 19.425 |
| Lung Transplant Status/Complications | 13.387 | 13.303 | 13.228 | 13.137 | 13.135 |
| Cystic Fibrosis | 48.718 | 48.241 | 48.201 | 48.054 | 48.055 |
| Chronic Obstructive Pulmonary Disease, Including Bronchiectasis | 1.658 | 1.507 | 1.403 | 1.267 | 1.264 |
| Severe Asthma | 1.323 | 1.171 | 1.045 | 0.889 | 0.885 |
| Asthma, Except Severe | 0.320 | 0.250 | 0.170 | 0.102 | 0.100 |
| Fibrosis of Lung and Other Lung Disorders | 1.490 | 1.361 | 1.249 | 1.115 | 1.111 |
| Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infec- tions | 11.216 | 11.250 | 11.261 | 11.287 | 11.287 |
| Kidney Transplant Status/Complications | 11.660 | 11.580 | 11.544 | 11.505 | 11.503 |
| End Stage Renal Disease | 29.641 | 29.391 | 29.371 | 29.278 | 29.278 |
| Chronic Kidney Disease, Stage 5 | 0.787 | 0.749 | 0.722 | 0.685 | 0.683 |
| Chronic Kidney Disease, Severe (Stage 4) | 0.787 | 0.749 | 0.722 | 0.685 | 0.683 |
| Ectopic and Molar Pregnancy | 0.864 | 0.731 | 0.565 | 0.411 | 0.406 |
| Miscarriage with Complications | 0.474 | 0.369 | 0.227 | 0.089 | 0.086 |
| Miscarriage with No or Minor Complications | 0.474 | 0.369 | 0.227 | 0.089 | 0.086 |
| Pregnancy with Delivery with Major Complications | 3.166 | 2.876 | 2.634 | 2.231 | 2.219 |
| Pregnancy with Delivery with Complications | 3.166 | 2.876 | 2.634 | 2.231 | 2.219 |
| Pregnancy with Delivery with No or Minor Complications | 2.399 | 2.179 | 1.914 | 1.475 | 1.460 |
| (Ongoing) Pregnancy without Delivery with Major Complications | 0.420 | 0.308 | 0.152 | 0.039 | 0.036 |
| (Ongoing) Pregnancy without Delivery with Complications | 0.420 | 0.308 | 0.152 | 0.039 | 0.036 |
| (Ongoing) Pregnancy without Delivery with No or Minor Complications | 0.276 | 0.187 | 0.079 | 0.037 | 0.036 |
| Chronic Ulcer of Skin, Except Pressure | 1.877 | 1.782 | 1.712 | 1.634 | 1.632 |
| Extensive Third-Degree Burns | 22.876 | 22.657 | 22.576 | 22.440 | 22.437 |
| Major Skin Burn or Condition | 2.441 | 2.286 | 2.187 | 2.056 | 2.053 |
| Severe Head Injury | 22.876 | 22.657 | 22.576 | 22.440 | 22.437 |
| Hip and Pelvic Fractures | 4.636 | 4.428 | 4.327 | 4.191 | 4.188 |
| Vertebral Fractures without Spinal Cord Injury | 4.483 | 4.293 | 4.176 | 3.999 | 3.994 |
| Traumatic Amputations and Amputation Complications | 3.818 | 3.627 | 3.528 | 3.362 | 3.357 |
| Stem Cell, Including Bone Marrow, Transplant Status/Complications | 13.387 | 13.303 | 13.228 | 13.137 | 13.135 |
| Artificial Openings for Feeding or Elimination | 5.711 | 5.551 | 5.525 | 5.451 | 5.450 |
| Amputation Status, Upper Limb or Lower Limb | 3.818 | 3.627 | 3.528 | 3.362 | 3.357 |

Interacted HCC Counts Factors

| | | | | | |
|--------------------------------------|----------|----------|----------|----------|----------|
| Severe illness, 1 payment HCC | – 11.216 | – 11.250 | – 11.261 | – 11.287 | – 11.287 |
| Severe illness, 2 payment HCCs | – 11.137 | – 11.200 | – 11.218 | – 11.265 | – 11.266 |

TABLE 2—CHILD HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR—Continued

| Factor | Platinum | Gold | Silver | Bronze | Catastrophic |
|---|----------|---------|---------|---------|--------------|
| Severe illness, 3 payment HCCs | – 9.692 | – 9.760 | – 9.689 | – 9.658 | – 9.655 |
| Severe illness, 4 payment HCCs | – 8.984 | – 8.987 | – 8.809 | – 8.652 | – 8.645 |
| Severe illness, 5 payment HCCs | – 6.593 | – 6.543 | – 6.303 | – 6.068 | – 6.059 |
| Severe illness, 6 or 7 payment HCCs | – 2.061 | – 1.828 | – 1.468 | – 1.064 | – 1.051 |
| Severe illness, 8 or more payment HCCs | 17.868 | 18.550 | 19.132 | 19.858 | 19.877 |
| Transplant severe illness, 4 or more payment HCCs | 14.488 | 14.558 | 14.580 | 14.612 | 14.613 |

^a For the 2025 benefit year HHS risk adjustment models, we made the following changes to improve the prediction of sickle cell disease costs: (1) updated mappings for sickle cell disease so that additional diagnosis codes are included in the model (within HCC 71); (2) ungrouped HCCs 70 and 71 in the adult and child models; and (3) reassigned HCC 70 and 71 to a higher severity in the infant models. To reflect these changes, we also relabeled HCC 70 and HCC 71. These updated mapping and HCC label changes parallel the reclassified Medicare Part C V28 CMS–HCCs. See, for example, the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (February 1, 2023). <https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf>.

^b Consistent with fiscal year 2024 updates to ICD–10 codes (effective October 1, 2023; see <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>), we updated the label for HCC 122 from “Coma, Brain Compression/Anoxic Damage” to “Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage.” The specific ICD–10 code update that prompted this label change was the addition of code R402A “Nontraumatic coma due to underlying condition”, which we have mapped to HCC 122. HCC 122 is only assigned to enrollees who do not also have a head injury code, because HCC 223 (Severe Head Injury) captures codes for head injury with loss of consciousness and supersedes HCC 122 in a hierarchy. As such, the scope of HCC 122 is better reflected by the updated label. Because this ICD–10 update is effective October 1, 2023, future releases of the benefit year 2023 and benefit year 2024 DIY software will also reflect the updated label and diagnosis-to-HCC mapping.

TABLE 3—HCCs SELECTED FOR THE HCC INTERACTED COUNTS VARIABLES FOR THE ADULT AND CHILD MODELS FOR THE 2025 BENEFIT YEAR

| Payment HCC | Severity illness indicator | Transplant indicator |
|--|----------------------------|----------------------|
| HCC 2 Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock | X | |
| HCC 3 Central Nervous System Infections, Except Viral Meningitis | X | |
| HCC 4 Viral or Unspecified Meningitis | X | |
| HCC 6 Opportunistic Infections | X | |
| HCC 23 Protein-Calorie Malnutrition | X | |
| HCC 34 Liver Transplant Status/Complications | X | X |
| HCC 41 Intestine Transplant Status/Complications | X | X |
| HCC 42 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis | X | |
| HCC 96 Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes | X | |
| HCC 121 Hydrocephalus | X | |
| HCC 122 Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage | X | |
| HCC 125 Respirator Dependence/Tracheostomy Status | X | |
| HCC 135 Heart Infection/Inflammation, Except Rheumatic | X | |
| HCC 145 Intracranial Hemorrhage | X | |
| HCC 156 Pulmonary Embolism and Deep Vein Thrombosis | X | |
| HCC 158 Lung Transplant Status/Complications | X | X |
| HCC 163 Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections | X | |
| HCC 218 Extensive Third-Degree Burns | X | |
| HCC 223 Severe Head Injury | X | |
| HCC 251 Stem Cell, Including Bone Marrow, Transplant Status/Complications | X | X |
| G13 (Includes HCC 126 Respiratory Arrest and HCC 127 Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes) | X | |
| G14 (Includes HCC 128 Heart Assistive Device/Artificial Heart and HCC 129 Heart Transplant Status/Complications) | X | X |
| G24 (Includes HCC 18 Pancreas Transplant Status and HCC 183 Kidney Transplant Status/Complications) | X | X |

TABLE 4—INFANT HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR

| Group | Platinum | Gold | Silver | Bronze | Catastrophic |
|--|----------|---------|---------|---------|--------------|
| Extremely Immature * Severity Level 5 (Highest) | 204.040 | 202.652 | 202.406 | 201.915 | 201.913 |
| Extremely Immature * Severity Level 4 | 149.999 | 148.437 | 148.051 | 147.377 | 147.372 |
| Extremely Immature * Severity Level 3 | 32.887 | 31.619 | 31.251 | 30.693 | 30.687 |
| Extremely Immature * Severity Level 2 | 32.887 | 31.619 | 31.251 | 30.693 | 30.687 |
| Extremely Immature * Severity Level 1 (Lowest) | 32.887 | 31.619 | 31.251 | 30.693 | 30.687 |
| Immature * Severity Level 5 (Highest) | 121.913 | 120.553 | 120.309 | 119.828 | 119.827 |
| Immature * Severity Level 4 | 71.026 | 69.564 | 69.264 | 68.692 | 68.689 |
| Immature * Severity Level 3 | 32.887 | 31.619 | 31.251 | 30.693 | 30.687 |
| Immature * Severity Level 2 | 30.558 | 29.332 | 28.960 | 28.403 | 28.398 |
| Immature * Severity Level 1 (Lowest) | 25.110 | 23.887 | 23.485 | 22.871 | 22.863 |
| Premature/Multiples * Severity Level 5 (Highest) | 108.585 | 107.335 | 107.096 | 106.631 | 106.628 |
| Premature/Multiples * Severity Level 4 | 29.666 | 28.404 | 28.060 | 27.490 | 27.486 |
| Premature/Multiples * Severity Level 3 | 13.527 | 12.617 | 12.148 | 11.482 | 11.467 |
| Premature/Multiples * Severity Level 2 | 8.071 | 7.368 | 6.849 | 6.149 | 6.131 |
| Premature/Multiples * Severity Level 1 (Lowest) | 5.765 | 5.167 | 4.644 | 4.023 | 4.005 |
| Term * Severity Level 5 (Highest) | 81.884 | 80.752 | 80.438 | 79.915 | 79.909 |
| Term * Severity Level 4 | 16.190 | 15.254 | 14.803 | 14.170 | 14.158 |
| Term * Severity Level 3 | 5.770 | 5.207 | 4.688 | 4.061 | 4.041 |
| Term * Severity Level 2 | 3.712 | 3.231 | 2.707 | 2.109 | 2.092 |
| Term * Severity Level 1 (Lowest) | 1.968 | 1.597 | 1.135 | 0.784 | 0.776 |
| Age 1 * Severity Level 5 (Highest) | 69.391 | 68.741 | 68.568 | 68.287 | 68.284 |
| Age 1 * Severity Level 4 | 12.653 | 12.170 | 11.942 | 11.641 | 11.635 |
| Age 1 * Severity Level 3 | 2.829 | 2.569 | 2.374 | 2.179 | 2.174 |
| Age 1 * Severity Level 2 | 1.855 | 1.628 | 1.423 | 1.216 | 1.210 |

TABLE 4—INFANT HHS RISK ADJUSTMENT MODEL FACTORS FOR THE 2025 BENEFIT YEAR—Continued

| Group | Platinum | Gold | Silver | Bronze | Catastrophic |
|---|----------|-------|--------|--------|--------------|
| Age 1 * Severity Level 1 (Lowest) | 0.581 | 0.487 | 0.431 | 0.394 | 0.393 |
| Age 0 Male | 0.604 | 0.566 | 0.539 | 0.475 | 0.473 |
| Age 1 Male | 0.090 | 0.076 | 0.060 | 0.042 | 0.041 |

TABLE 5—HHS HCCs INCLUDED IN INFANT MODEL MATURITY CATEGORIES

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

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

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

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

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

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

| Severity category | HCC/description |
|------------------------|--|
| Severity Level 1 | Amputation Status, Upper Limb or Lower Limb. |

^a Consistent with fiscal year 2024 updates to ICD-10 codes (effective October 1, 2023; see <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>), we updated the label for HCC 122 from “Coma, Brain Compression/Anoxic Damage” to “Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage.” The specific ICD-10 code update that prompted this label change was the addition of code R402A “Nontraumatic coma due to underlying condition”, which we have mapped to HCC 122. HCC 122 is only assigned to enrollees who do not also have a head injury code, because HCC 223 (Severe Head Injury) captures codes for head injury with loss of consciousness and supersedes HCC 122 in a hierarchy. As such, the scope of HCC 122 is better reflected by the updated label. Because this ICD-10 update is effective October 1, 2023, future releases of the benefit year 2023 and benefit year 2024 DIY software will also reflect the updated label and diagnosis-to-HCC mapping.

^b For the 2025 benefit year HHS risk adjustment models, we made the following changes to improve the prediction of sickle cell disease costs: (1) updated mappings for sickle cell disease so that additional diagnosis codes are included in the model (within HCC 71); (2) ungrouped HCCs 70 and 71 in the adult and child models; and (3) reassigned HCC 70 and 71 to a higher severity in the infant models. To reflect these changes, we also relabeled HCC 70 and HCC 71. These updated mapping and HCC label changes parallel the reclassified Medicare Part C V28 CMS-HCCs. See, for example, the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (February 1, 2023). <https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf>.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the 2025 benefit year risk adjustment model factors as proposed. We summarize and respond to public comments received on the proposed 2025 benefit year risk adjustment model factors below.

Comment: Many commenters were concerned about the treatment of high-cost prescription drugs, such as gene therapy drugs, in the risk adjustment model factors. One commenter was specifically concerned about the changes to the classification of Sickle Cell Disorders and the HCC mapping changes that align with the CMS-HCC model used for Medicare Advantage. This commenter recommended adding a new RXC for gene therapy for sickle-cell anemia and Beta Thalassemia in the adult models, stating that a gene therapy RXC would be a more reliable indicator of the presence of sickle cell disease or its severity. For similar reasons, this commenter also recommended continuing to group HCCs 70 (Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero) and 71 (Sickle-Cell Disorders, Except Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major) in both the adult and child models. The commenter further recommended that we avoid relying on coding specificity where the diagnostic severity relies on measures of pain, which is why they state a gene therapy RXC would be more reliable. The commenter also stated any changes to HCC 70 (Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero) and HCC 71 (Sickle-Cell Disorders, Except Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major) should anticipate the impact of gene therapy treatments for sickle cell disease by having enrollees with a condition treatable by the same therapy grouped together.

Another commenter recommended the creation of a new, separate RXC for pre-exposure prophylaxis (PrEP) and one commenter recommended mapping Tepezza (a new treatment for thyroid eye disease) to an RXC in the risk adjustment models due to its high costs. Several commenters also expressed concern about the decline in RXC 01 (Anti-HIV Agents) and RXC 01 x HCC001 (Additional Effects for enrollees with RXC 01 and HCC 01) coefficients since the 2023 benefit year HHS risk adjustment adult models were adopted in the 2023 Payment Notice. Another commenter suggested creating a new, separate high-cost reimbursement pool for ultra-high-cost drugs, including mostly cell and gene therapy drugs.

Response: We did not propose to change the treatment of high-cost drugs, such as gene therapy drugs, in the 2025 benefit year risk adjustment models in the proposed rule and are not finalizing such updates in this rule. As we discussed in the 2022 Payment Notice (86 FR 24163), we recognize that the data used to recalibrate the risk adjustment models lag by several benefit years behind the applicable benefit year for risk adjustment and therefore do not account for the costs of new, expensive drugs, such as gene therapy drugs, that are expected to be available in the market by the applicable benefit year of risk adjustment. Thus, we have continued to consider ways that we could better account for high-cost drugs in the risk adjustment models and, as part of this effort, analyze new data as they become available. For example, when we were analyzing the changes to the sickle cell disorder related HCCs in the 2025 benefit year risk adjustment models, we considered whether to add a RXC for existing high-cost sickle cell drugs and new gene therapy treatments, but we found that we need to continue to analyze the evolution and availability of drug treatments for sickle cell

disease. Specifically, the new gene therapy drugs for sickle cell disease were not approved for the market when we were developing the proposed 2025 benefit year risk adjustment models and coefficients.⁴⁹ Therefore, there were no data available on the use of the new gene therapy drugs for sickle cell disease when we were developing the 2025 benefit year proposals and with this final rule, there currently continues to be a general lack of data on the use of gene therapy drugs for sickle cell disease in the individual, small group, and merged markets. We are committed to continuing to analyze new data as they become available and, consistent with § 153.320(b)(1), we would propose the addition of any new RXCs to the risk adjustment models through notice and comment rulemaking. We also note that if an enrollee in an issuer's risk adjustment covered plan has claims for gene therapy, other high-cost drugs, or other expensive treatments, that enrollee would be eligible for the high-cost risk pool payments if claims for that enrollee are over \$1 million.⁵⁰

Considering the absence of adequate data at the time of development of the proposed 2025 benefit year risk adjustment models and coefficients for inclusion in the 2025 Payment Notice proposed rule, we did not propose and

⁴⁹ We published the proposed 2025 benefit year coefficients in the 2025 Payment Notice proposed rule in November 2023. The first gene therapy treatment for sickle cell disease were not approved for use until December 2023. See <https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease>.

⁵⁰ For example, the new sickle cell gene therapy treatments are expected to exceed the high-cost risk pool payment threshold. See, DeMartino P, Haag MB, Hersh AR, Caughey AB, Roth JA. A Budget Impact Analysis of Gene Therapy for Sickle Cell Disease: The Medicaid Perspective. *JAMA Pediatr.* 2021 Jun 1;175(6):617–623. doi: 10.1001/jamapediatrics.2020.7140. Erratum in: *JAMA Pediatr.* 2021 Jun 1;175(6):647. PMID: 33749717; PMCID: PMC7985816. Accessed at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7985816/>.

are not finalizing a new RXC or other model adjustments for sickle cell gene therapy drugs for the 2025 benefit year. We intend to continue to assess sickle cell gene therapy drugs to consider whether model updates for future benefit years are warranted to address their anticipated costs. In response to the comment that HHS should continue to group HCCs 70 (Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero) and 71 (Sickle-Cell Disorders, Except Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major), we note that we removed the grouping of HCC 70 (Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero) and HCC 71 (Sickle-Cell Disorders, Except Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major) in the adult and child models in the 2025 benefit year risk adjustment model factors because we found in our analysis that HCC 70 (Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero) and HCC 71 (Sickle-Cell Disorders, Except Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major) each pose sufficient independent risk characteristics to sever the grouping. Additionally, we kept the hierarchical relationship between the HCC 70 (Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero) and 71 (Sickle-Cell Disorders, Except Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major), therefore, we do not allow the coefficient for HCC 71 (Sickle-Cell Disorders, Except Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major) to be higher than HCC 70 (Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero). These updates to HCCs 70 (Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero) and 71 (Sickle-Cell Disorders, Except Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major) were also informed by and align with the reclassified Medicare Part C V28 CMS-HCCs.⁵¹

We also did not propose and are not finalizing the addition of PrEP as an RXC in the 2025 benefit year adult risk adjustment models. As explained in the 2021 Payment Notice (85 FR 29164, 29187), we have not incorporated 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. 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 (that RXCs are incorporated into HHS risk adjustment adult models to impute a missing diagnosis) to add it as an RXC at this time. However, like previous years, we reassessed the use and availability of the different types of PrEP in the market as we developed the 2025 benefit year risk adjustments models. Our most recent analysis affirmed our prior findings that the use of PrEP does not represent an active condition. In addition, as we have done in previous years, we incorporated 100 percent of the 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 map to RXC 01 (HIV/AIDS) will still receive credit for RXC 01 (HIV/AIDS) in the 2025 benefit year of risk adjustment. We intend to continue to explore the treatment of PrEP in the risk adjustment models to consider whether changes are needed in future benefit years, as appropriate.

We also did not propose and are not finalizing changes to add an RXC to the HHS risk adjustment model's treatment for Tepezza, which treats thyroid eye disease. Under the HHS risk adjustment models, thyroid eye disease (thyrotoxicosis) is currently captured within the non-payment HCC, HCC33 (Other Endocrine/Metabolic/Nutritional Disorders) and all RXCs in the HHS risk adjustment adult models are associated with a payment HCC. For this reason, HHS did not propose and is not finalizing any changes with respect to the treatment of Tepezza for thyroid eye disease in the 2025 benefit year risk adjustment models. However, HHS intends to continue analysis of thyrotoxicosis and the use of Tepezza as more data becomes available and consider its treatment in risk adjustment models for future benefit years.

Lastly, the change identified by some commenters in the RXC coefficients relative to the 2023 benefit year is due to decisions we made starting in the 2024 benefit year regarding the trending costs for traditional and specialty drugs, which have been trended separately from medical expenditures since the

2017 benefit year.⁵² As stated in the 2024 Payment Notice,⁵³ in our annual assessment of the trending factors for the 2024 HHS risk adjustment models, we determined that the trend factors used for specialty drugs were higher than the market data supported. Therefore, for the 2024 benefit year, we used trend factors for specialty drugs that aligned with the market data rather than continuing use of the historical, higher trend factors. In determining these trend factors, we consulted our actuarial experts, reviewed relevant URRT submission data, analyzed multiple years of enrollee-level EDGE data, and consulted NHEA data as well as external reports and documents⁵⁴ published by third parties. In this process, we also ensured that the trends we used reflected changes in cost of care rather than gross growth in expenditures.

In our annual recalibration of the 2025 risk adjustment models, we continued the approach used for the 2024 benefit year, again reflecting the lower market-supported trend factors for specialty drugs rather than the historical, higher trend factors we used in benefit years prior to 2024. While there was a change to RXC 01 (HIV/AIDS) between the 2023 benefit year and the 2024 benefit year, the decrease between the final 2024 risk adjustment models and the 2025 risk adjustment models was much smaller in magnitude (from 4.669 to 4.345 for silver plans; a 6.9 percent decrease) and is consistent with normal year-to-year variation. For example, over the period between 2018 model recalibration (when RXCs were first introduced) and 2023 model recalibration (the last model recalibration before the change to the trending approach), the median year-to-year absolute change (that is, increase or decrease) across all silver RXC coefficients was 10.7 percent. The 6.9 percent decrease seen in RXC 01 (HIV/AIDS) between the 2024 and 2025 model recalibrations is therefore well within the range of changes that we normally see year-to-year.

⁵² See 81 FR 12218.

⁵³ See 88 FR 25753.

⁵⁴ See, for example, "How much is health spending expected to grow?" by the Peterson-Kaiser Family Foundation, available at <https://www.healthsystemtracker.org/chart-collection/how-much-is-health-spending-expected-to-grow/>. See also "Medical cost trend: Behind the numbers 2024" by PwC Health Research Institute, available at <https://www.pwc.com/us/en/industries/health-industries/library/assets/pwc-behind-the-numbers-2024.pdf>. See also "MBB Health Trends 2023" by MercerMarsh Benefits, available at <https://www.marsh.com/na/services/employee-health-benefits/insights/health-trends-report.html>.

⁵¹ See, for example, the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (February 1, 2023), <https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf>.

For these reasons, we believe the trend factors we currently use for specialty drugs are appropriate and reflect the most recent trends we have seen in the market, and that the prior model trend factors were too high relative to the actual state of the current market. We believe the RXC coefficient values that we finalize in this rule reflect the appropriate amount of growth between the data years used to fit the models and the 2025 benefit year. As part of our annual model recalibration activities, we intend to continue to reassess the trend factors used to update the HHS risk adjustment models, including those specific to specialty drugs, in future benefit years.

Comment: Some commenters requested HHS not remove GLP-1 drugs from RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) and instead make market pricing adjustments to RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) due to the expanded use of GLP-1 drugs in the market. Commenters mentioned the significant pricing changes that occurred between the data years used to recalibrate the models and the applicable benefit year of risk adjustment as support for making market pricing adjustments or other updates to RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) to account for the costs and expanded use of GLP-1 drugs. These commenters stated they did not believe the current HHS risk adjustment models represent the increase in cost of diabetes treatment using GLP-1 drugs due to increased utilization since the 2021 benefit year. These commenters noted that cost and utilization trends for GLP-1 drugs are expected to continue to change, as GLP-1 drugs are relatively new treatment for chronic weight management. Another commenter expressed concerns about the off-label usage of GLP-1 drugs and preserving the integrity of RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only).

Response: We did not change the inclusion of GLP-1 drugs in RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only), or propose to change our current approach to RXC inclusion in recalibrating 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.⁵⁵ However, in developing the proposed 2025 benefit year risk adjustment models and coefficients, we considered our

treatment of GLP-1 drugs using our previous established criteria on inclusion and exclusion of drugs in model recalibration. Specifically, as we explained in the 2023 Payment Notice (87 FR 27208, 27231 through 27235), in extenuating circumstances where HHS believes there would be a significant impact from a change in an RxNorm Concept Unique Identifiers (RXCUI) to RXC mapping, we will consider whether changes to the RXCUI to RXC mapping from the applicable data year crosswalk are appropriate.

As background, RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) is a pharmacotherapeutic class of drugs, which contains a broad array of anti-diabetic medications that vary in cost. RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) does not include all GLP-1 drugs currently on the market; drugs that carry an FDA indication for chronic weight management are excluded from RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only). The RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) coefficient in the HHS risk adjustment adult models is meant to reflect the average enrollee cost for individuals being treated by any of the drugs in this class. To assess the current mapping of certain GLP-1 drugs to RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) and whether any changes were warranted, we considered the positive predictive value (PPV) of these drugs. The PPV is a conditional proportion of patients who are diagnosed with the HCC and prescribed a drug ("drug" defined as a single RXCUI)⁵⁶ to the total patients prescribed that drug. A PPV of 100 percent means that all enrollees taking a drug within a RXCUI had the associated HCC, and a PPV of 0 percent means that none of the enrollees taking a drug within a RXCUI had the associated HCC. In our analysis for the proposed rule, we found a marginal downward trend in the PPVs for the GLP-1 drugs mapping to RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) in the enrollee-level EDGE data years used to recalibrate the 2025 benefit year risk adjustment models. Based on comments received for the proposed rule, we reassessed PPVs for the GLP-1 mapping to RXC 07 (Anti Diabetic Agents, Except Insulin

and Metformin Only) using the 2022 benefit year enrollee-level EDGE data, and we found that the GLP-1 drugs have high enough PPVs that they did not warrant exclusion under our criteria and that the enrollees' use of certain GLP-1 drugs in the market remains indicative of the condition, meaning we do not see PPVs indicative of a large enough change in clinical indications or practice patterns to warrant a change to the current mapping of GLP-1 drugs to RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only). It is not clear how the trend in PPV of these drugs will continue, but we believe that further years of enrollee-level EDGE data are needed to evaluate this trend. For these reasons, at this time, we did not propose and are not making mapping changes for GLP-1 drugs to RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only). As more enrollee-level EDGE data becomes available, HHS will continue to reassess the PPVs of GLP-1 drugs for potential future targeted changes as part of our ongoing efforts to continually improve the precision of the HHS risk adjustment models.

In addition, HHS did not propose and is not finalizing the application of a pricing adjustment for GLP-1 drugs in the risk adjustment models. As discussed above, the only such adjustment that HHS currently applies is the market pricing adjustment to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models for the narrow purpose of accounting for significant pricing changes between the data years used for recalibrating the models and the applicable benefit year of risk adjustment as a result of the introduction of new and generic Hepatitis C drugs. We do not expect similar significant pricing changes of GLP-1 drugs between the data years used to recalibrate the models and the applicable benefit year of risk adjustment to justify applying a similar pricing adjustment to GLP-1 drugs under RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) at this time. We understand GLP-1 drug utilization patterns are changing and HHS will continue to assess any new drugs and any change in costs as more enrollee-level EDGE data become available for potential targeted refinements to the HHS risk adjustment models, as appropriate.

Comment: A few commenters recommended assessing the behavioral HCC coefficients, such as HCC 102 (Autistic Disorder), to consider the impact of State benefit mandates in creating cost and utilization differentials

⁵⁶ Drugs that appear on claims data, either through National Drug Codes (NDCs) or Healthcare Common Procedural Coding System (HCPCS), are cross walked to RXCUIs. RXCUI mappings are always matched to the NDCs and HCPCS applicable to the particular EDGE data year as the NDC and HCPCS reflect the drugs that were available in the market during the benefit year.

⁵⁵ 87 FR 27231 through 27235.

that reduce the ability of HCC coefficients to accurately reflect costs. These commenters suggested the State-to-State differences in plan liabilities for treating autistic disorder are likely the result of State coverage mandates for behavioral analysis. These commenters recommended HHS consider remedies that might be appropriate to mitigate coefficients that are too low to cover treatment costs in States with these benefit mandates. One commenter specifically noted that we should ensure that the HCC 102 (Autistic Disorder) coefficient fully reflects the cost of treating children with this diagnosis.

Response: HHS did not propose and is not finalizing changes to the behavioral HCC factors. The HHS risk adjustment models are national models developed using nationwide data that apply in all States where the HHS-operated risk adjustment program exists, which for the 2025 benefit year includes all States and the District of Columbia. Because these models are used nationally, they are intended to reflect the relative national average costs for HCCs and do not produce separate results based on State variations in plan liability, actuarial risk, or costs. Based on our experience in developing the HHS risk adjustment models, we have found that use of the nationwide dataset is often necessary to ensure that we have adequate sample size and stability in our risk adjustment models, including the models' factors and coefficients. We note that while the 2021 benefit year enrollee-level EDGE data has a field that allows the data to be aggregated by State, the 2019 and 2020 benefit years of enrollee-level EDGE data being used to recalibrate the risk adjustment models for the 2025 benefit year do not contain the State field.⁵⁷ Therefore, our ability to analyze potential State variations and trends in the recalibration sample is currently limited. We intend to analyze additional years of enrollee-level EDGE data, which will contain the State indicator in the future. We also note that HHS continuously performs analysis on model performance to ensure the current model coefficients are appropriate. For example, we conduct regular out-of-sample model evaluations that support continued model improvement efforts to evaluate how

accurately the models predict plan liability for various groups of enrollees and health plans. Using out-of-sample 2021 data, we evaluated the final payment year 2024 blended factors (calibrated using 2018–2020 data) and the final payment year 2021 blended factors (calibrated using 2015–2017 data). Outcomes of these evaluations were generally as expected and indicate that the national risk adjustment models are performing at a reasonable level.

Comment: Several commenters stated that the 2025 benefit year risk adjustment models will undercompensate issuers for enrollees with serious chronic conditions where coefficients have declined, which they stated would incentivize issuers to avoid these enrollees. A few commenters recommended that we update the risk adjustment models so that the coefficients are additive rather than hierarchical for the HCCs for kidney failure and transplant hierarchy, including HCCs 183 (Kidney Transplant Status/Complications), 184 (End Stage Renal Disease), 187 (Chronic Kidney Disease, Stage 5), and 188 (Chronic Kidney Disease, Severe (Stage 4)). One commenter stated that over the past several model recalibrations, they observed a steady decline in the proportion of aggregate issuer risk scores that are attributable to clinical factors and an increase in the proportion of risk scores attributable to demographic factors.

Response: We understand commenters' concerns about ensuring the HHS risk adjustment models adequately compensate issuers of risk adjustment covered plans for enrollees with serious chronic conditions. Several factors may contribute to the trend commenters observed with respect to declining HCC coefficients. For example, such a decline is expected in HHS risk adjustment models as diagnostic coding trends toward being more thorough and complete which results in capturing more HCCs per enrollee over time.⁵⁸ As a result of this improved coding, some enrollees would have more HCCs count towards their risk score with each HCC individually contributing a smaller amount towards the enrollee's overall risk score. Consequently, because enrollees are likely to have more HCCs, the lower coefficients do not necessarily result in lower risk scores for enrollees with multiple HCCs.

Additionally, the observed decreases in coefficients can also be attributed to the revised interacted HCC counts model specification that was introduced beginning with the 2023 benefit year HHS risk adjustment adult and child models because this model specification shifts some of the predicted risk score away from the individual HCC coefficients and towards the severe interacted counts for the sickest enrollees. Specifically, in the 2023 Payment Notice (87 FR 27208, 27221 through 27230), HHS finalized major changes to add the interacted HCC counts model specifications to the adult and child models.⁵⁹ As discussed in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes,⁶⁰ the purpose of the interacted HCC counts model specifications is to address the identified underprediction of plan liability in the adult and child models for the very highest-risk enrollees (that is, those in the top 0.1 percentile and those enrollees with the most HCCs) because while this highest-risk subpopulation represents a small number of enrollees, it represents a large portion of expenditures. However, the impact of the interacted HCC counts model specification is that risk scores for some severe HCCs and for enrollees with severe HCCs and fewer comorbidities decrease, while risk scores for enrollees with severe HCCs and more comorbidities increase. Therefore, overall coefficient changes due to trends in coding and model changes such as the interacted HCC counts model specification would lead to lower risk scores for some enrollees and higher risk scores for others.

As part of our effort to strive for continual improvement of the precision of the HHS risk adjustment models, our intention is to monitor the impact of changes in the risk adjustment models over the years to consider whether additional changes or modifications are needed. To do this, we will continue to conduct analysis on the models and the models' predictions before considering whether changes are needed. Similarly, if we were to consider making changes to the models to restructure hierarchies (that would change whether certain HCCs could be additive) we would need to further assess the impact of those

⁵⁷ 87 FR 27241 through 27244. In the 2024 Payment Notice at 88 FR 25781, we finalized the proposal to extract plan ID and rating area data elements issuers have submitted to their EDGE servers from certain benefit years prior to 2021. However, at this time, HHS has not completed that the extraction and development of updated datasets for model recalibration using plan ID and rating area data from the benefit years prior to 2021.

⁵⁸ See Figure 4. Summary Report on Permanent Risk Adjustment Transfer for the 2022 Benefit Year <https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf>.

⁵⁹ See also Chapter 4 on Improving Predictive Accuracy for the Very Highest-Risk Enrollees—Interacted HCC Counts in the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes (2021, October 26) at: <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁶⁰ 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>.

changes before proposing those changes. As major risk adjustment model changes were finalized beginning with the 2023 benefit year, we seek to observe and analyze the outcome of those changes before considering other major changes to the HHS risk adjustment models and therefore, we are not considering changes to the kidney transplant HCCs at this time as the kidney transplant HCC is part of the interacted HCC counts model specification.

Lastly, we note that beginning with the 2023 benefit year, we also made substantial model changes intended to address observed underprediction of healthy enrollees that included the inclusion of the interacted HCC counts model specification in the adult and child models and the HCC-contingent enrollment duration factor updates in the adult models. For example, since the 2023 benefit year risk adjustment models, all costs for partial year with no-HCC-or-RXC enrollees are recalibrated into the age-sex factors.⁶¹ Thus, as a result of these model specification changes, the age-sex factors increased in the 2023 benefit year risk adjustment models. Since the 2023 benefit year, we have observed that on average, age-sex coefficient values have remained stable, suggesting that the total risk attributable to these factors for the average enrollee is unchanged. We do not yet have the data for risk adjustment benefit years 2024 or 2025, but any proportional changes in risk attributable to demographic factors would likely depend on changes in the population being enrolled and model changes.

Comment: A few commenters requested additional transparency in the determination of coefficients for the HHS risk adjustment models by making the full details of the methodology used for recalibration of the risk adjustment models publicly available to increase predictability for plans and therefore reduce plan incentives for discriminatory behavior used to protect the plans from future changes and for interested parties to have a better understanding of the rationale behind the updates to the HHS risk adjustment models. These commenters stated that this enhanced transparency would increase public confidence in the coefficients.

Response: We understand the importance of transparency, but do not believe it is necessary to release additional information on the risk

adjustment model recalibration methodology at this time. Since the program's inception, we have released several risk adjustment technical papers^{62 63 64 65} and rules that describe the key program goals that informed development of the HHS risk adjustment models, explain our HCC diagnostic classification, provide information on the data and methods used to develop the models for each age group (adult, child, and infant) and metal level (platinum, gold, silver, bronze, as well as catastrophic plans), and discuss updates to the models over the years. We share similar information as part of the discussion of the annual model recalibration proposals in the applicable benefit year's Payment Notice, and when we identify areas for targeted refinements to improve model prediction along with potential options to address the identified issues, including the rationale for those options. Whether engaging in the annual model recalibration activities or identifying potential refinements and options to address identified issues, we are mindful of the role risk adjustment can play in reducing plan incentives for discriminatory behavior. By way of example, the current HHS risk adjustment adult and child models aim to reduce plan incentives for discriminatory behavior through methods like the recently adopted interacted HCC counts model specification that seeks to more accurately reflect anticipated plan liability for the sickest enrollees. The current HHS risk adjustment adult models were also recently updated with new HCC-contingent enrollment duration factors that seek to improve the prediction of plan liability for partial year enrollees. We provided a technical paper on these changes⁶⁶ and also addressed them in notice and comment

rulemakings.⁶⁷ Our intention is to continue to provide technical papers where appropriate, such as when considering major modeling changes and engage in rulemaking to share a complete description of the applicable benefit year's models and any applicable updates to increase predictability for plans where possible. We also remain committed to continuing to test the performance of the models as part of our ongoing efforts to identify potential areas for targeted refinements to improve the prediction of the HHS risk adjustment models. We also provide background in this rule on the data used for recalibrating the 2025 benefit year models, including the analyses of the 2021 benefit year enrollee-level EDGE data to examine the potential impact of the COVID-19 PHE. As noted, we did not find any notable anomalous trends, especially when considering that every year of data can be unique, and therefore, some level of deviation from year to year is expected. We also provided extensive background when making significant model updates in the 2021 Payment Notice,⁶⁸ as well as in the technical paper released in 2019 that considered potential future HCC changes and our associated analyses of those changes.⁶⁹

Comment: Several commenters supported the continued inclusion of HCC 23 (Protein-Calorie Malnutrition) as a payment HCC in the 2025 benefit risk adjustment models due to the high-costs of malnutrition care, and malnutrition's negative effect on health care utilization and outcomes. These commenters also expressed concern about health equity related to malnutrition and the importance of prioritizing policies that identify and treat malnutrition.

Response: We agree with the commenters and continue to believe HCC 23 (Protein-Calorie Malnutrition) is appropriate for continued inclusion in the HHS risk adjustment models for the individual, small group, and merged markets as a predictor of costs. We recognize that the CMS-HCC risk adjustment models used for Medicare Advantage recently removed this HCC from its models; however, we did not propose any changes to the treatment of HCC 23 (Protein-Calorie Malnutrition) in the 2025 benefit year HHS risk

⁶² 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>.

⁶³ 2016 Risk Adjustment White Paper (2016, March 31). CMS. <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf>.

⁶⁴ Potential Updates to HHS-HCCs for the HHS-Operated Risk Adjustment Program. (2019, June 18). CMS. <https://www.cms.gov/ccio/resources/regulations-and-guidance/downloads/potential-updates-to-hhs-hccs-hhs-operated-risk-adjustment-program.pdf>.

⁶⁵ Risk Adjustment Implementation Issues. (2011, September 12). CMS. https://www.cms.gov/CCIIO/Resources/Files/Downloads/riskadjustment_whitepaper_web.pdf.

⁶⁶ 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>.

⁶⁷ 86 FR 24155 through 24162 and 87 FR 27221 through 27231.

⁶⁸ 85 FR 29164 at 29173 through 29185.

⁶⁹ Potential Updates to HHS-HCCs for the HHS-Operated Risk Adjustment Program. (2019, June 18). CMS. <https://www.cms.gov/ccio/resources/regulations-and-guidance/downloads/potential-updates-to-hhs-hccs-hhs-operated-risk-adjustment-program.pdf>.

⁶¹ Prior to the adoption of the HCC-contingent enrollment duration factors, risk from partial year, no-HCC-or-RXC enrollees was split between the age-sex factors and the enrollment duration factors defined using the previous model structure.

adjustment models, and therefore, HCC 23 (Protein-Calorie Malnutrition) will continue to be included as a payment HCC and 2025 benefit year model factor as proposed for the adult, child, and infant models for the HHS-operated risk adjustment program applicable to the individual, small group, and merged markets.

Comment: One commenter recommended allowing capitated claims without diagnoses to be submitted to the EDGE server, stating that the claims costs associated with capitated claims without diagnoses represent a large portion of medical costs. This commenter stated that this exclusion of capitated claims without diagnoses exacerbates the HHS-operated risk adjustment program's underprediction of lower-cost enrollees.

Response: A critical component of the HHS-operated risk adjustment program is mapping of diagnosis codes from the EDGE server to HCCs in the risk adjustment models and therefore, only claims with diagnosis codes⁷⁰ are allowed to be submitted to an issuer's EDGE server as these diagnosis codes are a critical component to the HHS-operated risk adjustment program's determination of actuarial risk and consideration for risk adjustment transfers. Should a capitated claim have a diagnosis, issuers may submit the claim to their EDGE server. Should a capitated claim not have a diagnosis, issuers may obtain diagnosis code(s) for the claim as directed in HHS guidance published in the EDGE Server Business

Rules (ESBR)⁷¹ Section 8 Supplemental Diagnosis Code File Processing, which includes specific guidelines regarding acceptable sources of diagnosis code(s) for claims data submissions to EDGE servers that accounts for unique health delivery models. Certain issuers who mainly submit capitated claims to their EDGE server should therefore ensure those claims have diagnosis codes and can use the ESBR to identify acceptable sources of diagnosis codes for claims data submitted to their respective EDGE servers.⁷² HHS encourages all issuers of risk adjustment covered plans, whether they submit capitated or non-capitated claims, to work with providers to ensure claims contain the relevant diagnosis code(s).

We also note that while HHS currently excludes enrollees with capitated claims for purposes of the risk adjustment model recalibration activities,⁷³ we plan to continue to evaluate this data and whether to include these enrollees in recalibrating the models in future benefit years.

d. Cost-Sharing Reduction Adjustments

We proposed to recalibrate the CSR adjustment factors for AI/AN zero-cost sharing and limited cost sharing CSR plan variant enrollees for the 2025 benefit year, and to retain these proposed AI/AN CSR adjustment factors, if finalized, for all future benefit years unless changed through notice and comment rulemaking. We also proposed to maintain the current CSR adjustment factors for silver plan variant enrollees (70 percent, 73 percent, 87

percent, and 94 percent AV plan variants)⁷⁴ for the 2025 benefit year, as well as proposed to retain the same factors for the 2026 benefit year and beyond, unless changed through notice and comment rulemaking. The proposed 2025 Payment Notice provided our reasoning for our proposals and the history of inclusion of the CSR adjustment factors in HHS-operated risk adjustment as well as our analysis of these factors' performance.⁷⁵ In short, based on analysis of all CSR adjustment factors, HHS proposed to not make changes to the CSR adjustment factors, with the exception of the AI/AN CSR plan variant factors.⁷⁶ As explained in the proposed rule, our continued study of CSR adjustment factors found that adjustments for AI/AN CSR plan variant enrollees were needed and would be appropriate⁷⁷ because the AI/AN CSR plan variant enrollees experienced higher expenditures than non-CSR silver enrollees, which may reflect increased demand associated with enrollee receipt of the AI/AN zero cost sharing or limited cost sharing CSR plan variants or risk characteristics specific to the AI/AN population which are not specifically captured by HCCs or other model factors.⁷⁸ To address concerns about this observed underprediction among AI/AN CSR plan variant enrollees, we proposed to update the CSR adjustment factors for AI/AN zero-cost sharing and limited cost sharing plan variants and use the proposed factors for these enrollees as shown in Table 7.

TABLE 7—CSR ADJUSTMENT FACTORS FOR THE 2025 BENEFIT YEAR AND BEYOND

| Plan AV | Current adjustment factors for the 2024 benefit year | Adjustment factors for the 2025 benefit year and beyond |
|--|--|---|
| Silver Plan Variant Recipients (and Enrollees in State wrap-around or Medicaid-expansion plans of any metal level, as applicable) | | |
| Plan Variation 94% | 1.12 | 1.12 |
| Plan Variation 87% | 1.12 | 1.12 |
| Plan Variation 73% | 1.00 | 1.00 |
| Standard Plan 70% | 1.00 | 1.00 |

⁷⁰ The only exception to this use of diagnosis codes to determine actuarial risk is the High-Cost Risk Pool, which uses claims costs.

⁷¹ Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight (CCIIO). (Dec. 2023). EDGE Server Business Rules (ESBR) Version 24.0. https://regtap.cms.gov/reg_librarye.php?i=3765 (Login Required).

⁷² https://regtap.cms.gov/reg_library_openfile.php?id=2183&type=k&pid=3 (Login Required).

⁷³ Enrollees with at least one capitated claim in EDGE are excluded from recalibration because we have some concerns that the methods for computing and reporting derived amounts from capitated

claims could be inconsistent across issuers and would not provide reliable or comparable data.

⁷⁴ See 83 FR 16930 at 16953; 84 FR 17478 through 17479; 85 FR 29190; 86 FR 24181; 87 FR 27235 through 27236; and 88 FR 25772 through 25774.

⁷⁵ 88 FR 82510 at 82545 through 82548.

⁷⁶ In the 2021 Risk Adjustment Technical Paper, we concluded that, in aggregate, most of the current CSR adjustment factors contribute to a reasonable prediction of what plans are paying for CSR enrollees, with the exception of CSR adjustment factors for AI/AN enrollees. Our continued study of these issues, including the more recent analysis of 2021 benefit year data, affirmed these initial conclusions. Therefore, we proposed and are finalizing in this rulemaking updates to the CSR

adjustment factors for AI/AN zero-cost sharing and limited cost sharing plan variants while maintaining the existing CSR adjustment factors for other enrollees. See 88 FR 82510 at 82545 through 82548. Also 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>.

⁷⁷ 88 FR 82510 at 82545 through 82548.

⁷⁸ 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>.

TABLE 7—CSR ADJUSTMENT FACTORS FOR THE 2025 BENEFIT YEAR AND BEYOND—Continued

| Plan AV | Current adjustment factors for the 2024 benefit year | Adjustment factors for the 2025 benefit year and beyond |
|---|--|---|
| Zero Cost Sharing Plan Variant Recipients (that is, AI/AN Recipients) | | |
| Platinum (90%) | 1.00 | 1.31 |
| Gold (80%) | 1.07 | 1.39 |
| Silver (70%) | 1.12 | 1.46 |
| Bronze (60%) | 1.15 | 1.51 |
| Limited Cost Sharing Plan Variant Recipients (that is, AI/AN Recipients) | | |
| Platinum (90%) | 1.00 | 1.04 |
| Gold (80%) | 1.07 | 1.10 |
| Silver (70%) | 1.12 | 1.15 |
| Bronze (60%) | 1.15 | 1.19 |

Lastly, separate from the policy pertaining to AI/AN CSR adjustment factors, we noted that for all plan liability risk score calculations under the State payment transfer formula, we use the CSR adjustment factor that aligns with the AV of the applicable plan for the enrollee. Thus, for unique State-specific plans, we apply the CSR adjustment factors that correspond to each plan's AV. However, this approach does not apply in the case of States whose State-specific plans take the form of Medicaid expansion plans offered on the Exchange (for example, Arkansas), because these plans are identical in all their parameters, including AV and degree of plan liability, to other plans offered on the Exchange in those States and are differentiated from their comparable plans only in eligibility criteria and sources of funding.⁷⁹ As we

⁷⁹ The structure of wrap-around plans in some States, such as Massachusetts, differs from the coverage in States who offer Medicaid expansion plans on the Exchange. For example, in Massachusetts, the higher cost sharing wrap-around plans are variations of lower cost sharing plans. As such, the Massachusetts wrap-around plans do not have the same AVs as their comparable plans. That is why we use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans with AVs above 94 percent. In contrast, Arkansas' Medicaid expansion plans are identical to other 94 percent and 100 percent AV CSR plan variants offered on the Exchange and are distinguished from these identical plans only in their sources of funding and eligibility criteria. As such, we presently direct issuers in Arkansas who provide Medicaid expansion plans with AVs of 94 percent and 100 percent to use specified plan variant codes for their Medicaid expansion plans only to differentiate the sources of funding and to differentiate between populations eligible for the Medicaid expansion plans from those who are eligible for standard 94 percent and 100 percent AV CSR plan variants. Because the Arkansas Medicaid expansion plans are identical to other 94 percent and 100 percent AV CSR plan variants available in Arkansas and therefore have the same AVs, we would use the proposed CSR adjustment factor of 1.12 for Arkansas 94 percent AV Medicaid-expansion plans and the proposed CSR adjustment factor that corresponds to the silver metal level zero cost

identify unique State-specific plans that have higher plan liability than the standard plan variants, such as those in Massachusetts, we work with the relevant State Department of Insurance and other relevant State agencies to identify the applicable CSR adjustment factor that corresponds to the unique State-specific plan's AV.⁸⁰ We explained that we will continue to follow this approach, working with the State to identify the applicable CSR adjustment factor that corresponds to that State's unique State-specific plan's AV, unless changed through notice and comment rulemaking.

We sought comment on these proposals and policies. After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these provisions and policies as proposed. We summarize and respond to public comments received on the proposed CSR adjustment factors and related policies below.

Comment: Several commenters supported the proposed recalibration of the CSR adjustment factors for AI/AN zero-cost sharing and limited cost sharing plan variant enrollees for the 2025 benefit year and beyond because the recalibration would better capture increased utilization from zero-cost

sharing variants (that is, the proposed 1.46 CSR adjustment factor for zero cost sharing variants) for Arkansas 100 percent AV Medicaid-expansion plans in the plan liability risk score calculation. See CMS approval of Arkansas's section 1115(a) demonstration, "Arkansas Health and Opportunity for Me." <https://www.medicaid.gov/sites/default/files/2021-12/ar-arhome-ca.pdf>.

⁸⁰ For a list of the unique State-specific CSR levels that have higher plan liability than the standard plan variants, for which we utilize the corresponding CSR adjustment factor that maps to the plan's AV, refer to the applicable benefit year's DIY Software on the CMS website. See, for example, the 2023 Benefit Year DIY Software on the CMS website (January 9, 2024). <https://www.cms.gov/files/zip/hhs-hcc-software-v0723141c3.zip>.

sharing and limited cost sharing enrollments and mitigate incentives that could discourage issuers from enrolling AI/AN populations. These commenters stated that the adjustments will have the effect of stabilizing premiums and incentivizing issuers to enroll the AI/AN population. Another commenter recommended HHS continue to monitor the predictive ratios of the CSR adjustment factors for the AI/AN population to ensure that they accurately estimate additional plan liabilities associated with these enrollments and to make further adjustments, as needed.

One commenter, who did not oppose recalibrating the CSR adjustment factors for AI/AN zero-cost sharing and limited cost sharing plan variant enrollees, preferred to comprehensively reform how CSR variants are handled in HHS-operated risk adjustment program, such as creating CSR specific risk adjustment models and modifying the rating term⁸¹ to reflect issuer silver loading practices.

⁸¹ The State payment transfer formula may be understood to be composed of two key higher-level terms, the risk term and the rating term. The risk term generally defines the revenue required by a plan (relative to the Statewide market average). It is determined by three component variables, the plan liability risk score (PLRS), which reflects the plan's AV as well as the plan's enrollee health status risk; the induced demand factors (IDF), which reflects the anticipated induced demand associated with the plan's cost-sharing (metal) level, and the geographic cost factor (GCF), which accounts for differences in premium due to allowable geographic rating variation. The rating term defines the revenue that a plan can be expected to generate given the allowable rating factors (relative to the Statewide market average). It is determined by four component variables: AV, which adjusts for relative differences between the plan actuarial value in a market; an Allowable Rating Factor (ARF), which accounts for the impact of allowable rating factors (age or family tier) based on State rating method; an IDF; and a GCF. For more information see section 1.2.3 of the in the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes (2021, October 26) at:

Continued

Response: We are finalizing as proposed the updates to the CSR adjustment factors for AI/AN zero-cost sharing and limited cost sharing CSR plan variant enrollees for the 2025 benefit year, and to retain these AI/AN CSR adjustment factors, along with the CSR adjustment factors for other enrollees, for future benefit years unless changed through notice and comment rulemaking. We agree with commenters that these targeted refinements to the AI/AN CSR adjustment factors would better capture increased utilization from zero-cost sharing and limited cost-sharing enrollments and help mitigate incentives that could discourage issuers from enrolling AI/AN populations. We also intend to continue to study the non-AI/AN CSR adjustment factors for potential updates in future benefit years, as may be appropriate.

We did not propose and are not finalizing comprehensive changes to risk adjustment, such as changes to the rating term in the State payment transfer formula,⁸² to account for CSR plans and silver loading in this final rule. In Appendix A of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Change,⁸³ we outlined a variety of policy options, including a change to the rating term in the State payment transfer formula, that we have considered to improve the precision of the HHS risk adjustment models and better account for CSR plan variants and issuer silver loading practices. We continue to consider policy options and conduct additional analyses on potential changes in this area before considering whether to propose any comprehensive reform of how CSR plan variants are handled in the HHS-operated risk adjustment program. If we were to pursue such comprehensive changes to the treatment of CSR plans in the HHS-operated risk adjustment program, we would propose and solicit comments on those types of changes in future notice and comment rulemaking.

Comment: One commenter recommended that HHS increase the Massachusetts wrap-around CSR adjustment factor from the current 1.12 factor (which aligns with the CSR

adjustment factor for plans with actuarial value (AV) of 94 percent) because Massachusetts wrap-around plans have higher AVs (99.7 percent and 96.1 percent AVs) than a 94 percent AV plan. This commenter explained that Massachusetts used higher CSR adjustment factors between 2014 and 2016 benefit years when the State operated its own risk adjustment program, and those factors were lowered when Massachusetts transitioned into the HHS-operated risk adjustment program beginning with the 2017 benefit year.⁸⁴ Another commenter appreciated that the HHS Federally certified risk adjustment methodology accounts for Massachusetts-specific market factors resulting from the design of the ConnectorCare program.

Response: As we noted in the proposed rule, for all plan liability risk score calculations under the State payment transfer formula, we use the CSR adjustment factor that aligns with the AV of the applicable plan for the enrollee. Thus, for unique State-specific plans, we apply the CSR adjustment factors that correspond to each plan's AV. When we identify unique State-specific plans that have higher plan liability than the standard plan variants, we work with the relevant State Department of Insurance and other relevant State agencies to identify the applicable CSR adjustment factor that corresponds to the unique State-specific plan's AV.⁸⁵ HHS worked with Massachusetts for the 2014 through 2016 benefit years when the State established its CSR adjustment factors for use in its State-based risk adjustment program to account for its wrap-around plans⁸⁶ and when Massachusetts transitioned into the HHS-operated risk adjustment program beginning in the 2017 benefit year, we continued to work with Massachusetts to incorporate CSR adjustment factors into the HHS-operated risk adjustment program for Massachusetts' wrap-around plans and set them as a 1.12 factor.⁸⁷ As detailed in the 2014 Payment Notice,⁸⁸ the CSR adjustment factors in the Federally certified risk adjustment methodology applicable in States where HHS operates

the risk adjustment program (specifically calibrated for target AVs of 73 percent, 87 percent and 94 percent) may not be adequate for Massachusetts. To overcome this limitation, Massachusetts fit a polynomial trend line to the HHS proposed CSR adjustment factors by metal level, which Massachusetts extended to 100 percent.

Since then, the Massachusetts Health Connector, Massachusetts' Exchange, has consistently supported continued use of the 1.12 factor for their wrap-around plans⁸⁹ and has not indicated that a change is needed. Therefore, we do not believe that it is necessary to make changes to Massachusetts wrap-around CSR adjustment plan factor at this time and will continue to apply the 1.12 factor for the 2025 benefit year.

e. Model Performance Statistics

Each benefit year, to evaluate the HHS risk adjustment model performance, we examine each model's R-squared statistic and predictive ratios (PRs). The R-squared statistic measures the percentage of individual variation explained by the model. The PRs measure how accurate the model's predictions are for specific subpopulations. For a given population, the PR is defined as the ratio of the weighted mean predicted plan liability to the weighted mean actual plan liability.

A subpopulation that is predicted perfectly would have a PR of 1.0. For each of the current and proposed HHS risk adjustment models, the R-squared statistic and the PRs are in the range of published estimates for concurrent HHS risk adjustment models.⁹⁰ Because we are finalizing a blend of the coefficients from separately solved models based on the 2019, 2020, and 2021 benefit years' enrollee-level EDGE data, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared statistics for the final 2025 benefit year HHS risk adjustment models are shown in Table 8.

<https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁸² Id.

⁸³ See CMS. (2021, October 26). HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. Appendix A. <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁸⁴ This commenter also stated a recent study on AI/AN zero cost sharing plans' CSR adjustment factors suggests that higher CSR adjustment factors are needed for the three ConnectorCare plans, but the commenter did not cite the study; therefore, we were not able to verify the study's findings that the commenter was highlighting.

⁸⁵ For a list of the unique State-specific CSR levels that have higher plan liability than the standard plan variants, for which we utilize the corresponding CSR adjustment factor that maps to the plan's AV, refer to the applicable benefit year's DIY Software on the CMS website. See, for example, the 2023 Benefit Year DIY Software on the CMS website (January 9, 2024). <https://www.cms.gov/files/zip/hhs-hcc-software-v0723141c3.zip>.

⁸⁶ See 78 FR 15442.

⁸⁷ See 81 FR 12228–12229.

⁸⁸ 78 FR 15442.

⁸⁹ For examples, see for Massachusetts Health Connector's comments on the proposed 2025 Payment Notice at: <https://www.regulations.gov/comment/CMS-2023-0191-0081>; also, see the Massachusetts Health Connector's comments on the proposed 2024 Payment Notice at: <https://www.regulations.gov/comment/CMS-2022-0192-0102>.

⁹⁰ Hileman, G., & Steele, S. (2016). Accuracy of Claims-Based Risk Scoring Models. Society of Actuaries. <https://www.soa.org/4937b5/globalassets/assets/files/research/research-2016-accuracy-claims-based-risk-scoring-models.pdf>.

TABLE 8—R-SQUARED STATISTIC FOR THE 2025 HHS RISK ADJUSTMENT MODELS

| Models | 2019 Enrollee-level EDGE data | 2020 Enrollee-level EDGE data | 2021 Enrollee-level EDGE data |
|---------------------------|-------------------------------|-------------------------------|-------------------------------|
| Platinum Adult | 0.4448 | 0.4360 | 0.4174 |
| Gold Adult | 0.4394 | 0.4302 | 0.4118 |
| Silver Adult | 0.4371 | 0.4278 | 0.4094 |
| Bronze Adult | 0.4330 | 0.4236 | 0.4051 |
| Catastrophic Adult | 0.4329 | 0.4236 | 0.4051 |
| Platinum Child | 0.3569 | 0.3436 | 0.3539 |
| Gold Child | 0.3541 | 0.3404 | 0.3511 |
| Silver Child | 0.3522 | 0.3383 | 0.3491 |
| Bronze Child | 0.3491 | 0.3351 | 0.3459 |
| Catastrophic Child | 0.3490 | 0.3350 | 0.3458 |
| Platinum Infant | 0.3165 | 0.2913 | 0.3059 |
| Gold Infant | 0.3133 | 0.2878 | 0.3025 |
| Silver Infant | 0.3122 | 0.2865 | 0.3012 |
| Bronze Infant | 0.3101 | 0.2842 | 0.2989 |
| Catastrophic Infant | 0.3101 | 0.2842 | 0.2989 |

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

In part 2 of the 2022 Payment Notice (86 FR 24183 through 24186), we finalized the proposal to continue to use the State payment transfer formula finalized in the 2021 Payment Notice for the 2022 benefit year and beyond, unless changed through notice and comment rulemaking. We explained that under this approach, we will no longer republish these formulas in future annual HHS notice of benefit and payment parameter rules unless changes are being proposed. We did not propose any changes to the formula in this rule, and therefore will continue to apply the formula as finalized in the 2021 Payment Notice (85 FR 29191 through 29193⁹¹) in the States where HHS operates the risk adjustment program in the 2025 benefit year. We also will not republish the formulas in this rule. Additionally, as finalized in the 2020 Payment Notice (84 FR 17466 through 17468), we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice and comment rulemaking. We did not propose any changes to the high-cost risk pool parameters for the 2025 benefit year; therefore, we are maintaining the \$1 million attachment point and 60 percent coinsurance rate.⁹²

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the 2025 benefit year risk adjustment methodology as proposed. We summarize and respond to public comments received on the State payment transfer formula below.

Comment: One commenter recommended updating the State payment transfer formula to scale risk adjustment State transfers using State-average claims multiplied by a ratio of claims to actuarial risk, relying on medical loss ratio (MLR) claims data rather than data issuers submit to their respective distributed data environments (EDGE servers). A few commenters expressed concern that overall risk adjustment transfers are too small. Several commenters expressed concern about the potential negative consequences risk adjustment can have on new or small health insurance issuers attempting to enter the market. These commenters referred to recent plan failures that affected other carriers who are owed risk adjustment payments.

Response: We did not propose and are not finalizing changes to the use of the Statewide average premium as the scaling factor in the State payment transfer formula. We also did not propose and are not finalizing the use of MLR data instead of issuers' EDGE data to calculate risk adjustment transfers. As detailed in prior rulemakings,⁹³ HHS chose to use Statewide average premium to convert required revenue and allowable premium State average factors in the State payment transfer formula from relative factors to dollar amounts so that the total calculated payment amounts equal total calculated charges

in each State market risk pool. Thus, each plan in the State market risk pool receives a risk adjustment State transfer payment or charge that is scaled based on the determination of plan average risk within a State market risk pool, resulting in balanced, budget-neutral transfers. Furthermore, as detailed in the 2018 Payment Notice,⁹⁴ we adopted a 14 percent reduction to the Statewide average premium to account for administrative costs that are unrelated to the claims risk of the enrollee population. To derive this parameter, we analyzed administrative and other non-claims expenses in the MLR Annual Reporting Form and estimated, by category, the extent to which the expenses varied with claims. We compared those expenses to the total costs that issuers finance through premiums, including claims, administrative expenses, and taxes, and determined that the mean administrative cost percentage in the individual, small group and merged markets is approximately 14 percent. We believe this amount represents a reasonable percentage of administrative costs on which risk adjustment should not be calculated. This approach supports the overall goal of the risk adjustment program to encourage issuers to rate for average risk and mitigates incentives for issuers to operate less efficiently, or to develop benefit designs or create marketing strategies to avoid high-risk enrollees. And, while we have not tested using Statewide average MLR claims data in the State payment transfer formula, we have concerns about whether we could operationally use MLR data for this purpose and the limitations of using the MLR data especially when compared to

⁹¹ Discussion provided an illustration and further details on the State payment transfer formula.

⁹² See 81 FR 94081. See also 84 FR 17467.

⁹³ See, for example, the Adoption of the Methodology for the HHS-operated Risk Adjustment Program under the Patient Protection and Affordable Care Act for the 2017 Benefit Year; Final Rule, 83 FR 36456 (July 31, 2018); and the Adoption of the Methodology for the HHS-operated Risk Adjustment Program for the 2018 Benefit Year; Final Rule, 83 FR 63419 (December 10, 2018). Also see the HHS Notice of Benefit and Payment Parameters for 2020; Final Rule, 84 FR 17454 at 17480 through 17484 (April 25, 2019).

⁹⁴ 83 FR 63419 at 63422 through 63427.

the benefits of using data issuers submit to their EDGE server for this purpose. For example, it would not be feasible to use current MLR data as the timelines for reporting for a particular benefit year of MLR data by July 31 of the year following the applicable benefit year does not align with the regulatory timeline at § 153.310(e) that requires States and HHS to notify issuers of risk adjustment payment due and charges owed by June 30 of the year following the applicable benefit year.

Additionally, using the MLR data's usable claims fields for this purpose would need to be further investigated as the "Claims Paid" data field has several exclusions and deductions.⁹⁵ More importantly, we have previously researched using Statewide average claims as a scaling factor in the State payment transfer formula and found that it was a volatile measure, both across States within a year and across years within a State and would be sensitive to unexpected claims experience. Furthermore, unexpected claims experience could particularly cause instability for smaller issuers, thereby reducing the predictability of risk adjustment transfers.⁹⁶ For these reasons, we did not propose or otherwise consider proposing updates to use Statewide average claims or relying on MLR claims data for calculating transfers under the State payment transfer formula. We will continue to scale risk adjustment transfers based on Statewide average premiums, as they are less subject to the instability of Statewide average claims.

We continue to believe that the State payment transfer formula is working as intended by more evenly spreading the financial risk carried by health insurance issuers that enroll higher-risk individuals in a particular State market risk pool, thereby protecting issuers against adverse selection and supporting them in offering products that serve all types of consumers.⁹⁷ We also continue

to find that risk adjustment transfers calculated under the State payment transfer formula as a percent of total premiums correlate with the amount of paid claims rather than issuer size,⁹⁸ and that per-member-per-month risk adjustment transfer amounts tend to be similar for smaller and larger issuers. Although we do not agree that risk adjustment is biased against new and small issuers, we have implemented policies as part of the HHS-operated risk adjustment program to assist small issuers, such as allowing issuers with 500 or fewer billable member months Statewide to be assessed a lower, separate default risk adjustment charge if they fail to set up an EDGE server, fail to submit sufficient data for HHS to calculate transfers, or otherwise opt to accept the default risk adjustment charge for a particular benefit year of risk adjustment.⁹⁹ We also do not agree with commenters that risk adjustment transfers are too small,¹⁰⁰ and we note that risk adjustment transfers as a percent of premium have been increasing, which is indicative of risk adjustment transfers growing, as detailed in the Summary Report on Permanent Risk Adjustment Transfer for the 2022 Benefit Year:¹⁰¹

- Nationwide, the absolute value of risk adjustment State transfers across all State market risk pools (excluding the high-cost risk pool) was about 10.4 percent of total premiums, as compared to the absolute value of 2021 benefit year State transfers, which was 8.7 percent of total premiums.

- In the 2021 benefit year, the absolute value of risk adjustment State transfers as a percent of premiums averaged 11.7 percent of premiums in the individual non-catastrophic risk pool, and 4.4 percent of premiums in the small group risk pool.

- In the 2022 benefit year, the absolute value of risk adjustment State transfers increased to 14.2 percent of

premiums in the individual non-catastrophic risk pool and 4.5 percent of premiums in the small group risk pool.

We acknowledge that large risk adjustment charges can be unpredictable for small, new, or fast-growing issuers. We will continue to monitor risk adjustment implications and challenges for these issuers. HHS has regularly discussed with issuers and State regulators ways to encourage new participation in the health insurance markets and to mitigate any disruptive effects of substantial risk adjustment charges. We intend to continue these discussions and note that HHS remains committed to working with States and other interested parties to encourage new market participants, mitigate adverse selection, and promote stable insurance markets through strong risk adjustment programs. Finally, we note that to minimize the impact of issuers that fail to pay charges owed to the risk adjustment program, HHS will use all available debt collection tools to fully collect risk adjustment charges from issuers with plan failures that affected other issuers who are owed risk adjustment payments, which includes netting those charges against certain other payments owed to the issuer,¹⁰² where applicable.

4. HHS Risk Adjustment User Fee for the 2025 Benefit Year

In the 2025 Payment Notice proposed rule (88 FR 82510, 82549), HHS proposed a risk adjustment user fee for the 2025 benefit year of \$0.20 PMPM. Under § 153.310, if a State is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate risk adjustment on its behalf. For the 2025 benefit year, HHS will operate risk adjustment in every State and the District of Columbia. As described in the 2014 Payment Notice (78 FR 15416 through 15417), HHS' operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. 45 CFR 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

⁹⁵ See CMS MLR Annual Reporting Form Filing Instructions for 2022 MLR Reporting Year at: <https://www.cms.gov/files/document/2022-mlr-form-instructions.pdf>.

⁹⁶ 84 FR 17454 at 17480 through 17482.

⁹⁷ See, for example, *Summary Report on Permanent Risk Adjustment Transfer for the 2022 Benefit Year*. (2023, June 30). CMS. <https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf>; *Summary Report on Permanent Risk Adjustment Transfer for the 2021 Benefit Year (Revised)*. (2022, July 19). CMS. <https://www.cms.gov/ccio/programs-and-initiatives/premium-stabilization-programs/downloads/ra-report-by2021.pdf>; and *Summary Report on Permanent Risk Adjustment Transfer for the 2020 Benefit Year*. (2021, June 30). CMS. <https://www.cms.gov/ccio/programs-and-initiatives/premium-stabilization-programs/downloads/ra-report-by2020.pdf>.

⁹⁸ We recently reconducted this analysis. Also, see the *Summary Report on Permanent Risk Adjustment Transfer for the 2022 Benefit Year* at: <https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf>.

⁹⁹ Other examples of HHS policies to assist small issuers including exempting small issuers under 45 CFR 153.630(g)(1) and 45 CFR 153.630(g)(2) from being required to participate in risk adjustment data validation under certain circumstances.

¹⁰⁰ We note that, prior to the 2018 benefit year, HHS used 100 percent of Statewide average premium in the transfer formula but reduced it to 84 percent of Statewide average premium in order to account for administrative costs that do not vary with claims. See 81 FR 94099 through 94101.

¹⁰¹ *Summary Report on Permanent Risk Adjustment Transfer for the 2022 Benefit Year*. (2023, June 30). CMS. <https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf>.

¹⁰² See 45 CFR 156.1215.

recipient for special benefits derived from Federal activities beyond those received by the general public.¹⁰³ The HHS-operated risk adjustment program provides special benefits as defined in section 6(a)(1)(B) of OMB Circular No. A–25 to issuers of risk adjustment covered plans because it mitigates the financial instability associate with potential adverse risk selection.¹⁰⁴ The HHS-operated risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

To calculate the HHS risk adjustment user fee, we divided HHS' projected total costs for administering the HHS risk adjustment program on behalf of States by the expected number of billable member months (BMM) in risk adjustment covered plans in States where the HHS-operated risk adjustment program will apply in the 2025 benefit year. We estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for the 2025 benefit year will be approximately \$66 million, which is more than the approximately \$60 million estimated for the 2024 benefit year. We projected increased costs due to increased contracting costs combined with increased labor costs.

We also projected higher enrollment than our prior estimates in the 2024 and 2025 benefit years based on the increased enrollment, as measured by BMM, between the 2021 and 2022 benefit years in the individual non-catastrophic market risk pool in most States, likely due to the increased PTC subsidies provided for in the American Rescue Plan Act of 2021 (ARP).¹⁰⁵ ¹⁰⁶ In light of the passage of the Inflation Reduction Act of 2022 (IRA), in which section 12001 extended the enhanced PTC subsidies in section 9661 of the ARP through the 2025 benefit year, we projected there will continue to be increased enrollment levels through the 2025 benefit year.¹⁰⁷ Because we projected an increased budget to operate the HHS-operated risk adjustment program and estimated higher enrollment through the end of the 2025 benefit year, we proposed a HHS risk

adjustment user fee of \$0.20 PMPM for the 2025 benefit year.

We sought comment on the proposed HHS risk adjustment user fee for the 2025 benefit year.

After reviewing public comments and revising our projections based on newly available data that impacted our enrollment projections, we are finalizing a risk adjustment user fee rate of \$0.18 PMPM for the 2025 benefit year. We summarize and respond to public comments received on the proposed 2025 benefit year risk adjustment user fee rate below.

Comment: Some commenters supported lowering the risk adjustment user fee rate. Several commenters supported a risk adjustment user fee rate that adequately funds Federal programs.

Response: We are finalizing a risk adjustment user fee rate for benefit year 2025 of \$0.18 PMPM. The final 2025 benefit year risk adjustment user fee rate is lower than the proposed 2025 benefit year user fee rate because we revised our enrollment projections based on newly available data from the 2024 benefit year individual market Open Enrollment (OE) period, which occurred between November 2023 and January 2024. In particular, the 2024 OE cycle saw larger than projected plan selections, which resulted in us increasing our projected BMMs for the risk adjustment user fee for the 2025 benefit year,¹⁰⁸ and with a projected budget of \$66 million, it resulted in a lower risk adjustment user fee.

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

We proposed amending § 153.620(c)(4) to require issuers of risk adjustment covered plans to complete, implement, and provide to HHS written documentation of any corrective action plans when required by HHS if a high-cost risk pool audit results in the inclusion of certain observations¹⁰⁹ in

the final audit report. Currently, under § 153.620(c)(4), a corrective action plan is only required, at HHS' direction, if the audit results in the inclusion of a finding in the final audit report. Upon completion of the first benefit year of high-cost risk pool audits (2018 benefit year audits), HHS found that some issuers of risk adjustment covered plans made data submission errors to their EDGE servers that constituted instances of noncompliance but did not result in a financial impact and were therefore recorded as observations in the final audit report. Under this proposal, HHS would communicate to the issuer, as part of the final audit report, which findings and observations require a corrective action plan.

Under this policy, consistent with the existing framework in § 153.620(c)(4), HHS would require an issuer of a risk adjustment covered plan to provide, within 45 calendar days of the issuance of the final audit report, a written corrective action plan for any audit findings, as well as audit observations when there is evidence of non-compliance with applicable Federal requirements, to HHS for approval, implement that plan, and provide to HHS written documentation of the corrective actions taken to resolve the root cause of the non-compliance identified.¹¹⁰ We proposed to apply this change beginning with 2020 benefit year high-cost risk pool audits, which we anticipate beginning in 2024.¹¹¹

We sought comment on this proposal. After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this amendment and the accompanying policies as proposed. We summarize and respond to public comments received on the proposed amendments to § 153.620(c)(4) to require a corrective action plan for audit observations under certain circumstances below.

Comment: Several commenters supported the proposal. One commenter agreed that allowing instances of non-compliance to be unaddressed could impact EDGE data integrity and that a corrective action plan is an effective tool to address this concern. Other commenters generally supported the proposed policy, noting that it allows HHS to run sufficiently and efficiently, and provide oversight of, its risk

evidence of non-compliance with applicable Federal requirements.

¹¹⁰ See 45 CFR 153.620(c)(4). Also see 86 FR 24192 through 24194.

¹¹¹ If 2020 benefit year high-cost risk pool audits begin in early 2024, we anticipate the final audit reports would be completed, with findings and observations identified, in early 2025.

¹⁰³ See Circular No. A–25 Revised, <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>.

¹⁰⁴ *Id.*

¹⁰⁵ ARP, Public Law 117–2 (2021).

¹⁰⁶ CMS, (2023, June 30). Summary Report on Permanent Risk Adjustment Transfers for the 2022 Benefit Year. (p. 8). <https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf>.

¹⁰⁷ Inflation Reduction Act, Public Law 1217–169 (2022).

¹⁰⁸ For additional information, see <https://www.cms.gov/newsroom/fact-sheets/marketplace-2024-open-enrollment-period-report-final-national-snapshot>.

¹⁰⁹ In the context of high-cost risk pool audits, an “observation” results from the identification of areas for improvement when there is no evidence of actual non-compliance with applicable Federal requirements or when there may be evidence of non-compliance with applicable Federal requirements that does not require recoupment of these payments. Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight (CCIIO). (Dec. 2022). Best Practices Overview: Benefit Year (BY) 2018 HCRP Payment Audits and General EDGE Server Requirements. https://regtap.cms.gov/reg_library_openfile.php?id=4234&type=1 (Login Required). This amendment and accompanying policies are limited to observations where there may be

adjustment program, which aligns with professional industry organizations' goals to support continuous improvement in their members' compliance with local, State, and Federal requirements and their own policies and procedures.

Other commenters opposed the proposal stating concerns that the changes to the audit would be applied retrospectively to observations that do not have monetary impacts. Other commenters were concerned about a perceived lack of rights and processes available for issuers to appeal audit findings or observations that require completion of corrective action plans. These commenters were concerned that there is not enough information regarding how HHS uses data collected during the audit processes. Commenters were also concerned that the use of corrective action plans in this manner would require issuers to provide data they do not readily have available in order to take the necessary corrective actions and that this access and use of data goes beyond what is necessary for the HHS-operated risk adjustment program. Commenters were also concerned that the timing of the amendments would not give issuers sufficient time to prepare and implement new processes. One commenter also raised concerns that the proposal lacked details on the audit process and asked that interested parties receive more information about the risk adjustment, specifically high-cost risk pool, audits.

Response: We are finalizing the proposal to require issuers to complete corrective action for certain risk adjustment audit observations as proposed. We agree with commenters that requiring the implementation of corrective action plans if a risk adjustment audit results in the inclusion of observations in the final audit report when there is evidence of non-compliance with applicable Federal requirements would help to ensure that HHS is able to efficiently run and provide oversight of its risk adjustment program.

As stated in the proposed rule, since enrollee-level data that HHS extracts from issuers' EDGE servers is also used for HHS risk adjustment model recalibration, updates to the AV methodology and calculator, and other analyses for the commercial individual and small group (including merged) market, and Federal HHS related programs (for example, Medicaid expansion, QHP population, and non-

Federal governmental plans),¹¹² it is important that issuers of risk adjustment covered plans also take corrective action to address instances of non-compliance, which may have material impacts to the enrollee-level data, even if they did not result in a financial impact and were therefore recorded as observations in the final audit report.

We do not believe this change goes beyond the data uses and access necessary for the risk adjustment program, because the primary purpose of this policy is to strengthen the program integrity tools available to HHS when conducting risk adjustment audits to ensure the integrity of the data used for the HHS-operated risk adjustment program.¹¹³ A major goal of requiring corrective action plans for observations where there is evidence of non-compliance with applicable Federal requirements is to ensure data use and integrity issues identified via audits are corrected timely; otherwise, these issues may have material impact on the enrollee-level EDGE data or data submission for future benefit years if they persist. We also note that this policy is not being retrospectively or retroactively applied. We are finalizing, as proposed, that this change will apply beginning with 2020 benefit year high-cost risk pool audits, which we anticipate beginning in 2024 with audit findings and observations being communicated to issuers in early 2025. Additionally, the requirements evaluated in the 2020 benefit year audits will reflect the standards that issuers were required to comply with at the time of the 2020 benefit year EDGE data submission deadline (April 30, 2021). Further, current audit processes use corrective action plans as a tool to provide evidence that an issuer has sufficiently remediated an error or instance of non-compliance identified through an audit finding. Amending the regulation to capture the ability for HHS to require a corrective action plan for certain audit observations where there is evidence of non-compliance with Federal requirements would help to enhance data and program integrity by ensuring that issuers remedy EDGE data submission issues identified through audit, including those that did not result in a financial impact, so identified issues do not persist and impact future

¹¹² See, for example, 84 FR 17488 and 87 FR 27243.

¹¹³ As previously noted, HHS uses data issuers submit to their EDGE servers to calculate transfers under the State payment transfer formula and the high-cost risk pool parameters, as well as for recalibration of the HHS risk adjustment models and for development of risk adjustment policies, among other permitted uses.

data submission years. Consistent with current requirements for addressing late-filed discrepancies to address errors identified in EDGE data submission, if the issuer, after conducting an impact analysis of the data submission error that covers the period of non-compliance, identifies a potential overpayment resulting from the error, the issuer is required to report the overpayment to HHS as a prior benefit year discrepancy.¹¹⁴

We also do not believe that issuers would need to provide data that is not readily available. The audit process validates the accuracy of the data submitted by issuers of risk adjustment covered plans to their respective EDGE servers.¹¹⁵ With data coming from the EDGE servers, issuers should not have to provide additional data beyond what is required for the audit process, which are the same data necessary to administer the HHS-operated risk adjustment program.

We understand concerns regarding time to implement new processes to properly respond to corrective action plans. As stated in the proposed rule, we proposed to amend the established audit process to require corrective action plans for certain audit observations identified through HHS risk adjustment (including high-cost risk pool) audits (88 FR 82510) and the process would align with the existing framework detailed in § 155.620(c)(4).¹¹⁶ The only change to the existing framework is that HHS, at its discretion, may require a corrective action plan for certain audit observations identified through the risk adjustment audits where there is evidence of non-compliance with applicable Federal requirements. As previously stated, this amendment does not alter the requirements evaluated through the risk adjustment audit. For example, 2020 benefit year high-cost risk pool audits will evaluate issuer compliance with the 2020 benefit year data submission requirements for their respective 2020 benefit year EDGE data.¹¹⁷ The amendment to § 155.620(c)(4) to also require corrective

¹¹⁴ See 86 FR 24195. Also see Distributed Data Collection (DDC) for Risk Adjustment (RA) Including High Cost Risk Pool (HCRP): EDGE Server Announcements webinar presentation slides from August 18, 2020 on "EDGE/RA Discrepancy Reporting: Prior Benefit Year Discrepancy Web Form," available at https://regtap.cms.gov/reg_library.php?prog=3&page=1&i=3357.

¹¹⁵ See CMS. (2023, September 06). 2018 Benefit Year (BY) High-Cost Risk Pool (HCRP) Audit Report. (p. 3). <https://www.cms.gov/files/document/2018-hcrp-audit-summary-publish-508.pdf>.

¹¹⁶ See 45 CFR 153.620(c)(4).

¹¹⁷ The deadline for issuers to submit 2020 benefit year data to their respective EDGE servers was April 30, 2021. See 45 CFR 153.730.

action plans for certain audit observations aligns with previously established regulations requiring corrective action plans for audit findings for risk adjustment audits. Issuers can find more information about corrective action plans and the general high-cost risk pool audit process by reviewing past audit reports¹¹⁸ and high-cost risk pool audit summary reports.¹¹⁹ An issuer selected for a high-cost risk pool audit will also have the opportunity to ask questions during the entrance conference¹²⁰ and throughout the audit process. Additionally, we will continue to communicate with issuers selected for audit throughout the audit process to ensure they understand the process and to respond to any questions if issuers are required to address findings or certain observations in final audit reports through a corrective action plan.

We understand concerns regarding rights to address or remedy issues during the audit process. Current audit procedures provide issuers with ample opportunities to raise issues or concerns with findings and observations to HHS before the issuance of the final audit report. For example, prior to issuing a final report, HHS shares its preliminary audit findings with issuers,¹²¹ and issuers have the opportunity to dispute any findings or observations.¹²² Additionally, if HHS and the issuer do not agree with the final audit report, both HHS's final audit report and the issuer's disagreement is publicly released. In short, the risk adjustment audits are collaborative and involve coordination with issuers to resolve data discrepancies and address any questions or concerns issuers may have throughout the audit process.¹²³ Further, not every observation will require a corrective action plan. If, during the audit process, an issuer proactively takes steps that HHS evaluates as sufficient to address an audit observation or finding for which HHS would have otherwise required a corrective action plan, HHS may elect to

not require additional action after the final audit report is issued.

D. 45 CFR Part 155—Exchange Establishment Standards and Other Related Standards

1. Approval of a State Exchange (§ 155.105)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82551), we proposed to amend § 155.105(b) to require that, in addition to meeting all other approval standards under § 155.105(b), a State seeking to operate a State Exchange must first operate a State-based Exchange using the Federal platform (SBE-FP), meeting all requirements under § 155.200(f), for at least one plan year, including an open enrollment period. This proposal was intended to give States sufficient time to create, staff, and structure a State Exchange that could transition to operating its own platform and establish relationships with interested parties critical to a State Exchange's success in operating an Exchange, including standing up and operating a Navigator and consumer outreach program, assuming plan management responsibilities, and communicating effectively with consumers to support enrollment and avoid health care coverage gaps.

As stated in the proposed rule (88 FR 82511), over the past several years, we have observed the benefits of States first operating an SBE-FP for at least one plan year prior to transitioning fully from an FFE to a State Exchange. Operating an SBE-FP for at least one plan year, including its open enrollment period, prior to transitioning to a State Exchange gives States an opportunity to focus on investing time and resources needed to implement key Exchange functions that involve the establishment of critical and necessary relationships with consumers, consumer assisters, partners in the coordination of eligibility functions, issuers, and other interested parties. Operating an SBE-FP for at least one plan year prior to transitioning to a State Exchange also affords States time to implement eligibility and enrollment functions which require information technology platforms, call centers, and coordination with partners, such as State Medicaid agencies. In addition, operating an SBE-FP for at least one plan year prior to transitioning to a State Exchange gives States more time to engage with partners and interested parties to develop various consumer-facing content and consumer outreach strategies, all while establishing and gaining experience operating a consumer assistance

program. Further, when States operate an SBE-FP for at least one plan year before operating a State Exchange, they are more likely to have the time and resources needed to coordinate with the State's Department of Insurance to establish policies and procedures associated with carrying out plan management functions, engage with the issuer community, and develop QHP certification requirements and processes. Finally, operating an SBE-FP for at least one plan year before transitioning to a State Exchange allows States time to familiarize consumers, consumer assisters, partners in the coordination of eligibility functions, issuers, and other interested parties with operations of the new State Exchange organization ahead of engaging with that Exchange, and it mitigates the risks and disruption associated with a transition to a State Exchange and simultaneous replacement of *HealthCare.gov* as the eligibility and enrollment pathway for those parties.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed to require that a State seeking to operate a State Exchange must first operate an SBE-FP, meeting all requirements under § 155.200(f), for at least one plan year. We summarize and respond to public comments received on the proposed policy below.

Comment: A majority of the comments we received supported the proposal. Many commenters supported the policy, suggesting it would provide needed time to prepare and implement a successful Exchange, including establishing and testing technical operations, establishing relationships with QHP issuers and other government entities, and creating greater transparency and opportunities for public and interested party engagement with the process. Some commenters also suggested that the extended time for State Exchange establishment would protect consumers by ensuring network adequacy and that all functions for consumer support are in place before a State Exchange is launched, and that the additional time would help SBE-FPs refine their plans and processes before transitioning to a State Exchange model.

Response: We agree that the extended time afforded by this policy will help to ensure the success of newly-established State Exchanges.

Comment: A few commenters stated that several States have successfully implemented State Exchanges without these provisions. These commenters suggested that this may be an indication

¹¹⁸ For additional information see CMS. (2023, December 2023). High-Cost Risk Pool (HCRP) Audits. https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Exams_Audits_Reviews_Issuer_Resources/#high-costriskpool.

¹¹⁹ For additional information see CMS. (2023, September 06). 2018 Benefit Year (BY) High-Cost Risk Pool (HCRP) Audit Summary. <https://www.cms.gov/files/document/2018-hcrp-audit-summary-publish-508.pdf>.

¹²⁰ See 45 CFR 153.620(c)(1)(i).

¹²¹ See 45 CFR 153.620(c)(3).

¹²² See 45 CFR 153.620(c)(3)(i)-(ii).

¹²³ See 2018 Benefit Year (BY) High-Cost Risk Pool (HCRP) Audit Summary. (p. 3).

that the proposed provisions are unnecessary, and that a State should be given flexibility to decide its path forward. They recommended that HHS only apply these new requirements to States that propose operating an Exchange in a way that differs significantly from the traditional model.

Response: Over the past several years, all States that have transitioned to a State Exchange have first operated an SBE-FP. Our experience in overseeing these transitions has made evident the advantage a State has in operating an SBE-FP prior to transitioning to a State Exchange. Notably, operating an SBE-FP first provides States an opportunity to implement certain significant Exchange functions that are needed for State Exchange operations, such as operating the State's Navigator program and developing plan management capabilities. The interim period operating an SBE-FP will provide States with sufficient time to continue developing resources and establishing strong relationships with interested parties, which are both critical for implementing key State Exchange functions. We have particularly observed this in regard to developing eligibility and enrollment functions, including implementing and operating information technology platforms, call centers, and coordination with the State Medicaid agency and other partners.

Furthermore, based on our work with SBE-FPs that have transitioned to State Exchanges over the past several years, we have learned the importance of having an established consumer assistance and outreach program as an SBE-FP prior to the implementation of a State Exchange. State Exchanges that previously operated an SBE-FP have stated that this experience, as well as an SBE-FP's developed communication line with consumers, helps mitigate potential disruption to consumer enrollment when *HealthCare.gov* is no longer the eligibility and enrollment pathway for the State Exchange's consumers, and in turn, the State Exchange takes on this role.

Given these benefits, we believe that implementing a regulatory requirement that States must first operate an SBE-FP for at least one plan year prior to transitioning to a State Exchange will benefit both the State's implementation of a State Exchange, as well as the Exchange's long-term success.

Comment: A few commenters stated that these new rules could introduce delays in the process for a State to establish a State Exchange. Some of these commenters expressed concern that these delays could prevent a State from transitioning to a State Exchange

due to increased costs in meeting requirements. One commenter stated that a longer establishment period could impede a State from standing up its own Exchange because the initial implementation of an SBE-FP and then a subsequent State Exchange might occur over election periods, and there would be a risk that new State executive or legislative leadership might decide to no longer pursue the transition to a State Exchange during a State's SBE-FP status.

Response: We recognize that a State's implementation of a State Exchange may depend on the State's specific needs and the decisions of its elected officials. We also understand that a State could decide for various reasons to stop pursuing or operating a State Exchange. However, we are of the view that requiring a State Exchange to first operate an SBE-FP is appropriate because a State's elected officials have always had the ability to change the State's plans to become or remain a State Exchange, and therefore that fact alone should not hinder adoption of the proposed policy that aims to ensure the success of State Exchanges.

Comment: One commenter expressed concern that delays in transitioning to a State Exchange would result in the State receiving less user fee revenue, and that the need to pay or remit user fees to CMS as an SBE-FP could result in a State ultimately not being able to establish a State Exchange.

Response: Our experience has shown that SBE-FPs that have transitioned to State Exchanges are able to fund these activities, at least in part, with additional user fees that a SBE-FP may charge issuers on top of the Federal Platform user fee. Section 1311(d)(5)(A) of the ACA permits an Exchange to charge user fees on participating health insurance issuers as a means of generating funding to support its operations.¹²⁴ Under § 156.50(c), a participating issuer offering a plan through a SBE-FP must remit a user fee to HHS each month that is equal to the product of the SBE-FP 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 the SBE-FP. SBE-FPs may also assess an additional State-level user fee, beyond the Federal Platform user fee, on issuers for the purposes of operating their SBE-FP, which could theoretically amount to

the total user fee a State would assess issuers as a State Exchange. In our experience, SBE-FPs have utilized additional State-level user fees assessed on issuers to support a State's eventual State Exchange implementation.

Comment: One commenter stated that because the ACA directs States to establish an Exchange, this proposal oversteps the authority granted to HHS by the ACA, as it could prevent a State that felt it was prepared to take on the responsibilities of operating a State Exchange from doing so.

Response: We seek to support States in successfully implementing State Exchanges. Section 1321 of the ACA directs HHS to issue regulations setting standards for establishing and operating an Exchange, which it implemented at § 155.105. States may subsequently elect to establish and operate Exchanges, as prescribed by HHS and per the requirements of § 155.105, which requires HHS to approve a State Exchange only if it is able to meet other required functions of an Exchange. All States considering transitioning to a State Exchange must consider if they are able to meet these requirements. As we stated above, our experience is that first operating an SBE-FP is necessary for successfully implementing and operating a State Exchange. Therefore, HHS is using the authority granted to it in section 1321 of the ACA to include in § 155.105 the requirement for a State transitioning to operate a State Exchange to first operate an SBE-FP for one plan year.

Comment: One commenter suggested that CMS modify this proposal so that States with demonstrated capabilities in technology planning and Exchange management could be granted the flexibility to transition directly to a State Exchange if they meet certain readiness criteria.

Response: Regardless of a State's ability to meet any readiness criteria we might set from a technological perspective, there are other factors, including establishing relationships with other State agencies and programs, that make this technological readiness not sufficient on its own to bypass the 1-year-SBE-FP requirement. We agree that a key component of a State's readiness to implement and operate a State Exchange is being ready to implement an eligibility platform to support key State Exchange functions, including the display and selection of QHPs and the processing of eligibility applications and determinations for Exchange enrollment and insurance affordability programs. However, we believe that a State that met any technology requirements that we set

¹²⁴ 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.

would still need to demonstrate the non-technology capabilities and functions required of a State Exchange, gained from experience, operating an SBE-FP that we discuss above. For example, State Exchanges need to coordinate sharing of plan information and plan management work with issuers, plan and provide training to Navigators and Assistants, and plan and implement consumer outreach activities, such as drafting notices, providing training to call center and other staff on relevant policies and procedures, and writing and updating website and other consumer-facing materials.

Often, States that are transitioning from an FFE to operating a State Exchange draw on the work of contracted vendors and companies that have assisted with other States' Exchange transitions in developing that State's eligibility and enrollment platform or website. It is possible that a State might indicate that it would be technologically ready to transition directly to operating a State Exchange, without first operating an SBE-FP, due to its decision to contract with vendors and companies, who would apply the same or similar plans for development and implementation of its eligibility and enrollment platform. However, it is not possible for a State seeking to newly establish a State Exchange to identically apply development and implementation plans and other resources utilized for an eligibility platform in already-established State Exchanges, because in our experience those Exchanges may operate with partner State agencies and programs, such as Medicaid and CHIP, differently from the State that is seeking to newly establish a State Exchange. As Insurance Affordability Programs may require State-specific programming for an eligibility platform to make a correct eligibility determination, or for appropriate information to be displayed on consumer-facing resources, a State's readiness to operate an eligibility platform requires consideration and work on other elements than prior demonstrated capabilities in technology planning and Exchange management. Additionally, some States may pursue an integrated eligibility system between the State Exchange and the State Medicaid agency in which the State Exchange's eligibility system can determine eligibility for non-MAGI Medicaid, as well as other State programs, while other States may have different eligibility determination agreements between the State Exchange and the State Medicaid agency.

As a result, we believe that the experience gained from first operating

an SBE-FP and providing additional time for interoperability with other State programs and establishing relationships with consumers and advocates makes it necessary to first operate an SBE-FP before operating a State Exchange.

Comment: One commenter stated that although experience gained operating an SBE-FP for States transitioning from the FFE to a State Exchange would be valuable, the options for plan management activities provided to States operating State Exchanges are more flexible than the options provided to States operating an SBE-FP. They also stated that relationships with interested parties may also change when operating an SBE-FP and later operating a State Exchange, due to the difference in responsibilities and authorities granted to SBE-FPs and those granted to State Exchanges. They expressed concern that the need to attend to these differences in responsibilities and flexibilities could strain the resources of smaller States whose ultimate goal is to establish a State Exchange rather than an SBE-FP.

Response: While we agree that some plan management responsibilities differ for a State Exchange and an SBE-FP, the differences are relatively minor and therefore the experience operating an SBE-FP can generally be applied to the responsibilities of State Exchanges. As an example, both State Exchanges and SBE-FPs have the legal authority and responsibility to establish QHP certification processes with issuers, review QHP applications, and make QHP certification decisions, including the responsibility for coordinating with their participating QHP issuers on plan data corrections. Given the similarity between State Exchange and SBE-FP plan management activities, as well as the significant resources and planning required for an SBE-FP to conduct plan management activities, we believe that implementing a SBE-FP before implementing a State Exchange will allow a State to demonstrate its capacity to manage and implement this key Exchange functionality.

2. Election To Operate an Exchange After 2014 (§ 155.106)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82551), we proposed changes to the Exchange Blueprint (OMB control number: 0938-1172) requirements for States seeking to operate a State Exchange. We proposed to revise § 155.106(a)(2) to add a requirement that a State, as part of its activities for its establishment of a State Exchange, provide upon request, supplemental documentation to HHS

detailing the State's implementation of its State Exchange functionality. Such supporting documentation would inform HHS's decision to approve or conditionally approve a State Exchange and could include, for example, materials demonstrating progress toward meeting State Exchange Blueprint requirements, documentation that details a State's plans to implement and meet the Exchange functional requirements as laid out in the State Exchange Blueprint, or plans to engage in consumer assistance programs and activities. In the proposed rule (88 FR 82552) we noted, we would provide guidance and direction to each State with our requests for supplementary information so that each State understands the purpose of the requests and how the requested information would help us determine whether the State meets the functional requirements for operating a State Exchange. Because the ability to request additional detail on a State's Exchange implementation plans is crucial for identifying risk areas for a State Exchange's operations, it is essential to determining that a State Exchange is ready to operate. The current State Exchange Blueprint application provides that we may require live demonstrations of Exchange functionality on the State Exchange's platform, as well as supporting documentation, as evidence of the State's progress toward meeting State Exchange Blueprint application requirements. In order to set clear expectations, we proposed to codify that as part of the State's submission of a State Exchange Blueprint application, HHS has the authority to request any evidence HHS determines necessary for the State to detail its implementation of the required State Exchange functionality. This could include HHS requiring a State to submit detailed plans regarding its State Exchange consumer assistance programs and activities, such as information on its direct outreach plans. In the proposed rule we noted, we would request supporting documentation from States with the goal of imposing minimal burden on a State's ability to meet its State Exchange Blueprint requirements, while maintaining the objective of gathering sufficient information to assess a State's readiness to operate a State Exchange and ensure that a State is sufficiently implementing and scaling policies, procedures, operations, technology, and administrative capacities to meet the needs of the State's consumers. We would use the information in a State's State Exchange Blueprint application, as well as any

supporting documentation and evidence, to make a determination of whether to grant approval for a State's establishment and operation of a State Exchange for its intended first open enrollment period.

We also proposed to add new § 155.106(a)(2)(i) and (ii) to require that when a State submits its State Exchange Blueprint application to HHS for approval, the State must provide the public with notice and a copy of its State Exchange Blueprint application along with certain other information. We stated that, to facilitate such public notice, HHS would post a State Exchange Blueprint application, submitted by a State to its public-facing website within 90 calendar days of receipt. Further, we proposed to require that at some point following a State's submission of its State Exchange Blueprint application to HHS and before HHS's approval or conditional approval of the State Exchange Blueprint application, a State must conduct at least one public engagement event (such as a townhall meeting or public hearing) in a timeline and manner (for instance, considering whether to conduct in-person and/or virtually) considered effective by the State, with concurrence from HHS, at which interested parties can learn about the State's intent to establish a State Exchange and the State's progress toward executing that transition. We also proposed to require that while a State is in the process of establishing a State Exchange and until HHS has approved or conditionally approved the State Exchange Blueprint application, a State must conduct periodic public engagements at which interested parties would continue to learn about the State's progress towards establishing a State Exchange, in a timeline and manner considered effective by the State with concurrence from HHS. We are finalizing these provisions as proposed. However, based on comments we received, we now plan to publicly post the State's Blueprint application within 30 days of receipt.

The Exchange Blueprint serves as a vehicle for a State to document its progress toward implementing its intended Exchange operational model. The submission and approval of Exchange Blueprints is an iterative process that generally takes place over the course of 15 months prior to a State's first open enrollment operating a State Exchange. Further, the establishment of a State Exchange involves significant collaboration between HHS and States to develop plans and document readiness for the State to transition from an Exchange that uses the Federal platform to one

that operates its own eligibility and enrollment platform. State activities as part of this transition process include completing key milestones, meeting established deadlines, and implementing contingency measures. We believe that a mandatory process whereby States notify the public of their plans to establish State Exchanges and provide an opportunity to meet with interested parties to provide updates helps ensure that interested parties are aware these activities are occurring and can provide input on how States can successfully establish State Exchanges.

As stated in the proposed rule (88 FR 82553), a primary goal of these proposals is to strengthen the transparency requirements of the State Exchange Blueprint review and approval process. Based on our experience supporting and providing oversight to States in their establishment of State Exchanges, we believe that all States establishing Exchanges would benefit from having a more transparent process to facilitate input from interested parties, including consumers and issuers. A more transparent process would provide opportunities for consumers to learn more about a State's establishment process and plans, which can build consumer trust and help support a State's enrollment goals. States planning to establish State Exchanges could use public events like town halls or hearings to meet these transparency requirements.

We further note that compliance with these transparency requirements could help States that establish State Exchanges meet the consultation requirements with interested parties under § 155.130. Section 155.130 requires an Exchange to regularly consult on an ongoing basis with a list of eleven stakeholder groups, including educated health care consumers who are QHP enrollees and, if applicable, Federally recognized Tribes, as defined in the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a. For example, during a State's establishment of its Exchange, the State and these interested parties could formalize a process under which they would continue to confer as required by § 155.130.

We sought comment on this proposal, including comments related to additional ways States seeking to establish State Exchanges could provide greater transparency to interested parties, including consumers, regarding the process for establishing State Exchanges. After consideration of the comments and for the reasons outlined in the proposed rule and our responses

to comments, we are finalizing as proposed the amendment to § 155.106(a)(2) to require as part of a State's activities for its establishment of a State Exchange, the State provide, upon request, supplemental documentation to HHS detailing the State's implementation of its State Exchange functionality. Such supplemental documentation may, for example, demonstrate progress toward meeting State Exchange Blueprint requirements, or detail a State's plans for how it intends to implement and meet the Exchange functional requirements as laid out in the State Exchange Blueprint.

We also finalize as proposed new paragraph § 155.106(a)(2)(i) which states that, upon submitting an Exchange Blueprint application to operate a State Exchange, the State shall issue a public notice of its Exchange Blueprint application submission through its website and include a copy of the Exchange Blueprint application, a description of the Plan Year for which the State seeks to transition to a State Exchange, language indicating that the State is seeking approval from HHS to transition to a State Exchange, and information about when and where the State will conduct public engagements regarding the State's Exchange Blueprint application. To facilitate public notice, HHS will post a State Exchange Blueprint application submitted by a State to its public-facing website within 90 calendar days of receipt.

Finally, we finalize as proposed new paragraph § 155.106(a)(2)(ii) to require that at some point following a State's submission of its State Exchange Blueprint application to HHS and before HHS approves or conditionally approves the State's Exchange Blueprint application, a State must conduct at least one public engagement event (such as a townhall meeting or public hearing) in a timeline and manner (for instance, considering whether to conduct in-person and/or virtually) considered effective by the State, with concurrence from HHS, at which interested parties can learn about the State's intent to establish a State Exchange and the State's progress toward executing that transition.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these requirements with a modification to clarify that the State must submit supplemental information to HHS, upon request, detailing the State's implementation of its State Exchange functionality, including information on the ability to implement and comply

with Federal requirements for operating an Exchange. This information will assist in CMS determining whether the State meets the functional requirements for operating a State Exchange. We summarize and respond to public comments received on these proposals below.

Comment: Most commenters broadly supported the proposals associated with a State's election to operate a State Exchange, as it relates to both the requirements for a State to submit supporting documentation to HHS detailing the State's implementation of its State Exchange functionality, and, to provide the public with notice and a copy of its State Exchange Blueprint application and engage in periodic public hearings when a State submits its State Exchange Blueprint application to HHS for approval.

These commenters generally believed that the proposals would help States better implement and operate a State Exchange, provide transparency to States' interested parties, and improve consumer protections. One commenter stated that the resulting transparency may help interested parties become better aware of a State's transition plans and may submit helpful feedback to States, which States could consider in their transition planning.

Response: We appreciate and agree with these comments, many of which summarized or elaborated on the benefits that we described in the proposed rule.

Comment: A few commenters stated that the proposed provisions are arbitrary because all States that have transitioned to a State Exchange in the past several years have done so without the requirement for States to submit additional information or documentation on its State Exchange implementation progress or plans. One of these commenters requested that CMS provide a definitive list of additional documentation it may require from States, as well as stated that the request for additional information may impose additional burden, in terms of time and resources, on a State. Another commenter opposed these proposals more generally.

Response: HHS's collection of additional information and documentation demonstrating an Exchange's operational readiness is logically related to setting standards for establishing a State Exchange; thus these provisions are not arbitrary.¹²⁵ Regarding information we may require of States seeking to establish an Exchange, we anticipate requesting

additional documentation that demonstrates a State's ability to successfully operate a State Exchange, including documentation that demonstrates progress toward implementing a State Exchange. Moreover, we disagree that States that have previously established a State Exchange did not submit such documentation. The current State Exchange Blueprint application already includes requests for supporting documentation that a State is progressing toward meeting State Exchange Blueprint application requirements. Therefore, this provision codifies existing policy, which existing State Exchanges have complied with. We believe these regulations will underscore to States the importance of submitting supporting information that we request, which we have regularly pursued with all States that have transitioned to State Exchanges over the past several years.

Comment: One commenter stated that although they saw the benefit in our proposal to require that at some point following a State's submission of its State Exchange Blueprint application to HHS a State must conduct at least one public engagement, they did not agree with such public engagements taking place every 3 months. The commenter noted that conducting public engagements every 3 months could be too burdensome on a State, which would delay a State in its State Exchange implementation plans. This commenter requested additional detail on the significance of this proposal.

Response: We proposed that following a State's submission of its State Exchange Blueprint application to HHS, a State must conduct at least one public engagement (such as a townhall meeting or public hearing) in a timeline and manner (for instance, considering whether to conduct in-person and/or virtually) considered effective by the State. Additionally, we proposed that during a State's process of establishing a State Exchange, and until HHS has approved or conditionally approved the State Exchange Blueprint application, it must periodically conduct additional public engagements. We did not prescribe how often these public engagements must occur, and we encourage States to hold them as frequently as would be beneficial to its State Exchange planning and to keeping its interested parties informed.

We believe any potential burden on States from conducting regular public engagement is outweighed by the benefit to interested parties, such as consumers and advocate groups, in having the opportunity to learn about,

and provide input on, a State's Exchange implementation plans, which the State may utilize in developing its State Exchange implementation plans.

Comment: One commenter suggested that CMS require States to request feedback on its Blueprint application during the public engagements from a set group of interested parties which would include agents, brokers, and EDE entities.

Response: We encourage States that are establishing a State Exchange to utilize the public engagement provisions as a pathway to fulfilling its stakeholder consultation requirements under § 155.130, which requires a State Exchange to regularly conduct stakeholder consultations with certain entities, including agents and brokers. In meeting the public engagement policies being finalized in this rule, we encourage States to seek feedback from these particular groups as specified in § 155.130, as well as other groups, such as EDE entities, so that the State's efforts can translate into its required stakeholder consultation requirements under § 155.130.

Comment: One commenter stated that they supported the proposal, but urged CMS to ensure that it provides States with sufficient resources to facilitate a transitioning State's demands.

Response: We have established a robust program to support States that seek to establish a State Exchange and to ensure that the transition of consumers from the Federal platform to the State Exchange is as seamless as possible. This includes having dedicated teams to support States in establishing a State Exchange, well defined processes for assessing a State Exchange's operational readiness and transitioning of the State's consumers and Exchange functions off the Federal platform, and a technical assistance program to ensure State Exchange functions meet Federal requirements. We also have the ability to adjust the support we provide to respond to State-specific needs during a State's process for establishing a State Exchange. We will continue to consider these needs when supporting any State that decides to establish a State Exchange in the future.

Comment: One commenter stated that the proposed regulations do not address consequences if a State fails to meet Federal standards after implementing a State Exchange, and suggested that we delineate corrective action plans, civil monetary penalties, or other actions that would be taken if a State Exchange fails to meet Federal standards.

Response: We utilize specific oversight processes and tools (for

¹²⁵ See section 1321 of ACA.

example, the State-based Marketplace Annual Reporting Tool, along with independent external programmatic and financial audits), under the authority at § 155.1200, to assess State Exchange compliance with Federal rules on an ongoing basis. This process generally involves working with States to ensure that they are able to respond to, and take corrective action on, any identified deficiencies before civil monetary penalties are assessed or other enforcement actions are taken. Under section 1313(a)(4) of the ACA, if HHS determines that an Exchange has engaged in serious misconduct with respect to compliance with Exchange requirements, it has the option to rescind up to 1 percent of payments due to a State under any program administered by HHS until such misconduct is resolved. We will also consider the development of new guidance in the future to enhance transparency of Exchange operations and compliance by State Exchanges with Federal requirements.

Comment: A few commenters suggested that we require States that are establishing a State Exchange to provide a formal notice and comment period to the public after a State's Blueprint application is publicly posted. One commenter suggested that HHS publicly post a State's Blueprint application within 30 days of receipt, instead of the 90-day period mentioned in our proposal for this rule.

Response: We appreciate the suggestion to consider requiring that States provide a formal notice and comment period to the public after their Blueprint application is posted. At this time, we believe that the new requirement at § 155.106(a)(2)(ii) requiring a State to conduct at least one public engagement at which interested parties can learn about the State's intent to establish a State Exchange and the State's progress toward executing that transition, provides sufficient notice and ability for interested parties to comment. We will consider this suggestion for future rulemaking if we observe that the new requirement results in States being unable to obtain feedback from interested parties on a State's transition. Additionally, we appreciate the suggestion that HHS publicly post a State's Blueprint application within 30 days of receipt, instead of the 90-day period mentioned in our proposal for this rule, and we agree that publicly posting the application within this timeframe would benefit the public by providing more time and opportunities for interested parties to provide comments to us and the State. Accordingly, we

intend to publicly post a State's Blueprint application within 30 days upon receipt by HHS. HHS would only post a State's initial Blueprint application,

Comment: One commenter suggested that we require States, as part of their Blueprint application, to submit documentation providing enrollment targets and plans to reduce the uninsured population and improve coverage in the initial years following the establishment of their State Exchange. Another commenter suggested that we require States to demonstrate clear metrics towards meeting their Blueprint goals on a periodic basis, after completing the Blueprint approval process.

Response: We appreciate the suggestions from these commenters. We will consider the development of new tools in future rulemaking that would enhance transparency into the performance of Exchanges, both for States newly transitioning to a State Exchange and for existing State Exchanges.

3. Additional Required Benefits (§ 155.170)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82553), we proposed to amend § 155.170(a)(2) to provide that a covered benefit in a State's EHB-benchmark plan would be considered an EHB. We are finalizing this policy as proposed, except for minor grammatical changes to improve clarity.

Under this policy, there will be no obligation for the State to defray the cost of a State mandate enacted after December 31, 2011, that requires coverage of a benefit covered in the State's EHB-benchmark plan. Benefits that are covered in a State's EHB-benchmark plan would not be considered in addition to EHB and would remain subject to the various rules applicable to the EHBs, including the prohibition on discrimination in accordance with § 156.125, limitations on cost sharing in accordance with § 156.130, and restrictions on annual or lifetime dollar limits in accordance with § 147.126.

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

Under longstanding policy, benefits mandated after December 31, 2011, other than for compliance with Federal requirements, are considered in

addition to EHB (and thus not EHB) without regard as to whether the mandated benefits are embedded in the State's EHB-benchmark plan. Specifically, under § 155.170, a State mandate is considered 'in addition to EHB' if it: is the result of State action taken after December 31, 2011;¹²⁶ requires coverage of benefits specific to care, treatment, and services;¹²⁷ requires QHPs to cover the benefits;¹²⁸ and was not enacted to comply with Federal requirements. As a result, States must defray the associated costs of QHP coverage of such benefits, and those costs may not be included in the percentage of premium attributable to coverage of EHB for purpose of calculating APTC. In addition, because the benefits are not EHB, they are not subject to EHB nondiscrimination rules at § 156.125, the annual limitation on cost sharing at § 156.130, and restrictions on annual or lifetime dollar limits at § 147.126.

In the years since we finalized § 155.170, we received feedback from States and other interested parties, including in comments submitted to the EHB RFI (87 FR 74097) that we issued in 2022, that we should reconsider this provision. This feedback indicated that States struggle to understand and operationalize § 155.170, and that States that seek to mandate coverage of benefits are unintentionally removing EHB protections from benefits already included in the State's EHB-benchmark plan.

We believe that finalizing the proposal will promote consumer protections and facilitate compliance with the defrayal requirement by making the identification of benefits in addition to EHB more intuitive.

Under the policy, if a State mandates coverage of a benefit that is in its EHB-benchmark plan, the benefit will continue to be considered EHB and the State will not have to defray the costs of that mandate. However, if at a future date the State updates its EHB-benchmark plan under § 156.111 and removes the mandated benefit from its EHB-benchmark plan, the State may have to defray the costs of the benefit

¹²⁶ EHB Rule (78 FR 12838). A State action can be by statute, regulation, guidance, or other State action. 2017 Payment Notice (81 FR 12242).

¹²⁷ Requirements related to provider types, cost sharing, benefit delivery methods, or reimbursement methods are not specific to care, treatment, and services. EHB Rule (78 FR 12838).

¹²⁸ If a State action applies to the individual and small group markets, it applies to QHPs; if a State allows for the sale of large group plans as QHPs, a State-mandated benefit for the large group market applies to QHPs. EHB Proposed Rule (77 FR 70647 through 70648) (finalized without modification in the EHB Rule (78 FR 12838)).

under the factors set forth at § 155.170 as it will no longer be an EHB after its removal from the EHB-benchmark plan. In addition, starting in PY 2025, a State that is defraying the costs of a benefit required by a mandate that is in addition to EHB under § 155.170 will be permitted to cease defraying the costs of that benefit if the benefit is included in its EHB-benchmark plan or upon updating its EHB-benchmark plan in the future to include such benefit coverage.

As stated in the proposed rule (88 FR 82553), we acknowledge that there are States that may have been defraying the costs of benefits under the current policy that will be able to stop defraying those costs since we are finalizing this policy. We proposed this change to be effective starting with plan years beginning on or after January 1, 2025, to allow for issuers to make necessary modifications to their plan designs and plan filings to reflect any possible changes in designation of benefits as EHB as a result of this policy. For example, under this policy, if a State ceases defraying the costs of a State-mandated benefit to issuers because it is covered in its EHB-benchmark plan, issuers will update their plan filings accordingly beginning in PY 2025 to reflect that the benefit is covered as an EHB and will be included in the percentage of premium attributable to coverage of EHB for the purpose of calculating APTC. We also noted that those States will not be able to recoup the cost of benefits they have already defrayed. In addition, we acknowledge that the start and end dates of State legislative sessions vary greatly by State, and that this policy may occur during State legislative sessions that are considering State actions that will be impacted by the change.

We noted that this policy may impact health plans that are not directly subject to the EHB requirements, such as self-insured group health plans and fully-insured group health plans in the large group market that are required to comply with the annual limitation on cost sharing and restrictions on annual or lifetime dollar limits in accordance with applicable regulations with respect to such EHBs.¹²⁹ Such plans will be affected by this policy only to the extent that a State changes benefits in its EHB-benchmark plan and such plan selects that State's EHB-benchmark plan for purposes of defining EHBs covered by the plan that are subject to the annual

limitation on cost sharing and prohibition on lifetime and annual dollar limits under sections 2707 and 2711 of the PHS Act, respectively. It may also impact a Basic Health Program (BHP) established under section 1331 of the ACA and Medicaid Alternative Benefit Plans (ABPs) implemented pursuant to section 1937 of the Act.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed with minor grammatical changes to improve clarity. We summarize and respond to public comments received on the proposed defrayal policy below.

Comment: Most commenters supported the proposed updates to our EHB mandate defrayal policy. Commenters cited myriad concerns with current mandate defrayal policy that would be alleviated by the proposal.

State regulators and advocacy groups stated that there has been confusion around operationalizing existing Federal requirements for the defrayal of State-mandated benefits. Commenters asserted that this policy change would alleviate an apparent inconsistency between §§ 155.170 and 156.111 under which a benefit could be “essential” for purposes of a State's EHB-benchmark plan selected by each State under § 156.111, but “not essential” for purposes of the defrayal requirement under § 155.170. Many commenters noted that the confusion related to defrayal under current policy was deterring States from addressing benefit coverage in their States through mandates.

A few commenters noted that, currently, it is a costly and time-intensive process for States to conduct mandate reviews to determine whether a new benefit would be subject to defrayal. They noted that because the proposal ultimately would make it easier to understand what benefits are EHB, it will help State regulators ensure that patients and consumers receive the protections that attach to EHB and facilitate decision-making by State policymakers seeking to ensure a robust benefit package for Exchange consumers. Many commenters supported the proposal to ensure that EHB maintain their protections, regardless of whether a State mandates it.

Many commenters noted the clarity from the proposed change will allow States to be more responsive to the needs of their States and specifically help advance health equity, mitigate health disparities, and improve access for those with disabilities and chronic conditions. A commenter noted that

EHBs retaining protections, such as nondiscrimination rules, limitations on cost sharing, and restrictions on annual or lifetime dollar limits, is crucial for patients, particularly those with chronic conditions or complex health care needs, as it ensures access to essential health services with less financial burden.

Response: We understand that whether a State mandate will require defrayal is an important consideration for State policymakers. We agree with commenters that amending § 155.170(a)(2) to provide that a covered benefit in a State's EHB-benchmark plan is considered an EHB will make it easier for State policymakers to make defrayal determinations because it will be clearer that benefits in an EHB-benchmark plan do not require defrayal. We also anticipate that this change will help States and legislatures to understand the consequences of mandating benefits better and make it simpler overall for States to address health equity concerns in their States through mandates and EHB-benchmark plan updates.

Comment: State Departments of Insurance noted that the date-based cutoff for State-mandated benefit defrayal under § 155.170(a)(2)—under which a benefit that is required by State action taking place on or after January 1, 2012, is not EHB—inhibits State innovation in QHP benefit design. A comment from one State's Department of Insurance noted that, from the perspective of a legislator, the current defrayal rules can be perceived as an impediment to updating coverage to reflect new developments in health care delivery. One commenter stated that the current mandate defrayal policy discourages certain States from passing life-saving cancer-related mandates because of the cost or complications in implementing defrayal. Another commenter noted that several initiatives to expand mandated benefits in its State have either been unsuccessful or were delayed due to the possibility of a mandate defrayal.

Response: These comments are consistent with feedback we have received about this provision prior to this rulemaking. In the years since we finalized § 155.170, we have received feedback from States and other interested parties that we should reconsider the policy, including in comments submitted to the EHB RFI (87 FR 74097) that we issued in 2022. Many commenters to the EHB RFI specifically recommended repealing or modifying § 155.170(a)(2) to define benefits in a State's EHB-benchmark plan as not “in addition to EHB.” In our experience, States often are unsure whether they are

¹²⁹ See parallel requirements to § 147.126 at 26 CFR 54.9815–2711, and 29 CFR 2590.715–2711. Additionally, section 2707(b) of the PHS Act, as added by the ACA, was adopted by reference into section 9815 of the Code and section 715 of the Employee Retirement Income Security Act (ERISA).

making correct defrayal determinations due to the complexity of the current policy. Throughout the years of providing technical assistance to States analyzing whether mandates require defrayal, one of the most common areas of confusion has been an apparent inconsistency between Sections §§ 155.170 and 156.111, regarding whether a benefit can be “essential” for purposes of the Federally required EHB-benchmark plan selected by each State, but not be an EHB for the purposes of defrayal. We agree with commenters that States have struggled to understand and operationalize the requirements under current mandate defrayal policy and that the amendments we propose to § 155.170 will resolve such confusion. Therefore, we are finalizing the proposal to amend § 155.170(a)(2) to provide that a covered benefit in a State’s EHB-benchmark plan is considered an EHB. We believe this amendment will facilitate compliance with the defrayal requirement by making the identification of benefits in addition to EHB more intuitive.

Comment: Many commenters expressed concern that some State efforts to mandate certain benefits could unintentionally result in removing EHB protections from benefits already included in the State’s EHB-benchmark plan. Several commenters noted that the current policy has created unnecessary uncertainty related to EHB protections and financial barriers for people enrolled in EHB coverage.

Response: The finalization of this policy will preserve EHB protections for benefits in a State’s EHB-benchmark plan, and there would be no obligation for States to defray the cost of any State mandate enacted after December 31, 2011 that requires coverage of a benefit covered under a State’s EHB-benchmark plan. Benefits that are covered in a State’s EHB-benchmark plan will be subject to the various rules applicable to EHB, including the prohibition on discrimination in accordance with § 156.125, limitations on cost sharing in accordance with § 156.130, and restrictions on annual or lifetime dollar limits in accordance with § 147.126.

Comment: Several commenters that opposed the proposal asserted that permitting States to deem a benefit EHB by reference to its inclusion in an EHB-benchmark plan contradicts the statutory intent of the ACA’s EHB framework, which the commenters asserted intended a comprehensive assessment of typicality among commercial coverage amidst a series of clear statutory guardrails. A commenter asserted that section 1302 of the ACA authorizes HHS to define EHB, but

noted that it does not allow it to do so in a manner that elevates State EHB-benchmark plans to a place of prominence not envisioned by the statute. A commenter urged CMS to be cautious of interpreting what constitutes an EHB too broadly and suggested that the definition of “essential” health benefits should remain focused on a set of benefits that follow the categories established in the ACA and should be representative of benefits offered in a “typical employer plan,” as required under the statute.

A few commenters that opposed the proposal suggested that it would permit States to avoid defraying the cost of any additional benefit so long as they updated their EHB-benchmark plans, effectively nullifies the cost defrayal obligation, and cannot be squared with the statute’s requirements. Those commenters asserted that Congress struck a careful balance in section 1311(d)(3)(B) of the ACA; it afforded States the authority to mandate additional benefits but required them to defray costs when doing so.

Commenters who supported the proposal noted that the proposal is more consistent with the plain language and intent of section 1311(d)(3)(B) of the ACA which requires States to defray the cost of benefits that are “in addition to the essential health benefits” than the existing requirements related to defrayal. One commenter noted the proposal will benefit consumers by ensuring that QHPs include the full range of benefits commonly included in typical employer plans in a State, consistent with the intent of the ACA’s EHB provision. A few commenters noted that limiting EHB-benchmark benefits that do not require defrayal only to those enacted on or before December 31, 2011, was arbitrary and limits the ability of States to ensure plans meet the current needs of consumers. Another commenter noted that requiring a State to defray a mandate for coverage of a benefit for which coverage was already required under the State’s EHB-benchmark plan makes little sense and it also does not comport with the language of the ACA. Several commenters noted that the proposal applied a commonsense approach and would make the identification of benefits in addition to EHB more intuitive and innate.

Response: This policy change aligns with the plain language and intent of the ACA. Section 1311(d)(3)(B)(ii)(II) of the ACA requires States to defray the cost of any additional benefits described in clause (i), which refers to any benefits that the State requires a QHP to offer in addition to the essential health benefits

specified under section 1302(b). Section 1302 of the ACA grants the Secretary broad authority to define EHB, directs that the EHB be equal in scope to the benefits provided under a typical employer plan, and that they include items and services in at least 10 general categories of EHB. Exercising the authority under section 1302(b), in 2013 we defined EHB using a benchmark-based approach whereby the State selects an EHB-benchmark plan that is utilized as a reference document for all plans subject to the EHB requirements in the State. Even after revisions to the EHB-benchmark policy over the years, States remain primarily responsible for selecting an EHB-benchmark plan that complies with scope of benefit requirements that ensure the EHB-benchmark is equal to the scope of benefits provided under a typical employer plan. This EHB-benchmark selection process is the cornerstone of how States define EHB, and we believe finalizing a policy whereby all benefits covered in a State’s EHB-benchmark plan remain EHB revises the defrayal policy in a manner more consistent with the ACA, as well as the EHB-benchmark plan selection process. States will continue to be required to defray the cost of State mandated benefits that are in addition to EHB under the finalized standard.

We further note that this proposal is not introducing a change regarding benefits in an EHB-benchmark plan generally being EHB. Under longstanding policy, EHB are defined by HHS with a State benchmark-based framework, such that an issuer subject to EHB requirements must provide benefits that are substantially equal to the benefits selected by the State in its EHB-benchmark plan. Furthermore, statutory guardrails on States expanding EHB in their States remain in place. As described in the preamble to § 156.111, the typicality standard functions as both a ceiling and floor to limit a State’s EHB-benchmark plan selections. Benefits can be defined as EHB in a State through two avenues: (1) they were mandated by State action prior to December 31, 2011, and/or (2) they are included in a State’s EHB-benchmark plan or otherwise required as EHB pursuant to § 156.115. The distinction of which avenue defines a benefit as an EHB is meaningless for all purposes except for the analysis of defrayal obligations arising from State mandates and for whether the benefit can be substituted under § 156.115(b). Under the prior policy, a benefit that was selected as an EHB in a State’s EHB-benchmark plan could shift to being a

benefit that is “in addition to EHB” for purposes of defrayal if the State mandates such coverage after December 31, 2011, and the State did not have a mandate for such coverage in place prior to December 31, 2011. Under the finalized policy, there will be no obligation for the State to defray the cost of a State mandate enacted after December 31, 2011, that requires coverage of a benefit covered in the State’s EHB-benchmark plan.

Comment: One commenter suggested that the proposed change to the additional benefits rule is impermissibly arbitrary and capricious under the Administrative Procedure Act (APA) because it fails to address how the current rule is designed to guard against the concern, previously recognized by the agency, that a State could “embed any desired benefit mandate into the EHB-benchmark plan, without any requirement to defray the obligation” (83 FR 17010). Another commenter commended HHS for responding to interested party comments submitted to the EHB RFI (87 FR 74097). Another commenter suggested that the statutory language does not contain an exception to the defrayal process for benefits that become EHB because of their inclusion in a State’s EHB-benchmark plan. That commenter asserted that the proposal departs from the plain language of the ACA, as well as the defrayal framework as developed through years of rulemaking and guidance, and suggested that, rather than introducing further ambiguity into the EHB cost defrayal process, CMS reiterate the position it articulated in the 2019 Notice of Benefit and Payment Parameters that State-required benefits mandated by State action taking place after December 31, 2011, other than for purposes of compliance with Federal requirements, would continue to be considered in addition to EHB even if embedded in the State’s newly selected EHB-benchmark plan under the proposals at § 156.111.¹³⁰

Response: We acknowledge that a concern over States embedding any desired benefit mandate into their EHB-benchmark plan without any requirement to defray the obligation informed the finalization of the requirements in the 2019 Payment Notice. However, in the 5 years since that rule was finalized, we have received consistent feedback that the standard was confusing and hindering State compliance with defrayal requirements. Many commenters to the EHB RFI in 2022 specifically recommended repealing or modifying

§ 155.170(a)(2) to define benefits in a State’s EHB-benchmark plan as not “in addition to EHB.” Further, States are limited in the benefits that they can embed in their EHB-benchmark plans, as they must continue to meet the requirements as finalized in this rule at § 156.111(b)(2)(ii). We believe the consumer protections resulting from this policy change outweigh the prior concern over States embedding any desired benefit mandate into their EHB-benchmark plan without any requirement to defray.

Comment: Many commenters that opposed the proposal expressed concerns that it would lead to a dramatic increase in the volume of State benefit mandates and drive-up premiums for consumers and employers, increase costs for the Federal Government and taxpayers, and reduce the availability of affordable Exchange plan options. A few commenters who supported the proposal also noted that State policymakers must be cognizant of the impact any new mandates could have on premiums and Federal tax credits. A State’s Department of Insurance noted that allowing the State to require QHPs to cover additional benefits without defrayal of costs provides the State needed flexibility over plan benefits to optimize affordability and health benefit comprehensiveness.

Response: Based on experience providing technical assistance to States that are considering State-mandated benefits or changes to its EHB-benchmark plans, we believe that States appropriately balance the need for coverage of a specific benefit with the potential impact it may have on costs. This analysis typically includes a consideration of the impact on premiums and the corresponding impact on tax credits. We do not disagree with commenters that this amendment may result in increased Federal outlays in the form of higher APTC; however, this defrayal rule does not increase the opportunity for States to increase the generosity of their EHB-benchmark plans more than is already theoretically possible, as States have been always permitted to add benefits to their EHB-benchmark plan, provided those additions comply with the scope of benefits requirements at 45 CFR 156.111(b)(2). In States that update EHB-benchmark plans to add benefits, the costs of which are currently being defrayed by the State, the percentage of premium attributable to coverage of EHB for purpose of calculating would increase just as if the State updated its EHB-benchmark plan through the process set forth in § 156.111 and in

compliance with the scope of benefits requirements. In a State that enacts a mandate for a benefit that is currently covered in its EHB-benchmark plan, there will be no effect on premium tax credits as the benefit was already included in the percentage of premium attributable to coverage of EHB for purpose of calculating since it was EHB.

Comment: A few commenters expressed concern that under the proposed rule, there is no guardrail to prevent manipulation of the EHB-benchmark plan to avoid cost defrayal—especially because the agency is also proposing to eliminate the generosity standard at § 156.111 that limits the selection of benefits in EHB-benchmark plans. A commenter stated that in light of removing the generosity standard it is negligent of CMS to propose rules that do not require a financial analysis of the costs that may be incurred by mandates and expressed concern that without such financial analysis, CMS has no method of determining the cost of the new plan, which, with enhanced benefits, may have substantially higher premiums and increase the cost of APTC that will be incurred by the Federal Government.

A commenter articulated a sequence of events this commenter believes could lead to States manipulating the EHB-benchmark plan update process to avoid defrayal. The commenter supposed that a State enacts a mandate applicable only to large group health plans (and not QHPs) which would not require defrayal. Afterwards, the State updates its-EHB-benchmark to cover that benefit, using the large group plans that were required to cover it as a reference point for a “typical” employer plan. Individual and small group plans would then be required to cover the benefit as an EHB, with no cost defrayal—even though the benefit was not included in any typical employer plan before the State mandated it. The commenter stated that CMS has provided no reasonable justification for opening the door to such manipulation, nor any alternative guardrails. A different commenter noted a similar concern that under the proposal, States could seamlessly switch from State action to benchmarking for mandates without incurring costs, and existing mandates could transition into EHBs through EHB-benchmark plan updates.

Another commenter remarked that changes to a State’s EHB-benchmark plan take a long time (noting that if a State identifies a particular need in the summer of 2024, it would not be able to adopt a new EHB-benchmark plan that addressed that need until, at a minimum, plan year 2027). The

¹³⁰ 85 FR 29164, 29218.

commenter stated that States may legitimately believe that the EHB-benchmark update timeline is unacceptable when lack of coverage for a particular service is contributing to health disparities and worsening the health of the State's population. As a result, the commenter explained that some States have contemplated the option of enacting a mandate through legislation or administrative action that has immediate effect, while at the same time pursuing changes to the EHB-benchmark for a later date. While these States will likely be subject to defrayal requirements for the period of time that the State mandates coverage of a benefit without that benefit being covered under the State's EHB-benchmark plan, a State may be willing to assume temporarily the costs of mandated benefits in order for the benefit to be available to State residents sooner than the benefit can or will be added to the State's EHB-benchmark plan. The commenter noted that the policy, however, seems to indicate that once a State is subject to defrayal, it will continue to have to defray even if a benchmark change is subsequently adopted. The commenter suggested this result seems to be an unintended loophole in the current rules that is not necessary to advance the goals of the ACA, and its only effect is to deter States from seeking necessary coverage changes.

Response: We are not persuaded that States will use the additional flexibility afforded by this proposal to add unbounded benefits as EHB. In our experience providing technical assistance to States regarding State-mandated benefits and EHB-benchmark plan updates, States approach the provision of health benefits in good faith and with great consideration for ensuring balance between an appropriate scope of covered benefits with any corresponding increase in costs. States must continue to operate within the overall EHB framework established by HHS, and we intend to continue to provide robust technical assistance to States to ensure their compliance.

Further, we believe that the generosity standard is not necessary to ensure the State EHB-benchmark plan selections are not unbounded given that, as described in the preamble to section 156.111, the typicality standard functions as both a ceiling and floor to limit a State's EHB-benchmark plan selections. Specifically, the typicality standard alone limits the potential generosity of a State's EHB-benchmark plan to be no greater than the generosity provided by the most generous typical

employer plan, because a State would be unable to demonstrate that a more generous plan was equal in scope to any of the typical employer plans defined at § 156.111(b)(2)(i).

The scenario the commenter was concerned about would allow for manipulation of the EHB-benchmark plan update process would not, in practice, present an opportunity for manipulation. States have been able to add individual benefits to their EHB-benchmark plans through the update process outlined at § 156.111 since the 2019 Payment Notice (83 FR 16930, 17009), which provided States with additional flexibility with respect to the benefits and coverage in the EHB-benchmark plans. In addition, we note that the EHB-benchmark plan update process is not instantaneous, and States incur costs to update their EHB-benchmark plans.

We believe there is a high likelihood that confusion related to the existing mandate defrayal policy has made it difficult for interested parties to discern whether States are complying with the defrayal requirements. With clearer standards, there will be less confusion about State defrayal obligations.

We agree that the policy subjecting a State to defrayal of a benefit even if the State subsequently adds coverage of that benefit to the State's EHB-benchmark plan is counterintuitive and does not advance the goals of the ACA.

Comment: A commenter suggested that if the proposal is finalized, it would only apply to benefits that are "already covered in the State's EHB [benchmark plan]" at the time the mandate is passed rather than applying prospectively to benefits added to a benchmark plan after the mandate is passed.

Response: We believe this commenter's approach would not sufficiently address the concerns about benefits that States, issuers, and consumers believe are subject to EHB protections (based on their inclusion in a State's EHB-benchmark plan) not being EHB because of the defrayal provision. The approach would also further perpetuate a complex and confusing standard. Furthermore, under the commenter's suggestion, a State mandate would result in certain benefits never being able to become EHB (regardless of whether they are added to the EHB-benchmark plan in the future).

Comment: A commenter requested that HHS reiterate that State legislation stating that a benefit mandate is not to be considered an addition to EHB does not override the defrayal requirement. The commenter also expressed concern over the increasing trend for States to pass legislation with clauses stating that

a benefit mandate will not be operative if there is a finding that the mandate requires defrayal under the requirements in § 155.170.

Response: States may not exempt themselves from the Federal requirement to defray State mandated benefits that are in addition to EHB through State legislation. While clauses stating that a benefit mandate will not be operative if there is a finding that the mandate requires defrayal are not prohibited by § 155.170, we caution States that, absent clear direction from the State following the bill's passing as to whether or not the State has identified the required benefit as in addition to or not in addition to EHB, such clauses cause confusion for issuers about whether a benefit mandate is in effect and whether the benefit is in addition to EHB (and therefore whether the benefit is subject to the various rules applicable to the EHBs, including the prohibition on discrimination in accordance with § 156.125, limitations on cost sharing in accordance with § 156.130, and restrictions on annual or lifetime dollar limits in accordance with § 147.126). We recommend that States issue bulletins or guidance for issuers with a determination of whether the benefit mandate is in effect as soon as possible after conducting an analysis of whether the benefit mandate requires defrayal.

We have also noticed State legislative bills that include clauses stating that the requirement to defray mandates is precluded if HHS fails to respond to the State's request for confirmation of whether new mandates require defrayal within a certain time. Under § 155.170, such provisions do not comply with § 155.170 as they inappropriately put the onus on HHS to decide whether the mandate is in addition to EHB rather than on the State. Failure by HHS to respond to State requests asking for a determination of whether new mandates require defrayal does not excuse States from defrayal requirements. Under § 155.170, it is the State's responsibility to identify which State required benefits require defrayal. While States are encouraged to reach out to us concerning State defrayal questions in advance of passing and implementing benefit mandates, HHS does not provide determination of whether a benefit mandate requires defrayal.

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

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82554), we proposed at § 155.205(a) to establish additional minimum standards for Exchange call

center operations, including requirements that all Exchanges, other than SBE-FPs and SHOP Exchanges that do not provide for enrollment in SHOP coverage through an online SHOP enrollment platform, meet the following additional requirements: their call center must provide consumers with access to a live call center representative during the Exchanges' published hours of operation; and their live call center representatives must be able to assist consumers with their QHP application, which includes providing consumers information on their APTC and CSR eligibility, helping consumers understand their QHP options, helping consumers select a QHP, and helping consumers submit QHP enrollment applications to the Exchange. We are finalizing these standards with modifications.

Currently, § 155.205(a) requires that Exchanges provide for operation of a consumer-accessible, toll-free call center that addresses the needs of consumers requesting assistance. For a State requesting to establish a State Exchange, we review its plans to implement and meet call center requirements under § 155.205(a) as described in the State Exchange Blueprint application. Through the Blueprint process, we review and assess a State's call center operational plan for consistency with standards governing its hours of operation, staffing levels, and service level goals (including wait times and abandonment rates), as well as for consistency with best practices utilized by existing Exchanges, including the FFEs' call center. Once a State Exchange has been established and is operating, HHS monitors Exchange call center operations through the annual collection of performance monitoring data, as specified at § 155.1200(b)(3). The data collected includes call center volume, wait times, calls abandoned, and average call center handle time.¹³¹

As stated in the proposed rule (88 FR 82554), we recognize the value in each Exchange being able to tailor customer service level expectations based on their experience in the areas they serve, including setting hours of operation that meet the needs of their consumers. As such, we did not propose to establish minimum standards for customer service staffing levels. We will continue to assess and monitor Exchanges' compliance with § 155.205(a) through the Blueprint process and annual collection of compliance reports, as specified at § 155.1200(b)(2). We also intend to utilize the finalized requirement that transitioning States

submit documentation through their Blueprint application, which will strengthen our review of Exchange call center plans.

In this final rule, we are requiring that all Exchanges, other than SBE-FPs and SHOP Exchanges that do not provide for enrollment in SHOP coverage through an online SHOP enrollment platform, meet the following additional requirements: their call center must provide consumers with access to a live call center representative during the Exchanges' published hours of operation; and their live call center representatives must be able to assist consumers with their Exchange application, which includes providing consumers information on their APTC and CSR eligibility, facilitating a consumer's comparison of QHPs, and helping consumers submit their Exchange applications to the Exchange.

Sections 1311(d)(4)(B) and 1321 of the ACA require that Exchanges provide for the operation of a toll-free telephone hotline to respond to requests for assistance, and section 1413(b)(1)(A)(ii) of the ACA requires that a consumer's application for QHP coverage can be filed by telephone. We believe that our policy will support these statutory requirements by ensuring that consumers have access to live representatives with Exchange call centers, during a reliable window of time, who can assist consumers with their Exchange applications.

We believe that all State Exchange call centers already meet the minimum standards that were proposed, and we know that the call center for the Exchanges on the Federal platform are meeting them. As such, this policy seeks to standardize and strengthen Exchange consumer assistance capabilities without imposing additional burden on current Exchanges or hindering Exchanges' ability to be innovative in their call center functions. The changes finalized here will ensure that regardless of where a consumer is in the United States, the consumer will be able to speak to a live representative who can assist the consumer with the Exchange application process during the hours of operation for that State's call center. We also want to ensure that a State does not solely rely on an automated telephone system for Exchange application assistance because we believe speaking to a live representative will help troubleshoot consumer Exchange application issues, provide in real time an opportunity for a live representative to explain Exchange application terminology to a consumer, ensure the consumer provides the most correct information in the QHP application to

alleviate unnecessary follow-up, and provide greater overall consumer satisfaction. We believe that call centers should have a basic level of customer service especially as they relate to hours and operations and staffing levels to limit wait times for Exchange application assistance. We also know based on our work with State Exchanges and the Exchanges on the Federal platform that the Exchanges have created and continue to maintain robust call centers.

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision with modifications to the proposed language at § 155.205(a) to clarify the role of a live call center representative during the Exchanges' published hours of operation is to assist consumers with submitting their Exchange application as required at § 155.405(c)(2)(ii).

We summarize and respond to public comments received on the proposed minimum standards for Exchange call center operations below.

Comment: Some commenters expressed concerns that the proposed requirement was meant to replace or duplicate the act of insurance sales or to significantly increase the scope of the assistance currently provided through an Exchange's live call center representatives.

Response: The intent of the proposal was not to revise the scope of assistance currently provided by live call center representatives, and instead was meant to bolster the consumer experience while Exchanges meet the basic statutory requirements at sections 1311(d)(4)(B) and 1413(b)(1)(A)(ii) of the ACA, which requires Exchanges to provide for the operation of a toll-free telephone hotline to respond to requests for assistance and to provide consumers with the ability to file an Exchange application by telephone.

Comment: Several commenters cited benefits to the proposal including increased consumer understanding of the Exchange application process through real-time conversation; continuity of coverage across health insurance programs since call centers often also support Medicaid enrollment assistance; and increased assistance to those with limited health insurance literacy, computer literacy, or limited internet access.

Response: We agree with the consumer assistance benefits highlighted in these comments and believe the finalized live call center representative requirement will aid consumers in these ways.

¹³¹ OMB Control Number: 0938-1119.

Comment: Several commenters requested CMS also consider establishing a standard for call center wait times and abandonment rates.

Response: We did not consider wait times or abandonment rates in this proposal as we believe our current oversight mechanisms enable us to sufficiently review call center performance. Currently, § 155.205(a) requires that Exchanges provide for operation of a consumer-accessible, toll-free call center that addresses the needs of consumers requesting assistance. For a State requesting to establish a State Exchange, we review its plans to implement and meet call center requirements under § 155.205(a) as described in the State Exchange Blueprint application. Aside from the call center requirements under § 155.205(a), we utilize the Blueprint process to review and assess a State's call center operational plan for consistency with standards governing its hours of operation, staffing levels, and service level goals (including wait times and abandonment rates), as well as for consistency with best practices utilized by existing Exchanges, including the FFEs' call center. Once a State Exchange has been established and is operating, HHS monitors Exchange call center operations through the annual collection of performance monitoring data, as specified at § 155.1200(b)(3).

Comment: Several commenters requested CMS also consider establishing a standard requiring all call centers provide dedicated lines for consumers with disabilities and/or limited English proficiency.

Response: We did not consider dedicated lines for consumers living with disabilities and/or with limited English proficiency in this proposal. However, to ensure compliance with 155.205(a), we review to ensure that all Exchange call centers have a TTY line service available for consumers living with disabilities, a Spanish version of their website, and a dedicated line for oral interpretation services in at least 105 languages. Further, §§ 155.205(c)(1), (c)(2)(i), and (c)(3) require Exchanges, QHP issuers, and web brokers to provide both written translations and oral interpretations of information in plain language in a manner accessible to consumers with disabilities and limited English proficiency.

Comment: Several commenters stated that alignment of call center standards provides consumers with a more uniform experience regardless of Exchange model type or geography.

Response: We agree that the minimum standard finalized in this proposal will

secure a more level consumer call center experience regardless of where in the country a consumer is located or what Exchange model is operating in their State.

Comment: A few commenters requested CMS make all call center data public similar to the release of Medicaid Unwinding call center data.

Response: We appreciate commenters' interest in publishing Exchange call center data. We are committed to providing transparency into Exchange operations and are exploring the release of call center data at a future time. Additionally, in the interest of transparency, we are considering the development of new tools, potentially through future rulemaking, that will provide further public understanding into the performance of Exchanges.

Comment: A few commenters opposed the proposal citing the need for State flexibility in establishing call center standards including the incorporation of new call center technology to assist consumers.

Response: We appreciate and understand the need for State flexibility to meet the needs of their consumers. This policy does not aim to replace any technological investment States are willing to make to expand their call center offerings. Recognizing that budgetary constraints exist, and States often have to choose how to spend limited resources, we maintain that live call center representatives to assist consumers remains the minimum necessary to ensure sections 1311(d)(4)(B) and 1413(b)(1)(A)(ii) of the ACA are satisfied.

Comment: A few commenters opposed the proposal citing that CMS did not properly justify why the new live representative standard was needed.

Response: We disagree that this live call center representative minimum standard was not properly justified. We recognized and stated in the proposed rule that all Exchanges currently meet the newly proposed standard. However, we cannot guarantee that the minimum standard being finalized will continue to be met in future years by the present Exchanges or by States looking to transition to State Exchanges in the future. As we stated in the proposed rule, we believe speaking to a live representative would help troubleshoot consumer Exchange application issues, provide in real time an opportunity for a live representative to explain Exchange application terminology to a consumer, ensure the consumer provides the most correct information in the Exchange application to alleviate unnecessary follow-up, and provide

greater overall consumer satisfaction. Thus, to ensure continuity of the live call center representative standard, we have decided to finalize this proposal with the modifications noted above.

Comment: A few commenters opposed the proposal stating that requiring live call center representatives to assist a consumer with "selecting a QHP" violated their State laws since only licensed agents and brokers are permitted to engage in the business of insurance product solicitation in that State, and that the proposed standard would create de facto minimum staffing levels.

Response: As we previously explained in this final rule, the intent of this policy was not to revise the scope of assistance currently provided by live call center representatives and was instead meant to bolster the consumer experience while Exchanges meet the basic statutory requirements at sections 1311(d)(4)(B) and 1413(b)(1)(A)(ii) of the ACA, which requires Exchanges to provide for the operation of a toll-free telephone hotline to respond to requests for assistance and to provide consumers with the ability to file an Exchange application by telephone. This policy does not direct live call center representatives to solicit or sell insurance or engage in any similar practice related to insurance that generally requires a license under State law. As such, for the purpose of clarity, we have amended the regulatory language initially proposed in § 155.205(a) to clarify that live call center representatives will be required to facilitate a consumer's comparison of QHPs.

We recognize the value in each Exchange being able to tailor customer service level expectations based on their experience in the areas they serve. Consequently, we did not propose to establish minimum standards for customer service staffing levels. We will continue to assess and monitor Exchanges' compliance with § 155.205(a) through the Blueprint process and annual collection of compliance reports, as specified at § 155.1200(b)(2). As such, we are finalizing this provision with some changes to clarify that the role of a live call center representative during the Exchanges' published hours of operation is to assist consumers with their Exchange application as required at § 155.405(c)(2)(ii).

5. Requirement for Exchanges To Operate a Centralized Eligibility and Enrollment Platform on the Exchange's Website (§§ 155.205(b); 155.302(a)(1))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82554), we proposed to amend § 155.205(b)(4) to require that an Exchange operate a centralized eligibility and enrollment platform on the Exchange's website (or, for an SBE-FP, the Federal eligibility and enrollment platform), such that the Exchange allows for the submission of the single, streamlined application for enrollment in a QHP and insurance affordability programs by consumers, in accordance with § 155.405, through the Exchange's website, and that the Exchange performs eligibility determinations for all consumers based on submissions of the single, streamlined application. Further, we proposed to amend § 155.302(a)(1) to clarify that the Exchange, through the centralized eligibility and enrollment platform operated on the Exchange's website (or, for an SBE-FP, the Federal eligibility and enrollment platform), is the entity responsible for making all determinations regarding the eligibility for QHP coverage and insurance affordability programs regardless of whether an individual files an application for enrollment in a QHP on the Exchange's website or on a non-Exchange website operated by an entity described under § 155.220, such as a web-broker defined at § 155.20, or a DE entity or QHP issuer described under § 155.221. As we believe the eligibility determination function is inherently a function that should only be performed by the Exchange, the amendment to § 155.302(a)(1) also clarifies that only the private vendors or State entities that an Exchange contracts with to operate its centralized eligibility and enrollment platform can perform this function on behalf of an Exchange, and prohibits an Exchange from solely relying on non-Exchange entities, including a web-broker (defined at § 155.20) or other entities under §§ 155.220 or 155.221, to make such eligibility determinations on behalf of an Exchange.

We also proposed to amend § 155.205(b)(5) to require that an Exchange operate a centralized eligibility and enrollment platform on the Exchange's website (or, for an SBE-FP, by relying on the Federal eligibility and enrollment platform) so that the Exchange (or, for an SBE-FP, the Federal eligibility and enrollment platform) meets the requirement under § 155.400(c) to maintain records of all effectuated enrollments in QHPs,

including changes in effectuated QHP enrollments.

As background for these amendments, § 155.205(b) states that an Exchange must maintain an up-to-date website that allows consumers to receive eligibility determinations for QHPs and insurance affordability programs and provides standardized comparative information on each available QHP and a calculator to facilitate the comparison of available QHPs after the application of any APTC and any CSRs. Section 1413(c)(1) of the ACA also requires that Exchanges develop a secure electronic interface that allows consumers to apply for health insurance coverage online and electronically receive an eligibility determination and that Exchanges conduct verifications of eligibility through electronic data interfaces. However, currently, there is no explicit regulatory or statutory requirement that Exchanges operate a centralized eligibility and enrollment platform on their website for performing all eligibility determinations for QHPs and insurance affordability programs. Nonetheless, all Exchanges currently provide access to a centralized eligibility and enrollment platform and process for consumers that they serve, and all Exchanges also currently perform all eligibility determinations through the operation of a centralized eligibility and enrollment platform on their websites. In order to codify existing policy and practices and help set clear expectations for existing Exchanges and States that may seek to operate State Exchanges in the future, we proposed these amendments to require that Exchanges may not allow eligibility determinations to be made outside of the Exchanges' own centralized eligibility and enrollment platform by another entity for applications for QHP coverage nor for selections for enrollment in a QHP.

We also proposed to amend § 155.302(a) to codify the Exchange's obligation and role as the sole entity responsible for conducting eligibility determinations. For example, if an Exchange permits an eligible web-broker to operate a non-Exchange website that interfaces with an Exchange to assist consumers with DE in QHPs offered through the Exchange as described in §§ 155.220(c)(3) and 155.221, the Exchange must ensure that the Exchange continues to maintain responsibility for conducting all eligibility determinations for applications submitted for QHP coverage and related insurance affordability programs. While HHS has not delegated these functions to DE entities in FFE and SBE-FP States,

currently, Exchanges may allow entities described in § 155.220, among others that meet applicable requirements, to be able to function as an eligible contracting entity under § 155.110(a) that can carry out determinations regarding QHP coverage eligibility and eligibility for related insurance affordability programs on behalf of the Exchange. This amendment to § 155.302(a) prohibits Exchanges from delegating the responsibility to conduct eligibility determinations to any non-Exchange entities, besides entities that the Exchanges have elected to contract with to operate the centralized eligibility and enrollment platform. Consistent with these amendments, we proposed to maintain the current requirement under § 155.302(a) that SBE-FPs rely on HHS, through the operation of the centralized *HealthCare.gov* eligibility and enrollment platform, to carry out all eligibility determinations for their Exchanges.

As we also stated in the proposed rule (88 FR 82555), this proposal ties together the disparate, but related, requirements that exist across 45 CFR part 155 that speak to the real-time and tightly integrated nature of the online eligibility functions that Exchanges are required to perform (specifically the tight integration needed between the Exchange-operated website, single streamlined application, and back-end automated eligibility verifications based on information provided by applicants to arrive at an eligibility determination), by clearly stating the principle that Exchanges are solely responsible for conducting eligibility determinations, and that Exchanges need to meet the required eligibility functions that exist across 45 CFR part 155 through operating a centralized eligibility and enrollment platform on their website, regardless of whether an application is submitted through the Exchanges' website or through eligible non-Exchange entities that are assisting an individual in enrolling in a QHP.

We believe the lack of a clear statement in the regulations at 45 CFR part 155 affirming the requirement that the Exchange must make all determinations regarding eligibility for QHP coverage and related insurance affordability programs through a centralized eligibility and enrollment platform on the Exchange's website are oversights, as other sections of the regulations implementing the ACA in title 45 of the CFR allude to a requirement or expectation that an Exchange operates in this way already, or the regulations are written in a way such that it would be difficult to fulfill

their requirements if an Exchange did not operate as proposed in these amendments.

As an example of an implementing regulation of the ACA that would require an Exchange to operate in this manner, § 155.220 permits qualified individuals to be enrolled in a QHP through the Exchange with the assistance of a web-broker, while § 155.220(c)(3)(ii)(A), and by reference § 155.220(c)(3)(i)(F), require that if the non-Exchange website of a web-broker is used to complete an Exchange eligibility application, that web-broker's website must also provide consumers with the ability to withdraw from the process and use the Exchange's website described in § 155.205(b) instead at any time. If an Exchange did not provide an ability on its website for a consumer to complete an eligibility application, then it would not be possible to fulfill the requirements of §§ 155.220(c)(3)(ii)(A) and (i)(F).

To ensure that the requirements of §§ 155.220(c)(3)(ii)(A) and (i)(F), and 155.205(b) are fulfilled, we believe it is important that Exchanges allow a consumer to continue the application process through the centralized eligibility and enrollment platform operated on the Exchange's own website should the consumer chose to withdraw from the application process that was begun on a web-broker's non-Exchange website; or, if the Exchange is an SBE-FP, allow the consumer to continue the application process through the website of the Federal platform.

As another example, QHP issuers that assist consumers with enrollment in QHPs are currently required under § 156.265(b)(2) to either direct the consumer to the Exchange's website to file an eligibility application or ensure that the consumer's eligibility application is completed through the Exchange website or submitted through Exchange-approved web services in order for the Exchange to conduct an eligibility determination. To align with these requirements, we believe that it is important to finalize the amendment to § 155.302(a)(1) to provide that an Exchange must perform all eligibility determinations through operating a centralized eligibility and enrollment platform on the Exchange's website, and that only those entities that an Exchange chooses to enter into an agreement with to operate its centralized eligibility and enrollment platform, as allowed for under § 155.110(a), can carry out this function on behalf of the Exchange.

In addition to these examples of how current regulations may require an Exchange to operate according to the proposed amendments to § 155.205

and 155.302, we believe that consumers may be harmed without these policies in place. If an entity other than the Exchange conducted eligibility determinations, consumers might receive incorrect or inconsistent eligibility determinations, as entities other than the Exchange may not update their systems with the same eligibility determination rules or logic as the Exchange itself when Federal or State policies or regulations impacting eligibility for QHP coverage and insurance affordability programs come into effect or are updated, including the implementation and maintenance of State-specific eligibility rules and logic for Medicaid and CHIP programs. As a result, a non-centralized eligibility system model introduces increased program integrity risk as to the accuracy of eligibility determinations, which introduces increased risk of inaccurate APTC payments to QHP issuers and increased risk to consumers of potential tax liability when filing taxes and reconciling their APTC with the PTC allowed.

In addition, the websites and eligibility platforms provided by non-Exchange entities may not include the same informational content for consumers that an Exchange provides to consumers through the Exchange's website, such as information related to Medicaid and CHIP programs or the availability of special enrollment periods before or after the open enrollment period. As a result, some consumers might not provide information in their application in such a manner as to receive a correct eligibility determination and thus, enroll in the wrong coverage or not enroll in any coverage. Lastly, consumers may prefer to enroll directly through the eligibility and enrollment platform hosted and operated on an Exchange's website because they are more comfortable with sharing their personal information through a platform hosted by the Exchange.

In light of these considerations, we proposed to amend §§ 155.205(b)(4) and (5), and 155.302(a)(1) to address these gaps. Since all Exchanges currently provide access to a centralized eligibility and enrollment platform and process for consumers that they serve, and all Exchanges also currently perform all eligibility determinations through the operation of a centralized eligibility and enrollment platform on their websites, we believe the impact of these policies are minimal.

We sought comment on these proposals.

After consideration of comments and for the reasons outlined in the proposed

rule and our responses to comments, we are finalizing this provision as proposed. We summarize and respond to public comments received on the proposed requirement that an Exchange operate a centralized eligibility and enrollment platform on the Exchange's website below.

Comment: Several commenters opposed the proposed policy requiring a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website, citing that it undermines State flexibility to operate their own Exchanges. One commenter noted that State flexibility is the hallmark of the State Exchange model, and if HHS' goal is for more States to implement State Exchanges, then this proposal should not be implemented. A few commenters opposed to the proposal asserted that HHS is dictating a specific technical approach that will potentially restrict States from employing innovative or more suitable solutions.

Response: As we noted in the preamble to this provision, this proposal codifies and ties together existing regulatory requirements under 45 CFR part 155 that require a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website. Furthermore, all Exchanges currently provide access to a centralized eligibility and enrollment platform and process for the consumers that they serve, and all Exchanges also currently perform all eligibility determinations through the operation of a centralized eligibility and enrollment platform on their websites. While this proposal is consistent with current policy and State practice, there may be States transitioning to State Exchanges in the future that would not prioritize establishing a centralized eligibility and enrollment platform in the absence of this policy. This standard will ensure State Exchange accountability for conducting eligibility determinations, and ensure program integrity in adjudicating eligibility applications, while preserving State flexibility to allow consumers access to DE entity application assisters and permitting web-brokers and QHP issuers to assist consumers with direct enrollment in QHPs. Additionally, this provision does not limit State flexibility to contract with an eligible vendor, State Medicaid agency, or other State agency that may offer various technical solutions for eligibility system operations.

Based upon current State initiatives to transition from an FFE to a State Exchange, as well as ongoing interest in the State Exchange model from other FFE States, we do not believe that

finalizing this policy will meaningfully discourage States from transitioning to or maintaining their status as a State Exchange.

Finally, we disagree that the proposal could limit States' ability to employ innovative or more suitable technical solutions. While the proposal obligates a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website, it is not prescriptive concerning the technical infrastructure supporting the system, nor does it regulate the number and types of entities an Exchange may contract with to develop and operate a centralized eligibility and enrollment platform.

Comment: A few commenters opposed the proposal clarifying that the State Exchange is the entity responsible for making all determinations regarding eligibility for QHP coverage, citing that State Exchanges should have the flexibility to support eligibility and enrollment functions through contractual arrangements with web-brokers or DE entities.

One commenter opposed to the proposal sought clarification regarding whether State Exchanges could leverage EDE entities to support eligibility and enrollment operations, and questioned whether a State Exchange can contract with multiple entities to fulfill the requirement for an Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website. Relatedly, a few commenters opposed to the proposal observed that some State Exchanges' eligibility and enrollment platforms are provided by private entities that serve as web-brokers in other States; these commenters requested HHS clarify that this arrangement is allowable.

One commenter opposed this proposal noting it "conflicts with current regulations that allow web brokers to enroll people in QHPs 'in a manner that constitutes enrollment through the Exchange.'" The commenter asserted that through the regulation's use of the word "constitutes," this regulation allows State Exchanges to establish enrollment pathways that qualify as enrollment through the Exchange, but do not actually enroll consumers through the Exchange.

Response: We are amending § 155.302(a)(1) to clarify that the State Exchange, through the centralized eligibility and enrollment platform operated on the Exchange's website, is the entity responsible for making all determinations regarding eligibility for QHP coverage and insurance affordability programs, regardless of

whether an individual files an application for enrollment in a QHP on the Exchange's website or on a non-Exchange website operated by an entity described under § 155.220, such as a web-broker defined at § 155.20, a DE entity per § 155.221, or a QHP issuer described under §§ 155.221 and 156.1230.

It is necessary to elucidate the Exchange's obligation and role as the sole entity responsible for conducting eligibility determinations to ensure accountability for eligibility determinations, accuracy and uniformity in the eligibility determination process, and consistency with existing regulatory requirements under 45 CFR part 155.

In response to the comment seeking clarification regarding whether State Exchanges can contract with EDE entities for the centralized eligibility and enrollment platform on the Exchange's website, we point to the amendment at § 155.302(a)(1) that prohibits an Exchange from relying on an entity described under § 155.220, such as a web-broker defined at § 155.20, or a DE entity (which includes EDE entities) described under § 155.221, from making eligibility determinations on behalf of the Exchange. Therefore, this regulation precludes DE and EDE entities from entering into arrangements with an Exchange to operate its centralized eligibility and enrollment platform. However, §§ 155.220 and 155.221 detail the scope of the eligibility- and enrollment-related support functions DE and EDE entities can perform on behalf of an Exchange, through an agreement with the Exchange.

In response to the comment inquiring whether a State Exchange can contract with multiple entities to fulfill the requirement for an Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website, we confirm that a State Exchange can enter into an agreement with one or more entities to operate its centralized eligibility and enrollment platform, as allowed for under § 155.110(a), and in accordance with the regulation at § 155.302(a)(1).

As we believe the eligibility determination function is inherently a function that should only be performed by the Exchange, the amendment to § 155.302(a)(1) clarifies that only the private vendors or State entities that an Exchange contracts with to operate its centralized eligibility and enrollment platform can perform this function on behalf of an Exchange, and prohibits an Exchange from solely relying on non-Exchange entities, including a web-

broker (defined at § 155.20) or other entities under §§ 155.220 or 155.221, to make such eligibility determinations on behalf of an Exchange.

In response to the comments observing that some State Exchanges' eligibility and enrollment platforms are provided by private entities that serve as web-brokers in other States, we note that only those entities that an Exchange chooses to enter into an agreement with to operate its centralized eligibility and enrollment platform, as allowed for under §§ 155.110(a) and 155.302(a), can perform eligibility determinations on behalf of the Exchange. In turn, private entities that an Exchange has contractual relationships with outside of operating its centralized eligibility and enrollment platform, would not be allowed to perform eligibility determinations on behalf of the Exchange.

Finally, concerning the comment charging that this proposal conflicts with current regulations allowing web-brokers to enroll qualified individuals in QHPs in a manner that constitutes enrollment through the Exchange, we disagree that the requirement for an Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website is inconsistent with web-brokers' ability to assist consumers with direct enrollment in QHPs, as described in § 155.220(a)(2). A web-broker's ability to assist consumers with their eligibility application submission and enrollment in QHPs is separate and distinct from the eligibility determination function reserved for the State Exchange's centralized eligibility and enrollment platform on the Exchange's website (which can be delivered by a private vendor or State entity under contract with the State Exchange). The requirement for an Exchange to operate a centralized eligibility and enrollment platform does not preclude web-brokers' ability to assist consumers with enrollment in QHPs in a manner that constitutes enrollment through the State Exchange.

While § 155.220(a)(2) allows web-brokers to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange, the web-broker's non-Exchange website must interface with the State Exchange's centralized eligibility and enrollment platform to assist consumers with direct enrollment in QHPs. The State's centralized eligibility and enrollment platform serves as the system of record for all effectuated enrollments in QHPs, in accordance with § 155.400. Therefore, the amendments to §§ 155.205(b)(4) and 155.302(a)(1) requiring that an Exchange operate a centralized eligibility and

enrollment platform on the Exchange's website, and setting forth that the Exchange, through the centralized eligibility and enrollment platform, is the entity responsible for making all eligibility determinations for QHP coverage and insurance affordability programs, are codifying existing policy and practice, and are not limiting or negating the ability of web-brokers to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange, or otherwise restricting opportunities for State Exchanges to expand enrollment pathways. As Exchange enrollment channels continue to diversify, we are providing this clarification for DE entities, existing Exchanges, and States that may seek to operate State Exchanges in the future.

Comment: A few commenters opposed the proposal requiring a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website, stating that the proposal is too vague (which could lead to inconsistent State interpretation and implementation) or is not supported by CMS' rationale.

Response: We disagree with these comments, as the intent of the proposal is to codify and tie together existing regulations at 45 CFR part 155 that require an Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website (or, for an SBE-FP, the Federal eligibility and enrollment platform), such that the Exchange allows for the submission of the single, streamlined application for enrollment in a QHP and insurance affordability programs by consumers, and the Exchange performs eligibility determinations for all consumers based on submissions of the single, streamlined application.

Further, with this proposal we are making clear that the Exchange, through the centralized eligibility and enrollment platform operated on the Exchange's website (or, for an SBE-FP, the Federal eligibility and enrollment platform), is the entity responsible for making all determinations regarding the eligibility for QHP coverage and—in coordination with State Medicaid and CHIP agencies—insurance affordability programs, regardless of whether an individual files an application for enrollment in a QHP on the Exchange's website or on a non-Exchange website operated by an entity described under § 155.220, such as a web-broker defined at § 155.20, or a DE entity or QHP issuer described under § 155.221.

Comment: One commenter opposed the proposal and stated that it will increase the cost of health insurance.

Response: We disagree that this proposal will increase the cost of health insurance. The proposal codifies and ties together existing regulatory requirements across 45 CFR part 155 that require a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website. Furthermore, all Exchanges currently provide access to a centralized eligibility and enrollment platform and process for the consumers that they serve, and all Exchanges also currently perform all eligibility determinations through the operation of a centralized eligibility and enrollment platform on their websites. As the commenter did not explain how this proposal would increase the cost of health insurance, we cannot further address the commenter's assertion.

Comment: Many commenters supported the proposal requiring a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website and stated that it will increase consumer protections and reduce consumer risk. Several commenters emphasized the risk of individuals receiving inconsistent, confusing, or inaccurate results and information if entities other than the Exchange conduct eligibility determinations, including potential impact to consumers regarding their receipt of financial assistance, their plan choice, or their tax liability.

Response: We agree that consumers may be harmed without this policy in place. As we stated in the preamble, if an entity other than the Exchange conducts eligibility determinations, consumers might receive incorrect or inconsistent eligibility determinations, as entities other than the Exchange may not update their systems with the same eligibility determination rules or logic as the Exchange itself when Federal or State policies or regulations impacting eligibility for QHP coverage and insurance affordability programs come into effect or are updated, including the implementation and maintenance of State-specific eligibility rules and logic for Medicaid and CHIP programs. As a result, a non-centralized eligibility system model introduces increased program integrity risk as to the accuracy of eligibility determinations, increased risk of inaccurate APTC payments to QHP issuers, and increased risk to consumers of potential tax liability when filing taxes and reconciling their APTC with the PTC allowed.

Comment: Many commenters supported the proposal clarifying that a State Exchange, through the centralized eligibility and enrollment platform operated on the Exchange's website, is

solely responsible for making all determinations regarding consumer eligibility for QHP coverage and insurance affordability programs. Several commenters supported codifying the prohibition on non-Exchange entities (such as web-brokers or DE entities) rendering eligibility determinations.

Response: As noted in the preamble, we agree that the Exchange, through the centralized eligibility and enrollment platform operated on the Exchange's website (or, for an SBE-FP, the Federal eligibility and enrollment platform), is the entity responsible for making all determinations regarding the eligibility for QHP coverage and insurance affordability programs regardless of whether an individual files an application for enrollment in a QHP on the Exchange's website or on a non-Exchange website operated by an entity described under § 155.220, such as a web-broker defined at § 155.20, or a DE entity or QHP issuer described under § 155.221.

As we believe the eligibility determination function is inherently a function that should only be performed by the Exchange, the policy also clarifies that only the private vendors or State entities that an Exchange contracts with to operate its centralized eligibility and enrollment platform can perform this function on behalf of an Exchange, and prohibits an Exchange from solely relying on non-Exchange entities, including a web-broker (defined at § 155.20) or other entities under §§ 155.220 or 155.221, to make such eligibility determinations on behalf of an Exchange.

Comment: Several commenters stated that the proposed policy will make enrollment into coverage easier, more streamlined, or more efficient for consumers, will ensure transparency, accountability, and accuracy for applicants, or will help reduce administrative barriers for individuals seeking coverage through an Exchange.

Response: We agree that the proposal requiring a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website will support a more accurate and efficient eligibility determination and enrollment experience for applicants and reduce administrative barriers for consumers pursuing coverage through an Exchange. As noted in the preamble, an Exchange must maintain an up-to-date website that allows consumers to receive eligibility determinations for QHPs and insurance affordability programs. This proposal codifies existing policy and practices and helps set clear expectations for current Exchanges and

States that may seek to operate State Exchanges in the future.

Comment: Several commenters supported the proposal requiring a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website and noted that it would provide applicants with flexibility to continue applying for, and enrolling in, coverage through the centralized eligibility and enrollment platform on an Exchange's website, if they choose to withdraw an application initiated on the website of a non-Exchange entity. A few commenters observed that this flexibility is consistent with the "no wrong door" application process promoted by the ACA.

Response: To ensure that the requirements of §§ 155.220(c)(3)(ii)(A) and (i)(F), and 155.205(b) are fulfilled, we agree it is important that Exchanges allow a consumer to continue the application process through the centralized eligibility and enrollment platform operated on the Exchange's own website should the consumer choose to withdraw from the application process that was initiated on a web-broker's non-Exchange website (or, if the Exchange is an SBE-FP, allow the consumer to continue the application process through the website of the Federal platform). We also agree that by facilitating multiple pathways through which consumers can submit a single, streamlined application for QHP coverage and insurance affordability programs—whether through the State Exchange's centralized eligibility and enrollment platform on the Exchange's website, through non-Exchange websites hosted by web-brokers and DE entities (as allowed by the State Exchange), or through Medicaid and CHIP programs operating eligibility systems that aren't integrated with the State Exchange—this flexibility around application pathways for enrollment in QHP coverage and insurance affordability programs aligns with the ACA's "no wrong door" principle.

Comment: A few commenters supported the proposed policy requiring a State Exchange to operate a centralized eligibility and enrollment platform on the Exchange's website and stated that it would make it easier for State Exchanges to monitor and evaluate Exchange efficiency and effectiveness, as well as implement and maintain State-specific Medicaid and CHIP program rules.

Response: We agree that a State Exchange's centralized eligibility and enrollment platform, through which the Exchange conducts all eligibility determinations and maintains all

records of effectuated QHP enrollments, should facilitate State oversight and review of Exchange eligibility and enrollment efficacy. We also agree that an Exchange's centralized eligibility and enrollment platform should enable timely system updates reflecting changes to State-specific eligibility rules and logic for the Medicaid and CHIP programs.

6. 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(h))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82556 and 82557), we proposed to amend §§ 155.220(h)(2) and (3) by deleting the current references to "the HHS reconsideration entity" and replacing them with "the CMS Administrator" and by specifying that, instead of the HHS reconsideration entity, the CMS Administrator, who is a principal officer, would be the entity responsible for handling these reconsideration decisions. Agents, brokers, and web-brokers whose Exchange agreement(s) to participate in the FFEs or SBE-FPs have been terminated for cause would continue to have the ability to request a reconsideration of such action in the manner and form established by HHS by requesting a reconsideration within 30 calendar days of the date of the written termination notice from HHS. We proposed that the request for reconsideration would be made to the CMS Administrator. In the proposed rule, we stated this proposal would improve transparency by specifying who would review reconsideration requests under § 155.220(h).

Exchange agreement suspensions and terminations play a critical role in stopping potentially fraudulent enrollments or other fraudulent behavior in the FFEs and SBE-FPs. Currently, § 155.220(g) establishes the framework for suspension and termination of an agent's, broker's, or web-broker's Exchange agreement(s) for cause in four instances.¹³² First, § 155.220(g)(1) allows HHS to terminate an agent's, broker's, or web-broker's Exchange agreement(s) when there is a specific finding of noncompliance or pattern of noncompliance that is

sufficiently severe. Second, § 155.220(g)(3)(ii) enables HHS to terminate an agent's or broker's Exchange agreement(s) when an agent or broker fails to maintain the appropriate license in every State in which the agent or broker actively assists consumers with applying for APTC and CSRs or with enrolling in QHPs through the FFEs and SBE-FPs. Third, HHS will terminate an agent's, broker's, or web-broker's Exchange agreement(s) under § 155.220(g)(5)(ii) when there is a finding or determination by a Federal or State entity that an agent, broker, or web-broker engaged in fraud or abusive conduct that may result in imminent or ongoing consumer harm using personally identifiable information (PII) of Exchange enrollees or applicants or in connection with an Exchange enrollment or application. Fourth, under § 155.220(g)(5)(i)(B), HHS may terminate an agent's, broker's, or web-broker's Exchange agreement(s) following a suspension of the agreement(s) under § 155.220(g)(5)(i)(A) if the agent, broker, or web-broker submitted rebuttal evidence that does not persuade HHS to lift the suspension, or if the agent, broker, or web-broker fails to submit rebuttal evidence during the suspension period.

If an agent's, broker's, or web-broker's Exchange agreement(s) has been terminated for cause, under § 155.220(h)(1), the agent, broker, or web-broker can request reconsideration of such action in the manner and form established by HHS. The agent, broker, or web-broker must submit the reconsideration request to the HHS reconsideration entity within 30 calendar days of the date of the written termination notice from HHS.¹³³ Current regulations also require the HHS reconsideration entity to notify the agent, broker, or web-broker of its decision, in writing, within 60 calendar days of the date it receives the request for reconsideration.¹³⁴ Currently, § 155.220(h)(3) further provides that this decision constitutes HHS' final determination.

The current framework in § 155.220(h) does not define or identify "the HHS reconsideration entity" responsible for making these decisions. As noted earlier in this final rule, we proposed revising §§ 155.220(h)(2) and (3) by deleting the existing references to "the HHS reconsideration entity" and replacing them with "the CMS Administrator." This policy would ensure that authority to review requests for reconsideration of decisions to

¹³² Section 155.220(f) establishes the framework for an agent, broker, or web-broker to terminate an agent's, broker's, or web-broker's Exchange agreement(s) with HHS. We did not propose any changes with respect to the terminations under § 155.220(f). These terminations are not eligible for reconsideration under § 155.220(h) because they are agent, broker, or web-broker initiated actions.

¹³³ 45 CFR 155.220(h)(2).

¹³⁴ 45 CFR 155.220(h)(3).

terminate an agent's, brokers, or web-broker's Exchange agreement(s) for cause are vested in a principal officer.

We sought comments on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this proposal without modification. We summarize and respond to public comments we received on this proposal below.

Comment: A few commenters expressed their support for the proposal by stating their approval of the clarification and improved transparency it will provide.

Response: We appreciate these comments in support of the amendments to § 155.220(h). As previously noted, this amendment specifies that agents, brokers, and web-brokers assisting consumers on the FFEs and SBE-FPs can submit a request to the CMS Administrator to reconsider HHS' decision to terminate their Exchange agreement(s) for cause.

7. Adding and Amending Language To Ensure Web-Brokers Operating in State Exchanges Meet Certain HHS Standards Applicable in the FFEs and SBE-FPs (§ 155.220)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82557), we proposed to amend § 155.220 to apply certain existing HHS standards for Exchanges that use the Federal platform that apply to web-brokers¹³⁵ assisting the FFEs' and SBE-FPs' ¹³⁶ consumers with enrolling in QHPs and/or assisting consumers with applying for APTC/CSRs in State Exchanges, for both the State Exchange's Individual Exchange and SHOP. In the proposed rule, we stated our proposals would ensure that minimum HHS standards governing web-broker non-Exchange website display of standardized QHP comparative information, disclaimer language, information on eligibility for APTC/CSRs, operational readiness, standards of conduct, and access by web-broker downstream agents and brokers apply to web-brokers across all Exchanges.¹³⁷ We believe that extending

these standards across all Exchanges, to newly apply to State Exchanges, is important given the increased interest from State Exchanges in using web-brokers to assist consumers with enrollment in QHPs offered through Exchanges to maximize enrollment opportunities. The ability of consumers and applicants to have consistent, reliable information from web-brokers who, to the extent permitted by the State and the applicable Exchange, assist consumers with enrolling and applying for QHPs offered on the Exchange, with or without APTC and CSRs, in a manner that constitutes enrollment through the Exchange¹³⁸ is an important consumer safeguard, particularly given that web-brokers may operate across Exchange models. These proposals are intended to ensure that certain HHS standards are extended to protect State Exchange consumers as minimum requirements while also providing State Exchanges with continued flexibility and discretion to decide whether and how to utilize web-brokers to assist State Exchange consumers and applicants with enrolling in QHPs and applying for APTC/CSRs. Finally, these proposals align with other proposed changes to extend certain existing HHS standards at § 155.221 that currently apply to DE entities¹³⁹ assisting the FFEs' and SBE-FPs' consumers and applicants with direct enrollment in QHPs and applying for APTC/CSRs to also apply in State Exchanges. We proposed that these proposed changes would be effective on the date of publication of this final rule.

Section 1312(e) of the ACA provides that the HHS Secretary shall establish procedures under which a State may allow agents, brokers, and web-brokers to enroll individuals and small employers in QHPs offered through an Exchange and to assist individuals in applying for APTC/CSRs for QHPs sold through an Exchange. The Secretary also has authority under section 1321(a) of

web-brokers may assist consumers and applicants in SBE-FP States. Section 155.220(l) currently provides that an agent, broker, or web-broker who enrolls qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an SBE-FP or assists individual market consumers with submission of applications for APTC and CSRs through an SBE-FP, must comply with all applicable FFE standards in § 155.220. We did not propose and are not finalizing any changes to this existing framework for agents, brokers, or web-brokers who provide assistance in SBE-FP States.

¹³⁸ See 77 FR 18334 through 18336.

¹³⁹ DE entities permitted to participate in the FFEs and SBE-FPs include, to the extent permitted by applicable State law: (1) QHP issuers that meet the applicable requirements in §§ 155.221 and 156.1230, and (2) web-brokers that meet the applicable requirements in §§ 155.220 and 155.221. 45 CFR 155.221(a).

the ACA to promulgate regulations with respect to the establishment and operation of Exchanges, the offering of QHPs through such Exchanges, and such other requirements as the Secretary determines appropriate.¹⁴⁰ HHS previously leveraged these authorities to establish the existing agent, broker, and web-broker standards applicable in FFE and SBE-FP States codified in § 155.220.¹⁴¹

In new paragraph (n), we proposed to apply the web-broker standardized QHP comparative information and the accompanying Enrollment Support disclaimer requirements in § 155.220(c)(3)(i)(A) to web-brokers operating in State Exchanges, and consequently to these State Exchanges. Consistent with § 155.220(c)(3)(i)(A)(1) through (6), web-broker non-Exchange websites used to complete the QHP selection must disclose and display the standardized comparative QHP information provided by the Exchange or directly by QHP issuers, consistent with the requirements of § 155.205(c) for all QHPs, including Qualified Dental Plans (QDPs),¹⁴² offered through the Exchange. The standardized comparative information on each available QHP that must be displayed by the web-broker on its non-Exchange website is the following information provided by the Exchange or directly by QHP issuers: (1) premium and cost-sharing information (total and net premium based on APTC and CSR, if applicable);¹⁴³ (2) the summary of benefits and coverage; (3) identification of whether the QHP is a bronze, silver, gold or platinum level plan, or a catastrophic plan; (4) the results of the enrollee satisfaction survey; (5) quality

¹⁴⁰ Section 1321(a)(1)(A), (B), and (D) of the ACA.

¹⁴¹ See 77 FR 18444, as amended at 78 FR 15533; 78 FR 54134; 79 FR 13837; 81 FR 12338; 81 FR 94176; 84 FR 17563; 85 FR 37248; 86 FR 24288; 87 FR 27388; and 88 FR 25917.

¹⁴² With some limited exceptions, QDPs are considered a type of QHP. See 77 FR 18315. Web-brokers assisting consumers in the FFEs and SBE-FPs are expected to follow the same requirements for QDPs as for QHPs, including display of all applicable QDPs offered through the Exchange and all available information specific to each QDP on their websites. However, because it is not possible to enroll in QDPs through DE unless also enrolling in medical QHPs, web-brokers are permitted to modify their QDP displays accordingly (for example, by displaying QDPs after medical QHPs to ensure a consumer has first selected a medical QHP). See CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 4.3, p.47 and Section 4.4.2, p. 52. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>. Under this proposal, these same standards governing QDPs would apply to web-brokers in State Exchanges.

¹⁴³ See CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 4.4.2, p. 52. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

¹³⁵ Web-broker is defined at § 155.20 as "an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in § 155.220(c)(3) or § 155.221. The term also includes an agent or broker direct enrollment technology provider."

¹³⁶ See § 155.220(l).

¹³⁷ The amendments to § 155.220 we are finalizing will not impact how agents, brokers, or

ratings assigned by HHS; and (6) the provider directory made available to the Exchange. The results of the enrollee satisfaction survey should be displayed in accordance with instructions in the CMS Quality Rating Information Bulletin.¹⁴⁴ As described in the CMS Quality Rating Information Bulletin, State Exchanges already have some flexibility to customize the display of quality ratings assigned by HHS for their respective QHPs.¹⁴⁵ For example, State Exchanges can make some State-specific customizations, such as to incorporate additional State or local quality information or to modify the display names of the quality ratings assigned by HHS. Under this proposal, web-brokers in State Exchanges should use the same consumer-facing labels for the quality ratings that HHS displays on *HealthCare.gov* (that is, “Overall Rating,” “Medical Care,” “Member Experience,” and “Plan Administration”) unless the State Exchange modified the display names for these labels. If the State Exchange has modified the display names, web-brokers operating in State Exchanges should use the display names used on the State Exchange website. Web-brokers operating in State Exchanges should also align their display of the quality ratings to reflect any permitted State-specific customizations, such as the addition of State or local quality information. Additionally, consistent with the approach for display of quality ratings by web-brokers in the FFEs and SBE-FPs and by State Exchanges, if a QHP was not eligible to receive a rating or did not receive a rating for other reasons, web-brokers participating in State Exchanges would need to display “New plan—Not Rated” or “Not Rated” in place of the quality ratings.¹⁴⁶ When displaying the quality rating assigned by HHS on their non-Exchange websites, web-brokers operating in State Exchanges would be required to prominently display the disclaimer language specified in the CMS Quality Rating Information Bulletin, which mirrors the language that web-brokers in the FFEs and SBE-FPs must display on their non-Exchange websites.¹⁴⁷

State Exchanges are also currently required to display the quality ratings assigned by HHS and the results of the enrollee satisfaction survey, in the form and manner specified by the Secretary.¹⁴⁸ This includes prominently displaying the same disclaimer language on the State Exchange website or a static website when displaying the quality ratings assigned by HHS and the results of the enrollee satisfaction survey.¹⁴⁹ Web-brokers would be able to access QHP quality rating information for a State Exchange they are operating in, including the quality ratings assigned by HHS and enrollee satisfaction survey results,¹⁵⁰ from the State Exchange.

This list of standardized QHP comparative information that web-brokers must disclose and display on their non-Exchange websites used to complete QHP selection in FFE and SBE-FP States mirrors the information that Exchanges are required to disclose and display on their respective websites.¹⁵¹ This approach ensures consumers have access to the same QHP comparative information whether they elect to enroll through the Exchange’s website or through a web-broker’s non-Exchange website. We proposed to extend these same standardized comparative information requirements, as minimum HHS standards, that would need to be met by web-brokers participating in State Exchanges and consequently to these State Exchanges. We similarly proposed to extend the Enrollment Support disclaimer referenced in § 155.220(c)(3)(i)(A) beyond FFE and SBE-FP States to also extend to web-brokers participating in State Exchanges and consequently to these State Exchanges. The goal of this disclaimer is 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 the

Exchange website if they wish to enroll in those QHPs. In particular, when a website of a web-broker is used in FFE or SBE-FP States to complete the QHP selection, but it does not support enrollment for a QHP,¹⁵² the web-broker’s website must prominently display the standardized Enrollment Support disclaimer¹⁵³ provided by HHS, as follows:

“(Name of Company) does not support enrollment in this Qualified Health Plan at this time. To enroll in this Qualified Health Plan, visit the Health Insurance Marketplace® ¹⁵⁴ website at *HealthCare.gov*.”

To prominently display the disclaimer, it must be written in a font size no smaller than the majority of text on the website page and must be noticeable in the context of the website by (for example) using a font color that contrasts with the background of the website page.¹⁵⁵ In addition, the Enrollment Support disclaimer must appear on the web-broker’s non-Exchange website in close proximity to where the QHP information is displayed if the web-broker does not support enrollment in any such QHP, so it is noticeable to the consumer.¹⁵⁶ Web-brokers can also meet this prominent display requirement 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 disclaimer on the same website page or otherwise displays the required disclaimer (for example, in a pop-up bubble that appears while hovering over the visual cue).¹⁵⁷ We proposed to require web-brokers assisting consumers in State Exchanges to comply with these same requirements, while also providing these State Exchanges some flexibility regarding the disclaimer

¹⁴⁸ See §§ 155.1400 and 155.1405. Also see § 155.205(b)(1)(iv) and (v). Exchanges can satisfy the requirement to display the enrollee satisfaction survey results by displaying the quality ratings assigned by HHS (which incorporate member experience data from the survey). See 79 FR 30310 through 30311.

¹⁴⁹ See CMS. (2023, May 2). *Quality Rating Information Bulletin*. CMS. Section III, p. 3. <https://www.cms.gov/files/document/py2024-qrs-display-bulletin.pdf>.

¹⁵⁰ Consistent with the approach for Exchanges, for purposes of compliance with the HHS minimum standards, web-brokers would be able to satisfy the requirement to display the enrollee satisfaction survey results by displaying the quality ratings assigned by HHS (which incorporate member experience data from the survey).

¹⁵¹ See § 155.205(b)(1). Also see 87 FR 642 (explaining that “(i)ncluding this [list of] information within § 155.220, instead of through a cross-reference to § 155.205(b)(1), would provide better clarity and ease of reference. . .”).

¹⁵² A web-broker’s non-Exchange website may not support enrollment in a QHP if a web-broker does not have an appointment with a QHP issuer, and therefore, is not permitted under State law to enroll consumers in coverage offered by that issuer.

¹⁵³ CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 4.4.2, p. 52. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

¹⁵⁴ Health Insurance Marketplace® is a registered service mark of the HHS.

¹⁵⁵ See 78 FR 27260. Also see CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 4.4.1, p. 49–50 and Section 4.4.2, p. 54–55. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

¹⁵⁶ See 78 FR 27260. Also see CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 4.4.2, p. 52. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

¹⁵⁷ *Id.*

¹⁴⁴ See CMS. (2023, May 2). *Quality Rating Information Bulletin*. CMS. Section III, p. 3. <https://www.cms.gov/files/document/py2024-qrs-display-bulletin.pdf>. See Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule, 79 FR 30240 at 30310–30311 (May 27, 2014).

¹⁴⁵ §§ 155.1400 and 155.1405. Also see 85 FR 29214 through 29216.

¹⁴⁶ See CMS. (2023, May 2). *Quality Rating Information Bulletin*. CMS. Section III, p. 3. <https://www.cms.gov/files/document/py2024-qrs-display-bulletin.pdf>.

¹⁴⁷ *Id.*

language required to be displayed by their web-brokers.

For State flexibility, under this proposal, the HHS-provided disclaimer language must be used as a minimum starting point, but State Exchanges may add State-specific language to the Enrollment Support disclaimer, provided the additional language does not conflict with the HHS-provided standardized disclaimer. This would permit a State Exchange to replace references and links to the Health Insurance Marketplace® and *HealthCare.gov* in the HHS-provided disclaimer language with the appropriate reference or links to the State Exchange's website for the Enrollment Support disclaimer that web-brokers assisting consumers in the State Exchange would be required to prominently display on their non-Exchange websites. Additionally, State Exchanges may require web-brokers operating in their State to translate the disclaimer text into languages appropriate for the State as this type of additional requirement would not conflict with the HHS-provided disclaimer language or minimum standards. As with all informational materials, standard plain language practice is to write at or near a fourth-grade reading level and not to exceed an eighth-grade reading level. We explained that we expect that any additional State-specific customizations to this disclaimer would be written accordingly, and that we would be available to provide technical assistance to State Exchanges that want to add State-specific language. We proposed to codify this State flexibility at new paragraph (n)(1).

In addition, consistent with § 155.220(c)(3)(i)(G), when used to assist FFE consumers, the web-broker's non-Exchange website must also prominently display a standardized disclaimer¹⁵⁸ provided by HHS, referred to as the General non-FFE disclaimer, that informs consumers and applicants that the web-broker's website is not the Exchange website, notes that the web-broker's non-Exchange website may not support enrollment in all QHPs, and provides a web link to the Exchange's website. This same requirement extends beyond the FFEs and also applies to SBE-FPs today.¹⁵⁹ In new paragraph (n), we proposed to extend this disclaimer requirement to also apply to web-brokers operating in

State Exchanges, and consequently to these State Exchanges, while providing these State Exchanges some flexibility to add State-specific language to this disclaimer, provided the additional language does not conflict with the HHS-provided disclaimer language. We proposed to codify this State flexibility in new paragraph (n)(1). Similar to the adoption of this disclaimer for consumers in an FFE or an SBE-FP,¹⁶⁰ we stated in the proposed rule that we continue to believe this additional standard is in the best interest of consumers, as it would help them distinguish between the Exchange website and web-broker non-Exchange websites. We therefore also identified it as an important baseline consumer protection that should extend to consumers across all Exchanges.

The General non-FFE disclaimer provided by HHS that must be prominently displayed by web-brokers participating in the FFEs and SBE-FPs reads:

“Attention: This website is operated by (Name of Company) and is not the Health Insurance Marketplace® website. In offering this website, (Name of Company) is required to comply with all applicable Federal law, including the standards established under 45 CFR 155.220(c) and (d) and standards established under 45 CFR 155.260 to protect the privacy and security of personally identifiable information. This website may not support enrollment in all Qualified Health Plans (QHPs) being offered in your State through the Health Insurance Marketplace® website. For enrollment support in all available QHP options in your State, go to the Health Insurance Marketplace® website at *HealthCare.gov*.

Also, you should visit the Health Insurance Marketplace® website at *HealthCare.gov* if:

- You want to select a catastrophic health plan. (This only needs to be included if the web-broker does not offer catastrophic plans.)
- You want to enroll members of your household in separate QHPs. (This only needs to be included if the web-broker does not allow multiple enrollment groups for its Classic DE pathway; note that EDE Entities are required to support multiple enrollment groups.)
- You want to enroll members of your household in dental coverage. The plans offered here do not offer pediatric dental coverage and you want to choose a QHP offered by a different issuer that covers pediatric dental services or a separate dental plan with pediatric coverage. (This only needs to be included if the web-broker does not offer assistance with enrollment in adult coverage or pediatric dental coverage.)

(Name of web-broker's website) offers the opportunity to enroll in either QHPs or off-Marketplace coverage. Please visit *HealthCare.gov* for information on the benefits of enrolling in a QHP. Off-Marketplace coverage is not eligible for the cost savings offered for coverage through the Marketplaces. (This final paragraph must be displayed if the web-broker offers consumers assistance with off-Marketplace coverage options.)”

To prominently display this disclaimer, it must be written in a font size no smaller than the majority of text on the website page and must be noticeable in the context of the website by (for example) using a font color that contrasts with the background of the website page.¹⁶¹ In addition, the disclaimer must be prominently displayed on both the initial user landing page and on the landing page displaying QHP options that appear before the applicant makes a decision to purchase coverage (QHP selection page). In FFE and SBE-FP States, the disclaimer must use the exact language provided by HHS, must include a functioning web link to *HealthCare.gov*, and must be viewable without requiring the user to select or click on an additional link. The disclaimer must also be displayed in the same non-English language as any language(s) the web-broker maintains screens for on its website.¹⁶² The web-broker may change the font color, size, or graphic context of the information to ensure that it is noticeable to the user in the context of its website or the other written material. We proposed to require web-brokers assisting consumers in State Exchanges must comply with these same requirements for prominent display of this disclaimer.

Consistent with the policy for the extension of the Enrollment Support disclaimer to State Exchanges and their web-brokers, under this proposal, the HHS-provided disclaimer language must be used as a minimum starting point, but State Exchanges may add State-specific language, provided the additional language does not conflict with the HHS-provided standardized disclaimer.

This would permit State Exchanges to replace references and links to the Health Insurance Marketplace® and *HealthCare.gov* in the HHS-provided disclaimer language with the appropriate reference or links to the State Exchange's website for the

¹⁵⁸ CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 4.4.2, p. 54. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

¹⁵⁹ 45 CFR 155.220(l).

¹⁶⁰ 78 FR 37046.

¹⁶¹ See 78 FR 27260. Also see CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 4.4.1, p. 49–50 and Section 4.4.2, p. 54–55. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

¹⁶² See 45 CFR 155.205(c)(2)(iv)(C).

disclaimer under § 155.220(c)(3)(i)(G) that web-brokers assisting consumers in State Exchanges would be required to prominently display on their non-Exchange websites. Additionally, while web-brokers assisting consumers in State Exchanges would be required to specify in their disclaimer that they are subject to applicable Federal requirements, under this policy, we anticipate State Exchanges would leverage this flexibility to direct their web-brokers to omit citations to Federal requirements included in the HHS-provided language to the extent those provisions do not apply, such as § 155.220(d). State Exchanges would also be permitted under this proposal to modify the disclaimer required under § 155.220(c)(3)(i)(G) to specify applicable provisions of State law. Further, to the extent that web-brokers in State Exchanges may offer off-Exchange coverage options, we would require them to include the HHS-provided disclaimer language that distinguishes between such coverage options and QHPs sold through the Exchange, noting in particular that such off-Exchange coverage options are not eligible for cost savings offered with a QHP sold through the Exchange, and providing a link to the State Exchange website for more information. Similar to the approach adopted for web-brokers participating in FFE and SBE-FP States, bracketed language included in the HHS-provided disclaimer language would not be required for web-brokers assisting consumers in State Exchanges to comply with the HHS minimum standards unless applicable or otherwise required by the State Exchange. State Exchanges could also require web-brokers operating in their State to translate the disclaimer text required under § 155.220(c)(3)(i)(G) into languages appropriate for the State as this type of additional requirement would not conflict with the HHS-provided disclaimer language or minimum standards. As with all informational materials, standard plain language practice is to write at or near a fourth-grade reading level and not to exceed an eighth-grade reading level. We explained that HHS expects that any State-specific additions or customizations to this disclaimer would be written accordingly, and that we would be available to provide technical assistance to State Exchanges that want to add State-specific language to this disclaimer.

In new paragraph (n), we also proposed to extend the requirement in § 155.220(c)(3)(i)(I), which requires the prominent display by web-brokers of the

information provided by HHS pertaining to a consumer's eligibility for APTC or CSRs on the web-broker's non-Exchange website, to web-brokers operating in State Exchanges and, consequently, to these State Exchanges. We established this requirement for web-brokers in FFE and SBE-FP States to increase the likelihood that consumers understand their potential eligibility for APTC and CSRs and potential liability for excess APTC repayment and can factor those determinations into their QHP selection and the amount of APTC they elect to take.¹⁶³ We identified this as another important consumer protection that should be part of the HHS minimum web-broker standards in § 155.220 that also extends to web-brokers in State Exchanges. Consistent with the proposals described above to extend the requirements at § 155.220(c)(3)(i)(A) and (G), we proposed to also extend the display obligations in § 155.220(c)(3)(i)(I) to apply to web-brokers in State Exchanges. As such, to prominently display this information, it must appear in a font size no smaller than the majority of text on the website page and must be noticeable in the context of the website by (for example) using a font color that contrasts with the background of the website page.¹⁶⁴ We similarly proposed to require web-brokers in State Exchanges to display information provided by, and as specified by, the State Exchange regarding a consumer's eligibility for APTC or CSRs. Additionally, we proposed flexibility in how consumer eligibility information for APTC or CSRs is displayed on websites by web-brokers in State Exchanges, at the direction of the State Exchange on the display of that information. This flexibility is intended to provide State Exchanges the ability to define how consumer education information about the State Exchanges, including the consumer eligibility information for APTC or CSRs, is customized and presented on their web-brokers' websites. For example, we recognize that State Exchanges may wish to require their web-brokers include additional consumer educational information or State-specific content to meet the needs of their consumers and applicants. We explained that we believe allowing the flexibility for State Exchanges and their web-brokers to customize the consumer

eligibility information for APTC or CSRs that must be prominently displayed on the web-broker's non-Exchange website would provide a necessary baseline. More specifically, meeting these standards would provide consistency for all Exchange consumers receiving assistance from web-brokers through their non-Exchange websites and would ensure that all Exchange consumers are provided accurate and sufficient information on potential eligibility for APTC and CSRs and the potential liability for excess APTC repayment, whether they apply and enroll for coverage through the applicable Exchange's website or through a web-broker's non-Exchange website. We proposed to codify this State flexibility in new proposed paragraph (n)(1).

In the proposed rule (88 FR 82560 and 82561), we also proposed to add new § 155.220(c)(4)(iii) to extend certain downstream agent and broker requirements at § 155.220(c)(4)(i) that currently apply to web-brokers in FFE and SBE-FP States and govern the use of the web-broker's non-Exchange website by other agents or brokers assisting Exchange consumers to also apply to web-brokers, and their downstream agents and brokers, in States with State Exchanges, and consequently to these State Exchanges. Under the proposed new provision, web-brokers that permit other agents or brokers, through a contract or other arrangement, to use the web-broker's non-Exchange website to help an applicant or enrollee complete a QHP selection or complete the Exchange eligibility application would be required to meet the standards at § 155.220(c)(4)(i)(A), (B), (D), and (F) when assisting consumers in States with a State Exchange. To extend this framework to also apply in State Exchanges, we proposed to capture in new § 155.220(c)(4)(iii) that all references to "HHS" and "Federally-facilitated Exchange" in § 155.220(c)(4)(i)(A), (B), (D), and (F) would be understood to mean and be replaced with a reference to the applicable State Exchange.

The goal of the downstream agent and broker framework codified in § 155.220(c)(4)(i) is to ensure that agents or brokers who utilize a web-broker's non-Exchange website to help applicants complete a QHP selection or complete the Exchange eligibility application comply with necessary safeguards related to transparency, oversight, and consumer support. It ensures appropriate oversight by the web-broker and allows for closer monitoring by the applicable Exchange. In the proposed rule (88 FR 82561), we

¹⁶³ 81 FR 61499.

¹⁶⁴ See 78 FR 27260. Also see CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 4.4.1, p. 49–50 and Section 4.4.2, p. 54–55. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

explained that we believe the extension of the identified HHS minimum standards to State Exchanges and their web-brokers is especially important since some agents, brokers, and web-brokers operate in multiple States and would benefit from a standardized framework and set of requirements.

As part of the State Exchanges' oversight of the use of web-broker non-Exchange websites, we also encouraged State Exchanges to adopt a temporary suspension framework similar to § 155.220(c)(4)(ii) that applies in FFE and SBE-FP States. This provision permits HHS to temporarily suspend the ability of a web-broker to make its non-Exchange website available to its downstream agents and brokers to transact information with HHS if HHS discovers a security or privacy incident or breach. The suspension extends for the period in which HHS begins to conduct an investigation and until the incident or breach is remedied to HHS' satisfaction. It is another important feature of HHS' oversight of the use of web-broker non-Exchange websites in FFE and SBE-FP States that protects consumers data and safeguards Exchange operations and systems. State Exchanges that choose to permit web-brokers to host non-Exchange websites to assist consumers with QHP selections and submission of Exchange eligibility applications should consider adoption of similar measures.

In the proposed rule (88 FR 82561 and 82562), we proposed to add new paragraph (n)(2) to extend web-broker operational readiness requirements to State Exchanges and their web-brokers. Under this proposal, web-brokers operating in State Exchanges would be required to demonstrate operational readiness to the applicable State Exchange prior to the web-broker's website being used to complete an Exchange eligibility application or a QHP selection. The standards under § 155.220(c)(6) applicable to operational readiness reviews performed by HHS of web-brokers' non-Exchange websites used to assist the FFEs' and SBE-FPs' consumers to apply and enroll in QHP coverage through the Exchange, with or without APTC and CSRs, is a critical part of the oversight framework for HHS' Direct Enrollment (DE) program (including both Classic DE and Enhanced Direct Enrollment (EDE)).

In the 2018 Payment Notice final rule, we adopted rules to capture operational readiness requirements applicable to web-brokers that host non-Exchange websites to complete QHP selection.¹⁶⁵ In the 2020 Payment Notice final rule,

we finalized amendments that moved the parallel operational readiness requirements for web-brokers and QHP issuers to § 155.221(b)(4), accounting for the fact that DE entities participating in EDE in the FFEs and SBE-FPs host the Eligibility application in addition to QHP selection.¹⁶⁶ In the 2022 Payment Notice final rule, we finalized amendments to codify more detail describing the operational readiness reviews applicable to web-brokers participating in FFE and SBE-FP States by adding a new § 155.220(c)(6).¹⁶⁷ We identified these operational readiness requirements as necessary safeguards to protect consumer data and the efficient and effective operation of the Exchange while also supporting innovation and the creation of additional approved pathways for FFE and SBE-FP consumers to enroll in QHP coverage in a manner that constitutes enrollment through the Exchange.

As part of the proposal to extend an operational readiness review requirement to State Exchanges and their web-brokers, we proposed in new paragraph (n)(2) to require these State Exchanges to establish the form and manner for their web-brokers to demonstrate operational readiness, which may include submission or completion of the same items addressed in § 155.220(c)(6)(i)–(v) to the State Exchanges, in the form and manner specified by the applicable State Exchanges. These standards, which apply in FFE and SBE-FP States, ensure operational readiness and compliance with all applicable requirements prior to the web-broker's non-Exchange website being used to complete Exchange eligibility application or a QHP selection. They make sure consumers and applicants are not able to enroll in Exchange coverage nor submit an Exchange application via a web-broker's non-Exchange website that is not operationally ready. Websites that have not been tested to see if they are operationally ready may not provide consumers and applicants with proper eligibility determinations or may have security flaws that could make a breach involving consumer PII more likely. Mandating that web-brokers participating in State Exchanges meet standards set by the applicable State Exchange to demonstrate operational readiness helps reduce this risk in all Exchanges. In the proposed rule (88 FR 82562), we encouraged State Exchanges to adopt operational readiness review standards consistent with the requirements captured in

§ 155.220(c)(6)(i)–(v) and to also consider leveraging the audits that web-brokers use to demonstrate compliance with the operational readiness review requirements applicable in FFE and SBE-FP States. Such an approach would promote standardization across Exchanges in terms of operational readiness requirements applicable for web-brokers while building in flexibility for State Exchanges. We explained that we recognize it is important to provide State Exchanges flexibility to tailor the operational readiness review process to best serve their operational and business needs. For example, State Exchanges may have the need to structure their operational readiness reviews to emphasize or prioritize different web-broker functionalities that meet State-specific needs and rules. Therefore, we proposed the requirement that State Exchanges must establish operational readiness requirements for their web-brokers to demonstrate compliance with applicable requirements and technological readiness prior to the web-broker's website being used to complete an Exchange eligibility application or a QHP selection, while providing these State Exchanges with flexibility to define the contours of those requirements. We proposed to capture at the end of the new paragraph (n) the accompanying proposed requirement that web-brokers in States with State Exchanges comply with the applicable State Exchanges' operational readiness standards under paragraph (n)(2).

Finally, in the proposed rule (88 FR 82562), we proposed in new paragraph (n)(1) to extend the current web-broker FFE standard of conduct established at § 155.220(j)(2)(i) to also apply to web-brokers assisting consumers in State Exchanges, and consequently to these State Exchanges. This FFE standard already extends to web-brokers assisting consumers in SBE-FP States.¹⁶⁸ As proposed to be applied in State Exchanges, web-brokers would be required to provide consumers with correct information, without omission of material fact, regarding the applicable State Exchange, QHPs offered through the applicable State Exchange, and insurance affordability programs.¹⁶⁹ In addition, web-brokers who assist with

¹⁶⁸ See 45 CFR 155.220(l). A parallel requirement also applies to QHP issuer DE entities in FFE and SBE-FP States. See 45 CFR 155.221(a)(1) and (i), and 156.1230(b)(2). As discussed below, in this rulemaking, we proposed and are finalizing the extension of the parallel QHP issuer DE entity requirement to State Exchanges and their QHP issuer DE entities.

¹⁶⁹ See 42 CFR 435.4 for the definition of insurance affordability programs.

¹⁶⁵ 81 FR 94120.

¹⁶⁶ 84 FR 17522 through 17525.

¹⁶⁷ 86 FR 24208 through 24209.

or facilitate enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through a State Exchange, or assist individuals in applying for APTC and CSRs for QHPs sold through a State Exchange, would also be required to refrain from marketing or conduct that is misleading (including by having a website that the State Exchange determines could mislead a consumer into believing they are visiting the State Exchange's website), coercive, or discriminates based on race, color, national origin, disability, age, or sex. To extend this FFE standard of conduct to State Exchanges, we proposed in the last sentence of new paragraph (n) that all references to "HHS" and "the Federally-facilitated Exchanges" in § 155.220(j)(2)(i) would be understood to mean and be replaced with a reference to "the applicable State Exchange, applied to web-brokers," and the reference to "HealthCare.gov" in § 155.220(j)(2)(i) would be understood to mean and be replaced with a reference to "the State Exchange website, applied to web-brokers."

We sought comment on these proposals, especially from States operating, or seeking to operate, State Exchanges. We also sought comment on which of the other current provisions at § 155.220 should or should not apply to State Exchanges and web-brokers that assist consumers in State Exchanges.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these proposals without modification. Below, we summarize and respond to public comments received on the proposals to require web-brokers operating in State Exchanges meet certain HHS standards applicable in the FFEs and SBE-FPs.

Comment: Most commenters were broadly supportive of these proposals. Several commenters specifically cited that the provisions extending web-broker website display of standardized QHP comparative information, disclaimer language, information on eligibility for APTC/CSRs, operational readiness, standards of conduct, and access by web-broker downstream agents and brokers across all Exchange types are all important consumer safeguards. Several commenters stated these provisions would generally enhance the consumer shopping experience, by providing consumers with a higher-quality and more consistent user experience that allows them access to accurate information about coverage and insurance affordability programs, whether they

utilize the Exchange's website or web-brokers' non-Exchange websites.

A few commenters stated that if State Exchanges leveraged, where appropriate, HHS operational readiness reviews conducted for FFE and SBE-FP web-brokers, this may both help to alleviate the compliance burden on web-brokers participating in State Exchanges and on those State Exchanges, which would help increase the likelihood of web-broker participation in State Exchanges. One commenter further expanded on this, stating that the proposals to encourage streamlined operational readiness and compliance activities across State Exchanges via States leveraging HHS operational readiness reviews and artifacts (that is, findings) for web-brokers will make it easier for a web-broker to participate in multiple State Exchanges.

A few commenters expressed appreciation that the proposals afford State Exchanges sufficient flexibility, such as the ability to implement State-specific operational readiness assessments or to incorporate State-specific information into the standardized disclaimers.

Response: We appreciate and agree with these comments, many of which summarized or elaborated on these proposals' benefits that we described in the proposed rule.

Comment: Several commenters that expressed general support for these proposals also suggested that CMS should consider requiring web-brokers to implement additional consumer protection standards and other consumer-oriented tools and information on their websites in the future, citing that it is especially important that web-brokers provide streamlined and approved information on State Exchange coverage on their websites. These commenters, however, did not identify which additional standards in § 155.220 we should consider requiring web-brokers participating in State Exchange to meet for future benefit years nor did the commenters otherwise offer specific suggestions for other standards, tools, or information, that should similarly be considered for implementation in the future.

Response: We appreciate commenters' feedback and agree that adoption of consumer protection standards applicable to the use of web-broker non-Exchange websites to enroll consumers in QHPs and help consumers apply for APTC/CSRs via State Exchanges is important. As we explained in the proposed rule (88 FR 82557 and 82558), section 1312(e) of the ACA provides that

the HHS shall establish procedures under which a State may allow agents, brokers, and web-brokers to enroll individuals in QHPs offered through Exchanges. In the proposed rule, we sought comment on which of the current provisions at § 155.220 should or should not apply to State Exchanges and web-brokers that assist consumers in State Exchanges, and we continue to encourage specific feedback from interested parties on additional consumer protection standards, consumer-orientated tools, or information that we should consider adopting in the future, particularly from State Exchanges and web-brokers operating in Exchanges.

Comment: One commenter suggested that if State Exchanges wish to adopt standards for web-brokers that are different from the minimum HHS standards that HHS proposed to extend to web-brokers assisting consumers in State Exchanges and, consequently, those State Exchanges, HHS should establish a process to allow States to apply standards that are different from the HHS default minimum standards. This commenter noted the HHS standards are a reasonable starting point, but that States should have the flexibility to enforce their own standards.

Response: We appreciate the commenter's recommendation that State Exchanges should have the flexibility to establish and enforce their own standards for web-brokers. As explained in the proposed rule (88 FR 82557), the HHS standards we are finalizing as applicable to State Exchanges and their web-brokers are intended to serve as a starting point by extending certain baseline critical protections to consumers in all Exchanges. These standards focus on ensuring proper eligibility determinations, protecting against security breaches or incidents through implementation of operational readiness reviews, and minimizing consumer confusion. State Exchanges can establish additional standards for web-brokers that are more stringent than the HHS standards, as long as any standard established by the State for its web-brokers does not prevent, or conflict with, the application of the HHS standards¹⁷⁰ applicable to web-brokers operating in State Exchanges. For example, while a State Exchange could not forego requiring their web-brokers to participate in operational readiness activities, as required under new § 155.220(n)(2), a State Exchange may establish the form and manner for their web-brokers to demonstrate

¹⁷⁰ See section 1311(k) of the ACA.

operational readiness, including requiring their web-brokers to submit documentation the State Exchange believes would support its evaluation of a web-broker's operational readiness. If a State Exchange wants to replace an otherwise applicable HHS standard with an alternative State standard for its web-brokers, the State can consider using the existing process under section 1332 of the ACA to pursue such change, provided the State is able to do so in accordance with section 1332 requirements. Section 1332 of the ACA permits States to apply for a waiver from certain ACA requirements¹⁷¹ to implement innovative and individualized State strategies to provide State residents with access to high quality, affordable health insurance coverage. Section 1312(e) of the ACA is among the provisions that a State can seek to waive under section 1332 of the ACA.¹⁷² Therefore, a State with a State Exchange that wants to amend the new HHS minimum standards under § 155.220 applicable to its web-brokers and replace it with an alternative State standard can apply for a section 1332 waiver to pursue such a change. For a section 1332 waiver to be approved, the Departments must determine that the waiver meets certain statutory guardrails¹⁷³ and other applicable requirements.¹⁷⁴ For more information on the process to submit section 1332 waiver applications, see <https://www.cms.gov/marketplace/states/section-1332-state-innovation-waivers>. In addition, as outlined above, the framework adopted in this final rule as applicable to State Exchanges and their web-brokers incorporates certain flexibilities for State Exchanges. For

example, State Exchanges may add State-specific information to the standardized disclaimers required to be displayed by their web-brokers. As another example, State Exchanges may specify the form and manner for their web-brokers to demonstrate operational readiness prior to the web-broker's internet website being used to complete an Exchange eligibility application or a QHP selection.

Finally, to the extent that a State Exchange permits web-brokers to assist its consumers, the State Exchange will remain the entity with primary responsibility for oversight and enforcement of applicable standards.

Comment: A few supporting commenters requested that HHS share information on how the Department would track compliance by State Exchange web-brokers with the HHS minimum standards.

Response: An Exchange is the primary entity responsible for overseeing and ensuring compliance by their web-brokers with applicable Federal and State rules and regulations, while HHS has the authority to oversee the implementation and operation of Exchanges, including optional web-broker programs that a State Exchange may elect to operate, and Exchange compliance with Federal requirements. For new State Exchanges, under § 155.105, States that seek to operate a State Exchange must complete and submit an Exchange Blueprint application. The Exchange Blueprint application documents that an Exchange will meet the legal and operational readiness requirements required of a State Exchange. As part of a State's Blueprint submission, the State also agrees to demonstrate operational readiness to implement and execute the Federal requirements applicable to State Exchanges, which would include the new requirements under § 155.220 applicable to State Exchange that elect to implement a web-broker program. A State Exchange that elects to operate an optional web-broker program would be required to include information in its Blueprint to demonstrate operational readiness to implement and support ongoing operations of an optional web-broker program consistent with applicable requirements in § 155.220. As discussed in other sections of this rule, we are also codifying requirements related to the approval of a State Exchange whereby we will require a State seeking to establish a State Exchange to provide supplemental information in its Blueprint application to demonstrate its ability to implement and comply with the requirements for operating a State Exchange, including

requirements associated with the operation of a web-broker program. Such supporting information would inform HHS's decision to approve or conditionally approve a State Exchange and would help facilitate HHS' oversight of compliance with Federal requirements applicable to State Exchanges and their web-brokers.

Additionally, under § 155.105, an existing State Exchange must notify HHS in writing before making a significant change to its approved Exchange Blueprint, and no significant change to an Exchange Blueprint may be effective until it is approved by HHS in writing or 60 days after HHS receipt of a completed request. Accordingly, for existing State Exchanges that seek to newly implement and operate an optional web-broker program, we would require the State to submit an updated Exchange Blueprint and participate in operational readiness reviews related to the implementation and ongoing operation of such a web-broker program because we would consider a State Exchange implementing a web-broker program to be a significant change. Once implemented, for a State Exchange operating a web-broker program, HHS would monitor the operations of a State Exchange through the annual reporting by State Exchanges related to compliance with Federal requirements, consistent with our oversight authority at § 155.1200(b)(2). Specifically, HHS would use this oversight authority to evaluate State Exchange compliance with the policies we are finalizing at § 155.220 for those State Exchanges that elect to operate a web-broker program, as HHS does with other aspects of State Exchange operations on an annual basis. If there is information suggesting a State Exchange or one of its web-brokers does not meet the requirements of the policies we are finalizing at § 155.220, we would notify the State Exchange and give them an opportunity to address the potential non-compliance. We will consider the development of new, additional tools to assist with oversight that could enhance transparency into compliance by State Exchanges, including their web-broker programs, with applicable Federal requirements. We may also consider use of other oversight tools and authority, including those under Part 155 of our regulations, as appropriate.

Comment: A few commenters who opposed the proposals broadly stated that State Exchanges should maintain their current flexibility for establishing rules governing their web-broker programs, given that State Exchanges understand their markets best. One of these commenters further stated that the

¹⁷¹ The following provisions can be waived under section 1332 of the ACA: (1) Part I of subtitle D of Title I of the ACA (relating to the establishment of QHPs); (2) Part II of subtitle D of Title I of the ACA (relating to consumer choices and insurance competition through Health Benefit Exchanges); (3) Section 1402 of the ACA (relating to reduced cost sharing for individuals enrolling in QHPs); and (4) Sections 36B (relating to refundable credits for coverage under a QHP), 4980H (relating to shared responsibility for employers regarding health care coverage), and 5000A (relating to the requirement to maintain minimum essential coverage) of the Internal Revenue Code (Code)

¹⁷² See section 1332(a)(2)(B) of the ACA.

¹⁷³ In order for a section 1332 waiver to be approved, the Departments must determine that the waiver meets the guardrails such that the waiver will provide coverage that is at least as comprehensive as the coverage provided without the waiver; provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable as without the waiver; provide coverage to at least a comparable number of residents as without the waiver; and not increase the Federal deficit. See section 1332(b)(1)(A)–(D) of the ACA.

¹⁷⁴ See 45 CFR 155.1300–155.1332 and 31 CFR 33.100–33.132.

proposals may hinder web-broker creativity with how web-brokers display information on their non-Exchange websites in States with State Exchanges, but the commenter did not offer more specific feedback to explain how the proposal would hinder creativity or innovation by web-brokers. Another opposing commenter generally stated that HHS should focus on developing regulations that encourage web-broker participation in the Exchanges. One commenter who broadly supported the goals of the proposals stated that while measures should be taken in State Exchanges with regard to web-broker operations to incorporate necessary consumer safeguards, HHS should provide State Exchanges flexibility in identifying how to implement such safeguards.

Response: We agree that States and State Exchanges understand their market dynamics best, and as such, our goal with these proposals was to identify the subset of existing HHS minimum standards that should apply across all Exchanges to provide baseline consumer protections while also maximizing opportunities for State Exchange flexibility and encouraging broad web-broker participation. For example, while we are requiring that web-brokers in State Exchanges display specific disclaimers to provide consumers with clear and consistent information, we also are providing flexibility for State Exchanges to incorporate State-specific information into these website disclaimers, provided the additional language does not conflict with the HHS-provided standardized disclaimer. These disclaimers provide standardized information to consumers on important topics, such as the consumer's eligibility for APTC/CSRs and limitations on the choice of QHPs that consumers may enroll in on a web-broker's non-Exchange website.

We do not believe that the requirement for web-brokers to display such disclaimers should hinder web-broker participation, particularly since all web-brokers participating in a particular State Exchange will need to display the same disclaimers and will need to display similar disclaimers across all Exchanges. As another example, while we are requiring that web-brokers in State Exchanges demonstrate operational readiness to the applicable State Exchange, we are also providing State Exchanges flexibility in how they establish their operational readiness requirements and assessment process, while at the same time encouraging State Exchanges to leverage HHS operational readiness activities for

web-brokers participating in FFE and SBE-FPs where appropriate.

We believe that the application of these HHS minimum standards across all Exchanges will encourage web-broker participation, as State Exchanges implementing operational readiness requirements for web-brokers that align with the HHS framework would facilitate web-broker participation across multiple State Exchanges leveraging the same standards. While the HHS minimum standards we are finalizing as applicable to State Exchanges and their web-brokers provides a common set of baseline requirements, the framework adopted in this rule also provides State Exchanges flexibility to implement additional web-broker requirements based on the specific needs of their markets.

Additionally, we disagree that the HHS minimum standards we are extending to State Exchanges and their web-brokers will hinder creativity with respect to how web-brokers participating in State Exchanges display information on their non-Exchange websites. While these proposals represent a minimum set of standards for how information is presented on web-broker non-Exchange websites across all Exchanges, the standards are not prescriptive concerning how web-brokers can further customize their websites to better appeal to and serve consumers. For example, some web-brokers assisting consumers in the FFEs and SBE-FPs have implemented additional website functionalities that do not conflict with the minimum set of HHS standards concerning how information must be presented on web-broker websites, such as novel plan recommendation algorithms, affordability estimates, and plan filters.

8. Establishing Requirements for DE Entities Mandating *HealthCare.gov* Changes Be Reflected on DE Entity Non-Exchange Websites Within a Notice Period Set by HHS (§ 155.221(b))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82562), we proposed to revise § 155.221(b) to require that *HealthCare.gov* changes be reflected and prominently displayed on DE entity non-Exchange websites assisting consumers in FFEs and SBE-FPs within a specific notice period¹⁷⁵ set by HHS. We explained that we conduct various DE entity monitoring programs, including website display reviews, and

routinely identify areas where DE entity non-Exchange websites can improve the user experience and more closely align with *HealthCare.gov*. The changes that we proposed to require DE entities to make to their non-Exchange websites included changes that enhance the consumer experience, simplify the plan selection process, and increase consumer understanding of plan benefits, cost-sharing responsibilities, and eligibility for financial assistance. This proposal would codify our existing practice of communicating important changes to the *HealthCare.gov* display to EDE entities to ensure their EDE websites conform to those changes and provide the same vital information to consumers, expand our existing change requests processes to permit entities to request deviations from required display changes, require DE entities that do not participate in EDE to comply with this practice, and require State Exchanges that choose to implement a DE program to require their DE entities to implement and prominently display website changes in a manner that is consistent with display changes made to the State Exchanges' websites on their non-Exchange websites for purposes of assisting consumers with DE in QHPs offered through the Exchange in a manner that constitutes enrollment through the Exchange.

The display requirements for DE entity non-Exchange websites are captured in §§ 155.220, 155.221, 156.265, and 156.1230. The website display requirements are often technical in nature and can require subsequent release of guidance to provide technical and operational details to support their implementation. When HHS makes changes to the *HealthCare.gov* display, we notify EDE entities assisting consumers in the FFEs and SBE-FPs of these changes and require that they make them to their non-Exchange websites via the HHS-initiated change request process outlined in the Third-Party Auditor Operational Readiness Reviews for the Enhanced Direct Enrollment Pathway and Related Oversight Requirements guidance document referred to as the "Third-Party Auditor Guidelines."¹⁷⁶ This process helps ensure consumers receive vital information they need in a timely fashion. We refer readers to the 2025 Payment Notice proposed rule (88 FR

¹⁷⁵ "Notice period" refers to the time period that DE entities have to reflect and prominently display *HealthCare.gov* changes communicated to them by HHS pursuant to this proposal.

¹⁷⁶ CMS. (2023, March 1). *Third-party Auditor Operational Readiness Reviews for the Enhanced Direct Enrollment Pathway and Related Oversight Requirements*. CMS. Section IX.B., pp. 72–74. <https://www.cms.gov/files/document/guidelines-enhanced-direct-enrollment-audits-year-6-final.pdf>.

82563) for further discussion of the background for this proposal.

As stated in the proposed rule (88 FR 82563), this proposal codifies and expands this existing, HHS-initiated change request practice for EDE entities non-Exchange websites and supports consistency as to the timing of display changes across enrollment platforms, which will help ensure all Exchange consumers have timely access to accurate, clear information as they navigate the QHP selection and enrollment processes. Most DE partners in FFE and SBE-FP States participate in EDE and therefore are already familiar with and complying with this proposal because it is part of the existing requirements, as outlined in the Third-Party Auditor Guidelines. However, this will be new for some DE partners, such as those that only participate in Classic DE, because they are not currently subject to these requirements, which currently only apply to DE entities that participate in EDE in FFE and SBE-FP States. It is especially important that changes to the *HealthCare.gov* display are reflected on non-Exchange websites, including websites used for both Classic DE and EDE, as a steadily increasing number of the FFEs' and SBE-FPs' consumers enroll in Exchange plans via these DE pathways. This proposal will help ensure consumers using these DE pathways benefit from the policies we introduce to improve the *HealthCare.gov* website display by enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process.

We recognize that the technical details necessary to implement website display changes must be communicated to DE entities with sufficient notice for development prior to implementation. As such, we proposed that HHS would provide DE entities with advance notice to give them time to implement the changes on their non-Exchange websites. We explained that we intend for the duration of the advance notice period to correspond to the complexity of the change and the urgency with which the change must be reflected on the DE entity's non-Exchange website (that is, we intend to provide a longer advance notice period for implementation of changes requiring more complex website-development work, or for lower-urgency changes). We explained that we would categorize display changes as simpler versus more complex based on a combination of factors, including, but not limited to, consideration of the following: number of website pages affected; number of data fields affected; nature of the change

(that is, text-based versus data-based); whether the change is static or dynamic based on user input; whether the change updates QHP data provided by us¹⁷⁷ or involves the display of new data not previously provided by us (that is, new data types would be considered a more complex change due to the web-development work required to integrate a new PUF data field or MAPI data variable); and whether the change may affect backend algorithms for plan sorting, filtering, or recommendations. The complexity of the change would be the primary factor determining the length of the advance notice period. Generally, we would expect to provide approximately 30 calendar days' advance notice of simpler display changes and up to 90 or more calendar days' advance notice for more complex changes. However, in situations where we have determined that it is urgent that *HealthCare.gov* display changes are similarly made to DE entities' non-Exchange websites to communicate necessary information to consumers regarding their plan selection or enrollment, we explained that we may provide fewer than 30 days' advance notice, but not less than 5 business days' advance notice. When considering the urgency of a display change, we further explained that we would consider a number of factors, including, but not limited to, the following: potential to impact consumers' understanding of plan benefits and cost-sharing responsibilities; potential for consumers to receive an incorrect eligibility determination; potential impact to the consumer's understanding of their eligibility for financial assistance (that is, APTC or CSR); proximity to the Open Enrollment period (with changes becoming more urgent as Open Enrollment nears, as implementing changes prior to Open Enrollment is critical for ensuring the greatest number of consumers are able to benefit from the changes); and whether failure to implement the change may result in a display that is misleading or confusing to consumers.

We proposed to amend § 155.221 to add new paragraph (b)(6), which would require DE entities in FFE States to implement and prominently display

¹⁷⁷ We provide DE entities with the QHP comparative information that must be displayed in accordance with § 155.220(c)(3)(i)(A) and § 156.1230(a)(1)(ii). We provide this data via the Public Use Files (PUF) (<https://www.cms.gov/cciio/resources/data-resources/marketplace-puf>) and through non-Exchange website integration with the Marketplace Application Program Interface (MAPI) (<https://developer.cms.gov/marketplace-api/>). In this context, website integration refers to connecting the non-Exchange website with Exchange data by using the MAPI.

website changes in a manner that is consistent with display changes made by HHS to *HealthCare.gov* by meeting standards communicated and defined by HHS within a time period set by HHS, unless HHS approves a deviation from those standards. Consistent with § 155.221(i), this new DE entity non-Exchange website display requirement would also apply to DE entities that enroll qualified individuals in coverage in a manner that constitutes enrollment through an SBE-FP or assist individual market consumers with submission of applications for APTC and CSRs through an SBE-FP.

We are cognizant of, and support, DE entity non-Exchange websites' use of innovative decision-support tools and user interface design to help consumers shop for and select QHPs that best meet their needs. This proposal is not intended to prohibit or otherwise stand in the way of DE entities' development of such tools and consumer interfaces. Consistent with the existing approach for implementation of HHS-initiated changes described in the Third-Party Auditor Guidelines, we explained that we would implement this requirement with a focus on requiring DE entities in FFE and SBE-FP States to mirror any display changes made to *HealthCare.gov* that impact a consumer's understanding of plan benefits, cost-sharing responsibilities, and eligibility for financial assistance. For each required change, DE entities in FFE and SBE-FP States would need to implement on their non-Exchange websites conforming display changes in a manner that is consistent with display changes made by HHS to *HealthCare.gov* by meeting standards defined by HHS. We explained that we would provide DE entities flexibility in their user interface graphic design, provided that their design complies with the standards defined by HHS in the notification of required change(s). As part of this proposal, we would require that all front-end website changes (that is, website changes that would affect the visual aspects of the website that users see and interact with) be prominently displayed on DE entity non-Exchange websites. As used in this context, "prominently displayed" means that text must be written in a font size no smaller than the majority of the text on the web page, text must be displayed in the same non-English language as any language(s) the DE entity maintains translations for on its website,¹⁷⁸ and any display changes must be noticeable in the context of the website (that is, DE entity non-Exchange websites must use

¹⁷⁸ 45 CFR 155.205(c)(2)(iv).

a font or graphic color that contrasts with the background of the web page and ensure any graphics and iconography that they are required to display are readable without requiring the user to increase their magnification percentage greater than 100 percent). The DE entity may change the font color, size, or graphic context of the information to ensure that it is noticeable to the user in the context of its website or other written material.

For example, in a scenario where *HealthCare.gov* is updated to display new help text communicating educational content to consumers that is designed to help a consumer better understand plan benefits, cost-sharing responsibility, or eligibility for financial assistance, we would require the DE entity's non-Exchange website to display that help text or similar text. When notifying DE entities about the required change, we would establish and communicate the standards that must be met for display of the required change, such as the new help text that must be prominently displayed on their websites. If the standards allow the DE entity to display similar text to the language used on *HealthCare.gov* (for example, when information must be communicated but there is a low risk of misinterpretation of the information such that we will not require DE entities to display the exact language used on *HealthCare.gov*), we would provide DE entities with information on how the help text is displayed on *HealthCare.gov*, along with the standards that must be met, while also outlining the flexibility for DE entities to adapt the language to reflect their own entity branding if it generally conveys the same information and meaning as the help text displayed on *HealthCare.gov*. In this example, we would also allow flexibility as to the location of the help text if it adheres to the prominent display requirements discussed earlier in this proposal. In this scenario, DE entities would be able to adjust the language and decide on the location of the help text on the QHP selection page(s) without seeking prior approval from HHS. However, we would monitor implementation through existing periodic website review monitoring per § 155.220(c)(5) and, as described in the Third-Party Auditor Guidelines,¹⁷⁹ may notify the DE entity if we find that their language does not convey the same meaning as the help

text displayed on *HealthCare.gov* or if we find the help text is not prominently displayed. Such notification would occur via a letter that would provide the DE entity with feedback explaining the noncompliance and required corrective actions (such letter is referred to as "Technical Assistance"). If Technical Assistance fails, we may potentially take enforcement action to address the identified instances of non-compliance, which could include temporarily suspending the DE entity's ability to transact information with the Exchange if we discover circumstances that pose unacceptable risk to eligibility determination, Exchange operations, or Exchange systems, if warranted.¹⁸⁰

Additionally, we explained that we recognize that some DE entities may have system constraints that prevent them from precisely mirroring the *HealthCare.gov* display approach, and so we proposed that if a DE entity is unable to implement the standards defined by HHS, or the DE entity has an idea for implementation that does not meet the standards but would effectively communicate the same information to consumers, we may permit a deviation. We proposed that DE entities that are interested in pursuing a deviation must submit deviation requests to HHS and proposed that such requests would be subject to review by HHS in advance of implementation of any alternative display approaches. We explained that deviation requests must include a proposed alternative display and accompanying rationale. The rationale must explain why the DE entity is unable to implement the standards or how the DE entity's idea for implementation that does not meet the HHS standards would effectively communicate the same information to consumers. Therefore, similar to the differential website display requirements for standardized plans applicable to web-broker and QHP issuer DE entities at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv) and the HHS-initiated change request process, we proposed to allow DE entities to request a deviation from the standards communicated by HHS for required display changes to align with *HealthCare.gov* by submitting a proposed alternative display and accompanying rationale or explanation for why a deviation is necessary. In reviewing deviation requests, HHS would consider whether the same level of differentiation and clarity is being provided under the deviation requested by the DE entity as is provided on

HealthCare.gov. Other factors and criteria HHS would consider include, but are not limited to, whether the proposed alternative website display adheres to the standards for prominent display described in this proposal and whether the display provides correct information, without omission of material fact, that does not have the potential to be misleading to consumers.

Under the proposed approach, the deviation request would have to be submitted and approved by HHS before DE entities would be permitted to implement any alternative website displays. Deviation requests would not toll the advance notice period. This deviation request process is separate and distinct from the flexibilities in user interface graphic design that we would allow without preapproval as long as the design and display otherwise meets the applicable standards defined and communicated by HHS for the display change. DE entities would only need to request a deviation from the requirements of the standards communicated by HHS if the DE entity seeks to deviate from those standards or specifications when it implements a display change to its Non-Exchange website that is required by HHS pursuant to this proposal.

We also proposed in new § 155.221(j)(3) to extend this new proposed DE entity non-Exchange website display requirement to require State Exchanges that choose to implement a DE program to require their DE entities to implement and prominently display website changes in a manner that is consistent with display changes made by State Exchanges to the State Exchanges' website on their non-Exchange websites. We believe it is necessary for consumers utilizing DE entities in States with State Exchanges to have access to the same vital information pertaining to their plan selection and enrollment process as they would have if they were enrolling via the State Exchanges' websites. Under this proposal, we would require State Exchanges to establish and communicate standards for required display changes and to set the time period within which display changes must be implemented on DE entities' non-Exchange websites. State Exchanges would also be required to review deviation requests submitted by DE entities and establish their own deviation request process should the State Exchange elect to permit deviation requests. DE entities are required to follow the process established by the State Exchange. We would provide flexibility for State Exchanges to develop their own process for

¹⁷⁹ CMS. (2023, March 1). *Third-party Auditor Operational Readiness Reviews for the Enhanced Direct Enrollment Pathway and Related Oversight Requirements*. CMS. Section X.F., p. 69. <https://www.cms.gov/files/document/guidelines-enhanced-direct-enrollment-audits-year-6-final.pdf>.

¹⁸⁰ 45 CFR 155.221(e).

communicating those standards, setting advance notice periods, and establishing a deviation request process as needed to meet the business needs of the State Exchange. We would encourage State Exchanges that choose to implement a DE program to consider the same factors described above (that is, urgency and complexity of the change) when determining the advance notice period. Similarly, we would encourage State Exchanges to provide their DE entities with examples of the State Exchange website display change and technical assistance, including technical implementation guidance, to ease the burden of implementing and prominently displaying required changes. We would require State Exchanges to apply HHS's standard for "prominently display," explained earlier in this section of this final rule, to help ensure that important enrollment, eligibility, and other information is as noticeable and clear to consumers using DE entities' websites in State Exchanges as it is to consumers using State Exchange websites or *HealthCare.gov*, which we believe will enhance the user experience, increase understanding, and simplify the plan selection process for all consumers.

As part of this proposal to extend the requirement for DE entities to reflect Exchange website changes on their non-Exchange websites to State Exchanges and their DE entities, we would rely on State Exchanges that choose to implement a DE program to enforce compliance with these requirements and take enforcement action when their DE entities fail to comply and update their non-Exchange websites to mirror changes made to the State Exchange website. We would be available to provide technical assistance to support the State Exchanges' efforts to take appropriate enforcement action as needed to ensure compliance with applicable requirements. There may exist scenarios where the website display requirements may differ between the FFEs or SBE-FPs versus the State Exchanges (for example, in scenarios where a State Exchange uses the *HealthCare.gov* disclaimer language and adds State-specific information such as replacing a *HealthCare.gov* hyperlink with the State Exchange hyperlink). In such scenarios, DE entities would be required to tailor their non-Exchange website display to the requirements of the Exchange through which the consumer is seeking assistance. Based on our experience providing oversight of DE entity website displays in FFE and SBE-FP States, we understand that many DE entities are

familiar with and have the capability to tailor website displays based on different scenarios and, as such, we anticipate DE entities will have the capability to tailor website displays to mirror the website of the Exchange the consumer is shopping for coverage in.

With an increasing number of consumers utilizing the DE pathways to enroll in coverage through the Exchanges, we believe it is important to codify a requirement to mandate changes made to *HealthCare.gov* (or for State Exchanges, the State Exchanges' websites) be implemented on DE entity non-Exchange websites within a timeframe specified by HHS (or, for DE entities assisting consumers in State Exchanges, within a timeframe specified by the State Exchange). These proposals would ensure consumers using DE entity non-Exchange websites have a similar user experience, with access to the same information in a similar manner as provided on *HealthCare.gov* and State Exchange websites.

We sought comment on all aspects of these proposals.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these proposals without modification but with technical changes to the regulatory text. These changes clarify that DE entities in States with State Exchanges must implement and prominently display website changes in a manner consistent with display changes made to the State Exchange website, unless the State Exchange approves a deviation from those standards under the deviation request process that the State Exchange is required to establish, should the State Exchange elect to permit deviation requests. We acknowledge that the language in the proposed rule, including its regulatory text, may have been confusing and subject to different interpretations, and accordingly, we clarify our intent and the regulatory text in this final rule. The approach, as clarified by these technical changes, is consistent with the proposal as discussed in the preamble to the proposed rule (88 FR 82565), which stated that the State Exchange would be required to establish a deviation request process and review deviation requests submitted by DE entities, should the State Exchange want to permit deviations. The commenters appear to have interpreted the proposed rule consistent with these technical changes, with one commenter specifically suggesting HHS encourage State Exchanges to consider deviation requests. For clarity, we also are making technical changes to the regulatory text

at § 155.221(j)(3), which stated in the proposed rule (88 FR 82651) that State Exchanges must require their direct enrollment entities to implement and prominently display "changes adopted for display on the State Exchanges' websites." The revised regulatory text now states that State Exchanges must require their DE entities to implement and prominently display "website changes in a manner that is consistent with the display changes made by State Exchanges to the State Exchanges' websites." This technical change aligns the regulatory text of § 155.221(j)(3) with paragraph (b)(6) but does not represent a change in the policy discussed in the proposed rule (88 FR 82565).

We summarize and respond below to public comments received on the proposed requirement that *HealthCare.gov* or State Exchange website changes be reflected and prominently displayed on DE entity non-Exchange websites within a specific notice period set by HHS or the State Exchange.

Comment: Most commenters who addressed these proposals supported their adoption as proposed, stating benefits such as enhanced consumer protection, accuracy, efficiency, and consistency across Exchanges. One commenter noted these changes will also establish consistency between Classic DE and EDE websites in FFE and SBE-FP States. A few commenters noted these proposals expand HHS' existing practice of ensuring adequate communication of *HealthCare.gov* changes to consumers across platforms and Exchange types. One commenter stated these proposals will limit consumer confusion or consumer action based on "outdated eligibility or plan availability information." A few commenters recommended that web-brokers be required to display all plan information in a manner that exactly replicates the *HealthCare.gov* or State Exchange website display. One commenter emphasized that providing DE entities with technical and operational assistance is vital for ensuring changes are executed correctly and effectively. One commenter opposed these proposals, stating that it diminishes the value of DE and contradicts the ability for DE entities to tailor their experience to best suit consumers.

Response: We appreciate the comments in support of these requirements and agree they will ultimately minimize consumer confusion, support consistency across Exchanges, and promote increased consumer understanding by mandating

that DE entity non-Exchange websites reflect and prominently display changes made to the applicable Exchange's website within the notice period set by HHS or the State Exchange, as applicable. As described above and in the proposed rule (88 FR 82563 through 82565), we agree that this approach will codify our existing HHS-initiated change request practices for communicating *HealthCare.gov* changes to EDE partners and expand it to apply across all DE non-Exchange websites in FFE and SBE-FP States for both Classic DE and EDE.

We agree this policy may limit consumer confusion or consumer action based on outdated eligibility or plan information insofar as this policy requires DE entities to reflect and prominently display changes that increase consumer understanding of eligibility for financial assistance or plan information on their non-Exchange websites (for example, making plan information—or a link to it—more conspicuous on a web page). We note that this policy does not impact existing requirements for web-broker websites used to complete QHP selection in FFE and SBE-FP States¹⁸¹ to provide consumers the ability to view all QHPs offered through the Exchange.¹⁸² This policy also does not impact existing requirements for web-broker websites used to complete QHP selection in FFE and SBE-FP States to display QHP information and information pertaining to a consumer's eligibility for APTC or CSRs under §§ 155.220(c)(3)(i)(A) and (I), which also extends to web-brokers assisting consumers in State Exchanges under new § 155.220(n). We note that under § 155.221(a)(2), these requirements also apply to DE entity non-Exchange websites in the FFEs and SBE-FPs¹⁸³ to the extent those DE entities are web-brokers, and under proposed § 155.220(n), these requirements would apply to DE entity non-Exchange websites operating in State Exchanges to the extent those DE entities are web-brokers.

We appreciate the emphasis on the need for HHS to provide technical and operational assistance and are committed to providing such assistance to ensure DE entities in the FFEs and SBE-FPs have the tools and information required to implement the required display changes accurately and efficiently. We encourage State Exchanges that choose to implement DE programs to provide similar support to their DE entities.

We acknowledge the comments requesting that web-brokers be required to exactly replicate the *HealthCare.gov* or State Exchange website display. However, we did not propose nor are we finalizing such a requirement.¹⁸⁴ As described above and in the proposed rule (88 FR 82564), we support DE entity non-Exchange websites' use of innovative decision-support tools and user interface design, and we believe that requiring an exact replication of *HealthCare.gov* or State Exchange websites would hinder such innovation. We believe the approach we are adopting, including permitting flexibility in DE entity non-Exchange website user interface graphic design¹⁸⁵ when implementing required *HealthCare.gov* or State Exchange website display changes and the deviation requests process,¹⁸⁶ will allow

¹⁸⁴ We note that under § 155.220(c)(3)(i)(A), (B) and (D) web-brokers operating in FFEs are required to disclose and display 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, provide consumers the ability to view all QHPs offered through the Exchange, and display all QHP data provided by the Exchange. These same requirements currently apply to web-brokers operated in SBE-FPs. See 45 CFR 155.220(l). As finalized in this rule and reflected in new § 155.220(n), the web-broker requirement in § 155.220(c)(3)(i)(A) that web-brokers disclose and display on their non-Exchange website the standardized QHP information provided by the Exchange or directly by QHP issuers also extends to web-brokers in State Exchanges.

¹⁸⁵ This approach does not require entities to directly mirror the Exchange website displays. Rather, Exchanges will define and communicate standards that DE entities must meet when implementing and prominently displaying website display changes in a manner that is consistent with the display changes made to the Exchange websites. DE entities will have flexibility in how they reflect and incorporate those changes within the context of their user interface graphic design, provided their display meets the standards communicated by the Exchanges. For further discussion and an example of how this flexibility will be applied. See 2025 Payment Notice proposed rule (88 FR 82564–82566).

¹⁸⁶ In the proposed rule (88 FR 82565), we proposed that if a DE entity is unable to implement the standards defined by HHS, or the DE entity has an idea for implementation that does not meet the standards but would effectively communicate the same information to consumers, HHS may permit a deviation. We proposed that DE entities that are interested in pursuing a deviation must submit deviation requests to HHS and proposed that such requests would be subject to review by HHS in advance of implementation of any alternative display approaches. We explained that deviation requests must include a proposed alternative display and accompanying rationale. The rationale must explain why the DE entity is unable to implement the standards or how the DE entity's idea for implementation that does not meet the standards would effectively communicate the same information to consumers. Finally, we proposed

DE entities sufficient flexibility to integrate required changes within the context of their non-Exchange website. The approach will simultaneously provide necessary consumer protections by requiring the DE entity's user interface design to comply with the standards defined by HHS or the State Exchange or, in the case of deviation requests submitted to HHS, by requiring HHS to consider whether the same level of differentiation and clarity is provided under the deviation requested by the DE entity as is provided on *HealthCare.gov* when considering deviation requests. We encourage State Exchanges to establish a deviation request process, and we expect that State Exchanges will consider the business needs of their Exchange and the interests of consumers in their State, including consumer protection, when they review deviation requests, should the State Exchange elect to permit deviation requests.

We do not agree with the commenter that suggested these requirements diminish the value of DE or contradict the ability for DE entities to tailor their experience to best suit consumers. As discussed previously in this section of this final rule, these requirements support flexibility in the implementation of required changes by DE entities. They are not intended to impair DE entities' ability to tailor their user interface design. For example, DE entities are allowed to make changes to the font color, size, or graphic context of the information to ensure that it is noticeable in the context of its website. Rather, they establish a pathway for DE entities to innovate while ensuring that DE entity non-Exchange websites provide the same level of differentiation and clarification for consumers as is provided on *HealthCare.gov* or a State Exchange's website. We continue to believe that, as explained in the proposed rule (88 FR 82563), these requirements will help ensure all Exchange consumers have timely access to accurate, clear information as they navigate the QHP selection and enrollment processes. As a result, we expect they will help make DE an

that State Exchanges would also be required to establish their own deviation request process and review deviation requests submitted by their DE entities should the State Exchange elect to permit deviation requests. State Exchanges would have flexibility to establish a deviation request process as needed to meet the business needs of the State Exchange and would have discretion to approve or reject a deviation request from one of its DE entities. We are finalizing this approach as proposed but with technical changes to affirm that State Exchanges must establish a deviation request process should the State Exchange elect to permit deviation requests.

¹⁸¹ See § 155.220(l).

¹⁸² See § 155.220(c)(3)(i)(B).

¹⁸³ See § 155.221(i).

accessible, valuable tool for all Exchange consumers.

Comment: A few commenters expressed concern that the deviation request process could be used to circumvent Federal policy. The commenters requested that HHS only grant deviations upon a demonstration of a special need and that HHS clarify that it may request additional documentation to periodically reassess whether the deviation remains justified.

Response: We acknowledge the concern that the deviation request process could be used to circumvent Federal policy. However, we do not share this concern. As described above and in the proposed rule (88 FR 82565), we intend to review all deviation requests submitted by DE entities assisting consumers in the FFEs and SBE-FPs to ensure the deviation, at a minimum, provides the same level of differentiation and clarification as is provided on *HealthCare.gov*. We do not intend to approve deviation requests for display approaches that are inconsistent with the display change made to *HealthCare.gov*. We encourage State Exchanges to establish deviation requests processes and anticipate State Exchanges that opt to establish such a process will adopt a similar framework to review deviations requests and monitor implementation of approved deviations to ensure compliance by their DE entities.

Although we appreciate the suggestion that deviation requests should be limited to demonstration of special need, we note that the commenter did not define what they meant by “special need” in this context. If the commenter means to suggest that deviation requests should only be granted when system constraints prevent DE entities from precisely mirroring the *HealthCare.gov* display approach, and that deviation requests should not be granted when a DE entity has an innovative idea for implementation that does not meet the standards but would effectively communicate the same information to consumers, then we do not agree with this suggestion. This suggestion, if implemented, would be in opposition to our longstanding support for and encouragement of innovation by DE entities because it would prohibit the ability of DE entities to use the deviation request process to propose innovative website displays, decision-support tools, and user interface designs. Our experience operating the DE program in the FFE and SBE-FPs, particularly in soliciting feedback from DE entities regarding the effects of innovative website displays, decision

support tools, and user interfaces, has helped inform display updates to *HealthCare.gov*.

We acknowledge the comment requesting we clarify that we may request additional documentation to periodically reassess whether the deviation remains justified. As described above and in the proposed rule (88 FR 82564), for DE entities assisting consumers in the FFEs and SBE-FPs, we will monitor DE entity implementation through existing periodic website review monitoring per § 155.220(c)(5) and as described in the Third-Party Auditor Guidelines. Our periodic reviews will include review of DE entities’ implementation of approved deviations and may also include a review of the documentation submitted in connection with the deviation request. We may request updated documentation from DE entities if our review suggests that the deviation no longer remains justified. For example, if the initial approval was granted based on a factor which appears no longer relevant (for example, if approval was granted for the DE entity to implement an alternative display while the entity was in the process of switching to a new DE Technology Provider¹⁸⁷), we would request updated documentation from the DE entity confirming whether the initial approval conditions are still relevant (for example, has the entity completed its transition to a new DE Technology Provider, using the previous example). We encourage State Exchanges to adopt these same practices in reviewing deviation requests and monitoring implementation of approved deviations to ensure compliance by their DE entities.

Comment: One commenter noted that members of the web-broker and DE community appreciate the general regulatory framework offered by HHS for the FFEs and SBE-FPs under §§ 155.220 and 155.221 and would appreciate the adoption of uniform regulatory standards by State Exchanges, including as to DE entity non-Exchange website implementation of Exchange website display changes under new § 155.221(b)(6) and (j)(3). One commenter requested that HHS clarify what would happen in instances where State Exchanges that choose to implement a DE program do not meet the requirements associated with this proposal. One commenter supported the proposal to require DE entities operating in States with State Exchanges to

implement State Exchange website display changes on their non-Exchange websites but wanted HHS to encourage these States to implement the following practices when requiring DE entities to make changes to their websites: solicit feedback from industry partners; provide ample advance notice; provide flexibility in website user interfaces; and permit deviations subject to the approval of the State Exchange. One commenter similarly supported the proposal to require DE entities utilized by State Exchanges to implement State Exchange website display changes on their non-Exchange websites but encouraged HHS “to grant the maximum amount of flexibility to State Exchanges in how they implement that process,” explaining that this would allow State Exchanges to “innovate and reduce the burden needed for EDE entities to produce novel tools to benefit consumers and agents.”

Response: We generally agree with the commenter that suggested State Exchanges should adopt web-broker and DE entity standards consistent with the standards for web-brokers and DE entities in the FFEs and SBE-FPs. In the proposed rule (88 FR 82564 through 82565), we proposed extending the requirements under § 155.221(b)(6) to State Exchanges and DE entities assisting consumers in those State Exchanges. We also proposed extending certain HHS minimum standards applicable to web-brokers (88 FR 82557 through 82562) and DE entities (88 FR 82566 through 82571) operating in the FFEs and SBE-FPs to web-brokers and DE entities in States with State Exchanges and, consequently, those State Exchanges.

If there is information that suggests a State Exchange or one of its DE entities does not meet the requirements of § 155.221(j) and in particular, (j)(3), we would notify the State Exchange and give them an opportunity to address the concerns. We intend to consider the development of new, additional tools to assist with oversight that could enhance transparency into compliance by State Exchanges, including their DE programs, with applicable HHS requirements including those relating to DE under § 155.221(j)(3). We may also consider use of other oversight tools and authority, including those under part 155 of our regulations, as appropriate.

As described in the responses to comments received on the proposals to require that DE entities and web-brokers operating in State Exchanges meet certain standards applicable in the FFEs and SBE-FPs (sections III.D.7 and III.D.9 of this final rule), pursuant to § 155.105, States that seek to operate a State

¹⁸⁷ See § 155.20 for definitions of an “Agent or broker direct enrollment technology provider” and “Qualified health plan issuer direct enrollment technology provider.”

Exchange must complete and submit an Exchange Blueprint application. The Exchange Blueprint application documents that an Exchange will meet the legal and operational readiness requirements required of a State Exchange. As part of a State's Blueprint submission, the State also agrees to demonstrate operational readiness to implement and execute the Federal requirements applicable to State Exchanges, which would include the new requirements under §§ 155.220 and 155.221 applicable to State Exchanges that elect to implement a web-broker or DE program. A State Exchange that elects to operate an optional web-broker or DE program would be required to include information in its Blueprint to demonstrate operational readiness to implement and support ongoing operations of an optional web-broker or DE programs consistent with applicable requirements in §§ 155.220 and 155.221. As discussed in other sections of this final rule, we are also codifying requirements at § 155.105 related to the approval of a State Exchange whereby we will require a State seeking to establish a State Exchange to provide supplemental information in its Blueprint application to demonstrate its ability to implement and comply with the requirements for operating a State Exchange, including requirements associated with the operation of a DE program should a State elect to operate one. Such supporting information would inform HHS's decision to approve or conditionally approve a State Exchange and would help facilitate HHS' oversight of compliance with Federal requirements applicable to State Exchanges and their DE entities. Additionally, under § 155.105(e), an existing State Exchange must notify HHS in writing before making a significant change to its approved Exchange Blueprint, and no significant change to an Exchange Blueprint may be effective until it is approved by HHS in writing or 60 days after HHS receipt of a completed request.

Accordingly, for existing State Exchanges that seek to newly implement and operate a DE program, HHS would require the State to submit an updated Exchange Blueprint and participate in operational readiness reviews related to the implementation and ongoing operation of such a DE program, as we would consider a State Exchange implementing a DE program a significant change. We would also use this information in the Blueprint Application from a State Exchange on how they intend to implement the DE entity non-Exchange website display

update requirements to assess a State Exchange's compliance with § 155.221(j)(3), and we would generally look to the State Exchange to oversee implementation by DE entities of non-Exchange website display changes pursuant to § 155.221(j)(3) on an ongoing basis.

We acknowledge the commenter's suggestion that we encourage State Exchanges to solicit feedback from industry partners, provide ample advance notice, provide flexibility in website user interfaces, and permit deviations subject to the approval of the State Exchange. Although we also acknowledge the commenter's suggestion that we should grant the maximum amount of flexibility to State Exchanges in how they implement these requirements, we note the commenter did not provide further details or clarification on what additional flexibilities, if any, should be granted to State Exchanges. As a result, we are unsure what the commenter is referring to. However, we agree with several of the commenter's points. As we explained in the proposed rule (88 FR 82565), we encourage State Exchanges to develop their own processes that best meet their business needs. Consistent with the commenter's suggestion, we encourage State Exchanges to solicit feedback from industry partners, including web-brokers and DE entities, and provide an advance notice period whose length corresponds to the complexity of the required display change and the urgency with which the change must be reflected on the DE entity's non-Exchange website. Also consistent with the commenter's suggestion, our policy requires State Exchanges to establish a deviation request process while providing the State Exchange discretion to approve or reject deviation requests, should the State Exchange elect to permit deviation requests. If the State Exchange permits deviation requests, we encourage State Exchanges to consider granting deviation requests if the DE entity is unable to implement the standards defined by the State Exchange or has an idea for implementation that does not meet those standards but would effectively communicate the same information to consumers. We also agree that State Exchanges should permit DE entities flexibility in how they reflect and incorporate required display changes within the context of their user interface graphic design, provided their display meets the standards communicated by the Exchanges. We also encourage State Exchanges to adopt the same requirements and framework

HHS will follow for DE entity non-Exchange website display updates for the FFEs and SBE-FPs, whenever possible.

9. Ensuring DE Entities Operating in State Exchanges Meet Certain Standards Applicable in the FFEs and SBE-FPs (§ 155.221)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82566), we proposed to amend § 155.221 to extend certain existing HHS standards applicable to DE entities assisting the FFEs' and SBE-FPs'¹⁸⁸ consumers and applicants with direct enrollment in QHPs and applying for APTC/CSRs to DE entities operating in State Exchanges, in both the Individual Market Exchanges and SHOPS. These policies would extend certain HHS DE program standards to DE entities operating in State Exchanges, and consequently to those State Exchanges that, to the extent permitted by applicable State law, permit DE entities to assist their consumers and applicants with direct enrollment in QHPs and applying for APTC/CSRs in a manner that constitutes enrollment through an Exchange.¹⁸⁹ These policies would also ensure that certain minimum HHS standards would apply to DE entities across all Exchanges, including standards governing DE entity marketing and display of QHPs and non-QHPs, providing consumers with correct information and refraining from certain conduct¹⁹⁰ marketing of non-QHPs, website disclaimer language, and operational readiness.

Notably, we stated in the proposed rule (88 FR 82566) that our regulations do not currently address whether and how DE entities may assist consumers and applicants with DE in QHPs and submission of applications for APTC/CSRs in a manner that constitutes enrollment through a State Exchange. We believe that current and future State

¹⁸⁸ See 45 CFR 155.221(i) ("A direct enrollment entity that enrolls qualified individuals in coverage in a manner that constitutes enrollment through a State Exchange using the Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through a State Exchange using a Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.").

¹⁸⁹ See 78 FR 37065 through 37066 and 78 FR 54124 through 54126.

¹⁹⁰ Consistent with the amendments and policies adopted in this final rule, this standard applies to both QHP issuer DE entities, as well as web-brokers DE entities, across all Exchange types. For QHP issuer DE entities, see 45 CFR 155.221(a)(1) and (i), and 156.1230(b)(2). For web-broker DE entities, see 45 CFR 155.220(j)(2)(i), (l), and (n), and 155.221(a)(2).

Exchanges may seek to implement DE programs similar to the FFEs and SBE-FPs. As such, we believe that DE entities seeking to assist State Exchange consumers with DE in QHPs and submission of applications for APTC/CSRs in a manner that constitutes enrollment through an Exchange should meet the same or, at a minimum, similar standards that DE entities in the FFEs and SBE-FPs are required to meet to protect consumers and safeguard Exchange operations. These standards would mitigate the potential for consumer confusion of QHPs with non-QHPs (including eligibility for APTC and/or CSR as it relates to QHPs versus non-QHPs) and about which products are or are not available through the Exchange, helping to ensure proper eligibility determinations and protect against security incidents through implementation of operational readiness reviews (as websites that have not been tested for operational readiness may provide improper eligibility determinations or have security flaws that could increase the likelihood of a breach involving consumer PII).¹⁹¹

We recognize that, to date, no State Exchanges have implemented DE programs; however, as we stated in the proposed rule (88 FR 82566 and 82567), we anticipate that there may be growing interest in doing so. As such, we recognize a potential burden on State Exchanges that would newly be subject to the standards being proposed, if they choose to implement DE programs. This would include drafting new policies, updating standards, and potentially hiring additional staff to perform functions not currently being performed by the State Exchanges, including providing technical assistance during development and implementation of DE programs in the State Exchanges, creating the framework for and conducting operational readiness reviews, including developing and maintaining documentation needed to complete the operational readiness reviews, as well as conducting ongoing oversight and taking appropriate enforcement action in response to DE entity non-compliance with applicable requirements. This potential burden

would also include requiring and overseeing web-development and the hosting of non-Exchange websites by DE entities participating in these State Exchanges to ensure compliance with the proposed minimum standards outlined in this rulemaking.

Similar to the agent, broker and web-broker requirements under § 155.220, currently, § 155.221 only applies to DE entities assisting consumers and applicants in the FFEs and SBE-FPs. Section 155.221(a) provides that the FFEs will permit the following entities to assist consumers with DE in QHPs offered through the Exchange in a manner that is considered to be through the Exchange, to the extent permitted by applicable State law: (1) QHP issuers that meet the applicable requirements in §§ 155.221 and 156.1230, and (2) web-brokers that meet the applicable requirements in §§ 155.220 and 155.221. These same entities are permitted to assist consumers with DE in QHPs offered through the Exchange in a manner that is considered to be through the Exchange, to the extent permitted by applicable State law, in SBE-FP States.¹⁹² The HHS DE Program includes two DE pathways: Classic DE and EDE. The proposal to extend certain existing HHS standards applicable to DE entities participating in FFE and SBE-FP States to State Exchanges and their DE entities would also apply to the operation of Classic DE and EDE within these State Exchanges. That is, under this policy, State Exchanges that choose to implement DE programs in their States would be permitted to adopt the same pathways or tailor their configuration in a manner best suited to their operational and business needs, so long as their DE programs meet the HHS minimum standards under § 155.221 that we proposed to extend to State Exchanges and their DE entities. We explained that we would be available to provide extensive technical assistance to State Exchanges that choose to implement DE programs.

As detailed further below, we proposed to add paragraph (j) to § 155.221 to extend certain HHS minimum DE entity standards in § 155.221 to DE entities operating in State Exchanges and, consequently, to these State Exchanges that choose to implement DE programs in their States. Through this proposed approach, we seek to ensure that DE entities assisting these State Exchanges' consumers with DE in QHPs and applying for APTC/CSRs in a manner that constitutes enrollment through the Exchange meet HHS minimum standards governing DE

entity marketing and display of QHPs, providing consumers with correct information and refraining from certain conduct, marketing of non-QHPs, website disclaimer language, and operational readiness. We explained that, under this proposed approach, we would encourage State Exchanges to require DE entities to engage a third-party auditor to perform the operational readiness review audits of their DE entities, consistent with the operational readiness framework adopted by HHS for the FFEs and SBE-FPs. As stated earlier, we recognize that there may be a growing interest from State Exchanges to operate DE programs, and we seek to establish a set of HHS minimum standards to ensure appropriate safeguards are in place, regardless of the Exchange model. Further, the proposed approach to establish a minimum set of HHS standards that would apply to DE entities across all Exchanges would support efficiency in DE entity operations across all Exchanges, including State Exchanges, while also providing flexibility for State Exchanges to tailor their DE program and establish their own standards with respect to operational readiness demonstrations by their DE entities, including whether to require third-party audits of DE entities and to impose additional requirements beyond the proposed HHS minimum standards as they determine may be appropriate based on their operational or business needs. As described above, if they choose to implement DE programs, the State Exchanges would be required to draft policies, update standards, and potentially hire additional staff to perform functions and activities not currently being performed by the State Exchanges in order to comply with these policies.

We proposed to update § 155.221(a), which identifies the entities permitted to be DE entities in FFE and SBE-FP States, to apply across all Exchanges, including State Exchanges. Under this proposal, State Exchanges that choose to implement a DE program may permit QHP issuers and web-brokers that meet applicable requirements to assist consumers with submitting applications for APTC/CSRs and DE in QHPs offered through the Exchange in a manner that is considered to be through the Exchange. Under the framework proposed in the proposed rule, the applicable requirements that would extend to web-broker DE entities in States with State Exchanges would include certain paragraphs of §§ 155.220(c) and (j) and 155.221(a), (b), (c), (d), and (j). We describe above the extension of certain HHS web-broker

¹⁹¹ The amendments to § 155.221 we are finalizing will not impact how DE entities may assist consumers and applicants in SBE-FP States. Section 155.221(i) provides that a DE entity that enrolls qualified individuals in coverage in a manner that constitutes enrollment through an SBE-FP or assists individual market consumers with submission of applications for APTC and CSRs through an SBE-FP, must comply with all applicable HHS standards in § 155.221. We did not propose and are not finalizing any changes to this existing framework for DE entities who assist consumers and applicants in SBE-FP States.

¹⁹² 45 CFR 155.221(i).

standards in § 155.220(c) and (j) to State Exchanges and their web-brokers and detail below the HHS web-broker DE entity standards in § 155.221(a), (b), (c), (d), and (j) we proposed extending to web-broker DE entities in State Exchanges. As described further below, we proposed that the applicable requirements that would apply to QHP issuer DE entities in State Exchanges would be certain HHS QHP issuer DE entity standards in §§ 155.221(a), (b), (c), (d), and (j) and 156.1230(b). The proposals to extend certain HHS requirements in § 155.221 to these State Exchanges' web-broker DE entities are intended to align with the proposals described above to extend certain HHS standards and consumer protections in § 155.220 to these State Exchanges' web-brokers.¹⁹³ The proposals to extend certain HHS requirements to QHP issuer DE entities are similarly intended to establish a minimum set of standards and consumer protections, with the HHS requirements generally serving as a floor for State Exchanges that choose to implement DE programs. As detailed further below, as part of these proposals to extend certain HHS requirements to DE entities, we would rely on State Exchanges to enforce compliance with these requirements and take enforcement action as needed when a DE entity fails to comply with applicable requirements. However, we would provide technical assistance to support State Exchange efforts to take appropriate enforcement action as needed to ensure compliance with applicable requirements.

Consistent with the cross-reference in § 155.221(a)(1), we proposed to extend the HHS requirements of § 156.1230(b) governing QHP issuer DE entities to also apply to QHP issuer DE entities assisting consumers with submitting applications for APTC/CSRs and DE in QHPs offered through the Exchange in States with State Exchanges. As reflected in new section § 155.221(a)(1)(i), for purposes of extending the HHS requirements of § 156.1230(b) to these States Exchanges and their QHP issuer DE entities, references in § 156.1230(b) to "Federally-facilitated Exchange," "HHS," and "*HealthCare.gov*" would be understood to mean "the applicable State Exchange," "the applicable State Exchange," and "the applicable State Exchange website," respectively. Consistent with §§ 156.1230(b)(1) and (2), to directly enroll consumers in a

manner that is considered to be through the Exchange, QHP issuer DE entities are required to comply with the applicable requirements in § 155.221 and provide consumers with correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the Exchanges, and insurance affordability programs,¹⁹⁴ and refrain from marketing or conduct that is misleading (including by having a DE website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex. These HHS standards already extend to QHP issuer DE entities in SBE-FP States.¹⁹⁵ We proposed to extend these HHS requirements to also apply them to QHP issuer DE entities in State Exchanges. State Exchanges' QHP issuer DE entities would similarly be required to provide consumers with correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the Exchanges, and insurance affordability programs.¹⁹⁶ In addition, QHP issuer DE entities in State Exchanges would also be required to refrain from marketing or conduct that is misleading (including by having a DE website that the State Exchange determines could mislead a consumer into believing they are visiting the Exchange's website), coercive, or discriminates based on race, color, national origin, disability, age, or sex. We solicited comments on whether § 156.1230 should also be amended to affirm its applicability to these State Exchanges and their QHP issuer DE entities.¹⁹⁷

In addition, we proposed that all Exchanges, including State Exchanges that choose to implement DE programs, must require their DE entities, both web-broker and QHP issuer DE entities, to meet the HHS standards under § 155.221(b)(1) governing plan display and marketing for QHPs and any other products offered on the Exchange. These HHS standards governing plan display and marketing for QHPs and any other products offered on the Exchange currently apply today to approved web-broker and QHP issuer DE entities in FFE and SBE-FP States.¹⁹⁸ As such, in

new paragraph (j), we proposed to extend § 155.221(b)(1), and the exceptions in § 155.221(c), to DE entities participating in State Exchanges and, consequently, to these State Exchanges. Under this proposal, DE entities participating in State Exchanges would be required to display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and any other products, such as excepted benefits, on at least three separate website pages on its non-Exchange website, except as permitted under § 155.221(c). Pursuant to the exception under § 155.221(c)(1), a DE entity operating in a State Exchange would be permitted to display and market individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated receipt of an offer of an individual coverage health reimbursement arrangement as described in § 146.123(c) (as a standalone benefit, or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage health reimbursement arrangement using a salary arrangement pursuant to a cafeteria plan under section 125 of the Internal Revenue Code) but would be required to clearly distinguish between the QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicate that APTC and CSRs are available only for QHPs purchased through the Exchange, that APTC are not available to individuals who accept an offer of an individual coverage health reimbursement arrangement or opt out of an individual coverage health reimbursement arrangement that is considered affordable, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange. Under this proposal, pursuant to the exception in § 155.221(c)(2), DE entities operating in States with State Exchanges would be permitted to display and market Exchange-certified stand-alone dental plans offered outside the Exchange and non-certified stand-alone dental plans on the same website pages.

¹⁹⁴ See 42 CFR 435.4 for the definition of insurance affordability programs.

¹⁹⁵ See 45 CFR 155.221(a)(1) and (i).

¹⁹⁶ *Id.*

¹⁹⁷ We noted in the proposed rule (88 FR 82568) that if § 156.1230 were amended to affirm its applicability to these State Exchanges and their QHP issuer DE entities, parallel revisions may be made to § 156.1230 in the final rule to also capture and affirm its applicability to SBE-FPs and their QHP issuer DE entities.

¹⁹⁸ 45 CFR 155.221(b)(1) and (i).

¹⁹³ As previously noted, the HHS requirements for web-brokers in §§ 155.220 and 155.221 also currently extend to web-brokers participating in SBE-FPs. See 45 CFR 155.220(l) and 155.221(i).

In new paragraph (j), we also proposed to extend the HHS marketing standard at § 155.221(b)(3) to DE entities participating in State Exchanges and, consequently, to State Exchanges that choose to implement a DE program, such that these DE entities would also be required to limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers will be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under § 155.221(c)(1). Refer to the discussion above regarding the exception in § 155.221(c)(1) pertaining to DE entities assisting individuals who have communicated receipt of an offer of an individual coverage health reimbursement arrangement as described in § 146.123(c), as a standalone benefit or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage health reimbursement arrangement using a salary arrangement pursuant to a cafeteria plan under section 125 of the Internal Revenue Code.

As we explained in the proposed rule (88 FR 82568 and 82569), we believe requiring DE entities participating in all Exchanges to meet the plan display and marketing requirements in § 155.221(b)(1) and (3) adopted by HHS for FFE and SBE-FP States would provide necessary safeguards for consumers who may participate in DE programs across all Exchange models, including in State Exchanges. Requiring DE entities across all Exchanges to meet these HHS plan display and marketing requirements would protect consumers by minimizing their confusion regarding which products and plans are available through the Exchange, which products and plans are not, and which products and plans are eligible for APTC and CSRs. Further, the adoption of uniform requirements across Exchanges in this regard can also alleviate burden on DE entities from having to build different programs and comply with a unique set of requirements for each State Exchange that chooses to implement a DE program, as well as burden on a State Exchange from having to develop an entirely new set of requirements for DE entities that participate in their State Exchange. We recognize that elsewhere in this rulemaking, we have built in flexibility for State Exchanges to tailor certain aspects of their DE programs and

associated oversight processes to best suit their State-specific needs and requirements (for instance, the operational readiness review requirements for web-brokers and DE entities participating in State Exchanges). In this case, however, we believe that the benefits to consumers of uniformly applying the plan display and marketing requirements in § 155.221(b)(1) and (3) to ensure they apply to all Exchanges as minimum standards outweigh the potential drawbacks of reducing discretion and flexibility to State Exchanges with respect to modifying these baseline requirements. We solicited comments on whether State Exchanges should instead be provided with broader discretion and flexibility to establish their own plan display and marketing requirements tailored to their consumers or local needs.

In new paragraph (j), we also proposed to extend the existing standardized disclaimer requirement in § 155.221(b)(2) to apply to DE entities participating in State Exchanges and, consequently, to these State Exchanges that choose to implement a DE program. Pursuant to § 155.221(b)(2) and (i), DE entities in FFE and SBE-FP States are required to prominently display a standardized disclaimer in the form and manner provided by HHS.¹⁹⁹ This disclaimer is separate from the Enrollment Support and General non-FFE standardized disclaimers under § 155.220(c)(3)(i)(A) and (G), respectively, that web-brokers are required to display when their non-Exchange websites are used to complete a QHP selection or complete the Exchange eligibility application.²⁰⁰ The standardized disclaimer required under § 155.221(b)(2) instead is intended to help consumers understand the difference between QHPs and non-QHPs, and that financial assistance (that is, APTC and CSRs) is only available for QHPs. Under this proposal, DE entities in State Exchanges, like DE entities in FFEs and SBE-FPs under existing § 155.221(b)(2), would also be required to prominently display a standardized disclaimer that similarly informs consumers about the differences between QHPs and non-QHPs, and that financial assistance is only available for QHPs. The purpose of this standardized disclaimer is to assist consumers in distinguishing between DE entity non-

Exchange website pages that display QHPs and those that display non-QHPs, and for which products APTC and CSRs are available. Consistent with the current practice for the other standardized disclaimers provided by HHS under §§ 155.220 and 156.1230, we would provide further details on the HHS standards for the text and other display details for the standardized disclaimer in technical guidance.

This proposal would require that the disclaimer be prominently displayed on the non-Exchange website of a DE entity assisting consumers in State Exchanges when a consumer navigates away from any website page that markets or displays QHPs offered through the Exchange (that is, on-Exchange QHPs) to any website page that markets or displays QHPs offered outside the Exchange (that is, off-Exchange QHPs) or non-QHPs. Each DE entity would be required to display this disclaimer on its own interstitial website page or on a pop-up window.

We proposed in paragraph (j)(1) to provide State Exchanges with flexibility regarding the standardized disclaimer language that would be required to be displayed by their DE entities, provided that the additional language does not conflict with the HHS-provided standardized disclaimer. This proposed flexibility is similar to the flexibility we are finalizing in section III.D.7 of this final rule for State Exchanges to modify the web-broker Enrollment Support and General non-FFE standardized disclaimers under § 155.220(c)(3)(i)(A) and (G), such that the HHS-provided language for the standardized disclaimer under § 155.221(b)(2) must be used as a minimum starting point but State Exchanges may add State-specific information to the disclaimers, provided the additional language does not conflict with the HHS-provided standardized disclaimer.²⁰¹ This would permit State Exchanges to replace references to the Exchange or Marketplace with the appropriate reference to the State-specific Exchange name. Under this proposal, State Exchanges may also require web-brokers and QHP issuers operating as DE entities in their States to translate the disclaimer text into languages appropriate for the States, as this type of additional requirement would not conflict with the HHS-provided disclaimer language or minimum standards. As with all informational materials, standard plain language

¹⁹⁹ See 84 FR 17523.

²⁰⁰ As detailed above, we proposed to extend the Enrollment Support and General non-FFE standardized disclaimers to State Exchanges and web-brokers participating in those State Exchanges and are finalizing these proposals without modification.

²⁰¹ Consistent with the current practice for the other HHS-provided standardized disclaimers under §§ 155.220 and 156.1230, we will provide details on the text for the standardized disclaimer under § 155.221(b)(2) in guidance.

practice is to write at or near a fourth-grade reading level and not to exceed an eighth-grade reading level. We explained that we expect that any State-specific additions or customizations to this disclaimer would be written accordingly. As we explained in the proposed rule (88 FR 82569), we would be available to provide technical assistance to State Exchanges that want to add State-specific language to the standardized disclaimer under § 155.221(b)(2). In using HHS-provided disclaimer language as a minimum starting point, DE entities in State Exchanges would be required to display a disclaimer that provides information to assist consumers in distinguishing between DE entity non-Exchange website pages that display QHPs and those that display non-QHPs and for which products APTC and CSRs are available, all during a single shopping experience for consumers.

We believe establishing the HHS language as a minimum standard for the standardized disclaimer under § 155.221(b)(2) that DE entities must display across all Exchanges would provide a necessary baseline. We also believe that meeting these standards would ensure consumers and applicants are receiving sufficient information to help them distinguish between DE entity website pages displaying QHPs versus pages displaying non-QHPs and provide general uniformity among the different Exchange models when enrollment or enrollment information is provided outside of the Exchange through a DE entity's non-Exchange website.

Similar to the proposed requirement to extend operational readiness requirements to web-brokers in States with State Exchanges, we also proposed to extend operational readiness requirements to DE entities in State Exchanges and, consequently, to these State Exchanges. DE entities that participate in FFE and SBE-FP States are required, pursuant to § 155.221(b)(4) and (i), to demonstrate to HHS operational readiness and compliance with applicable requirements prior to the DE entity's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection. In new paragraph (j)(2), we proposed to extend DE entity operational readiness requirements to State Exchanges. Under this policy, DE entities participating in State Exchanges would be required to demonstrate operational readiness and compliance with applicable requirements to the State Exchange prior to the DE entity's website being used to complete an Exchange eligibility application or a

QHP selection. We also proposed in new paragraph (j)(2) to require these State Exchanges to establish the form and manner for their DE entities to demonstrate operational readiness and compliance with applicable requirements, which may include submission or completion of the same items business audit documentation or security and privacy audit documentation in § 155.221(b)(4)(i) and (ii) to the State Exchange, in the form and manner specified by the applicable State Exchange. Pursuant to § 155.221(b)(4)(i) and (ii), HHS may request a DE entity submit a number of documents to demonstrate compliance with applicable requirements, as well as the operational readiness of its non-Exchange website. The required documentation may include privacy questionnaires, privacy policy statements, and terms of services, business audit reports, interconnection security agreements, security and privacy controls assessment and plans, security, and privacy assessment reports, plans of action and milestones, privacy impact assessments, system security and privacy plans, incident response plans, and vulnerability scan results. We proposed to codify these documentation standards in new paragraphs (j)(2)(i) and (ii) as illustrative examples of the type of requirements that we encourage State Exchanges that choose to implement a DE program to adopt as part of their operational readiness and compliance reviews of DE entities non-Exchange websites.

This proposal would require DE entities participating in State Exchanges to meet operational readiness requirements established by the State Exchanges, and State Exchanges would have flexibility when establishing operational readiness requirements for their respective DE programs, potentially leveraging the items in § 155.220(b)(4)(i) and (ii) as the starting point for their operational readiness requirements and associated reviews. Similar to the web-broker operational readiness reviews under § 155.220(c)(6), the standards under § 155.221(b)(4) governing the HHS operational readiness reviews of DE entity non-Exchange websites are also a critical part of the oversight framework for HHS' DE program (both Classic DE and EDE) available in the FFEs and SBE-FPs. These standards as they apply to DE entities participating in FFE and SBE-FP States help ensure operational readiness and compliance with applicable requirements prior to the DE entity's non-Exchange website being used to complete Exchange eligibility

application or a QHP selection and help ensure consumers would not be able to enroll via a DE entity's website that is not operationally ready. Websites that have not been tested to see if they are operationally ready may not provide consumers with proper eligibility determinations or may have security flaws that could make a breach involving consumer PII more likely. Mandating DE entities that participate in State Exchanges meet minimum standards set by the State Exchanges for operational readiness would help reduce this risk in all Exchanges.

We recognize that some State Exchanges that choose to implement a DE program may seek to utilize DE entities already participating in DE in the FFEs or SBE-FPs. As part of establishing its operational readiness requirements for participating DE entities, we specifically encourage those State Exchanges to adopt the same operational readiness requirements for DE entities established by HHS, including the third-party auditor framework adopted by HHS pursuant to § 155.221(f) and (g). We also encourage those State Exchanges to leverage HHS' review of those third-party audits and determinations made as to the DE entities' functionality and operational readiness to operate with the Federal platform (*HealthCare.gov*) as part of their assessment of DE entity compliance and readiness to operate in their State Exchange. We recognize that leveraging HHS' reviews may supplement other State-specific operational readiness reviews and requirements that State Exchanges that choose to implement a DE program might develop.

Adopting HHS's operational readiness requirements for DE entities under § 155.221(b)(4), (f), and (g) and leveraging HHS's review of third-party audits and determinations made as to DE entities' functionality and operational readiness would support State Exchanges in having confidence in the ability of those DE entities to also participate in State Exchanges when HHS determined that those DE entities have already demonstrated operational readiness and compliance with applicable requirements to operate with the Federal platform (*HealthCare.gov*). This approach would also help minimize the burden of operational readiness reviews on State Exchanges and on their DE entities. For example, if the State Exchange uses the single streamlined eligibility application described in § 155.405 and the DE entity has already been approved to participate in the FFEs or SBE-FPs, we would encourage State Exchanges to accept

HHS' review of and determinations made as to the DE entity's audit documentation without conducting further review to confirm operational readiness of the DE entity's non-Exchange website and compliance with the HHS minimum standards. However, we also recognize that to-date, all State Exchanges have implemented (or intend on implementing) alternative single, streamlined eligibility applications and eligibility systems that are tailored to their State-specific needs and rules. Thus, it is important to provide State Exchanges with flexibility to establish their own operational readiness requirements and associated reviews in a manner that is tailored to best meet their State-specific needs, since State Exchanges are best positioned to make those decisions. In the proposed rule (88 FR 82570), we therefore encouraged, but did not propose to require, these State Exchanges to adopt the same operational readiness requirements and third-party auditor framework that HHS adopted under § 155.221(b)(4), (f), and (g) for DE entities assisting FFE and SBE-FP consumers.

We explained that we would also encourage State Exchanges that choose to implement a DE program to consider requiring their DE entities to engage a third-party auditor, consistent with standards adopted by HHS at § 155.221(f) and (g) that apply in FFE and SBE-FP States, to perform the operational readiness reviews, for example, to provide an unbiased confirmation that the DE entities are able to appropriately conduct eligibility determinations. However, we did not propose to mandate that State Exchanges require their DE entities to perform such third-party audits as we recognize that State Exchanges may want to establish their own State-specific requirements and mechanisms to confirm DE entity operational readiness and compliance with applicable requirements (both HHS and State-specific standards), and we want to ensure State Exchanges have the flexibility to establish operational readiness review requirements that are tailored to meet State-specific rules and requirements. For example, as noted above in this section of this final rule, if the State Exchange uses an alternative to the single streamlined application described in § 155.405, we would not recommend leveraging HHS' eligibility application audit under § 155.221(b)(4)(iii), as the HHS audit results may not be applicable to the State Exchange's alternative eligibility applications and associated State-developed eligibility systems. However,

if the State Exchange uses the single streamlined application described in § 155.405 we would encourage the State Exchange to use the same third-party auditor framework and requirements that HHS adopted for FFE and SBE-FP States, as well as accept HHS' review of the third-party audits and determinations made as to the DE entity's operational readiness and compliance with the HHS minimum standards without conducting further review for DE entities that have already been approved to participate in the FFEs or SBE-FPs, unless there are other unique State-specific requirements that warrant further, targeted review.

As State Exchanges establish DE programs, we recognized that it may be in their interest to permit a DE entity to provide consumers with access to DE entity application assisters, as defined at § 155.20, to provide assistance with applying for a determination or redetermination of eligibility for individual market coverage through the Exchange and insurance affordability programs. As such, in new paragraph (j), we proposed to extend § 155.221(d) to State Exchanges and their DE entities to allow DE entity application assisters, when permitted by the applicable State Exchange and only to the extent permitted by applicable State law, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such DE entities ensure that each of its DE entity application assisters meets the requirements in § 155.415(b). Section 155.415(b) establishes minimum standards for QHP issuer and DE entity application assisters regarding required training on QHP options and insurance affordability programs, eligibility, benefits rules and regulations, and compliance with the Exchange's privacy and security standards and applicable State laws related to the sale, solicitation and negotiation of insurance products, including any applicable State licensure laws and State laws related to confidentiality and conflict of interest.

Although § 155.415(b) is generally applicable to all Exchanges, paragraph (b)(1) establishes required training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations with respect to providing assistance in the FFEs or SBE-FPs. As proposed to be applied in State Exchanges, DE entities and their application assisters would be required under new paragraph (j) to complete appropriate State-required training and registration in a manner specified by the

State Exchange consistent with § 155.415(b)(1). This State-required training and registration should similarly include training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations, as training on these topics would be necessary to ensure consumers are provided with vital information about these topics if DE entities and their application assisters were permitted to assist consumers with QHP shopping and DE in coverage offered through State Exchanges.

In addition, under this proposal, to meet the requirements of § 155.415(b)(2) and (3), DE entities that participate in a State Exchange and want to use DE entity application assisters would be required to coordinate with the State Exchange and appropriate State agencies to ensure they are meet the Exchange privacy and security standards at § 155.260 consistent with § 155.415(b)(2), as well as comply with State laws related to the sale, solicitation, and negotiations of health insurance products consistent with § 155.415(b)(3).

In the proposed rule (88 FR 82571), we also encouraged State Exchanges, as part of their establishment of DE programs, to adopt an immediate suspension framework, similar to § 155.221(e) that applies in FFE and SBE-FP States, that provides for the immediate suspension of a DE entity's ability to transact information with the State Exchange if the State Exchange discovers circumstances that pose unacceptable risk to the accuracy of the State Exchange's eligibility determinations, operations, or information-technology systems until the incident or breach is remedied or sufficiently mitigated to the State Exchange's satisfaction. This provision is an important feature of HHS' oversight of the use of DE entity non-Exchange websites in FFE and SBE-FP States that protects consumer data and safeguards Exchange operations and systems. State Exchanges that choose to establish a DE program and permit DE entities to use non-Exchange websites to assist consumers with QHP selection and submission of Exchange eligibility applications should consider adoption of similar measures.

Finally, under new proposed § 155.221(j)(3), we proposed to extend the new requirement that would be applicable in FFE and SBE-FP States under proposed § 155.221(b)(6) (the proposal discussed in section III.D.8 of this final rule to mandate that DE entities implement and prominently display website changes in a manner that is consistent with display changes

made by HHS to *HealthCare.gov* by meeting standards communicated and defined by HHS within a time period set by HHS) to apply to DE entities operating in State Exchanges and, consequently, to these State Exchanges. As reflected in the last clause of new proposed § 155.221(j)(3), for the purposes of extending this requirement to DE entities operating in the State Exchanges, references to an FFE website would be understood to mean the State Exchange website, references to HHS would be understood to mean the State Exchange, and references to “unless HHS approves a deviation from those standards” would be understood to mean “unless the State Exchange approves a deviation from those standards under the deviation request process the State Exchange is required to establish should the State Exchange elect to permit deviation requests.” Refer to the discussion in section III.D.8 of this final rule for additional details on the extension of this proposal to State Exchanges and their DE entities.

We sought comment on these proposals, especially from States operating, or seeking to operate, State Exchanges. We were particularly interested in comments regarding which of the other current HHS standards at § 155.221 should or should not apply to State Exchanges that choose to implement a DE program.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these provisions as proposed. Below, we summarize and respond to public comments received on our proposal to amend § 155.221 to extend certain existing HHS standards applicable to DE entities assisting the FFEs’ and SBE-FPs’ consumers and applicants with direct enrollment in QHPs and applying for APTC/CSRs to DE entities operating in State Exchanges, in both the Individual Market Exchanges and SHOPS.

Comment: Most commenters were broadly supportive of these proposals. Several commenters specifically cited that requiring DE entities to display and market QHPs through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and any other products on separate website pages (except as permitted under § 155.221(c)), and requiring DE entities to limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process, were important consumer safeguards. Several commenters additionally cited that the proposals would generally enhance the

consumer shopping experience by providing consumers with a higher-quality and more consistent user experience that allows them to access accurate coverage information whether they utilize the Exchange’s website or a DE entity’s non-Exchange website.

A few commenters stated that if State Exchanges leveraged HHS’s review of third-party audits and determinations made as to DE entities’ operational readiness and compliance with applicable requirements, particularly with respect to security and privacy, that would help reduce duplication of efforts and alleviate the compliance burden of operational readiness activities on DE entities participating in State Exchanges and those State Exchanges, helping to increase the likelihood of DE entity participation in State Exchanges. Some of these commenters further expanded on this, stating that if State Exchanges leveraged HHS’s review of third-party audits and determinations made as to DE entities’ operational readiness and compliance with applicable requirements, that would help DE entities avoid having to comply with a unique set of operational readiness requirements for each State Exchange that chooses to implement a DE program. This could provide consistency, and it may facilitate DE entities’ increased participation across Exchanges by potentially allowing them to leverage some of their operational readiness activities for FFE States in State Exchange States.

Response: We appreciate commenters’ support for these proposals. For the reasons we explained in the proposed rule (88 FR 82568), we agree that requiring DE entities to display and market QHPs through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and any other products on separate website pages (except as permitted under § 155.221(c)), and requiring DE entities to limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process, are important consumer safeguards that will help provide consumers across all Exchanges with a more consistent shopping experience. These safeguards are particularly important as there is increasing interest among State Exchanges in pursuing DE, which, absent this proposal, may result in divergence across Exchanges in terms of both DE plan display and marketing practices and the consumer experience.

We also agree that with the commenters that if State Exchanges that choose to implement a DE program

leveraged HHS’s review of third-party audits and determinations made as to DE entities’ operational readiness and compliance with applicable requirements, that would help alleviate the burden of operational readiness activities on DE entities in participating in State Exchanges and those State Exchanges. We further agree that the reduced burden may encourage DE entity participation in the State Exchanges. As we explained in the proposed rule (88 FR 82562), we generally encourage any State Exchange that elects to implement a DE program to leverage our operational readiness reviews conducted for DE entities in the FFEs and SBE-FPs, as appropriate.

We note that in establishing the standards for their DE programs, State Exchanges that elect to implement a DE program must develop criteria and a process for assessing the operational readiness and compliance of their DE entities with applicable rules, and these State Exchanges may develop operational readiness requirements that address or reflect State-specific needs and requirements. Notably, our policy provides State Exchanges with the flexibility to tailor their criteria and process to reflect such State-specific needs and requirements. For example, a State may develop standards and processes for testing the State-specific interfaces and associated functionality between their DE entity non-Exchange websites and the State Exchange’s centralized eligibility and enrollment platform that go beyond what is required by the HHS standards under § 155.221(b)(4), to ensure that eligibility applications completed on DE entity non-Exchange websites result in accurate eligibility determinations based on State-specific rules for eligibility. Similarly, a State may decide to develop processes to confirm a DE entity is able to effectively carry out eligibility functions with the State Medicaid agency that go beyond what is required by the HHS standards under § 155.221(b)(4), to ensure that an eligibility application completed on a DE entity non-Exchange website results in accurate eligibility determinations based on State-specific rules for Medicaid eligibility.

Comment: A few commenters who supported the proposals stated that the final rule should indicate how CMS will track compliance with the requirements applicable to State Exchanges that choose to implement DE programs under § 155.221(j).

Response: We monitor State Exchange compliance with Exchange requirements under Part 155 of our regulations through the annual

collection and review of State-submitted information, performance monitoring data, financial reporting, and independent external audits, as specified at § 155.1200. We will use that information and data to drive our efforts to monitor compliance with § 155.221(j) by State Exchanges that choose to implement DE programs. We also rely on regular communications with the State Exchanges to assess compliance with applicable requirements, as well as to gather information and provide technical assistance as needed. We may also consider the development of new additional tools to assist with oversight that could enhance transparency into compliance by State Exchanges with applicable requirements, including those applicable to their DE entities under § 155.221(j).

In addition, pursuant to § 155.105, States that seek to operate a State Exchange must complete and submit an Exchange Blueprint application. The Exchange Blueprint application documents that an Exchange will meet the legal and operational readiness requirements required of a State Exchange. As part of a State's Blueprint submission, the State also agrees to demonstrate operational readiness to implement and execute the HHS requirements applicable to State Exchanges, which would include the new requirements under § 155.221(j) applicable to State Exchanges that choose to implement a DE program. As discussed in other sections of this rule, HHS is also codifying requirements related to the approval of a State Exchange whereby HHS will require a State seeking to establish a State Exchange to provide supplemental information in its Blueprint application to demonstrate its ability to implement and comply with the requirements for a State Exchange, which would include the provision of information from State Exchanges that choose to implement a DE program on how they intend to implement the new requirements in § 155.221(j) and oversee compliance going forward. Such supporting information would inform HHS's decision to approve or conditionally approve a State Exchange and would help facilitate HHS' oversight of compliance with HHS requirements applicable to State Exchanges that choose to implement a DE program. Additionally, under § 155.105, an existing State Exchange must notify HHS in writing before making a significant change to its approved Exchange Blueprint, and no significant change to an Exchange Blueprint may be effective until it is approved by HHS in

writing or 60 days after HHS receipt of a completed request. Accordingly, for existing State Exchanges that seek to newly implement a DE program, HHS would require the State to submit an updated Exchange Blueprint and participate in operational readiness reviews related to the implementation and ongoing operation of such a DE program, as we would consider a State Exchange implementing a DE program a significant change. Once implemented, for State Exchange ongoing operation of a DE program, HHS would monitor State Exchange operations through the annual reporting by State Exchanges related to compliance with Federal requirements, consistent with our oversight authority at § 155.1200(b)(2). Specifically, HHS would use this oversight authority to evaluate State Exchange compliance with the policies we are finalizing at § 155.221 for those State Exchanges that elect to operate a DE program, as HHS does with other aspects of State Exchange operations on an annual basis. If there is information suggesting a State Exchange or one of its DE entities does not meet the requirements of § 155.221(j), we would notify the State Exchange and give them an opportunity to address the potential non-compliance. HHS intends to consider the development of new, additional tools to assist with oversight that could enhance transparency into compliance by State Exchanges, including their DE programs, with applicable Federal requirements. We may also consider use of other oversight tools and authority, including those under Part 155 of our regulations, as appropriate.

Comment: A few commenters suggested that CMS should implement even more stringent standards in the future, citing that it is especially important that DE entities provide consumers with clear, correct information about QHPs and insurance affordability programs, particularly that they display all plans in their cost comparison tools and not segregate plans that they do not sell.

Response: We agree with commenters that it is crucial that DE entities provide consumers with clear, correct information about QHPs and insurance affordability programs. The extension of certain standards applicable to DE entities assisting the FFEs' and SBE-FPs' consumers and applicants to DE entities operating in State Exchanges will help ensure that all DE entities consistently provide consumers with clear, correct information about their Exchange coverage options. The framework adopted in this final rule will do so by requiring that DE entities across all Exchanges meet minimum

standards governing DE entity marketing and display of QHPs and non-QHPs, providing consumers with correct information and refraining from certain conduct, marketing of non-QHPs, website disclaimer language, and operational readiness.

While there are other standards under § 155.221 that are applicable to DE entity operations in FFE and SBE-FP States, for the reasons stated in the proposed rule (88 FR 82566) and earlier in this section of this final rule, we are extending to DE entities in State Exchanges the subset of critical standards that we believe help ensure proper eligibility determinations, protect against security breaches or incidents through implementation of operational readiness reviews, and minimize consumer confusion. At the same time, for the reasons stated in the proposed rule (88 FR 82567) and earlier in this section of this final rule, our approach preserves flexibility for State Exchanges that choose to implement a DE program to tailor their programs and establish their own standards with respect to certain aspects of their DE programs, such as operational readiness demonstrations and suspension frameworks. We believe this flexibility will help ensure that State Exchanges' DE programs and their standards are designed to meet the particular operational and business needs of the State Exchanges.

In the proposed rule, we sought comment on which of the current provisions at § 155.221 should or should not apply to State Exchanges and DE entities that assist consumers in State Exchanges. We continue to encourage specific feedback from interested parties, particularly from State Exchanges and DE entities operating in State Exchanges, on additional provisions in § 155.221 we should consider extending to State Exchanges and their DE entities or new standards that we should consider adopting for all Exchanges and DE entities in the future.

Comment: Several commenters opposed the extension of certain HHS standards under § 155.221 to State Exchanges and their DE entities, with a majority of those commenters stating that it generally hinders State Exchanges' flexibility in establishing their own rules that govern their DE programs. One commenter who supported the proposal stated it supports measures to protect necessary consumer safeguards to ensure access to consistent, reliable information from DE entities. However, this commenter suggested that CMS permit State Exchanges additional flexibility to implement measures that they

determine will best support those consumer safeguards to ensure consumers can more easily access enrollment assistance from web-broker DE entities. A few commenters stated that State Exchanges best understand their market dynamics and can be the most creative in regulating a DE program in their States. Further, a few commenters stated that the proposed approach imposes an unnecessary burden on State Exchanges, which will now have to develop policies and procedures to enforce the HHS DE standards extended to them and their DE entities under § 155.221(j). One commenter requested that CMS provide additional detail on why current State Exchange standards related to DE programs are insufficient.

Response: We agree that State Exchanges are best positioned to make certain judgments about how to regulate DE programs in their States, and the framework we are finalizing gives them flexibility to do so. For example, as we stated in the proposed rule (88 FR 82570), we recognize that it is important to provide State Exchanges with flexibility to adopt their own operational readiness requirements in a manner that is tailored to best meet the State-specific needs and requirements of the State Exchanges. Accordingly, we encouraged, but did not propose to require, State Exchanges to adopt the same operational readiness requirements and third-party auditor framework that HHS adopted under § 155.221(b)(4), (f), and (g) for DE entities assisting FFE and SBE-FP consumers. Similarly, we also encouraged, but did not propose to require, State Exchanges to adopt an immediate suspension framework, similar to § 155.221(e) that applies in FFE and SBE-FP States, that provides for the immediate suspension of a DE entity's ability to transact information with the State Exchange if the State Exchange discovers circumstances that pose unacceptable risk to the accuracy of the State Exchange's eligibility determinations, operations, or information-technology systems until the incident or breach is remedied or sufficiently mitigated to the State Exchange's satisfaction.

At the same time, however, we continue to believe, for the reasons stated in the proposed rule (88 FR 82566) and earlier in this section of this final rule, that it is important to extend to DE entities in State Exchanges—and, consequently, those State Exchanges that choose to implement a DE program—certain HHS standards that we identified as critical consumer protections to help ensure proper

eligibility determinations, protect against security breaches or incidents through implementation of operational readiness reviews, and minimize consumer confusion. Still, we appreciate commenters' input on the degree of flexibility that should be afforded to State Exchanges, and we may consider that feedback to inform potential additional proposals or changes in this area in future rulemaking.

We recognize that this approach may impose a burden on State Exchanges that choose to implement DE programs, since they would newly be subject to the HHS standards being extended to them and their DE entities. We document that burden in the Regulatory Impact Analysis and Information Collection Requirement sections of this final rule.²⁰² However, we see potential for State Exchanges to realize benefits from implementing DE entity programs and adhering to the HHS standards being extended to them. For example, implementing DE programs would diversify and expand enrollment channels that State Exchange consumers could use to enroll in QHPs offered through the Exchange and apply for APTC/CSRs. As a result, more consumers may enroll in coverage offered on those State Exchanges, which would lead State Exchanges receiving a greater amount of user fees from issuers on their Exchanges. Furthermore, State Exchanges may benefit from reduced consumer traffic on their websites, given a shift in some consumer traffic to DE entity non-Exchange websites. That may reduce State Exchanges' website maintenance costs, as well as costs related to providing assistance to consumers with using those websites.

In response to the commenter who requested that we provide additional detail on why current State Exchange standards related to DE programs are insufficient, as we explained in the proposed rule (88 FR 82566) and noted earlier in this final rule, our regulations do not currently address whether and how DE entities may assist consumers and applicants with enrollment in QHPs and submission of applications for APTC/CSRs in State Exchanges, and to-date, no State Exchange has implemented a DE program. We pursued these proposals as we anticipate State Exchanges will be interested in exploring such programs to expand the available channels for consumers to apply for and enroll in Exchange coverage, and it is important for baseline consumer protections and

²⁰² Also see 88 FR 82615 through 82617, 82625, and 82633.

Exchange operation safeguards to apply across all Exchange types.

Comment: One commenter stated that the proposal could be viewed as overreaching, exceeding the statutory authority granted to HHS under the ACA. The commenter suggested that the ACA allows significant leeway for State Exchanges to manage their Exchange programs, including the operation of web-brokers and DE programs. This commenter stated that by imposing rigid HHS standards, CMS may inadvertently hinder the growth and success of DE pathways.

Response: We appreciate the commenter's feedback. As we explained in the proposed rule (88 FR 82566), section 1312(e) of the ACA provides that the HHS Secretary shall establish procedures under which a State may allow agents, brokers, and web-brokers to enroll individuals in QHPs. The Secretary also has authority under section 1321(a) of the ACA to promulgate regulations with respect to the establishment and operation of Exchanges, the offering of QHPs through such Exchanges, and such other requirements as the HHS Secretary determines appropriate.²⁰³ HHS previously leveraged these authorities to establish the existing agent, broker, and web-broker standards applicable in FFE and SBE-FP States, which are currently codified in §§ 155.220 and 155.221.²⁰⁴ In addition, section 1413 of the ACA directs the Secretary to establish, subject to minimum requirements, a streamlined enrollment process for enrollment in QHPs and all insurance affordability programs. This authority, along with the Secretary's rulemaking authority under section 1321(a) of the ACA, was previously leveraged to establish the existing QHP issuer DE entity requirements applicable in FFE and SBE-FP States, which are codified in §§ 155.221, 156.265, and 156.1230.²⁰⁵ We therefore disagree that the amendments to § 155.221 exceed the authority granted to HHS under the ACA.

We do not intend, or expect, for the extension of certain HHS standards applicable to DE entities assisting the FFEs' and SBE-FPs' consumers and applicants to DE entities operating in State Exchanges that choose to

²⁰³ Section 1321(a)(1)(A), (B) and (D) of the ACA.

²⁰⁴ See 77 FR 18334 through 18336; 78 FR 15533; 78 FR 54134; 79 FR 13837; 81 FR 12338; 81 FR 94176; 83 FR 16981 through 16982; 84 FR 17563; 85 FR 37248; 86 FR 24288; 87 FR 27388; and 88 FR 25917.

²⁰⁵ See 77 FR 18425 through 18426; 78 FR 54124 through 54126; 81 FR 12309 through 12310; 81 FR 94152; 81 FR 94184; 83 FR 16981 through 16982, 17030; 84 FR 17521 through 17525, 17546 through 17547; and 86 FR 24209 through 24214.

implement a DE program to hinder the growth or success of DE pathways. Notably, to date, no State Exchanges have implemented DE programs. As we explained in the proposed rule (88 FR 82566) and earlier in this section of this final rule, we are extending to DE entities in State Exchanges (that choose to implement DE programs) the standards that we identified as critical safeguards to help ensure proper eligibility determinations, protect against security breaches or incidents through implementation of operational readiness reviews, and minimize consumer confusion. At the same time, for the reasons stated in the proposed rule (88 FR 82567) and earlier in this section of this final rule, our policies preserve flexibility for State Exchanges to tailor their DE programs and establish their own standards with respect to certain aspects of their DE programs, such as operational readiness demonstrations and suspension frameworks. We believe this flexibility will help ensure that State Exchange DE programs and their standards are designed to meet the particular operational and business needs of the State Exchanges, while also protecting consumers and safeguarding Exchange operations. We also note that if State Exchanges leverage HHS's review of third-party audits and determinations made as to DE entities' operational readiness and compliance with applicable requirements, as our approach encourages them to, that would alleviate the burden of operational readiness activities on DE entities in participating in State Exchanges and those State Exchanges, which would encourage DE entity participation in those State Exchanges.

Comment: A few commenters suggested that in the future, CMS should require State Exchanges to implement DE programs. These commenters stated that Exchange DE programs can have a positive impact on enrollment in QHPs offered through those Exchanges given recent enrollment growth among FFE and SBE-FP States, which can be attributed in some part to the DE program HHS adopted for FFEs and SBE-FPs. One commenter requested that CMS regularly publish statistics on the number of consumers who select a plan and enroll in QHPs offered on the FFEs or SBE-FPs through DE entity non-Exchange websites, to support the ability of interested parties, particularly State Exchanges, to assess whether DE may benefit their consumers in the future.

Response: We appreciate commenters' feedback and agree that DE programs

can have a positive impact on enrollment in QHPs offered through Exchanges. As we explained in the proposed rule and earlier in this section of this final rule, section 1312(e) of the ACA provides that the HHS shall establish procedures under which a State may allow agents, brokers, and web-brokers to enroll individuals in QHPs. Accordingly, § 155.221(a), as finalized by this final rule, provides that Exchanges may permit QHP issuers and web-brokers that meet applicable requirements to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner that is considered to be through the Exchange, to the extent permitted by applicable State law. We did not propose to require State Exchanges to implement a DE program and decline to adopt such a requirement in this final rule. As finalized, the amendments to § 155.221 establish HHS minimum standards to ensure key consumer safeguards also apply to State Exchange consumers if the State Exchange elects to operate a DE program.

We note that we published data on the impact of the DE program HHS adopted for FFE and SBE-FP States and encourage interested parties to review such data.²⁰⁶ For example, we published a comparison of plan year 2020 and plan year 2021 open enrollment plan selection data by enrollment channel at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Impact-EDE-OEP-2021-Coverage.pdf>.

10. Failure To Reconcile (FTR) Process (§ 155.305(f)(4))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82571), we proposed changes and updates to § 155.305(f)(4). We proposed, in connection with the FTR process described in § 155.305(f)(4), to require all Exchanges, including State Exchanges, to send notices to tax filers for the first year in which they failed to reconcile APTC starting in PY 2025 as an initial warning to inform and educate tax filers that they need to file and reconcile or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive year. We are finalizing this policy as proposed, except that we have modified paragraph (f)(4)(i) and added paragraphs (f)(4)(i)(A) and (B) to clarify that an Exchange must either send a notice to a tax filer as described above or send a more general

notice to an enrollee or their tax filer explaining that they are at risk of losing APTC. This modification does not impact any substantive rights or obligations described in the proposed rule, but rather clarifies in regulation text the method by which Exchanges can comply with the requirement.

As part of the 2024 Payment Notice (88 FR 25814 through 25816), we changed the FTR process such that an Exchange may only determine enrollees ineligible for APTC after a tax filer (or a tax filer's spouse, if married) has failed to file a Federal income tax return and reconcile their past APTC for two consecutive years (specifically, years for which tax data will be utilized for verification of household income and family size). However, in that rule, we did not impose a requirement for Exchanges to notify enrollees during the first year that the applicable tax filer failed to file and reconcile.

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule, we proposed to require that all Exchanges be required to send informative notices at least annually to tax filers who have failed to file and reconcile. Since Exchanges are prohibited from sending protected Federal tax information (FTI) to an individual who may not be the tax filer, only the FTR Open Enrollment notices sent *directly* to the tax filer may directly state that the IRS data indicates the tax filer failed to file and reconcile, consistent with standards applicable protection of FTI. An Exchange may not always be able to send FTR Open Enrollment notices directly to the tax filer because Exchange notices may be sent to the household contact or enrollee on the household's Exchange account or insurance policy, as is done in the Exchanges on the Federal platform, and this person is not necessarily the tax filer. Therefore, to comply with the prohibition on sending FTI (including information about failing to file and reconcile) in cases where the household contact or enrollee is not the tax filer, the Exchange may send notices that contain broad, general language regarding FTR referred to as "combined notices." For example, an Exchange can send the same Exchange Open Enrollment Notice to multiple groups of consumers at risk for APTC discontinuation in the upcoming coverage year such as those flagged as having FTR status, those for whom the Exchange has received updated income information that suggests the consumers may have income too high to qualify for APTC, and those who did not permit the Exchange to check IRS data. Because the combined notices are sent to some

²⁰⁶ <https://www.cms.gov/marketplace/resources/forms-reports-other>.

consumers who are currently unaffected by FTR, and not exclusively to individuals who are affected by FTR, they are generally not considered FTI under IRS rules and may be sent using the standard notice functionality without the protections required for FTI.

As background, Exchange enrollees whose tax filer fails to comply with current § 155.305(f)(4) are referred to as having failed to “file and reconcile.” These individuals are referred to as having FTR status, and the Exchanges conduct the FTR process to identify such individuals. In the 2024 Payment Notice (88 FR 25814 through 25816), we finalized a new process for Exchanges to conduct FTR to address concerns that the pre-existing FTR process requiring Exchanges to determine an enrollee ineligible for APTC after one year of having an FTR status could be overly punitive. Under the previous policy, enrollees occasionally had their APTC ended due to delayed data processing, in which case their only remedy was to appeal to get their APTC reinstated. Enrollees or their tax filers also may have been confused by or received inadequate education on the requirement to file and reconcile. HHS’ and the State Exchanges’ experiences with running FTR operations showed that Exchange enrollees often do not understand the requirement that their tax filer must file a Federal income tax return and reconcile their APTC or that they must also submit IRS Form 8962 to properly reconcile their APTC, even though both the single, streamlined application used by Exchanges on the Federal platform and the QHP enrollment process require a consumer to attest to understanding the requirement to file and reconcile. Note, the updated policy in the 2024 Payment Notice does not relieve tax filers from their requirement to reconcile each year nor any potential tax liability. By making these changes to the FTR processes in the 2024 Payment Notice and requiring Exchanges to determine an enrollee ineligible for APTC only after having an FTR status for two consecutive years (specifically, years for which tax data will be utilized for verification of household income and family size), Exchanges now have more opportunity to conduct outreach and send notices to enrollees or their tax filers for whom data indicate the tax filer has failed to file and reconcile and to prevent erroneous terminations of APTC, as well as to provide access to APTC for an additional year even when APTC would have been correctly terminated under the original FTR process.

There are limitations to these notices; notices that are sent directly to the tax filers and explicitly describe their FTR status must be compliant with IRS requirements for disclosing FTI, which can be a complex process and incompatible with some Exchanges’ infrastructure. Alternatively, combined notices, which do not contain FTI, have limitations in that they do not explicitly inform the recipients that they are at risk of losing APTC due to the household tax filer being found to have failed to file and reconcile. However, both types of notices will create an opportunity for State Exchanges to educate enrollees or their tax filers on the requirement to reconcile their APTC with the PTC allowed. This will address the consumer confusion and knowledge gaps that were identified by both HHS and State Exchanges, which were key considerations in making the changes to the FTR process described in the 2024 Payment Notice, wherein tax filers now must be identified as FTR status for two years prior to having their APTC removed. With this additional year for tax filers to correct their FTR status, consumers will be better able to take appropriate action prior to losing their APTC and file and reconcile in response to these notices.

Under the policy finalized in this rule, Exchanges on the Federal platform will continue to send notices to enrollees and their tax filers for the year in which the tax filer has failed to reconcile APTC. Direct notices to the tax filer will provide an initial warning to inform and educate them that they need to file and reconcile, or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive tax year. A combined notice to the enrollee will provide more general information about the risk of losing APTC. State Exchanges will be required to send either one of these notices and may send a combined notice to the tax filer if desired. Our policy to codify this practice for Exchanges on the Federal platform and require State Exchanges to notify either an enrollee or their tax filer as described above, ensures that tax filers who have been determined to have FTR status for one year are adequately educated on the file and reconcile requirement, and have ample opportunity to address the issue and file and reconcile their APTC before they are determined to have FTR status for two consecutive years. This policy supports compliance with the filing and reconciling requirement under section 36B(f) of the Code and its implementing regulations at 26 CFR 1.36B–4(a)(1)(i) and (a)(1)(ii)(A), minimizes the potential

for APTC recipients to incur large tax liabilities over time, and supports eligible enrollees’ continuous enrollment in Exchange coverage with APTC by avoiding situations where enrollees become uninsured when their APTC is terminated. Additionally, this policy better aligns State Exchanges’ Failure to Reconcile processes with that of the Exchanges on the Federal platform.

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision with modifications to require all Exchanges to either send informative notices directly to a tax filer alerting them of their FTR status, or to send informative notices that do not contain FTI either to the enrollee or their tax filer if through the income verification processes described in § 155.320, they have been found to have failed to reconcile their APTC for only one year. We are reorganizing the regulatory text at § 155.305(f)(4)(i) to create paragraphs (f)(4)(i)(A) and (f)(4)(i)(B) for ease of readability, and are clarifying that new paragraph (f)(4)(i)(B) describes the notifications Exchanges may send to an enrollee or their tax filer that informs them that they may be at risk of being determined ineligible for APTC in the future, but does so without conveying FTI. We are also clarifying in this final rule that we will provide Exchanges with additional guidance on implementation, in particular around notice language, which is informative to the consumer without sharing protected FTI. We summarize and respond to public comments received on the proposed policy below.

Comment: The majority of commenters supported the proposal requiring an Exchange to notify enrollees and their tax filers of their FTR status when they are identified as having failed to reconcile for one year. Several of these commenters in particular cited its positive impact on continuity of coverage for consumers enrolled in Exchange coverage.

Response: We agree that the proposed FTR policy will have a positive impact on enrollee retention of APTC and coverage by ensuring enrollees and their tax filers are well informed of the tax reconciliation requirement and/or of a potential FTR status.

Comment: A few commenters opposed the proposal requiring all Exchanges to check FTR and send FTR notices on an annual basis to enrollees, or their tax filers, who have an FTR status. These commenters stated that it is prohibitively difficult to send notices

containing protected FTI to enrollees or their tax filers. One of these commenters agreed with the importance of informing tax filers of the tax credit reconciliation requirement but disagreed with the proposed method. This commenter stated that Exchanges and their consumers are better served by flexible real-time education, rather than annual mandatory notices.

Response: We recognize the complexity of sharing FTI with enrollees, which is why the proposed requirement allows for the use of combined notices. These combined notices may contain broad, general language, and can be sent to multiple groups of consumers at risk for APTC discontinuation in the following coverage year. We currently provide samples of such combined notices amongst other resources online at [Marketplace.cms.gov](https://www.cms.gov/marketplace). Additionally, we will provide technical assistance, guidance, and updated sample notice language to Exchanges in advance of implementation for plan year 2025.

While we are finalizing the requirement for Exchanges to send on an annual basis FTR notices to consumers identified as having an FTR status, we appreciate that there are other approaches to educating consumers on the FTR requirements. We wish to note that Exchanges will have flexibility in the notice content and process. While annual notices are a minimum requirement, Exchanges are welcome to expand on these with real-time education and other consumer outreach.

Comment: A few commenters opposed this proposal, citing the need for State flexibility in Exchange operations.

Response: Exchanges will still have flexibility in the manner of sending and content of FTR notices, but this policy provides important consumer protections by ensuring that enrollees and/or their tax filers are at a minimum informed of the APTC reconciliation requirement as well as the potential for loss of APTC eligibility each year. While Exchanges will have the opportunity to provide additional outreach and education, we see these annual notices as a minimum standard.

Comment: One commenter opposed this proposal, stating that they did not consider Exchanges to be the optimal choice to send annual FTR notices. This commenter suggested that the IRS would be a better agency to create and send out these notices, in particular due to the protections around FTI.

Response: The IRS has existing processes under which tax filers may be contacted if they file a tax return without reconciling APTC. However,

Exchanges are also well-suited to send these FTR notices. Exchanges are already equipped to send a variety of different notice types to QHP enrollees, both through mail and Exchange portals. Furthermore, we know through the “Annual Eligibility Redetermination Plans” shared by State Exchanges with HHS that prior to HHS pausing FTR operations for all Exchanges in 2020 due to the effects of the COVID-19 public health emergency, the majority of State Exchanges were already sending out either direct or combined FTR notices to enrollees or their tax filer, similar to the ones being described in this rule. Exchanges will be able to utilize these existing structures to develop and send FTR notices in compliance with this rule. Additionally, Exchanges are allowed to send out informative, combined notices that do not contain protected FTI.

Comment: Many commenters expressed support for the proposal, or support for the intention of the proposal, but also expressed the need for CMS to provide further guidance and support on best-practices and clear, actionable language for the notices. In particular, they requested that HHS provide guidance in developing the combined notices that do not contain protected FTI. Several of these commenters shared concerns that since these notices cannot explicitly state that the enrollee or their tax filer has FTR status due to FTI privacy rules, the notices may be confusing or ineffective, in particular since they will be warning about the possibility of losing APTC as far as one year out. Several of these commenters requested that HHS refine this language and provide templates to other Exchanges to ensure that notices are consistent. One of these commenters also suggested that these consumers would not be able to gain clarity by contacting the Exchange call-center, as its employees are similarly bound by rules surrounding the disclosure of FTI.

Response: We appreciate these comments and acknowledge that the tax reconciliation requirement is complex and can be complicated to convey to consumers. We are developing updated FTR notices for enrollees or their tax filers who are found with a one-year FTR status as well as for those found with a two-year FTR status. These notices will be posted publicly at [Marketplace.cms.gov](https://www.cms.gov/marketplace) once finalized, in advance of implementation for the PY 2025 open enrollment period.

Exchanges will be able to use this notice language to train and educate their call-center staff on different ways to educate consumers of the APTC reconciliation requirement, without disclosing FTI. We

will also work with Exchanges to provide technical assistance and guidance in advance of the restart of FTR operations.

In the meantime, sample notices that were sent out to individuals with FTR status prior to the pause in 2020 are available at [Marketplace.cms.gov](https://www.cms.gov/marketplace) and can help guide Exchanges as they prepare for implementation and further develop their own notices. We also would like to note that many State Exchanges have already developed FTR notices and noticing processes that were utilized prior to the FTR pause.

Comment: A few commenters expressed support for the current proposal, acknowledging that educating consumers through annual FTR notices protects them and their coverage. However, these commenters also stated that the FTR process overall is flawed, overly punitive to consumers, and a threat to continuity of coverage. As such these commenters urged its repeal.

Response: We believe that the changes finalized in the 2024 Notice of Benefit and Payment Parameters, along with the changes finalized in this rule, properly balance consumer protections and program integrity concerns, and therefore support that we should continue to improve the FTR process rather than repeal it entirely.

11. Verification Process Related to Eligibility for Enrollment in a QHP Through the Exchange (§ 155.315(e))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82572), we proposed changes and updates to § 155.315. We proposed to amend § 155.315(e) by revising paragraph (e)(1) to permit all Exchanges to accept an applicant's attestation of incarceration status and paragraph (e)(2) to allow Exchanges to electronically verify a consumer's current incarceration status using an HHS-approved verification data source. We also proposed to amend the reference in paragraph (e)(3) to reflect that if an Exchange verifies an applicant's attestation of incarceration status using an approved data source and the attestation is not reasonably compatible with the information provided from the stated data source or other information provided by the applicant or in the records of the Exchange, then the Exchange must follow the data matching issue (DMI) process set forth in § 155.315(f). We noted in the proposed rule that if the proposed policy was finalized, Exchanges using the Federal eligibility and enrollment platform, including SBE-FPs, that currently use the incarceration verification data source

offered through the Federal Data Services Hub (the “Hub”) would be able to accept consumer attestation of incarceration status without further verification of incarceration status.

As background, section 1312(f)(1)(B) of the ACA states that an individual shall not be treated as a qualified individual for enrollment in a QHP if, at the time of enrollment, the individual is incarcerated, other than incarceration pending the disposition of charges. Sections 155.315(e) and (e)(1) currently state that Exchanges must verify incarceration status with a data source approved by HHS and deemed accurate, current, and offering less administrative complexity than paper verification. When an individual's incarceration attestation conflicts with information from an approved data source or other information provided by the applicant or in the records of the Exchange, § 155.315(e)(3) requires Exchanges to create a DMI as outlined in § 155.315(f). However, if an approved data source is unavailable, an Exchange may accept attestation of incarceration without further verification under § 155.315(e)(2).

Under proposed paragraphs (e)(1) and (2), an Exchange would be able to accept a consumer's attestation of incarceration status or propose an electronic data source for incarceration verification to HHS for approval and use that approved source to verify incarceration status. Should a State Exchange choose to propose use of an alternative electronic data source for verifying incarceration status, HHS would review such proposals in accordance with the process under § 155.315(h), through which HHS would make a determination based on the proposed use of the alternative data source and whether it minimizes administrative costs and burdens on individuals while it maintains accuracy and minimizes delay. We proposed at paragraph (e)(3) that if an Exchange verifies an applicant's attestation of incarceration status using an approved data source as provided under proposed paragraph (e)(2), to the extent that the applicant's attestation is not reasonably compatible with information from the approved data source or other information provided by the applicant or in the records of the Exchange, the Exchange would be required to follow the DMI procedures at § 155.315(f).

In the Exchange Establishment Rule (77 FR 18362), we recognized that there may be challenges in the availability of electronic incarceration verification data but believed that so long as an incarceration verification data source existed that has been approved by HHS,

it should be used to verify incarceration status. We also recognized that requesting consumer attestation of incarceration status and accepting such attestation without further verification when an accurate data source was unavailable is necessary since incarceration status is a statutory standard for eligibility to enroll in a QHP.

Exchanges using the Federal eligibility and enrollment platform, including SBE-FPs, currently verify whether an applicant is incarcerated through the Hub by using the Social Security Administration's (SSA) Prisoner Update Processing System (PUPS). PUPS is currently maintained by SSA and is the only national database that reflects information from Federal, State, and local correctional records. Our experience administering the Federal eligibility and enrollment platform, along with the experience from the State Exchanges that have used the PUPS data, have demonstrated that verifying incarceration data using PUPS has resulted in a high number of DMIs, few of which identify QHP applicants who are incarcerated. For example, we conducted an internal study and found that out of 110,802 incarceration DMIs generated between PYs 2018 to 2019, 96.5 percent of them were resolved in favor of the applicant. More importantly of those 3,878 applicants whose DMIs were not resolved in their favor (3.5 percent of 110,802), we found that only a total of 2,469 applied for QHP coverage during PYs 2018 and 2019. Of these 2,469 ineligible applicants, 950 applicants were released from either prison or jail within 90 days after the application submission date. Excluding these individuals leaves 1,519 QHP-ineligible individuals, of which 921 applicants effectuated coverage (that is, made the binder payment), which is allowed while awaiting DMI clearance, thus resulting in an improper APTC payment. An average annual APTC per individual of \$1,569 was estimated for the 921 QHP ineligible applicants with effectuated policies.²⁰⁷ This yields

²⁰⁷ This per-person per-year estimate was calculated by multiplying the monthly APTC benefit that each ineligible and effectuated applicant was estimated to receive in their FFE application by the maximum number of months the applicant could have been enrolled in a QHP while still incarcerated and pending DMI clearance. For open enrollment applications, an enrollment start date of January 1 was used (45 CFR 155.410). For special enrollment period applicants, the previous coverage effective date rules were used where if the applicant applied between the 1st and 15th of the month, an enrollment start date of the 1st of the following month was used. If the applicant applied after the 16th of the month, an enrollment start date of the 1st of the month 2 months following the application month was used. 45 CFR 155.420.

potential improper payments of approximately \$361,262.25 over 3 months. Because only a very small number of incarcerated individuals apply to enroll in QHPs, verifying incarceration status using PUPS and conducting the DMI process outlined at § 155.315(f) results in Exchanges saving only a fraction of improper overpayment of APTC, and those savings are dwarfed by the administrative costs imposed by using PUPS and conducting the DMI process.

We conducted a cost-benefit assessment and determined that the cost to verify incarceration status electronically far exceeds potential savings. Should the Exchange conduct an electronic incarceration verification check, such as a verification check of a consumer's attestation using PUPS data, it would cost more than \$4 million to operate yearly, along with a one-time implementation startup cost of approximately \$200,000. Furthermore, connecting to an alternative incarceration data source, such as PUPS, and conducting the DMI process outlined at § 155.315(f) can be very costly to Exchanges. In PY 2019, nearly 38,000 out of 78,000 applicants with an incarceration DMI submitted documents to attempt to resolve the incarceration DMI. To process DMIs, the Exchange incurs costs for the eligibility-verification contractor on a fixed-price basis totaling about \$0.57 million per year for verification of incarceration. This figure does not include other costs related to sending notices to consumers, processing appeals, and handling call center transactions. Our 2019 study concluded that those who receive an incarceration DMI are statistically likely to be eligible to enroll in a QHP as the applicants were released from either prison or jail within 90 days after the application submission date. However, an unresolved incarcerated DMI can result in a complete loss of coverage.

The processes of notifying consumers of their DMIs and resolving them have been burdensome and has negatively impacted the consumer experience. When an incarceration DMI is generated, applicants are required to provide documentation to show that they are no longer incarcerated.²⁰⁸ This creates a significant enrollment burden for formerly incarcerated individuals, a population comprised of a significant number of people with disabilities.²⁰⁹

²⁰⁸ *HealthCare.gov*. (n.d.) How do I resolve a Data Matching Issue. Dept. of Health and Human Services. <https://www.healthcare.gov/help/how-do-i-resolve-an-inconsistency/#incarceration-status>.

²⁰⁹ Apel, R., and Sweeten, G. (2010, Aug. 1). The Impact of Incarceration on Employment during the

Many documents that can prove incarceration status cannot be obtained without an unexpired proof of identity document, and most cannot be obtained without submitting non-refundable payments. Incarceration may inhibit one's financial savings, and formerly incarcerated individuals are less likely to secure employment.²¹⁰

These findings support our beliefs that incarcerated individuals apply for QHP coverage at very low rates, and that their applications are considered to be a very low program integrity risk for Exchanges, which do not warrant always conducting an extensive incarceration verification check. We also believe that previous guidance to conduct incarceration status verification²¹¹ may have contributed to inequity in the Exchange population, as Black adults were imprisoned at five times the rate for White adults²¹² and are more likely to face systemic obstacles hindering their ability to secure employment post incarceration.²¹³

Given these concerns, we proposed to amend § 155.315(e) by revising paragraph (e)(1) to permit all Exchanges to accept consumer attestation of incarceration status without further electronic verification. We proposed to revise paragraph (e)(2) to permit Exchanges to verify consumer incarceration status using an HHS-approved verification data source that is current, accurate, and minimizes administrative costs and burdens. We believe these policies would improve the Exchange enrollment process, reduce operational challenges for Exchanges, and reduce burdens on applicants, all while maintaining program integrity and ensuring that the alternative incarceration verification data source that may be used by Exchanges is not unduly burdensome or costly to administer.

We also proposed changes to paragraph (e)(3) to reflect that if an

Exchange verifies an applicant's attestation of incarceration status using an approved data source, and the attestation is not reasonably compatible with the information from the approved data source or other information provided by the applicant or in the records of the Exchange, the Exchange must then follow the DMI process set forth in § 155.315(f).

We sought comment on this proposal, particularly from State Exchanges and other users of PUPS data through the Hub. We also expressed particular interest in comments about whether State Exchanges intend to continue using PUPS data to verify incarceration status. We also sought input from any State Medicaid agency that uses PUPS data available through the Hub.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed to require Exchanges to start accepting consumer attestation of incarceration status without further verification or for Exchanges to use a data source for incarceration verification approved by HHS. We summarize and respond to public comments received below.

Comment: Many commenters supported the proposal to amend the current process of incarceration status verification by accepting consumer attestation or through the verification of incarceration status with an alternative data source. Commentors commended CMS for acknowledging the barriers faced by justice-involved populations and taking steps to minimize inequitable access to health insurance coverage.

Response: We agree that the policy to accept consumer attestation of incarceration status without further electronic verification will reduce administrative costs and burdens associated with verification of incarceration status. Additionally, the policy allows Exchanges the flexibility to continue verification of incarceration status using an HHS-approved data source that is current, accurate, and reduces administrative costs and burdens. We believe that this policy will equitably improve access to health care coverage for justice-involved individuals.

Comment: One commenter supported the recommendation that CMS provide educational materials and outreach for those leaving the incarceration facilities to be better informed about their pathways to enrolling in health care.

Response: We thank the commenter for this recommendation and agree that educational materials and outreach should be made available for those

leaving the incarceration facilities. We have resources available on *HealthCare.Gov* and will continue to make updates as needed for accuracy.

Comment: One commenter recommended using commercially available incarceration data to connect with soon-to-be-released individuals with social services.

Response: We thank the commenter for bringing up the commercially available data that connects people with social services after their release and agree that such service could be useful. We will take this recommendation into consideration for future rulemaking.

Comment: One commenter asked CMS to clarify the process for HHS to approve a data source, including by listing the criteria that HHS will use to assess whether an alternative data source should be approved.

Response: We decline to specify additional criteria HHS will use to approve an alternative data source beyond those included in the proposal: that the data source provide data that are current and accurate, and that its use minimizes administrative costs and burdens. We also note that a data source that does not timely report release from incarceration for recently paroled individuals is unlikely to meet HHS' standard. We would need to conduct additional market research and secure funding for the purposes of identifying and utilizing an alternative incarceration verification data source that is approved for all Exchanges and Medicaid and CHIP agencies. Any State Exchange that is interested in using alternative data sources for incarceration verification should submit its proposal to HHS for review, as an update to their Exchange Blueprint, as described in § 155.315(h).

Comment: Some commentors stated that the proposed rule contradicts the recently published GAO guidance²¹⁴ on verification of self-attestation which was published to implement President Biden's Executive Order²¹⁵ for reducing improper payments, identity theft, and benefit fraud, issued in response to fraud, waste, and abuse during the COVID-19 Public Health Emergency.

Response: In alignment with GAO's published guidance to reduce fraud, we provided extensive cost benefit analysis in the proposed rule to outline the

Transition to Adulthood. Social Problems, 57(3), 448–479. <https://doi.org/10.1525/sp.2010.57.3.448>.

²¹⁰ *Id.*

²¹¹ 45 CFR 155.315(e).

²¹² Nellis, A. (2021). *The Color of Justice: Racial and Ethnic Disparity in State Prisons*. The Sentencing Project. <https://www.sentencingproject.org/app/uploads/2022/08/The-Color-of-Justice-Racial-and-Ethnic-Disparity-in-State-Prisons.pdf>; Sabol, W.J., and Johnson, T.L. (2022). *Justice System Disparities: Black-White National Imprisonment Trends, 2000 to 2020*. Council on Criminal Justice. <https://secure.counciloncj.org/np/viewDocument?>

²¹³ Sirios, C., and Western, B. (2017, Feb.). *Racial Inequality in Employment and Earnings after Incarceration*. Harvard University. https://scholar.harvard.edu/files/brucewestern/files/racial_inequality_in_employment_and_earnings_after_incarceration.pdf.

²¹⁴ Government Accountability Office. (2022, Feb. 10). Emergency Rental Assistance: Additional Grantee Monitoring Needed to Manage Known Risk. <https://www.gao.gov/assets/gao-22-105490.pdf>.

²¹⁵ <https://www.whitehouse.gov/briefing-room/statements-releases/2023/03/02/fact-sheet-president-bidens-sweeping-pandemic-anti-fraud-proposal-going-after-systemic-fraud-taking-on-identity-theft-helping-victims/>.

minuscule amount of improper payments made to incarcerated individuals, contrasted with the large administrative costs and burdens to verify incarceration status. Based on this analysis, we estimate that there would be expected cost savings for Exchanges of approximately \$20,317,000 resulting from this policy. This means that the finalized policy change to verify incarceration status will save taxpayer funds. Within the cost benefit analysis, we provided additional information on the potential costs of investing in an alternative data source to verify incarceration.

Comment: One commenter asked CMS to clarify whether Exchanges that currently using PUPS comply with the proposal.

Response: As the PUPS data that is made available through the Federal Data Services Hub has been an existing HHS-approved data source for incarceration verification, State Exchanges may consider the PUPS data current, accurate, and its use to minimize administrative costs and burdens for their State without seeking approval from HHS. State Exchanges that currently use the PUPS data may continue using this data source for incarceration verification, should they choose to do so, without seeking re-approval from HHS. We also encourage any State Exchange that is currently using this data source to conduct a similar evaluation as we described in the proposed rule (for the FFE and SBE-FPs), to determine whether continued use of the PUPS data is a cost-effective approach for incarceration verification. We will provide technical assistance to any State Exchange that is currently using PUPS data through the Federal Data Services Hub that wishes to modify its approach to instead accept self-attestation or to use an alternative data source for incarceration verification.

Comment: One commenter asked for an amendment to the Medicare regulation at 42 CFR 411.4(b) which describes when an individual is in custody to align with post-incarceration coverage policies in the Exchange and Medicaid.

Response: We thank the commenter for bringing this to our attention but note that the comment is outside the scope of this rule.

Comment: One commenter supported the proposal and noted that cost-benefit analysis for the proposed change is sufficient but advised that CMS should amend the proposed rule to omit any mentions of health and racial equities as it “might fall to an arbitrary and capricious challenge under the Administrative Procedures Act”.

Response: HHS has the authority to modify the incarceration verification process under section 1411(c)(4)(B) of the ACA, as well as under our general rulemaking authority in section 1321(a) of the ACA. We maintain that we have provided several non-arbitrary rationales for the policy described in this rule, including that mandatory verification of incarceration status is costly to taxpayers, burdensome for applicants, and reduces access to health care for justice-involved populations which reduces health and racial equity.

Comment: A few commenters appeared unclear about the proposal and vaguely opposed it, claiming that HHS did not provide enough evidence as to why current practices are insufficient, the proposal would increase the cost of health insurance, and the proposal would not provide Exchanges with sufficient operational flexibility.

Response: We clarify that the policy allows Exchanges to start accepting consumer attestation of incarceration status without further verification unless the Exchange chooses to verify consumer attestation using a data source approved by HHS to be current and accurate and minimize administrative costs and burdens. Exchanges must generate a DMI if a mismatch between consumer attestation and the data is present. Additionally, there is no basis to believe this rule will increase the cost of health insurance. As demonstrated in the cost benefit analysis provided in the rule, it will be cost effective for Exchanges to accept consumer attestation of incarceration status without further verification, and Exchanges that decline to use an alternative data source will not incur additional costs to verify incarceration status, as explicitly demonstrated in the RIA section of the rule. Finally, we believe that we provided sufficient flexibility in this rule as State Exchanges may elect to accept attestation of incarceration status or use an alternative data source approved by HHS.

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

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82574), we proposed to reinterpret State Exchange and State Medicaid and Children’s Health Insurance Program (CHIP) agency use of the Federal Data Services Hub (Hub) to access and use the income data provided by the optional Verify Current Income (VCI) Hub service as a State Exchange or a State Medicaid and CHIP

agency function, because these State entities use this optional service to implement eligibility verification requirements applicable to them. While we proposed to redesignate use of the VCI Hub service by State Exchanges and State Medicaid and CHIP agencies as a State function, HHS would continue to maintain contracts that make this service available through the Hub for State Exchange and State Medicaid and CHIP agency use as part of its ongoing implementation of sections 1411 and 1413 of the ACA. We proposed to amend § 155.320(c) to reflect this reinterpretation for the Exchanges. Under this proposal, States would pay annually in advance for the State Exchanges and Medicaid and CHIP agencies’ anticipated utilization of the optional VCI Hub service and be required to reconcile with HHS on an annual basis the anticipated utilization of CSI data provided by the VCI Hub service with the actual utilization. In the alternative, we proposed that HHS would invoice States on a monthly basis for their actual utilization of CSI data provided by the VCI Hub service after that utilization occurs. We noted that State Medicaid and CHIP agencies would be eligible for Federal matching for the cost of this service, as described in this section.

Under our proposal, Exchanges and State Medicaid and CHIP agencies may opt to continue to use the VCI Hub service to support their eligibility verification processes for Exchange QHP coverage or Medicaid and CHIP if they pay for the cost of their use of the service. For instance, Exchanges would still be able to use this current income information to verify a tax household’s annual income attestation if they are unable to verify income using SSA Title II data, IRS income tax data, or a combination of both SSA and IRS data, in determining eligibility for APTC. Because Exchanges and State Medicaid and CHIP agencies are permitted, but not required to use the VCI Hub service to fulfill the mandatory eligibility determination requirements imposed on them, accessing the CSI data via the VCI Hub service should be characterized as an Exchange or State Medicaid and CHIP agency function.

Consistent with section 1413 of the ACA, HHS would continue to provide access to optional data sources through the Hub to support the streamlined application processes. However, as these functions would be considered Exchange or State Medicaid and CHIP agency functions, and not HHS functions, HHS would no longer fund Exchange or State Medicaid and CHIP agency use of these sources and would

only provide access to States who paid for their use of the service. HHS bears a cost for Exchange and State Medicaid and CHIP agency use of the CSI data accessed through the VCI Hub service. Under the proposed interpretation, State Exchanges and State Medicaid and CHIP agencies would be required to pay for their use of the VCI Hub service. However, where applicable, State costs for State Medicaid and CHIP agencies may be eligible for Federal matching funds at the 75 percent match of the cost of a State Medicaid agency's utilization of the VCI Hub service, as outlined in 42 CFR 433.116, and match CHIP costs at a State's enhanced Federal Medical Assistance Percentage (FMAP).

Since the VCI Hub service was established in 2013 for use by both Exchanges and State Medicaid and CHIP agencies, utilization of the VCI Hub service has grown significantly over time, both in the number of State Exchanges and State Medicaid and CHIP agencies using the service, and the number of applicants and beneficiaries that require income verification as Exchange populations have increased over time. During the first open enrollment in 2013, only the Exchanges on the Federal platform, two State Exchanges, and eight State Medicaid and CHIP agencies used data from the VCI Hub service for eligibility determinations. In that first year, the Exchanges on the Federal platform initiated about 88 percent of all requests, or "pings," to the VCI Hub service for income verification. In the past decade, more State Medicaid and CHIP agencies and State Exchanges have started using the VCI Hub service; as of June 2023, 34 States, including the District of Columbia and Puerto Rico, use the VCI Hub service for their State Medicaid and CHIP programs, and 10 of those States also use the service to verify QHP eligibility for their State Exchanges. Our analysis shows that as of January 2024, over 76 percent of monthly pings to the VCI Hub service were from State Medicaid and CHIP applications, including renewals of eligibility for Medicaid or CHIP coverage, and the Exchanges on the Federal platform now account for less than 5 percent of the total volume.²¹⁶

If new State Medicaid and CHIP agencies or State Exchanges are permitted to request access to the VCI

Hub service, we forecast that in the next 5 years, transaction volume to the VCI Hub service would increase by over 17 percent. These trends in utilization have provided us with a clear picture of the primary uses and utilizers of the VCI Hub service. Specifically, we have learned that the queries submitted by States to the VCI Hub service have been for income verification by State Medicaid and CHIP agencies to determine Medicaid and CHIP eligibility, and by State Exchanges to assess or determine Medicaid and CHIP eligibility and determine APTC eligibility. Accordingly, we now believe this activity that has been categorized as an HHS function would be better categorized as: (1) a State Medicaid and CHIP agency eligibility determination function under title XIX or title XXI of the Act when the determination is initiated by a State Medicaid and/or CHIP agency; and (2) as an Exchange function when the determination is initiated by an Exchange.

While we believe the utilization of this optional data source is an Exchange or State Medicaid and CHIP agency function, making the optional data sources available through the Hub is consistent with the requirements at sections 1411 and 1413 of the ACA related to establishment and participation in a coordinated eligibility and enrollment system for all insurance affordability programs. As such, to facilitate Exchanges' and States Medicaid and CHIP agencies' access to this optional CSI data that is available through the VCI Hub service, HHS will continue to maintain contracts that make access to these resources available through the Hub for Exchange and State Medicaid and CHIP agency use.

In making this proposal, we noted that while use of the VCI Hub service is an integral part of the eligibility determination process in most States, Exchanges and State Medicaid and CHIP agencies may have access to other data sources to verify income. As noted previously, we are aware that many States have access to other comprehensive data sources, such as State quarterly wage data. Generally, as dictated by individual State law, employers are required to report employee information such as payroll and unemployment insurance contribution data to a State department, such as the State Department of Labor or a similar office. In place of the optional VCI Hub service, State Exchanges continue to have flexibility under 45 CFR 155.315(h) and 155.320(c)(3)(iv) to use an alternative verification source, like State wage data, when income is not verified using IRS

tax data or SSA title II data. We encouraged State Exchanges, State Medicaid and CHIP agencies, and other interested parties, to submit comments regarding any operational burden, policy, or budget challenges regarding access to other State data sources of the proposed change.

As part of our consideration of the policies in this rulemaking, we considered requiring State Medicaid and CHIP agencies and State Exchanges to obtain their own contracts to administer their CSI data usage; however, we had concerns that these services cannot be procured reasonably and expeditiously, which would undermine the system we have implemented under section 1413 of the ACA. We also believe that there may be benefits to the State Medicaid and CHIP agencies and State Exchanges that prefer to use the CSI data accessible through the VCI Hub service in their States. Therefore, we proposed to retain optional access to the VCI Hub service on behalf of State Medicaid and CHIP agencies and State Exchanges that prefer to continue to use this service and are willing to pay for their CSI data usage. Under this policy, State Medicaid and CHIP agencies and State Exchanges can choose to discontinue their use of the CSI data accessible through the VCI Hub service.

Given these considerations, we proposed to amend 45 CFR 155.320(c)(1) to add new paragraph (c)(1)(iii) to require that beginning July 1, 2024, State Exchanges would be required to pay for 100 percent of their utilization of the CSI income data provided by the VCI Hub service.²¹⁷ We refer readers to the proposed rule (88 FR 82576) for an explanation of implementation of this policy.

Similarly, we proposed to require that beginning July 1, 2024, States pay in advance for their Medicaid and CHIP utilization of the optional, and not required, VCI Hub service to fulfill their Medicaid and/or CHIP eligibility determination requirements. As noted above, consistent with the requirements at section 1413 of the ACA (related to establishment and participation in a coordinated eligibility and enrollment system for all insurance affordability programs), which is incorporated into the Medicaid and CHIP statutes at sections 1943(b)(3) and 2107(e)(1), respectively, of the Act, in order to facilitate States' access to this optional CSI data that is available through the VCI Hub service, we would continue to

²¹⁶ In the proposed rule (88 FR 82576), we reported that as of March 2023, over 70 percent of monthly pings to the VCI Hub service were from State Medicaid and CHIP applications, including renewals of eligibility for Medicaid or CHIP coverage, and the Exchanges on the Federal platform accounted for less than 10 percent of the total volume.

²¹⁷ The FFEs' and SBE-FPs' costs for accessing these services would be covered by the FFEs' and SBE-FPs' user fees.

maintain contracts that enable States to efficiently access CSI data through the VCI Hub service. However, under our proposal, States would be required to pay the cost incurred by HHS when the State requests CSI data through the VCI service offered by the Hub.

In the alternative, HHS also considered whether it could invoice States on a monthly basis for their actual utilization of CSI data provided by the VCI Hub service after that utilization occurs. If appropriate, this alternative policy could be adopted in the final rule. We considered these mechanisms for implementing State Exchange and Medicaid and CHIP agency payments for use of the VCI Hub service and solicited comments on whether a different implementation approach would be more efficient or otherwise preferable. We refer readers to the proposed rule (88 FR 82576 through 82577) for an explanation of implementation of this policy and an alternative payment structure.

Finally, we proposed that the interpretation characterizing use of the VCI Hub service as a function of State Exchanges and Medicaid and CHIP agencies and not an HHS function be effective on July 1, 2024. We recognize that this implementation date may be difficult for States, especially those with biennial budget cycles. However, given our determination that eligibility verifications using CSI data by State Exchanges and Medicaid and CHIP agencies is most appropriately characterized as a function of these agencies and not an HHS function, we believe it is appropriate to move forward with this change as expeditiously as possible, while giving States some time to plan for the change. For this reason, we proposed a July 1, 2024, effective date for this provision.

We sought comment on these proposed changes, including whether we should make this interpretation effective as of July 1, 2024, or a different date. We were interested in learning whether State Exchanges and Medicaid and CHIP agencies would seek to cease or restrict their use of the VCI Hub service, possibly using it as a last resort, and what impact, if any, might these proposed changes have on the amount of time it takes applicants to verify their income or the time it takes for States to make an eligibility determination. We also sought comment on the extent to which States may be interested in potential avenues to reduce operational burdens or address budget challenges facing State Exchanges and Medicaid and CHIP agencies. Namely, we were interested in whether States would be interested in opportunities to pay an

additional fee that would allow them to reuse VCI Hub service verification results across multiple Federally-funded and State-administered human service programs (with cost allocation across those programs); whether States have separate, direct access to the same or similar source of VCI Hub services, and the cost of such direct access; and whether States anticipate that reuse of verification data, coupled with cost allocation across programs, would reduce operational burdens or address budget challenges facing State Exchanges and Medicaid and CHIP agencies.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed to reinterpret State Exchange and State Medicaid and CHIP agency use of the Hub to access and use the income data provided by the optional VCI Hub service as a State Exchange or a State Medicaid and CHIP agency function, and that beginning July 1, 2024, State Exchanges and State Medicaid and CHIP agencies will be required to pay for the costs of their access to and use of the VCI Hub service. We are also finalizing the proposal with a modification: rather than requiring States to pay in advance for their use of the VCI Hub Service, HHS will invoice States monthly for the amount the State must pay to reimburse HHS for the costs of their access and actual utilization of CSI income data from the prior month. Specifically, HHS will invoice States on a monthly basis for their actual utilization of the CSI income data accessed through the VCI Hub Service, as well as an administrative fee to account for any direct or indirect costs of making CSI income data accessed through the VCI Hub service available to Exchanges and State Medicaid and CHIP agencies, in accordance with the Intergovernmental Cooperation Act and interpretive OMB Circulars A-97 and A-25.²¹⁸ As such, we have revised the regulatory text to remove language stating that State Exchanges must pay for their utilization of the VCI Hub service annually and in advance, as well as references to reconciliation. We summarize and respond to public comments received on the proposed policy below.

Comment: One commenter supported our proposal to reinterpret State Exchange and State Medicaid and CHIP agency use of the VCI Hub service to access CSI income data as a State

Exchange or a State Medicaid and CHIP agency function. The commenter stated that being able to access CSI income data through the Hub would enhance the accuracy and efficiency of eligibility determinations for either Exchange QHP or Medicaid and/or CHIP coverage, while also improving the overall accuracy and protecting the integrity of the income verification process for eligibility for either of these programs.

Response: We agree that use of the VCI Hub service and the CSI income data accessed through the service is an integral part of the eligibility determination process in most State Exchanges and State Medicaid and CHIP agencies and provides an optional means to improve the overall accuracy of income verifications, especially in cases where an applicant's annual or current income is not verified using other Federal data sources, such as IRS income tax data or SSA Title II income. We also agree that access and use of the VCI Hub service ensures the program integrity of Exchanges, as the income data accessed through the VCI Hub service can ensure that applicants who are eligible to receive APTC do so. Because of these benefits to both State Exchanges and State Medicaid and CHIP agencies, HHS will continue to maintain existing contracts that make access to these resources available through the Hub for State Exchange and State Medicaid and CHIP agency use, as HHS has over the course of the last decade. Additionally, State Exchanges and State Medicaid and CHIP agencies that do not have access to the VCI Hub service and wish to begin utilizing and paying for CSI income data accessed through the VCI Hub service may do so by submitting a request to HHS for review and approval to connect to the VCI Hub services, as States are not permitted to begin using the service without prior HHS approval. However, even though CSI income data accessed through the VCI Hub service is optional, we still believe that it is appropriate that this service be considered a State Exchange or State Medicaid and CHIP agency function.

Comment: Several commenters opposed the proposal to require State Exchanges and State Medicaid and CHIP agencies to pay for their utilization of the CSI income data accessed through the VCI Hub service as they noted that it would negatively impact consumers in various ways. For example, some commenters were concerned that the proposal would undermine current State efforts to improve renewals of a consumer's eligibility for Medicaid or CHIP coverage. In particular, these commenters were concerned that the

²¹⁸ See Circular No. A-25 Revised. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>. See also Circular No. A-97. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-097.pdf>.

proposal would limit States' use of available data to determine eligibility before requesting additional income information from the consumer, often referred to as *ex parte* renewals, which have been especially important since the Medicaid continuous enrollment condition ended and Medicaid unwinding began. One commenter noted that *ex parte* renewals allow a State Medicaid or CHIP agency to renew a consumer's coverage without requiring the consumer to submit a renewal form, and thus reduce the risk of loss of coverage due to procedural reasons. The commenter also noted that charging State Medicaid and CHIP agencies for their use of the VCI Hub service would only impede efforts to increase *ex parte* renewals (as has been encouraged by the Administration) because this policy would have significant fiscal impacts for Medicaid and CHIP agencies if additional income data is needed from the VCI Hub service. As a result, the commenter predicted that some State Medicaid and CHIP agencies may choose to stop using the VCI Hub service, which would impact Medicaid and CHIP renewals.

A few commenters also expressed their concern that if State Exchanges or State Medicaid and CHIP agencies pivot to alternative data sources rather than using the CSI income data accessed through the VCI Hub service, less accurate data may lead to inaccurate eligibility determinations for either Exchange QHP or Medicaid and/or CHIP coverage, which could harm consumers by causing them to incur large tax liabilities due to income inaccuracies or increasing churn. Finally, a few commenters noted that the proposal could also lead to consumer harm due to increases in premiums, as States make budget adjustments to pay for their use of the VCI Hub service, whereas other commenters were concerned that charging Hub data fees could have negative impacts, such as reducing State flexibility to operate their own Exchanges as they see fit.

Response: We believe that this policy change, which will take effect on July 1, 2024, should not significantly impact State Medicaid unwinding activities. After the continuous enrollment condition ended on March 31, 2023, States were required to, over time, complete renewals consistent with Federal requirements for all individuals enrolled in their Medicaid program as of that date, disenroll individuals if they were no longer eligible, and determine potential eligibility of those individuals for certain other sources of coverage. States are required under 42 CFR 435.916(a) to redetermine eligibility

without requiring information from the individual (that is, *ex parte* renewal), unless necessary. Per 42 CFR 435.948(a), States generally have flexibility to decide what data sources are useful when conducting electronic data matches to verify income as part of the *ex parte* renewal process. Examples of income data sources that could be used in lieu of or in addition to the VCI Hub service to conduct *ex parte* renewals include but are not limited to: State quarterly wage data, State unemployment compensation data, State income tax data, Supplemental Nutrition Assistance Program (SNAP) data, and Temporary Assistance for Needy Families (TANF) data. We encourage States to use a variety of available data sources to maximize utilization of the *ex parte* process and ensure coverage is maintained for eligible individuals. Additionally, to support States facing significant operational and Medicaid eligibility and enrollment system issues and to help minimize procedural disenrollments as they resumed routine operations, we have granted States section 1902(e)(14)(A) waivers to support unwinding efforts.^{219 220} A number of these strategies are focused on facilitating the renewal process by limiting the need for requests for additional information from beneficiaries, thus leading to fewer procedural disenrollments and reducing State administrative burdens during this transition period.

We acknowledge the concern raised by commenters that if a State chooses to reduce its use of the VCI Hub service due to this policy change, this may result in additional requests for additional documentation or other information from individuals to verify income. However, we believe there are ways to mitigate this concern. Other reliable government data sources, whether State or Federal, are available to verify income, some of which must be accessed if useful (for example, quarterly wage data, income information from a SNAP case file if the individual is receiving SNAP benefits) before a

State may require additional documentation from the individual.²²¹ Additionally, States have the flexibility to implement strategic data hierarchies, which would allow States to implement business logic regarding how data sources and other available information are used in making an *ex parte* eligibility determination, including only requesting CSI income data from the VCI Hub service in cases where income could not be verified using these other data sources, such as the examples listed above. Because States have flexibility to adjust how and when they access the VCI Hub service, and because other reliable government sources of income information are available, we do not predict the policy will result in inaccurate eligibility determinations.

We understand the concern raised from States that up-to-date and accurate income data is essential for both State Exchanges and State Medicaid and CHIP agencies to make accurate eligibility determinations for Exchange QHP, Medicaid, or CHIP coverage and that this policy may lead to consumers incurring large tax liabilities when filing their Federal income taxes or increase churn in and out of Medicaid or CHIP coverage. However, there are consumer protections in place to protect consumers from incurring large tax liabilities. For example, all Exchanges are required to give consumers the opportunity to provide more up-to-date and accurate income information through the income DMI process. There are also protections in place to help mitigate Medicaid and CHIP churn. For example, 42 CFR 435.916 and 457.343 generally require that the State Medicaid and CHIP agency provide a 90-day reconsideration period, or a longer period elected by the State, which allows Medicaid or CHIP beneficiaries who are disenrolled for failure to submit the renewal form or necessary information, to provide a renewal form or necessary information to their State Medicaid and CHIP agency to reconsider eligibility for Medicaid and/or CHIP without having to complete a new application. Furthermore, as finalized in the 2024 Payment Notice (88 FR 25831), Exchanges now have the option under § 155.420(c)(6) to provide consumers losing Medicaid or CHIP with 90 days (instead of 60 days) after the loss of such coverage to enroll in a

²¹⁹ SHO # 22-001: Promoting Continuity of Coverage and Distributing Eligibility and Enrollment Workload in Medicaid, the Children's Health Insurance Program (CHIP), and Basic Health Program (BHP) Upon Conclusion of the COVID-19 Public Health Emergency: <https://www.medicaid.gov/sites/default/files/2022-03/sho22001.pdf>.

²²⁰ Available State Strategies to Minimize Terminations for Procedural Reasons During the COVID-19 Unwinding Period: Operational Considerations for Implementation, December 2023: <https://www.medicaid.gov/sites/default/files/2023-12/considerations-for-procedural-termination-strategies.pdf>.

²²¹ We note, as discussed in the 2012 final rule on Eligibility Changes Under the Affordable Care Act of 2010, "[t]he time lag in the availability of quarterly wage data would not justify a State concluding that such data is not useful to verifying income eligibility and routinely relying instead on documentation provided by the individual" (77 FR 17175).

QHP through an Exchange through a special enrollment period (SEP), which could also help ease transitions into Exchange QHP coverage.

Finally, we acknowledge that this policy change may cause State Exchanges to raise their user fees to pay for accessing CSI income data through the VCI Hub service and that this may lead to premium increases for consumers. However, we believe that there are ways for States to prevent this potential outcome, such as accessing alternative data sources for income verification or implementing logic changes to their eligibility and enrollment systems to only request CSI income data when income cannot be verified using other data sources such as IRS income data, State quarterly wage data, etc.

Comment: Several commenters expressed concern that the proposed effective date of July 1, 2024, would give States little time to account for the VCI Hub service costs into their FY 2025 budgets, explore the viability of alternative verification methods and/or data sources, or devise strategies to reduce their utilization of the VCI Hub service. A few of these commenters proposed specific delayed dates for implementation, ranging from 1 to 3 years after the proposed effective date of July 1, 2024. One commenter stated that 46 States have fiscal years that run from July 1 to June 30, allowing little time to account for the policy change that requires States to pay for their utilization of the CSI income data accessed through the VCI Hub service in their FY 2025 budgets, as some State legislatures begin this activity as early as January 2024. Another commenter noted that its State Exchange sets its user fee each year in February, and so would not have the opportunity to increase the user fees to pay for the policy until February 2025, and expressed concern that increasing user fees would have a chilling effect on issuer participation.

Response: We are finalizing that beginning July 1, 2024, State Exchanges and State Medicaid and CHIP agencies will be required to reimburse HHS for the costs of their access to and use of the VCI Hub service. Because use of the VCI Hub service is optional for State Exchanges and State Medicaid and CHIP agencies to verify income, we do not believe that it is prudent to delay the implementation of this policy. State Exchanges and State Medicaid and CHIP agencies are responsible for determining eligibility for their respective programs (Exchange QHP coverage or Medicaid/CHIP) and thus responsible for the cost to access the optional CSI income data

accessed through the VCI Hub service used to determine eligibility. Furthermore, States can utilize other government data sources (for example, IRS tax data and SSA title II data) that are free and, in most cases, will verify an applicant's income without the need to also access CSI income data accessed through the VCI Hub service.

While we recognize States' concerns about funding this use of the CSI data by July 1, 2024, we have been proactively working with States since before the publication of the proposed rule to prepare States for this possible transition and will continue to do so. We believe that some of these concerns can be mitigated by strategizing ways to reduce their reliance on CSI income data by either using alternative data sources, such as State quarterly wage data to verify income, or only accessing CSI income data if States are unable to verify income using other available data sources. For example, an Exchange may implement logic changes within their eligibility systems to only request CSI data in cases where a consumer's current income could not be verified using IRS income tax or SSA title II income data, which would act as a cost-saving measure for States. To ease the transition by July 1, 2024, we will work with States to help navigate how to pay for their use of the CSI income data, including those States with only one VCI Hub service connection for both their State Exchange and State Medicaid and CHIP agency which may require additional effort to allocate the payment responsibility between the State Exchange and State Medicaid and CHIP agency.

Lastly, we reiterate that Exchanges and State Medicaid and CHIP agencies are not required to use the VCI Hub service to fulfill the mandatory eligibility determination requirements.²²²

Comment: Commenters stated that the proposal will create numerous operational and cost challenges for States and charging States for use of the VCI Hub service poses an unfair cost burden on State Exchanges. One commenter stated that the policy may cause costly system redesign or alternative arrangements, such as States establishing their own income verification service contracts, as well as increased complexity and costs associated with identifying usage of the VCI Hub service that is eligible for FMAP. Furthermore, the commenter

stated that the new costs introduced by this proposal could discourage States from transitioning to or maintaining their status as a State Exchange in the future. Accordingly, these commenters suggested that HHS should make grants available to establish alternate income verification sources for States transitioning to a State Exchange, asserting that existing State Exchanges have had time to charge user fees, build reserves upon which to draw, and have benefited from years of the VCI Hub service without any cost to them. Another commenter cautioned that, given increasingly tight State budgets, this policy would represent an unanticipated outlay that might draw funds away from other critical programs.

A few commenters objected to the policy on the grounds that HHS has not given States an estimate of the costs or historical volume of States' use of the VCI Hub service and requested that HHS do so before finalizing the policy. One commenter stated that HHS did not provide enough evidence as to why Hub data use fees are necessary, especially given that States have been successful in enrolling and protecting consumers using standards and processes that work best for the residents of their respective States. Another commenter noted that this policy, if finalized, would result in significant cost to States which could be detrimental to further utilization of the VCI Hub service and stated that States with a larger Medicaid and CHIP population will bear greater cost shift. The commenter stated that it is uncertain if the expense will remain sustainable for those States in future budget years.

Response: It is appropriate to reinterpret State Exchange and State Medicaid and CHIP agency use of the VCI Hub service to access and use the income data provided by the optional VCI Hub service as a State Exchange or a State Medicaid and CHIP agency function. Therefore, it is also appropriate for States to be responsible for the cost of administering the program. Specifically, it is appropriate for States with greater Medicaid population and therefore higher use of the service to bear a greater cost because the costs of the service are driven by the number of returned data matches that the VCI Hub service initiates for consumers. Therefore, costs to States will be calculated by multiplying the actual number of purchased transactions returned from the VCI Hub service by the price per transaction for HHS to provide the VCI Hub service, as well as an administrative fee to reimburse HHS for any direct or indirect costs of making

²²² State Exchanges continue to have flexibility under §§ 155.315(h) and 155.320(c)(3)(iv) to use an alternative verification source, like State wage data, when income is not verified using IRS tax data or SSA title II income data.

CSI income data accessed through VCI Hub service available to Exchanges and State Medicaid and CHIP programs. More detailed cost information will be set forth in an Intergovernmental Cooperation Act Agreement (IGCA) between HHS and the State Exchange or State Medicaid and CHIP agency. We acknowledge that some States may choose to reduce or discontinue their use of the VCI Hub Service in response to the costs that the finalization of this policy represents to States. We will continue to provide the VCI Hub Service to States that choose to continue or begin using the VCI Hub service.

We do not believe that the finalization of this policy will meaningfully discourage States from transitioning to, or maintaining, their status as a State Exchange. We anticipate that existing State Exchanges, as well as States considering transitioning to a State Exchange, will employ strategies to encourage efficient use of the VCI Hub service, as well as leverage other existing sources of income data.²²³ We believe that these strategies will help to keep costs below levels that would discourage States from transitioning to, or maintaining, their status as a State Exchange.

Regarding the request that HHS provide grants to States newly transitioning to a State Exchange to obtain other data sources for income verification, currently, HHS is unable to establish such a grant program because it lacks the Congressional appropriation to do so. States transitioning to a State Exchange should set their Exchange user fees appropriately to fund their anticipated utilization of the VCI Hub Service (or establish an alternative income verification source such as State quarterly wage data) as HHS is setting the FFE and SBE-FP user fees to fund the FFE and SBE-FP utilization of the VCI Hub service.

We also note that, to assist States in estimating the costs of continued utilization of the VCI Hub Service, and in anticipation that this proposal could be finalized, we made historical cost and utilization data of the VCI Hub service available to States with State Exchanges and State Medicaid and CHIP agencies that currently utilize the VCI Hub Service. We may share historical use data with other States that are considering using the VCI Hub service. However, we note that this information may be of limited value because of the wide variation in factors, such as

individual State policy, whether or not a State Exchange shares an integrated eligibility system with the State Medicaid and CHIP agency, etc., which greatly impacts a State's utilization of the VCI Hub service. As noted earlier in this rule, we intend to work with States to help navigate how to pay for their use of the CSI income data.

Comment: Several commenters stated that, should HHS finalize the proposal to reinterpret use of the VCI Hub service as a function of State Exchanges and Medicaid and CHIP agencies and not an HHS function, they would prefer a monthly invoice ("postpay") approach because billing for their actual utilization of CSI income data accessed through the VCI Hub service would be simpler, more efficient, and would avoid additional costs associated with prebilling and reconciliation.

A few commenters supported the proposal for HHS to charge State Exchanges and State Medicaid and CHIP agencies in advance for their projected annual use of the VCI Hub service ("to prepay"). One commenter stated that paying in advance for their anticipated annual usage with an annual reconciliation process would be easier administratively and would allow for more certainty in budgeting the State's share of the matching costs each year. Another commenter stated that a prepay approach may align well with a State's budget processes and the regular Advance Planning Document (APD) process used to obtain Federal Financial Participation (FFP). Further, the commenter also stated that a more frequent than annual (for example, monthly) invoicing and estimating usage of the VCI Hub service cadence would increase the administrative burden of maintaining the service and would be unlikely to alter the methodology by which the State develops cost estimates related to their use of the VCI Hub service. Another commenter stated that, if a prepay approach is finalized, it would be efficient to align the payment to HHS with the State's FFP schedule to allow more frequent reconciliation of VCI Hub service usage estimates.

A few commenters suggested that, because different State Medicaid and CHIP agencies have different preferences on how they are invoiced, that HHS should consider providing States with several different invoicing options so that States can choose which invoicing cadence, such as monthly, quarterly, or annually, works best for their State.

Response: In light of comments received, rather than require that States pay in advance for their utilization of

the VCI Hub service as proposed, we are finalizing the alternative approach we proposed, whereby HHS will invoice States on a monthly basis for their actual utilization of the CSI income data accessed through VCI Hub service, as well as an administrative fee to account for any direct or indirect costs of making CSI income data accessed through VCI Hub service available to State Exchanges and State Medicaid and CHIP agencies.²²⁴ We agree with commenters that a postpay approach will reduce administrative burden on States, increase efficiency, and reflect a State Exchange's or State Medicaid and CHIP agency's actual utilization of the VCI Hub service from the month prior, rather than a yearly estimate that could vary widely due to unforeseen events. Even though monthly invoicing increases the frequency of invoices compared to annual invoicing, it will also allow State Exchanges and State Medicaid and CHIP agencies to quickly realize cost savings from efficient utilization of the VCI Hub service and allow State Exchanges and State Medicaid and CHIP agencies to become aware of inefficient utilization trends, which an annual invoice will not easily capture. We also agree with commenters that this alternative approach will avoid additional costs associated with prebilling and reconciliation.

Furthermore, this alternative or "postpay" approach will negate the need for States to establish, and for HHS to approve, an estimation methodology for their projected annual utilization of the VCI Hub service, which we believe would be challenging for States to estimate. While States could rely on historical utilization of the VCI Hub service to project future utilization, as Exchange populations continue to grow, past data could become less reliable and could result in inaccurate estimates, which could lead to an overly expensive and burdensome reconciliation process. Each of the States will execute an IGCA with CMS that must be in effect before the VCI Hub service can be utilized by the States. Under the terms of the IGCA, CMS will invoice the State for the actual costs of the State's use of CSI data provided via the VCI Hub service for the previous month.

We also acknowledge the preference of a few commenters for a prepay approach for administrative ease and more certainty in budgeting the State share of the matching costs each year. However, we believe that a postpay

²²³ State Exchanges continue to have flexibility under §§ 155.315(h) and 155.320(c)(3)(iv) to use an alternative verification source, like State wage data, when income is not verified using IRS tax data or SSA title II data.

²²⁴ See Circular No. A-25 Revised. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>. See also Circular No. A-97. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-097.pdf>.

approach will be administratively simpler for both participating States and HHS compared to a prepay approach. Additionally, we note that, the finalization of a postpay approach notwithstanding, States will still need to budget for the State's share of matching costs based on their utilization estimates of the VCI Hub service.

At this time, we are unable to facilitate a mixed approach, wherein participating States choose between a prepay and postpay approach. A mixed approach would require administering parallel sets of policies, timelines, and system builds. The operational complexity and inefficiency of such an approach would increase the cost of administering the VCI Hub Service.

Comment: One commenter asked HHS to clarify that SBE-FP States would not be charged for VCI Hub service Exchange-related expenses as this should already be accounted for in the SBE-FP user fees that HHS already receives. One commenter proposed a discount on the FFE or SBE-FP user fee for States that opt to use their own verification services instead of the VCI Hub service, stating that such an approach would encourage States to invest in alternative verification technologies, potentially leading to more tailored and State-specific solutions. One commenter opposed any attempt by HHS to apportion VCI Hub service fees for Exchange verification activities that result in determination of Medicaid, CHIP, or BHP, if applicable, eligibility, stating that these activities should be charged to the program for which the individual is determined eligible.

Response: HHS will not invoice SBE-FPs for the cost of access to and use of the VCI Hub service when initiated by HHS to the VCI Hub service for income verification on behalf of SBE-FPs. Instead, a portion of the Exchange user fees that HHS already collects from issuers in FFEs and SBE-FPs will fund HHS' access to and use of the VCI Hub service on behalf of the FFE and SBE-FPs. HHS will charge Medicaid and CHIP agencies in States with SBE-FPs for their access to and use of the VCI Hub service.

We will not reduce the FFE or SBE-FP user fee in an FFE or SBE-FP State where the State, State Medicaid and/or CHIP agency opts to use their own data source or service for verifying income, instead of the VCI Hub Service. Because the FFE and SBE-FP user fee rates are set as a percent of premium for all issuers in an FFE or SBE-FP and account for the cost of all special benefits provided to the FFE and SBE-

FP, we do not make specific State adjustments.

For apportionment of costs between various State programs, we clarify that in States with a single Hub connection, the allocation between the State Exchange and State Medicaid and CHIP agencies will be determined by the States and reported to HHS through the Advance Planning Document processes. Conversely, in States with multiple Hub connections, each purchased transaction that returned matched data from the VCI Hub service will be attributed to the Hub connection through which the purchased transaction was initiated. As previously noted, to help States assess the potential implications of this proposed policy change, we shared data with States on their historical usage of the VCI Hub service, broken out by Hub connection in States with more than one connection.

Comment: A commenter stated that Congress should appropriately fund HHS and the Hub to ensure that Medicaid and CHIP agencies can access important sources of income data. Furthermore, that commenter sought clarification from HHS on FFP support for States that sought a direct contracting option with a commercial vendor. Another commenter supported that Medicaid and CHIP agencies would be eligible for Federal matching funds for the cost of the service.

Response: We note that the finalization of this policy will fund State Exchanges' and State Medicaid and CHIP agencies' use of the VCI Hub service through monthly charges to those agencies, and fund FFE and SBE-FP use of the VCI Hub service through FFE and SBE-FP user fees and not by a new Congressional appropriation. We also note that States that choose to pursue a direct contracting option with a commercial vendor may be eligible for enhanced FFP from HHS for Medicaid utilization of these types of services, but not for State Exchange utilization of those services. We further note that States that choose to pursue a direct contracting option with a commercial vendor for their State Medicaid usage may be eligible for 75 percent matching for the operation of mechanized claims processing and information retrieval systems²²⁵ and 90 percent matching for any design, development, and installation (including for modifications) of eligibility and enrollment systems and/or other related Medicaid Enterprise System (MES) components used for Medicaid eligibility and determination

purposes.²²⁶ For CHIP utilization of commercial vendor services, States may be eligible for Federal matching funds under the State's CHIP allotment. States should work with their MES State Officers through the APD process and ensure that any Federal cost allocation requirements (applicable where an expenditure supports multiple benefiting programs) for the acquisition and/or contract for these services are met.

Comment: Another commenter opposed HHS' reinterpretation of the use of the VCI Hub service to verify APTC eligibility as a State Exchange function and not a Federal function, stating that section 1411 of the ACA makes HHS responsible for verification. The commenter asserted that section 1411(d) of the ACA allows HHS to delegate responsibility for verification to Exchanges, but not for verification of information outlined in section 1411(c) of the ACA (which includes income), and therefore HHS cannot delegate this verification to Exchanges.

Response: We acknowledge that section 1411 of the ACA requires HHS to be responsible for income verification and clarify that the policy at issue here does not delegate income verification to the States. Section 1411(c)(3) of the ACA requires that the Secretary submit the information described in subsection (b)(3)(A) provided under paragraph (3), (4), or (5) of subsection (b) to the Secretary of the Treasury for verification of household income and family size for purposes of eligibility. However, in some situations, if government sources of income (like IRS tax data) indicate that the applicant(s)' attested income is significantly different from what IRS returns for the year for which coverage is requested, the applicant or enrollee is considered to have experienced a change in circumstances, which allows HHS to establish procedures for determining eligibility for APTC and CSRs on information other than IRS tax return data as described in § 155.320(c)(3)(iii)-(vi).²²⁷ In these situations, and where government sources of income are unavailable, data on current income may be used for eligibility determinations and redeterminations for financial assistance and is accessed through the VCI Hub service. In other words, the purpose of the optional VCI Hub service is to verify income in those instances where the Department of Treasury is unable to do so and would only be used once the Department of Treasury fails to verify income. Therefore, HHS is interpreting

²²⁶ See 42 CFR 433.112.

²²⁷ See section 1412(b)(2) of the ACA.

²²⁵ See 42 CFR 433.116.

the statute such that the obligation of the Secretary of HHS to verify income is fulfilled once the information has been verified against data provided by the Secretary of the Department of Treasury, and any additional efforts to verify income (such as through the VCI Hub Service) should be construed as being subject to section 1413 of the ACA, which gives the Secretary of HHS broad discretion in administering the program.

Comment: A few commenters responded to our request for information regarding the extent to which States may be interested in potential avenues to reduce operational burdens or address budget challenges facing State Exchanges and Medicaid and CHIP agencies, including whether the reuse of verification data, coupled with cost allocation across programs, would reduce operational burdens or address budget challenges, and whether States have separate, direct access to the same or similar source of VCI Hub services. One commenter stated that it is currently using the CSI data source for all Medicaid and CHIP applications but, in the future, will pursue streamlining by using the VCI Hub service only for a subset of applications that require additional post-eligibility verification. Another commenter was interested in the potential efficiencies gained from re-using Hub information across multiple State-managed programs but stated that more time would be needed to further evaluate such an option.

Response: We appreciate commenters' interest in the re-use of CSI data delivered through the VCI Hub service. We will continue to evaluate this option and confer with States regarding efficiencies that could result from the re-use of CSI data.

13. Eligibility Redetermination During a Benefit Year (§ 155.330(d))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82578), we proposed updates and changes to 155.330. At § 155.330, we proposed to redesignate paragraph (d)(3) as paragraph (d)(3)(i) and add paragraph (d)(3)(ii) to require Exchanges to conduct periodic checks for deceased enrollees twice yearly and subsequently end deceased enrollees' QHP coverage beginning with the 2025 calendar year. Additionally, we proposed to add § 155.330(d)(3)(iii) to grant the Secretary the authority to temporarily suspend the periodic data-matching (PDM) requirement during certain situations or circumstances that lead to the unavailability of data needed to conduct PDM.

Under § 155.330(d), Exchanges are required to periodically examine available data sources, referred to as PDM, to identify whether enrollees become deceased, and to identify whether enrollees on whose behalf APTC or CSRs are being paid have been found eligible for or are enrolled in Medicare, Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange. Additionally, upon such identification, § 155.330(e)(2)(i) requires Exchanges to notify the enrollee of the updated information and provide the notified enrollees 30 days from the date of the notice to appeal PDM findings.

Currently, § 155.330(d)(3) defines "periodically" only for PDM activities that identify enrollment in Medicare, Medicaid, CHIP, and, if applicable, BHP, meaning that Exchanges must conduct Medicare PDM, Medicaid or CHIP PDM, and, if applicable, BHP PDM, twice a year. The current regulation does not specify the frequency by which PDM activities to identify deceased enrollees must occur, but the 2019 Program Integrity Rule requires that Death PDM be conducted once annually, and we noted that we intended to update the frequency for Death PDM in future rulemaking. As explained in the 2019 Program Integrity Rule, we did not require Exchanges to perform PDM for death at least twice in a calendar year so that Exchanges could prioritize the implementation of the new requirement to conduct PDM for Medicare, Medicaid, CHIP and, if applicable, BHP eligibility or enrollment at least twice yearly. In the proposed rule, we proposed to add § 155.330(d)(3)(ii) to require Exchanges beginning with the 2025 calendar year to conduct periodic checks for deceased enrollees twice yearly and subsequently end deceased enrollees' QHP coverage after following the procedure specified in § 155.330(e)(2)(i).

Periodic checks for deceased enrollees help ensure Exchange program integrity. This policy would not only align with current FFE policy and operations but would also prevent overpayment of QHP premiums and APTC/CSRs, and accurately capture household QHP eligibility based on household size. Additionally, by conducting Death PDMs twice a year, Exchanges can prevent future auto re-enrollments or policy effectuation for deceased enrollees for the next plan year.

Additionally, we proposed to add § 155.330(d)(3)(iii) to grant the Secretary the authority to temporarily suspend the PDM requirement during certain situations or circumstances that lead to an unavailability of data needed to

conduct PDM. PDMs are conducted as a program integrity measure where the prerequisite for conducting a proper PDM is assurance of data quality. We recognize that during certain circumstances data quality may be incomplete or lagging. For example, during the COVID-19 Public Health Emergency, State and local agencies had to strain their resources to address backlogs due to job losses and other administrative gaps further slowing down response times,²²⁸ thereby, increasing the risk of the Exchanges making inaccurate eligibility determinations due to potential data lags. In such cases, using such data could pose a risk of improper termination of coverage or APTC/CSRs for large numbers of enrollees. These improper terminations may be particularly harmful to the consumers. These potential harms can be even more likely to occur when the additional burdens of DMI resolution are imposed on Medicare and Medicaid beneficiaries, who can be vulnerable and underserved and more likely to encounter gaps in coverage or a complete lack of coverage as a result of failing to resolve the DMIs.²²⁹ Allowing the Secretary the flexibility to temporarily suspend the PDM requirement during certain situations where there may be enrollment or data lags may be able to prevent an inadvertent increase in the uninsured population, which largely consists of vulnerable consumers. We will notify Exchanges of such a suspension of PDM activities, and a resumption of PDM activities, through subregulatory guidance.

We anticipate most State Exchanges would be able to meet the proposed requirements for Death PDM based on operations already reported through the State-based Marketplace Annual Reporting Tool (SMART) as well as discussions we have had with the State Exchanges on PDM. We also anticipate that changes, including a suspension of the PDM requirement, would be well received by the Exchanges and issuers, as it is important that consumer information, such as eligibility for APTC or QHP coverage, be accurate to avoid expending administrative resources on complex processes to correct errors. Eleven State Exchanges reported in their

²²⁸ McDermott, D., Cox, C., Rudowitz, R., and Garfield, R. (2020, Dec. 9). *How Has the Pandemic Affected Health Coverage in the U.S.?* KFF. <https://www.kff.org/policy-watch/how-has-the-pandemic-affected-health-coverage-in-the-u-s/>.

²²⁹ Hirsch, M. (1994). *Health Care of Vulnerable Populations Covered by Medicare and Medicaid*. *Health Care Finance Rev.* 15(4):1–5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193433/>.

2022 SMART submissions that they curtailed PDM checks only due to the exigency resulting from the COVID-19 Public Health Emergency, which expired in May of 2023. Furthermore, we do not anticipate the new periodicity requirement for the Death PDM to result in a significant administrative burden for State Exchanges because States previously conducted PDM checks for deceased enrollees.

Under section 1313(a)(4) of the ACA, if HHS determines that an Exchange has engaged in serious misconduct with respect to compliance with Exchange requirements, it has the option to rescind up to 1 percent of payments due to a State under any program administered by HHS until such misconduct is resolved. These existing authorities apply to the PDM requirements in § 155.330(d). If HHS were to determine that it is necessary to apply this authority due to non-compliance by an Exchange with § 155.330(d), HHS would also determine the HHS-administered program from which it would rescind payments that are due to that State. However, if State Exchanges do not comply with the PDM requirements, we generally first direct a State Exchange to take corrective action. We utilize specific oversight tools (for example, the SMART, independent external programmatic & financial audits) to ensure compliance and that State Exchanges take appropriate corrective action. HHS also provides technical assistance and ongoing monitoring to track those actions until the State Exchange remediates the issue fully. We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision with modifications. The final rule will require Exchanges to start conducting Death PDMs two times a year beginning calendar year 2025 and will allow the Secretary to temporarily pause PDM during certain situations or circumstances that lead to the limited availability of data (instead of the unavailability of data, as proposed) needed to conduct PDM. We are also adding that the Secretary may temporarily pause PDM during certain situations or circumstances that lead to the limited availability of documentation needed for an enrollee to notify the Exchange that the result of PDM is inaccurate, as described in paragraph (e)(2)(i)(C). We summarize and respond to public comments received on the proposed policy below.

Comment: Many commenters supported the proposal to allow the

Secretary of HHS to temporarily pause PDMs in the event data is unavailable to conduct PDM, which may harm consumer enrollment, and for the Exchanges to start conducting Death PDMs twice a year starting PY 2025, in compliance with the ACA requirement.

Response: We thank the commenters for their support of the proposed rule to allow the Secretary of HHS to temporarily pause PDMs in certain situations that lead to the unavailability of data needed to conduct PDM to limit inadvertent harm to the consumers, and for the Exchanges to conduct Death PDMs two times a year and end coverage for identified deceased enrollees, thus stopping premium payments and ending coverage after proper notification. In the proposed rule, we proposed the “unavailability” of data is when the Secretary would exercise the authority to temporarily pause PDMs. In this final rule, we are changing “unavailability” to “limited” availability. From an operational and consumer experience standpoint, if complete data is not readily available for either the Exchanges or consumers, running a PDM may cause inadvertent harm. As a PDM results in termination of coverage or complete cessation of financial assistance, Exchanges may be rendering consumers uninsured and consumers may also not have sufficient documentation to appeal their dual enrollment or deceased status due to limited data available from the respective entities.

Comment: One commenter asked for a clarification that the requirement to conduct PDMs is an Exchange requirement and not an issuer or DE requirement. The commenter proposed that CMS create unique transaction codes to communicate identified deceased enrollee amongst entities.

Response: This policy is for Exchanges to maintain program integrity of its operations by identifying and removing deceased enrollees twice a year. We ask issuers in Exchanges on the Federal platform to direct callers who wish to report a deceased enrollee to the Marketplace Call Center at 1-800-318-2596 (TTY: 1-855-889-4325). We thank the commenter for the recommendation to implement unique transaction codes so Exchanges and issuers can communicate identified deceased enrollees. If an enrollee has been verified as deceased through the Death PDM process, Exchanges on the Federal platform send the issuer an Outbound 834 with a Maintenance Reason Code of “Term-PDM” or “Cancel-PDM” which notifies the issuer of upcoming termination or cancellation of the deceased enrollee’s Exchange

coverage, unless otherwise resolved within 30 days of initial notification to the consumer.

Comment: A few commenters supported the proposal and asked CMS to provide clarity and specific examples and scenarios as to when the Secretary of HHS can pause PDM operations, as poor enrollment data can occur outside a public health emergency.

Response: This policy will allow the Secretary to pause PDM operations under certain circumstances that lead to the limited availability of data needed to conduct PDM. Outside of a public health emergency, such circumstances may include enrollment or data lags. We are also finalizing that the Secretary may temporarily pause PDM during certain situations or circumstances that lead to the limited availability of documentation needed for an enrollee to notify the Exchange that the result of PDM is inaccurate, as described in paragraph (e)(2)(i)(C). If a consumer cannot provide sufficient documentation to appeal the PDM findings, they are likely to remain uninsured as the PDM process will likely cause the termination of their coverage or financial assistance.

Comment: One commenter stated that requiring States to conduct PDM two times a year limits States’ flexibility. A few commenters firmly opposed the proposed amendment, claiming that the rationale provided does not justify additional Federal requirements and that Death PDM is unlikely to identify inappropriate enrollments such that the program integrity benefits outweigh the cost.

Response: Based on our experience operating the Federal Platform, running Death PDMs two times per year has proven to identify a substantial number of deceased enrollees. We believe that this two-times-a-year requirement is a vital program integrity measure to reduce the amount of QHP premiums paid by the deceased enrollees and the amount of APTC paid on behalf of the deceased enrollees. As allowed under § 155.315(h), State Exchanges have the ability to propose to HHS alternative approaches for verifying the consumer information required under 45 CFR part 155, subpart D, which includes the periodic verification of death status by Exchanges. Per § 155.315(h), HHS’ criteria for evaluating these alternative approaches include reduction of administrative costs and burdens on individuals while maintaining accuracy and minimizing delay, as well as maintaining coordination of eligibility with Medicaid and CHIP.

14. Incorporation of Catastrophic Coverage Into the Auto Re-Enrollment Hierarchy (§ 155.335(j))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82579), we proposed to incorporate catastrophic coverage as defined in section 1302(e) of the ACA into the auto re-enrollment hierarchy at § 155.335(j). We proposed this policy because the regulation did not address auto re-enrollment for catastrophic coverage enrollees, nor did it address a scenario in which a catastrophic coverage enrollee would lose eligibility for catastrophic coverage in the coming plan year either because they exceeded the 30-year age limit or lost eligibility for the exemption that allowed them to enroll in a catastrophic plan in spite of exceeding the age limit.²³⁰ Specifically, we proposed to amend § 155.335(j)(1) and (2) to require Exchanges to re-enroll individuals who are enrolled in catastrophic coverage, and who no longer meet the criteria for enrollment in a catastrophic plan, into a bronze metal level QHP in the same product as the enrollee's current QHP (in the case of paragraph (j)(1)), or in the product offered that is the most similar to (in the case of paragraph (j)(2)) the enrollee's current product, and that has the most similar network compared to the enrollee's current QHP; or if no bronze plan is available through this product, in the QHP with the lowest coverage level offered under this product and that has the most similar network compared to the enrollee's current QHP. We also proposed to amend § 155.335(j)(1)(ii) to (iv) and § 155.335(j)(2)(i) to (iii) to use the term "coverage level" instead of "metal level" so that the rules in this section are inclusive of catastrophic coverage enrollees. Finally, we proposed to add new § 155.335(j)(5) to establish that an Exchange may not newly auto re-enroll into catastrophic coverage an enrollee who is currently enrolled in coverage of a metal level as defined in section 1302(d) of the ACA. We stated that as part of this proposed policy, we would update the Federally-facilitated Exchange (FFE) Enrollment Manual to incorporate catastrophic coverage into the re-enrollment hierarchy for alternate enrollments, sometimes referred to as cross issuer enrollments.²³¹

²³⁰ See § 155.305(h).

²³¹ The FFE Enrollment Manual includes the hierarchy that we use to implement § 155.335(j)(3) in Exchanges using the Federal platform to crosswalk enrollees whose current issuer no longer offer plans available to them through the Exchange. For example, see CMS. (2023, July 12). *Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 3.2.4, pp 29–30. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

We solicited comment on these proposals, including whether they reflected the State Exchanges' current practices, whether we should consider proposing changes to the auto re-enrollment hierarchy to prioritize re-enrollment in catastrophic coverage for enrollees who remain eligible for catastrophic coverage in a way that is similar to current prioritization of silver level coverage per § 155.335(j)(1)(ii), and whether there are additional strategies to help ensure continuity of coverage for enrollees in catastrophic QHPs.

After consideration of comments and for the reasons outlined in the proposed rule and in our responses to comments, we are finalizing this policy as proposed, except that we are amending the new language that we proposed at § 155.335(j)(1)(v) and (j)(2)(iv) to incorporate the phrase, "to the extent permitted by applicable State law." This change aligns these new policies with existing re-enrollment hierarchy rules, including § 155.335(j)(2) and (j)(3), which include this phrase to indicate that Exchanges must take into account applicable State law when implementing auto re-enrollment. As discussed in further detail below, this change is also in response to a public comment that said Connecticut State law does not permit auto re-enrolling catastrophic coverage enrollees losing eligibility for catastrophic coverage. We summarize and respond to public comments below.

Comment: Many commenters supported the proposed policy because they agreed that it would help promote continuous coverage for Exchange enrollees with catastrophic coverage who do not actively select a plan for the upcoming plan year, including enrollees who lose eligibility for catastrophic coverage. Several commenters cited State Exchanges, including Washington Healthplanfinder and MNsure, that already automatically re-enroll catastrophic coverage enrollees.

Response: We appreciate the information that some State Exchanges already auto re-enroll catastrophic coverage enrollees. We agree that the policy will help promote continuity of coverage, and as noted in the proposed rule, believe that it will also promote transparency and clarity for all Exchanges' interested parties.

Comment: One commenter stated that CMS should explain why current State Exchange practices are insufficient. Another commenter stated that the proposal did not appear to address an industry issue. Many commenters

recommended that CMS provide State Exchanges with flexibility in terms of whether or when to implement the policy, including a number of commenters who otherwise supported the goal of helping enrollees maintain continuous coverage. A few commenters that opposed the proposal cited their general opposition to limits on State flexibility.

One commenter stated that the Idaho State Exchange had already addressed the problems that the proposed rule intended to solve, including this proposal. A few commenters stated that the proposal would not be effective because several State Exchanges do not currently have the ability to auto re-enroll catastrophic coverage enrollees. Another commenter stated that Connecticut law prohibits auto re-enrolling enrollees losing eligibility for their catastrophic coverage, because a law specifies that only a licensed producer or agent may recommend a specific plan to a consumer.

Several commenters recommended that, rather than requiring State Exchanges to automatically re-enroll catastrophic coverage enrollees, CMS should allow Exchanges to encourage these consumers to actively select a new plan, especially in cases where an enrollee would lose eligibility for catastrophic coverage. One commenter stated that Connect for Health Colorado does not auto re-enroll enrollees losing eligibility for catastrophic coverage, and instead performs outreach encouraging them to choose a plan that works best for them.

Several commenters asked that, if the proposal is finalized, CMS continue allowing Exchanges to determine their own auto re-enrollment hierarchy.

Response: In response to the comment that Connecticut State law does not permit auto re-enrolling catastrophic coverage enrollees losing eligibility for catastrophic coverage, we are amending the proposed language at § 155.335(j)(1)(v) and (2)(iv) to incorporate the phrase, "to the extent permitted by applicable State law," to reflect that Exchanges must take into account applicable State law when implementing auto re-enrollment. This language aligns paragraph (j)(1)(v) with the rest of § 155.335(j); for example, the language at paragraphs (j)(2) and (3) specifies that those policies are subject to applicable State law. CMS' technical assistance materials also account for the fact that Exchange re-enrollment practices may vary based on applicable State law. For example, the Frequently Asked Questions for the 2023 Marketplace Open Enrollment Period Public Use Files explains that certain

plan crosswalk metrics are not reported for State Exchanges because since not all State Exchanges allow for consumers whose product is discontinued or whose issuer no longer offers any QHPs to be automatically re-enrolled in a new plan.²³²

We are otherwise finalizing the policy as proposed, because we believe that automatically re-enrolling all Exchange enrollees who do not actively select a plan or terminate their coverage is important to help ensure continuity of coverage. We intended this policy to protect against disruptions in care that could be avoided through implementation of a re-enrollment hierarchy for enrollees in catastrophic coverage. We explained in the proposed rule (88 FR 82579) that while Exchanges on the Federal platform generally already auto re-enroll these enrollees, the absence of a re-enrollment hierarchy in regulation for catastrophic coverage enrollees meant that we could not, as operator of Exchanges on the Federal platform, require issuers to provide plan crosswalk information for enrollees losing eligibility for catastrophic coverage. We are of the view that this consumer-protective policy is reasonable and appropriate regardless of whether it addresses an industry issue.

State Exchanges that cannot implement or choose not to implement the re-enrollment hierarchy as described in this rule may seek approval from the Secretary to conduct their own annual eligibility redetermination process, as described in § 155.335(a)(2)(iii). We already consider State Exchanges' requests for flexibility in this area on an annual basis, as part of their submission of their eligibility re-determination and re-enrollment plans, both in order to mitigate burden and to permit innovation that allows Exchanges to best serve their enrollees.

We also appreciate the additional detail from commenters on the extent to which State Exchanges do or do not incorporate enrollees in catastrophic coverage into their auto re-enrollment processes, including that some Exchanges do not currently auto re-enroll catastrophic coverage enrollees, or do not automatically re-enroll those who will lose eligibility for catastrophic coverage. We agree that an ideal enrollment experience is one in which an enrollee actively chooses a plan that best fits their needs for the coming year,

and we note that auto re-enrollment does not prevent Exchanges from also performing robust outreach and engagement encouraging all enrollees, including those with catastrophic coverage, to actively select a new plan for the coming year. This policy, like the rest of the auto re-enrollment hierarchy at § 155.335(j), is a safeguard to prevent enrollees from losing coverage if they do not actively select a plan or cancel their coverage by the end of the annual open enrollment period.

Comment: Two commenters said that this proposal would increase health insurance premiums due to increased burden on State Exchanges and QHP issuers.

Response: We disagree that this policy will increase health insurance premiums due to increased burden on QHP issuers or State Exchanges. As discussed in the proposed rule (88 FR 82580), as the operator of Exchanges on the Federal platform, we already include almost all catastrophic coverage enrollees in our annual auto re-enrollment process; therefore, this policy will not increase burden on us or on issuers that participate in Exchanges on the Federal platform. Furthermore, while two commenters raised general concerns associated with increased costs of health insurance, they did not specify how or why an Exchange or issuer would incur costs associated with incorporating catastrophic coverage enrollees into existing auto re-enrollment processes already required by § 155.335(j). Thus, we do not anticipate that finalization of this policy will result in sufficient Exchange or issuer burden to cause premium increases. Nevertheless, we note that in the unlikely event that compliance with this policy would be burdensome for an Exchange to the point that it would result in increased premiums, as discussed earlier, Exchanges may seek approval from the Secretary for flexibility as described in § 155.335(a)(2)(iii).

We also do not anticipate that implementation of this policy would increase QHP issuer burden that would lead to increases in premiums, because issuers participating in Exchanges on the Federal platform have not raised concerns about supporting auto re-enrollment for catastrophic coverage enrollees. As discussed in the proposed rule (88 FR 82580), only one QHP issuer participating in our auto re-enrollment process for Exchanges on the Federal platform did not submit a crosswalk option for enrollees losing catastrophic coverage eligibility, indicating that compliance with this policy would not increase issuers' costs beyond those

associated with the existing annual QHP Certification process.

Comment: A few commenters raised the concern that auto re-enrolling catastrophic coverage enrollees into a metal level plan could increase enrollees' monthly premium payments without their knowledge. One commenter added that catastrophic coverage enrollees who are re-enrolled into bronze coverage could experience further increases in premiums in the event the more generous subsidies provided for in the ARP and extended by the IRA expire.²³³

Response: Section 155.335(c)(3) mitigates the risk that enrollees could be enrolled in a metal level plan that increases their premiums without their knowledge by requiring all Exchanges to provide a qualified individual with an annual redetermination notice that includes projected eligibility for the following year, including, if applicable, the amount of any APTC and the level of any CSRs or eligibility for Medicaid, CHIP or BHP. We send enrollees covered through an Exchange on the Federal platform their first reminder to update their application and select coverage for the upcoming plan year by November 1, the start of Open Enrollment. Also, re-enrollment notices that we send to enrollees in all Exchanges on the Federal platform are already designed to advise enrollees of the possibility of increased cost when applicable, because monthly premiums regularly increase from year to year, even for the same plan.²³⁴

Finally, we acknowledge that catastrophic coverage enrollees who are re-enrolled into bronze coverage could experience increases in premiums, including in the event the more generous subsidies provided for in the ARP and the IRA expire, and that the expiration of the more generous subsidies may cause the amount of premium that must be paid directly by the catastrophic coverage enrollee to increase. This, however, would be true

²³³ Section 9661 of the ARP amended section 36B(b)(3)(A) of the Internal Revenue Code for tax years 2021 and 2022 to decrease the applicable percentages used to calculate the amount of household income a taxpayer is required to contribute to their second lowest cost silver plan, which generally result in increased PTC for PTC-eligible taxpayers. For those with household incomes no greater than 150 percent of the FPL, the new applicable percentage is zero, resulting in availability of one or more silver-level plans with a net premium of \$0, if the lowest or second-lowest cost silver plan covers only EHBs. The Inflation Reduction Act of 2022 extended these changes through tax year 2025.

²³⁴ For a more detailed discussion of CMS annual auto re-enrollment noticing practices see the HHS Notice of Benefit and Payment Parameters for 2024 Final Rule (88 FR 25824).

²³² See 2023 Public Use Files FAQs (PDF) (<https://www.cms.gov/files/document/2023-public-use-files-faqs.pdf>), and 2023 Marketplace Open Enrollment Period Public Use Files (<https://www.cms.gov/data-research/statistics-trends-and-reports/marketplace-products/2023-marketplace-open-enrollment-period-public-use-files>).

for enrollees at all metal levels, and the risk of increased out-of-pocket premium costs for enrollees does not outweigh the benefits of this policy, which is intended to ensure continuity of coverage for as many people as possible, including catastrophic coverage enrollees who do not return to the Exchange to actively re-enroll in coverage.

Comment: A few commenters supported the goal of maintaining continuous coverage but raised concerns that auto re-enrollment hierarchies may not take into account certain important factors. One commenter stated that the current auto re-enrollment hierarchy might not adequately account for children's unique health care needs because of its focus on providing continuity regarding cost-sharing requirements. This commenter recommended stronger universal standards for benefits and provider networks, and additional mechanisms to ensure alignment between enrollees' current and future plans. Another commenter stated that a metal level QHP might not be affordable for enrollees who previously had catastrophic coverage and suggested that CMS consider a limit on premium or out-of-pocket cost increases for automatic enrollment or require plans to provide appropriate notification before auto re-enrolling. One commenter asked CMS to consider the importance of non-EHB benefits in the auto re-enrollment hierarchy, such as dental, vision, or allergy testing benefits.

Response: We did not propose changes to the re-enrollment hierarchy other than incorporating catastrophic coverage into § 155.335(j); therefore, any comments on other elements of the re-enrollment hierarchy are outside the scope of this rulemaking. We also note that this policy does not impact potential issues of benefit or network continuity. We acknowledge comments on potential drawbacks to the current re-enrollment hierarchy and recommendations to improve continuity of coverage based on prioritization of factors that enrollees may value. In particular, we will consider potential future parameters based on total out-of-pocket cost, though we note that this consideration may in some cases conflict with prioritizing plan benefit, network type, or product continuity.

Comment: Several commenters stated that CMS should also allow Exchanges to automatically re-enroll enrollees losing catastrophic coverage eligibility into a higher metal level QHP when possible, without increasing the enrollee's monthly premiums or changing their provider network. Some

of these commenters added that this would be especially helpful for enrollees in catastrophic coverage who would qualify for CSRs if automatically re-enrolled in a silver plan. One commenter stated that Washington Healthplanfinder already implements this policy and has auto re-enrolled more than 50 people aging out of catastrophic coverage into a silver QHP with the same or lower premium and same carrier and network. The commenter noted that this was possible due to a State-based subsidy of up to \$250 per month for those with incomes under 250 percent FPL who enroll in a silver or gold level standard plan.

Response: We appreciate comments on potential benefits of amending the re-enrollment hierarchy to allow Exchanges to auto re-enroll catastrophic coverage enrollees into a silver level QHP based on financial assistance eligibility. We are not finalizing this policy as we need more time to explore the benefits and detriments of such a policy. We will consider these comments for future rulemaking. Additionally, as discussed earlier, an Exchange may request to apply a modified hierarchy to its auto re-enrollment process if approved by the Secretary pursuant to § 155.335(a)(2)(iii), including to auto re-enroll catastrophic enrollees into a higher metal level.

Comment: One commenter stated that an SEP for former catastrophic coverage enrollees who are auto re-enrolled to a bronze plan could help consumers avoid a tax liability if they are auto re-enrolled in a plan with a higher premium.

Response: We did not propose and will not finalize any changes to SEPs related to incorporating catastrophic coverage into the re-enrollment hierarchy at § 155.335(j). We appreciate and will take the comment under consideration.

Comment: A few commenters recommended that CMS delay the implementation deadline for the policy. One commenter stated that a delayed deadline would be helpful because of the 9–12-month lead time needed to implement most changes to State Exchanges' IT systems. A few commenters stated that flexibility would be helpful given that CMS was also proposing a number of other requirements with which Exchanges would be required to comply. Another commenter stated that Exchanges might need additional time to implement this and other proposed policies given increases in enrollment of new or returning consumers whose Medicaid coverage is ending due to the expiration

of the Medicaid continuous enrollment condition in section 6008(b)(3) of the Families First Coronavirus Response Act (Pub. L. 116–127).

Response: We are finalizing this policy with the implementation deadline proposed because we believe that automatically re-enrolling all Exchange enrollees who do not actively select a plan or terminate their coverage is important to help ensure continuity of coverage. As discussed previously, State Exchanges that cannot implement or choose not to implement the re-enrollment hierarchy as described in this rule make seek approval from the Secretary to conduct their own annual eligibility redetermination process, as described in § 155.335(a)(2)(iii), including to defer implementation of this policy to a plan year after 2025.

Comment: A few commenters supported prioritizing auto re-enrollment in catastrophic coverage the same way that the current hierarchy prioritizes auto re-enrollment in a silver plan—that is, if a silver level plan is no longer available in the same product, the Exchange must crosswalk to a silver plan in another product that is most similar.

Response: We appreciate these comments in response to our solicitation for comments. We did not propose and therefore are not incorporating this policy into the final rule but may consider proposing this policy in future rulemaking.

15. Premium Payment Deadline Extensions (§ 155.400(e)(2))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82581), we proposed to amend § 155.400(e)(2) to codify that the flexibility for issuers experiencing billing or enrollment problems due to high volume or technical errors, or issuers directed to do so by applicable State or Federal authorities, is not limited to extensions of the binder payment.

Section 155.400(e) specifies that Exchanges may require, and the FFEs and SBE-FPs will require, enrollees to make a binder payment to effectuate enrollment, and paragraph (e)(1) specifies the range of dates within which an issuer may establish a deadline to pay binder, depending on whether coverage is being effectuated under regular, prospective, or retroactive effective dates. In the 2018 Payment Notice (81 FR 94058), we added paragraph (e)(2) to address situations in which an issuer is unable to timely process binder payments submitted by enrollees, which may impact an enrollee's ability to effectuate

coverage. Specifically, we noted that based on our experience during several open enrollment periods, issuers occasionally experience technical errors, or a processing backlog caused by an unusually high volume of enrollments. As a result, enrollees may be temporarily unable to submit premium payments, or the issuer may be unable to process payments in a timely manner. We thus established an option for issuers to implement a reasonable extension of binder payment deadlines,²³⁵ which ensures that enrollees do not have coverage cancelled due to non-payment when the enrollee did not have adequate time to pay the binder payment.

Although we only addressed extensions to the binder payment deadlines in § 155.400(e)(1), we did not intend to exclude other premium payment scenarios in which Exchanges could, and the Exchanges on the Federal platform would, provide similar flexibility. In published guidance, such as the 2023 *Federally-facilitated Exchange (FFE) Enrollment Manual*,²³⁶ we stated that we will exercise enforcement discretion with regard to regulatory requirements, such as the binder payment and the deadline for payment of premiums under grace periods if an issuer is complying with a State regulatory authority's request to extend premium payment deadlines and delay termination of coverage due to a natural disaster or other emergency within the State.

For example, in connection with the COVID-19 Public Health Emergency declared by the Secretary, HHS exercised enforcement discretion²³⁷ regarding issuers extending premium payment deadlines and delaying cancellations or terminations of coverage with the permission of the applicable State regulatory authority. We proposed to codify that Exchanges may, and Exchanges on the Federal platform would, provide flexibility in such circumstances, including circumstances in which an issuer is directed to do so by applicable State or Federal authorities.

Because current paragraph (e)(2) may be read to limit the flexibility Exchanges could provide issuers regarding

payments other than the binder payment, we also proposed to add the phrase "and other premium payment deadlines." Doing so clarifies for interested parties, particularly issuers, that Exchanges may, and Exchanges on the Federal platform will, provide flexibility regarding premium payment requirements other than the binder payment, such as the requirement to trigger a grace period to enrollees receiving APTC under § 156.270(d) if enrollees fail to pay premiums timely.

We requested comments on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed to amend § 155.400(e)(2) to codify that the flexibility for issuers experiencing billing or enrollment problems due to high volume or technical errors is not limited to extensions of the binder payment. We summarize and respond to public comments received on the proposed policy below.

Comment: Most commenters who weighed in on the proposal supported it, and stated that it would benefit States, consumers, and issuers. One commenter stated that the proposal would make it easier for State Exchanges to explore options to improve the consumer experience. Another commenter stated that the proposal would allow consumers to maintain continuous coverage when technical issues arise that are beyond the consumer's control. Finally, another commenter stated that the proposal would help issuers experiencing billing or enrollment problems due to high volume or technical errors.

Response: We agree that codifying that the flexibility for issuers experiencing billing or enrollment problems due to high volume or technical errors is not limited to extensions of the binder payment will help support States, consumers, and issuers by allowing consumers to maintain continuous coverage when they are unable to satisfy premium payment deadlines for certain reasons outside of their control.

Comment: A few commenters supported the proposal but with limitations. One commenter supported the proposal but only in meaningfully extenuating circumstances. Another commenter stated that they support the proposal but are concerned about consumers falling too far behind in payments and requested that the length of the extension be kept to a minimum.

Response: We agree that it is important for this flexibility to be limited to specific circumstances where

an issuer requires a reasonable extension of a binder or premium payment deadline, such as a State declaration of natural disaster, and we note that such flexibility is always time limited in scope. We expect that payment extensions would extend until the high volume or technical errors have been corrected or until a reasonable period of time thereafter. We also generally do not anticipate extensions due to high volume or technical errors to be greater than 45 calendar days based on previous experience with binder payment extensions, though extensions related to a State declaration of a natural disaster or public health emergency may be longer.

Comment: One commenter supported the proposal but opposed implementing the policy in a manner that creates retroactive terminations or otherwise places consumers at risk for non-coverage and providers at risk for non-payment during any payment deadline extension. The commenter recommended that CMS clarify that any premium payment deadline extension must be exhausted before any 3-month grace period begins and cannot operate to extend the grace period. In other words, the commenter recommended that an APTC-eligible consumer has not "fail[ed] to timely pay premiums" under § 156.270(d) unless and until any premium payment deadline extension has been exhausted, meaning that coverage could be maintained during the extension period and the 3-month grace period (if applicable). One commenter supported the proposal but proposed additional flexibility for plans to hold payments for prescriptions in a pending status during any extension period.

Response: We clarify that this proposal would not allow retroactive termination beyond that already allowed under § 156.270(d). We also clarify that we would not consider the 3-month grace period to have begun until a consumer has failed to pay any required premium by the end of any premium payment deadline extension, consistent with this commenter's recommendation. Although we may allow an issuer, in connection with a billing or enrollment problem due to high volume or technical errors, or at the direction of State or Federal authorities (such as the declaration of natural disaster or other emergency), to delay placing an enrollee in delinquency, once the grace period has begun, issuers must allow enrollees no more than 3 months to pay outstanding premium. If the enrollee does not pay all past due premium by the end of the third month coverage, subject to any

²³⁵ We also stated that we do not anticipate extensions to be greater than 45 calendar days.

²³⁶ CMS. (2023, July 12). *2023 Federally-facilitated Exchange (FFE) Enrollment Manual*. CMS. Section 6.1.3, p. 89, and Section 6.10, p. 110. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

²³⁷ Pate, R. (2020, March 24). *Payment and Grace Period Flexibilities Associated with the COVID-19 National Emergency*. CMS. <https://www.cms.gov/files/document/faqs-payment-and-grace-period-covid-19.pdf>.

applicable threshold policy consistent with § 155.400(g), the issuer must terminate the enrollee's coverage retroactively to the end of the first month. We also require, in accordance with § 156.270(d)(1), that during the grace period, the QHP issuer must pay all appropriate claims for services rendered to the enrollee during the first month of the grace period, including for prescription drugs, and may pend claims for services rendered to the enrollee in the second and third months of the grace period, including prescription drugs. We do not see a reason to treat prescription drugs differently from other claims during the grace period. For example, in connection with the COVID-19 Public Health Emergency declared by the Secretary, issuers complying with a State's Department of Insurance order or recommendation to not terminate individual market health insurance coverage through a specified date were informed that once a grace period was triggered, the requirements applicable to the grace period would remain unchanged and would follow the rules outlined in § 156.270(d).

Comment: A few commenters stated that the proposal would be especially helpful to low-income enrollees who may be impacted by factors such as unstable housing or lack of reliable broadband access.

Response: While we agree that the flexibility codified by this proposal may aid consumers, many of whom may be low-income and impacted by factors such as housing or lack of reliable broadband access, these conditions would not trigger the flexibilities allowed by this policy. However, consumers who experience certain hardships may benefit from this policy when State or Federal authorities direct issuers to provide an extension on payments, such as due to a natural disaster or other emergencies in which extenuating circumstances would prevent an issuer from being able to receive payment.

16. Initial and Annual Open Enrollment Periods (§ 155.410)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82581), we proposed changes and updates to § 155.410. At § 155.410, we proposed to amend paragraph (e)(4)(ii) to revise parameters around the adoption of an alternative open enrollment period by a State Exchange. We proposed to require that for benefit years beginning on or after January 1, 2025, State Exchanges must adopt an open enrollment period that begins on November 1 of the calendar

year preceding the benefit year and ends no earlier than January 15 of the applicable benefit year, with the option to extend the open enrollment period beyond January 15 of the applicable benefit year.

In part 3 of the 2022 Payment Notice (86 FR 53429 through 53432), where we extended the open enrollment period for the Exchanges on the Federal platform to January 15, we noted several observations regarding a 6-week open enrollment period ending on December 15 including that certain consumers may be subjected to unexpected plan cost increases that they may not be notified about until January, after open enrollment concludes. We also observed that extending the open enrollment period for the Exchanges on the Federal platform to January 15 would ensure ample time for Navigators, assisters, certified application counselors, agents, and brokers to fully assist all interested consumers. We further noted that ending open enrollment on January 15 would give consumers additional time to react to updated plan cost information and more time to seek enrollment assistance, which could improve access to health care coverage, particularly for those in underserved communities who face additional barriers to accessing health care coverage.

In the proposed rule (88 FR 82851), we expressed that these observations hold true as to State Exchanges and warrant requiring that their open enrollment periods also end no earlier than January 15. Since we extended the open enrollment period for Exchanges on the Federal platform in part 3 of the 2022 Payment Notice final rule, four States have transitioned to the State Exchange model, and we anticipate that there will be additional State Exchanges in future benefit years, which increases the potential for differing open enrollment periods. While most of the State Exchanges already hold an open enrollment period that ends on or after January 15 of the benefit year, we expressed our belief that the risk of shorter open enrollment periods in the future requires ensuring a minimum open enrollment period across all Exchanges, including State Exchanges. We predicted that this policy would impose a minimal burden on most of the State Exchanges.

Additionally, we stated that ensuring State Exchanges' open enrollment periods begin on November 1 of the calendar year and continue through at least January 15 of the benefit year—thereby ensuring substantial overlap among all Exchange open enrollment periods—would reduce consumer

confusion in States with State Exchanges that currently hold open enrollment periods that are shorter than the open enrollment period for the Exchanges on the Federal platform, or that begin before November 1 and end earlier than January 15. Consumers in these States would have more time to enroll in coverage and would be less likely to miss opportunities to enroll due to confusion about the duration of the open enrollment period. The combined benefits of this policy in terms of reducing consumer confusion and building in additional time for consumers to enroll could further increase Exchange enrollment and potentially have downstream impacts like improving the uninsured rate in States.

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the provision that for benefit years beginning on or after January 1, 2025, State Exchanges must adopt an open enrollment period that begins on November 1 of the calendar year preceding the benefit year and ends January 15 of the applicable benefit year or later. However, we are finalizing the rule with an addition: we are adding paragraph (e)(4)(iii) to grandfather the open enrollment period of any State Exchange that held an open enrollment period that began before November 1, 2023, and ended before January 15, 2024, for the 2024 benefit year so that it can continue to begin open enrollment before November 1 in consecutive future benefit years, so long as that State Exchange's open enrollment period continues uninterrupted for at least 11 weeks. If the State Exchange changes the dates of its open enrollment period after the effective date of this rule, it must for that and subsequent benefit years hold an open enrollment period that is compliant with the requirements of (e)(4)(i) and (ii). We are also amending 155.410(e)(4)(i) to add a reference to new paragraph (e)(4)(iii).

We are providing this flexibility in recognition of several commenters who cited the operational success of certain State Exchanges that have recently held open enrollment periods earlier than November 1 and requested that we reconsider providing an additional measure of flexibility. We do not intend to discourage operational success or generate negative downstream impacts (for instance, decreased enrollment or revenue) for any State Exchanges that held an open enrollment period that began before November 1, 2023, and ended before January 15, 2024, for the

2024 benefit year. We also seek to minimize the potential for significant disruption to Exchange operations currently in place to the extent possible consistent with this policy, as well as to minimize potential burden to Exchanges, consumers, and other interested parties (for instance, navigators, assisters, and issuers) acting in reliance on existing Exchange operations. We believe this modification to allow State Exchanges to grandfather the dates of their open enrollment period as described above strikes an appropriate balance between standardizing a minimum open enrollment period across Exchanges while minimizing operational disruption. This flexibility does not extend to State Exchanges that began open enrollment before November 1, 2023, and ended before January 15, 2024, for any benefit year other than the 2024 benefit year.

We summarize and respond to public comments received on the proposed policy below.

Comment: Many commenters cited the potential benefits of this policy, echoing some rationales that CMS provided including: helping to maximize the time consumers need to navigate plans and get assistance from Navigators/assisters; creating a more consistent window of consumer outreach; providing more time for consumers to take into account potential plan cost increases in January before enrolling; reducing consumer confusion about open enrollment periods due to consistency across Exchanges, including after an Exchange transition, and more seamless nationwide messaging to consumers given this consistency; allowing consumers to shop for coverage after the holiday season during which they may be busy and/or more financially-burdened; reducing administrative burdens on plans, assisters, and regulators; allowing for easier plan switching for auto-re-enrolled consumers; helping to increase Exchange enrollment; and eliminating the probability of truncated open enrollment periods in future benefit years. Several commenters asserted that this proposal would help maximize enrollment through greater alignment with the open enrollment periods for Medicare and employer-sponsored coverage.

Response: We thank commenters for their support of this proposal. We considered many of these potential benefits and appreciate the insight on others.

Comment: Many commenters appreciated that this policy provides the flexibility to extend open enrollment

beyond January 15 of the benefit year. However, one commenter noted that allowing variation beyond January 15 of the benefit year undercuts the stated benefits of aligning open enrollment periods across Exchanges.

Response: While we acknowledge that there is, and may continue to be, variation in open enrollment end dates under this policy, we underscore that the policy still generally prescribes a consistent minimum time-period during which open enrollment will occur across Exchanges, which includes the 11 weeks between November 1 through January 15 for the vast majority of Exchanges, as required under (e)(4)(ii), and at least 11 weeks for any State Exchange that has grandfathered its open enrollment period. We think this minimum period provides ample opportunity for consumers to select a plan and will provide an appropriate measure of consistency. We believe this policy strikes the appropriate balance of standardization and flexibility for State Exchanges since it allows for flexible open enrollment period end dates and grandfathering of existing open enrollment periods, while generally codifying a national minimum open enrollment period. We appreciate commenters that supported this aspect of the policy.

Comment: Many commenters, including those both opposing and supporting the proposal, asserted that States should have the flexibility to set their own open enrollment periods, stating that States are best positioned to decide on an open enrollment period that suits the needs of local markets and consumers, and/or that the proposal unnecessarily curtails State flexibility to set an appropriate open enrollment period. Several commenters argued specifically that States should maintain the flexibility to begin their open enrollment periods earlier than November 1 of the benefit year.

Response: We reiterate that this rule properly balances flexibility with uniformity. Currently, all Exchanges except one, including 18 State Exchanges, begin their annual open enrollment periods on November 1 of the calendar year preceding the benefit year, and therefore we thought that a mandatory November 1 open enrollment start date would minimize disruption for Exchanges while promoting consistency. Additionally, for the reasons described above and in the proposed rule, we believed it was important to extend the open enrollment period to January 15 for all Exchanges, but we are allowing States to end their open enrollment period later, if desired. Finally, paragraph (e)(4)(iii)

provides flexibility by grandfathering the open enrollment periods for certain Exchanges, as described in more detail in this rule.

Comment: A few commenters expressed concern that the proposal provides too much flexibility to continue open enrollment indefinitely and should prescribe a deadline to prevent States from operationalizing a continuous open enrollment period throughout the year, which could impose financial burden and create adverse selection.

Response: We thank commenters for highlighting an important consideration. We believe States are best positioned to balance the benefits to their consumers of a longer open enrollment period with the market impacts of adverse selection when deciding when, on or after January 15, to end their open enrollment period.

Comment: One commenter recommended that Exchanges be prohibited from extending the annual open enrollment deadlines at the last minute, particularly toward the end of the open enrollment period, and that Exchanges should not deviate from their publicized open enrollment timeframes, to help prevent undue administrative burden and potential consumer confusion.

Response: We thank the commenter for highlighting an important operational consideration that Exchanges may wish to take into account in choosing when and how to end their open enrollment periods. We are not prohibiting State Exchanges from providing additional flexibility because unforeseen or exceptional circumstances (for instance, technical system issues that impact consumers' ability to enroll in coverage) may necessitate extending open enrollment to ensure consumers have the opportunity to enroll.

Comment: One commenter recommended that State Exchanges be provided the flexibility to set their own open enrollment periods after the first year of operating a State Exchange following a State Exchange transition.

Response: We are finalizing this policy to generally make consistent the open enrollment period across Exchanges, in part because it will reduce consumer confusion, especially after a State Exchange transition. While we have allowed some flexibility for Exchanges in the grandfathering provision of paragraph (e)(4)(iii), we have done so only to minimize disruption of existing open enrollment periods, and believe that moving towards more aligned open enrollment

periods going forward will benefit consumers and increase enrollment.

Comment: One commenter suggested that they would be amenable to a more flexible policy that simply prescribed a minimum number of open enrollment days or weeks. This commenter suggested that longer open hours or concentrated promotion during open enrollment may have a more significant impact than simply prescribing a specific time-period.

Response: We considered, but did not propose, this type of approach. We believe that the proposed policy better balances State flexibility with the benefits of consistency for consumers of generally requiring a national minimum open enrollment period upon which consumers can rely. We note one exception to this which will allow certain Exchanges to hold an 11 week open enrollment period consistent with the requirements of paragraph (e)(4)(iii).

Comment: One commenter suggested that current regulations already “partially achieve” the alignment of open enrollment periods across Exchanges and that this policy is, therefore, unnecessary.

Response: The goals of this policy are to largely align open enrollment periods across Exchanges and to capitalize on the benefits to consumers of a longer open enrollment period. Even if open enrollment periods are currently partially aligned, this rule will ensure that in the future, all Exchanges hold their open enrollment period between November 1 and January 15.²³⁸

Comment: Several commenters recommended that States be provided the flexibility to, or that CMS instead prescribe, an open enrollment period that ends no later than December 31 of the calendar year preceding the benefit year, to encourage consumers to enroll in a full 12 months of coverage.

Response: We reiterate the various benefits of requiring the open enrollment period to continue until at least January 15 of the benefit year. These include ensuring consumers are not subjected to plan cost increases that they may not be notified about until after open enrollment ends; giving Navigators, certified application counselors, and agents and brokers ample time to assist all interested applicants; providing consumers with additional time to enroll in coverage after the holiday season when they

otherwise might be unable to as a result of financial or other limitations; and improving access to health coverage. Consumers who would like to, and are able to, enroll before December 31 still have that option, and Exchanges and interested parties may encourage consumers, through marketing, outreach, or other means, to obtain coverage for 12 months by enrolling before January 1. Therefore, we believe that requiring the annual open enrollment period to continue until at least January 15 of the benefit year best accommodates different consumer’s needs.

Comment: A few commenters recommended that, in other rulemaking, CMS should consider requiring that short-term limited duration insurance coverage end by December 31 of a given plan year or that CMS should lengthen the period of short-term limited duration insurance beyond 3 months.

Response: We appreciate these comments on short-term limited duration insurance but note that term limits for such insurance is outside the scope of this rulemaking.

Comment: One commenter asserted that this proposal is unnecessary, as only the Idaho State Exchange held a shorter open enrollment period for the 2024 benefit year than what is required under this new policy, and that even Idaho’s open enrollment period was sufficient in length.

Response: We thank the commenter for highlighting that this policy primarily would impact the operations of one State Exchange among all Exchanges nationally. To minimize disruption, we have finalized this policy by providing the flexibility for any State Exchange that began open enrollment before November 1, 2023, and ended before January 15, 2024, for the 2024 benefit year to continue to begin open enrollment before November 1 and end before January 15 for consecutive future benefit years, so long as the open enrollment period continues uninterrupted for at least 11 weeks, and unless this State Exchange later changes their open enrollment dates. This is to ensure alignment with the minimum number of weeks prescribed at paragraphs (e)(4)(i) and (ii) for any State Exchange that grandfathers its open enrollment period while not requiring that such a State Exchange hold a longer open enrollment period than other Exchanges. Aside from this flexibility, requiring a national minimum open enrollment period across Exchanges for the 11 weeks between November 1 and January 15 strikes an appropriate balance between providing State flexibility and ensuring substantial

overlap of Exchange open enrollment periods nationwide. Finally, we underscore that this policy will generally codify this national minimum open enrollment standard moving forward.

17. Special Enrollment Periods

a. Effective Dates of Coverage (§ 155.420(b))

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82582), we proposed amending § 155.420(b)(1) and (b)(3)(i) to align the effective dates of coverage after selecting a plan during certain SEPs across all Exchanges, including State Exchanges, so that qualifying individuals or enrollees who select and enroll in a QHP during certain SEPs receive coverage beginning the first day of the month after the consumer selects a QHP. In order to consolidate and integrate the requirements in § 155.420(b)(3), without affecting any rights or obligations, we also proposed to include the requirements currently in paragraph (b)(3)(ii) into proposed paragraph (b)(3)(i) and to delete paragraph (b)(3)(ii).

In accordance with § 155.420(b)(3)(i), in the FFEs, SBE-FPs, as well as several State Exchanges, during a SEP, consumers who select a QHP through the Exchange to which regular effective dates specified in § 155.420(b) apply have the plan’s coverage begin on the first day of the month after the consumer’s selection. For example, if a consumer selects a QHP on March 31, their QHP coverage would start April 1.

However, in some State Exchanges, a consumer’s coverage is only made effective on the first day of the month after the consumer has selected a plan during a SEP to which regular effective dates specified in § 155.420(b) apply if the consumer selects their plan between the 1st day and the 15th day of the previous month, per § 155.420(b)(1). In these State Exchanges, if a consumer selects a plan between the 16th day and the last day of the month, coverage will not become effective until the first day of the second month after plan selection. For example, for these State Exchanges, if a consumer selects a plan on March 1, Exchange QHP coverage would start April 1, but if that consumer selected a plan on March 16, their Exchange QHP coverage would start on May 1. This may result in a coverage gap of more than a month for these consumers.

As consumers typically qualify for SEPs due to a life event that may disrupt their previous coverage (such as a move to a new State, or a change in household

²³⁸ Any Exchange availing itself of the grandfathering provision described in § 155.410(e)(4)(iii) will be required to hold an open enrollment period at least between November 1 and January 15 if their open enrollment period deviates from that set beginning after the effective date of this rule.

size due to birth or divorce, or a loss of other health insurance, such as a loss of Medicaid), these consumers are less likely to have health insurance coverage while they wait for their selected QHP coverage to begin.

In addition, when transitioning between Exchanges, such as from an Exchange in a State that operates on the Federal platform to a State Exchange that does not offer first-of-the-following-month coverage, consumers may expect that their coverage becomes effective on the first day of the month after selecting a QHP. These consumers might not be aware that the effective dates of coverage may differ between Exchanges, and they might not take appropriate steps to maintain or access alternate coverage while waiting for their QHP to become effective. As a result, these consumers may be at risk of coverage gaps due to the existing policies governing effective dates of coverage.

To address this, we proposed amending § 155.420(b)(1) and (b)(3)(i) to align effective dates of coverage across all Exchanges under these SEPs. We noted that the proposal would require all State Exchanges, beginning on January 1, 2025, or an earlier date at the option of the Exchange to provide coverage that is effective on the first day of the month following plan selection, if a consumer enrolls in a QHP during a SEP to which regular effective dates specified in § 155.420(b) apply.

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed to amend § 155.420(b)(1) and (b)(3)(i) to align the effective dates of coverage after selecting a plan during certain SEPs across all Exchanges, including State Exchanges, and to require qualifying individuals or enrollees who select and enroll in a QHP during certain SEPs to receive coverage beginning the first day of the month after the consumer selects a QHP. We are also finalizing the proposed modifications to incorporate section § 155.420(b)(3)(ii) into the proposed paragraph (b)(3)(i) and deleting paragraph (b)(3)(ii) for purposes of simplifying and streamlining this section. We summarize and respond to public comments received on the proposed policy below.

Comment: There was broad support for this proposal from many commenters, including health care providers, issuers, disease and general advocacy groups, and State Exchanges. Many of these commenters agreed with our assertion that requiring a regular effective date of coverage for SEPs that is no later than the first day of the

month after plan selection would reduce the number of consumers who experience gaps in coverage. Several commenters also agreed that this proposal would ease the experience and reduce potential confusion for consumers who transition between Exchanges in different States, due to the standardization across States of when QHPs become effective under a SEP subject to regular coverage effective date rules. Some current State Exchanges noted that they observed that consumers in their States experienced fewer gaps in coverage after they adopted the effective dates of coverage that we propose here to require in all Exchanges.

Response: We appreciate, and agree with, the comments and additional information provided on how adoption of this proposal may benefit consumers.

Comment: One commenter opposed this proposal, stating that State Exchanges are best able to determine the appropriate coverage effective dates, and that State Exchanges should retain the flexibility to adopt earlier effective dates as they see appropriate. Another commenter supported the proposal but encouraged CMS to consider allowing States to have more flexibility in determining their own effective dates.

Response: This proposal does not change the existing ability for State Exchanges to elect an earlier coverage effective date under § 155.420(b)(3)(i) (as currently exists and as proposed). Due to the potential for consumers to face gaps in coverage under the existing policies governing regular SEP coverage effective dates in certain State Exchanges, we believe a regular SEP coverage effective date of no later than the first day of the month after plan selection is in the best interest of consumers.

Comment: One commenter stated that this policy would increase costs for State Exchanges. One commenter opposed this proposal, stating that we had not provided evidence as to why this rule change was needed. Another commenter opposed this proposal because it would expand the availability of SEPs, stating generally that SEPs encourage adverse selection, which may increase costs for health insurance issuers.

Response: As we note in the proposed rule, we expect that any costs to Exchanges and issuers would be minimal. We provided a cost estimate in section IV.C of the proposed rule that showed that issuers would not incur substantial new costs. The commenter did not provide evidence or examples of why a first of the month coverage effective date would cause adverse selection, nor have we received

information from issuers that operate in State Exchanges that such coverage effective dates cause adverse selection. In addition, we believe the benefit of reducing coverage gaps among consumers outweighs any speculative harm.

Comment: One commenter stated that health insurance issuers may have operational concerns regarding State Exchanges that collect premium payments from enrollees on behalf of QHP issuers. The commenter stated that in these States, issuers sometimes face difficulty with data-sharing and determining if a consumer has made a binder payment for their coverage to become effective. As such, they are concerned that the shorter time until the effective date will not provide enough time to ensure a binder payment is paid prior to effectuating coverage.

Response: Although we did not hear from any current State Exchanges that they would have difficulty in implementing this proposal, we will provide any State Exchange with the appropriate technical assistance to ensure that they are able to implement this proposal while also promptly providing issuers with updates to Exchange enrollment or enrollee data so as not to adversely affect effectuation of coverage. If issuers receive binder payment confirmations after the effective date required by this new provision, they would be permitted to effectuate enrollment after the effective date, with coverage beginning retroactively to the required effective date. This is consistent with the premium payment policy for Exchanges on the Federal platform at § 155.400(e), which permits issuers to set binder payment deadlines after the coverage effective date.

Comment: One commenter suggested that HHS require that this policy begin in the 2024 plan year, rather than the 2025 plan year, stating that consumers now would benefit from an earlier implementation date. Another commenter requested that HHS delay the required implementation of this policy until January 1, 2026, so that State Exchanges would have more time to implement any needed technical changes in their enrollment systems. Finally, a commenter urged HHS to assist QHPs in addressing any operational challenges that come with the alignment of effective coverage dates.

Response: Because it will take time for the State Exchanges to update their enrollment systems to comply with this change, we do not believe it is appropriate to require State Exchanges to implement this policy before January

1, 2025, which is the date that many other provisions of this rule will go into effect. We believe that a January 1, 2025, effective date will give State Exchanges adequate time to make any system changes necessary to implement this rule. Additionally, we note that State Exchanges maintain the ability to offer an earlier coverage effective date under § 155.420(b)(3)(i) (as currently exists and as proposed) if desired. We will continue to provide technical assistance to State Exchanges to ensure that they are able to effectively implement this policy in coordination with their issuers.

Comment: One commenter suggested that we also permit Exchanges to provide an SEP when Medicaid ends before the end of the month and when a health provider leaves the QHP network mid-plan-year.

Response: In the Notice of Benefit and Payment Parameters for 2024, we finalized a modification to 45 CFR 155.420(b)(2)(iv) to allow Exchanges to offer earlier coverage effective dates for consumers attesting to a future loss of Minimum Essential Coverage (MEC) under § 155.420(d)(1). Specifically, we added language stating that if a consumer loses Medicaid or CHIP that is MEC, and a plan selection is made on or before the last day of the month preceding the loss of MEC, the Exchange must ensure that coverage is effective on the first day of the month in which the loss of MEC occurs.²³⁹ This policy change was intended to mitigate coverage gaps and allow for a more seamless transition between coverage when consumers lose MEC mid-month. With regard to the second comment, we appreciate the suggestion to permit Exchanges to provide an SEP when a health provider leaves the QHP network mid-plan-year but note that it is not within the scope of this rulemaking.

b. Monthly Special Enrollment Period for APTC-Eligible Qualified Individuals With a Projected Annual Household Income At or Below 150 Percent of the Federal Poverty Level

At § 155.420, we proposed to amend paragraph (d)(16) to revise the parameters around the availability of a SEP for APTC-eligible qualified individuals with a projected annual household income at or below 150 percent of the Federal Poverty Level (FPL), hereinafter referred to as the “150 percent FPL SEP.” We proposed an amendment to the current text from “no

greater than” to “at or below” for improved readability and understanding. Specifically, we proposed the removal of the limitation that this SEP is only available to a consumer whose applicable percentage, which is used to determine the amount of the consumer’s premium not covered by APTC, is zero.

As background, in part 3 of the 2022 Notice of Benefit and Payment Parameters (86 FR 53429 through 53432), we finalized, at the option of an Exchange, a monthly SEP for APTC-eligible qualified individuals with a projected annual household income at or below 150 percent of the FPL. We also finalized a provision stating that this SEP is available only during periods of time during which APTC is available such that the applicable taxpayers’ applicable percentage is set at zero, such as during tax years 2021 through 2025, as provided by section 9661 of the ARP and extended by the IRA.²⁴⁰ We also amended § 147.104(b)(2)(i) to specify that issuers are not required to provide the SEP in the individual market with respect to coverage offered outside of an Exchange.

As a result of the enhanced financial assistance established by the ARP and extended by the IRA until December 31, 2025, many consumers with a projected annual household income at or below 150 percent of the FPL, have the opportunity to enroll in a much wider range of affordable coverage. Specifically, as a result of the legislative changes passed by Congress in the ARP and IRA, more consumers have access to Exchange and QHP coverage with zero-dollar premiums after financial subsidies, including more opportunities to enroll in zero-dollar silver-level plans with significant levels of CSRs. To provide these consumers—many of whom might have had difficulty enrolling during standard SEP timelines due to lack of awareness or other logistical difficulties—with the chance to access this generous Exchange coverage, we finalized the 150 percent FPL SEP.

We remain committed to ensuring that affordable Exchange coverage is available for individuals with lower household incomes and who are uninsured, and we believe that the availability of the 150 percent FPL SEP has made significant strides in ensuring that this population has real opportunities to enroll in free or extremely low-cost Exchange coverage.

Executive Order (E.O.) 14070, signed on April 5, 2022 (which expanded upon E.O. 15009 signed on January 28, 2021),

directs Federal agencies to identify ways to continue to expand the availability of affordable health care coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health care coverage. To that end, this proposed change may further ensure continued improved access to affordable coverage for this population.

Continuing to make this SEP available also may continue to help consumers who lose other MEC coverage, especially those disenrolling from Medicaid or CHIP coverage to regain health care coverage. We are aware of the challenges many consumers disenrolling from Medicaid or CHIP coverage have faced due to the end of the Medicaid continuous enrollment condition as of March 31, 2023. During this time period, we have observed, and expect to continue to observe, a higher than usual volume of individuals with lower household incomes transitioning from Medicaid or CHIP coverage to coverage through Exchanges due to the end of the Medicaid continuous enrollment condition. As discussed in our guidance released on January 27, 2023, consumers disenrolling from Medicaid or CHIP because of the Medicaid continuous enrollment condition are especially vulnerable and may face challenges with transitioning from Medicaid or CHIP into other forms of coverage, such as Exchange coverage.²⁴¹ These challenges may include consumers’ confusion as to why their Medicaid coverage is ending due to irregular or untimely communications from State Medicaid agencies about the termination of coverage or coverage options for individuals with lower household incomes. Due to these factors, consumers may be unable to make an informed decision about their coverage options within the 60-day window provided by the SEPs at § 155.420(c)(1) and (d)(1) or within the 90-day window provided at the option of the Exchange at § 155.420(c)(6) beginning on January 1, 2024. Given our observations of these challenges, we believe that the existence of the 150 percent FPL SEP provides an additional safety-net, particularly for consumers impacted by the Medicaid continuous enrollment condition, but also generally for those who have historically faced challenges

²³⁹ We note that this modification is not limited to situations where a consumer loses Medicaid or CHIP. For more information, see 88 FR. 25740, 25827.

²⁴⁰ Public Law 117–169.

²⁴¹ CMS. (2023, Jan. 27). *Temporary Special Enrollment Period (SEP) for Consumers Losing Medicaid or the Children’s Health Insurance Program (CHIP) Coverage Due to Unwinding of the Medicaid Continuous Enrollment Condition—Frequently Asked Questions (FAQ)*. CMS. <https://www.cms.gov/technical-assistance-resources/temp-sep-unwinding-faq.pdf>.

transitioning from Medicaid or CHIP into other coverage, like Exchange coverage.

Finally, our experience with the 150 percent FPL SEP suggests that the policy has been successful. Based on our analysis, between October 2022 and August 2023, about 1.3 million consumers who reside in States with Exchanges on the Federal platform were APTC-eligible, had projected annual household incomes at or below 150 percent of the FPL, and enrolled in Exchange coverage under the 150 percent FPL SEP. In 2022, 41.8 percent of enrollees on Exchanges on the Federal platform had a projected annual household income of less than 150 percent of the FPL, compared to 46.9 percent of Exchange enrollees in 2023, after the implementation of the 150 percent FPL SEP. We believe the current 150 percent FPL SEP is one factor that significantly contributed to the increase in the enrollees on the Federal platform with a projected annual household income at or below 150 percent of the FPL.

In previous rulemaking, we expressed concern about offering the 150 percent FPL SEP when APTC does not always reduce the applicable percentage of a taxpayer with projected annual household income at or below 150 percent FPL to zero. We were also receptive to concerns raised by issuers that this SEP would impact the Exchange risk pool, lead to higher premiums, and impact the population with household incomes above 400 percent FPL with higher premium contributions as the APTC phases out. The possible increasing premiums also present a risk of financial hardship for consumers who purchase insurance off Exchange including those who are not eligible for APTC due to immigration status, or any other consumers who would purchase unsubsidized plans, or only receive small subsidies. At the time, we believed that the risk for adverse selection was mitigated because consumers would not have an incentive to drop their Exchange plans when healthy and resume coverage when sick using the 150 percent FPL SEP since they would be enrolled in zero-dollar premium plans due to the enhanced financial subsidies provided by the ARP and IRA. Previously, we estimated that the adverse selection risk may result in issuers increasing premiums by approximately 0.5 to 2 percent, and a corresponding increase in APTC outlays and decrease in income tax revenues of approximately \$250 million to \$1 billion annually, when the enhanced APTC provisions of the ARP (and later extended by the IRA) are in effect.

While it is challenging to predict the future nature of the Exchanges in 2026, we estimate that some adverse selection, though unknowable at this time, may occur once enhanced subsidies sunset on December 31, 2025, and may result in issuers increasing premiums. We acknowledge that there is a wide range of predictions for an increase to premiums due to the adverse selection risk associated with this proposed change and discuss this further in the regulatory impact analysis section of this rule.

However, an analysis of the plans available to consumers in 2020, just before implementation of the enhanced subsidies, suggests that the risk of adverse selection we acknowledged may be lower than expected, and therefore, downstream impacts of that risk may be mitigated. When consumers with household incomes at or below 150 percent of the FPL are no longer eligible for enhanced subsidies, these consumers may still be eligible for low-cost silver or bronze plans with zero-dollar premiums after regular subsidies. In 2020, before the ARP provided enhanced financial assistance in the form of enhanced subsidies, about 900,000 consumers were enrolled in bronze plans, which were fully subsidized by APTC and where the consumer portion of premium was zero dollars. Additionally, in 2020, 77 percent of the consumer population at or below 150 percent FPL had access to a zero-dollar bronze plan with 16 percent of the same population having access to a zero-dollar silver plan in addition to the zero-dollar bronze plan. We believe that if the majority of consumers with income at or below 150 percent FPL would be eligible for a zero-dollar premium plan absent the enhanced subsidies provided under the ARP and IRA, then such consumers would be unlikely to use the proposed 150 percent FPL SEP in a way that caused adverse selection. In other words, we believe that the availability of these zero-dollar bronze plans for consumers at or below 150 percent FPL mitigates the risk pool impact this proposed change might cause in addition to mitigating downstream hardships for consumers who purchase insurance without subsidies or with only small subsidies.

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed to remove the requirement that the SEP only be available during periods of time when the applicable taxpayer's applicable percentage for purposes of

calculating the premium assistance amount, as defined in section 36B(b)(3)(A) of the Code, is set at zero. We summarize and respond to public comments received on the proposal below.

Comment: Many commenters agreed with the proposed removal of the limitation that this SEP is only available to a consumer whose applicable percentage, which is used to determine the amount of the consumer's premium not covered by APTC, is zero.

Commenters agreed that this proposal reduces coverage gaps and promotes expanded access to affordable coverage, providing a needed benefit to those with the highest need for coverage. A few commenters stated that consistency of care is linked to improved health outcomes, particularly for cancer patients and survivors with limited incomes. One commenter specifically pointed out that the proposal helps promote equitable coverage.

Additionally, several commenters believed that the availability of the 150 percent FPL SEP would help consumers facing a loss of Medicaid or CHIP coverage transition into Exchange coverage. Finally, a commenter also stated that the proposal would protect consumers from future changes to tax credit policy.

Response: We agree with commenters that the policy will benefit consumers by improving continuity of affordable coverage, which is vital for consumers with chronic health conditions, such as cancer, and especially benefits lower-income consumers. We also agree that the policy will help improve the transition from Medicaid and CHIP coverage to Exchange coverage for consumers facing a loss of Medicaid and CHIP coverage.

Comment: One commenter supported the proposed policy, but expressed concern that administrative hurdles, such as confusing qualification criteria, enrollment deadlines, and a lack of available information, prevent consumers from utilizing the 150 percent FPL SEP.

Response: We agree that the process for enrolling in coverage can be daunting, especially for lower-income consumers who may not be familiar with all of their options nor have the tools available to learn about them. We will continue to work with assisters, agents, brokers, and Navigators to educate consumers about this SEP and how to access it when applying for Exchange coverage.

Comment: Several commenters supported the proposed policy but asked HHS to consider increasing the income limit to benefit a greater number

of consumers and to better align with Medicaid and CHIP income limits, citing a lack of plan options with affordable premiums for consumers with projected annual household incomes between 150 to 250 percent of FPL. A commenter also urged HHS to consider expanding the SEP to consumers with projected annual household incomes up to 250 percent FPL so that more consumers could benefit from it.

Response: We acknowledge commenters' suggestion to make the 150 percent FPL SEP available to consumers with projected annual household incomes up to 250 percent of the FPL and appreciate the goal of broadening the pool of consumers who can access Exchange coverage. However, broadening the annual household income limit of the 150 percent FPL SEP may lead to adverse selection and cause unintended consequences, such as premium increases, for all Exchange enrollees with a projected annual household income above the SEP eligibility limit, particularly for those with a projected annual household income above the APTC eligibility limit (as any premium increases would not be offset by APTC). Thus, we believe that designing the SEP to target consumers with the lowest income—those with a projected annual household income at or below 150 percent FPL—allows for the greatest impact on the portion of the population that is generally vulnerable, as they are most likely to churn between Medicaid, CHIP and Exchange coverage, or experience gaps in coverage due to seasonal or temporary unemployment, if they have access to other coverage at all. Those who do not have access to other coverage may not seek out Exchange coverage for fear of the inability to pay, especially because their income tends to fluctuate. While consumers losing Medicaid, CHIP, or employer-sponsored coverage are eligible for an SEP under § 155.420(d)(1), consumers might be unaware that a loss of Medicaid or CHIP coverage is a qualifying life event and they may not report that loss of coverage to an Exchange and remain uninsured for potentially long periods of time until the next annual Open Enrollment period. The 150 percent FPL SEP provides an additional safety net for these vulnerable populations who often have lower health literacy and more frequent life stressors than other populations that would prevent them from enrolling in coverage when otherwise eligible. In addition, consumers with the lowest incomes are most likely to be eligible for zero-dollar plan options through the Exchange (if

they are not eligible for Medicaid or CHIP), which may reduce the risk for adverse selection. Because the majority of otherwise eligible consumers with household incomes at or below 150 percent FPL would be eligible for a zero-dollar premium plan absent the enhanced subsidies provided under the ARP and IRA, then such consumers would be unlikely to use the proposed 150 percent FPL SEP in a way that causes adverse selection. In other words, the availability of zero-dollar bronze plans for consumers with household incomes at or below 150 percent FPL mitigates the risk pool impact of this policy in addition to mitigating downstream hardships for consumers who purchase insurance without subsidies or with only small subsidies.

Comment: A few commenters supported the proposed policy but asked HHS to consider requiring State Exchanges to adopt the SEP instead of allowing it to be elective, citing benefits such as a reduced number of uninsured consumers and decreased racial disparities in coverage.

Response: We believe in promoting health equity and reducing disparities when possible and appreciate commenters' suggestions that State Exchanges be required to adopt the 150 percent FPL SEP. However, we believe continuing to allow the adoption of the 150 percent FPL SEP to be elective for State Exchanges is the correct approach at this time because many States with State Exchanges have expanded Medicaid to cover individuals with current monthly household income up to 138 percent FPL, allowing a greater number of consumers to enroll in Medicaid, and thus have access to affordable coverage. Because of this, many States with State Exchanges have had less of a need to provide an Exchange enrollment pathway for consumers with projected annual household income below 150 percent FPL. We will continue to evaluate this policy and whether it would be beneficial to require State Exchanges to adopt the 150 percent FPL SEP in the future.

Comment: One neutral commenter acknowledged the improved readability of the proposed policy's change from "no greater than" to "at or below" 150 percent FPL.

Response: We thank the commenter for their response and agree the change in wording improves readability and understanding of which consumers are affected by the proposed policy change.

Comment: A commenter who neither supported nor opposed the proposed policy requested that HHS take

additional time to evaluate the impact on premiums before finalizing the proposed policy change. The commenter cited concerns about adverse plan selection and impacts on the risk pool following the implementation of the proposal and recommended that HHS delay the proposal to gather additional data. Additionally, several commenters who were opposed to the proposed policy cited related concerns about the possible risk of "anti-selection" (a term we understand to refer to adverse selection) resulting in premium increases for consumers. A few commenters pointed out that implementing the policy change would encourage consumers to enroll in coverage only once they become sick or are in need of health care. Commenters pointed out that the resulting churn in and out of plans would ultimately harm the consumer, as it disrupts continuity of coverage. Commenters also expressed concerns that the policy as proposed would negatively impact the risk pool, disincentivize issuers from offering robust plan options given the challenges of managing the stability of the risk pool, and ultimately lead to narrower networks and limited consumer choice.

Response: As discussed in the proposed rule, our analysis of the plans available to consumers in 2020, just before implementation of the enhanced subsidies, suggested the risk of adverse selection may be lower than expected. This analysis, conducted in 2020 before the ARP provided enhanced financial assistance in the form of enhanced subsidies, found that about 900,000 consumers were enrolled in bronze plans, which were fully subsidized by APTC and where the consumer portion of the premium was zero dollars (referred to as zero-dollar bronze plans). Additionally, in 2020, 77 percent of Exchange consumers with projected annual household incomes at or below 150 percent FPL had access to a zero-dollar bronze plan with 16 percent of the same population having access to a zero-dollar silver plan in addition to the zero-dollar bronze plan. We believe that if the majority of consumers with projected annual household income at or below 150 percent FPL would be eligible for a zero-dollar plan absent the enhanced subsidies provided under the ARP and IRA, then such consumers would be unlikely to use the proposed 150 percent FPL SEP in a way that caused adverse selection because they would have no incentive to disenroll from a zero-dollar plan when healthy. In other words, we believe that the availability of these zero-dollar bronze

plans for consumers with projected annual household incomes at or below 150 percent FPL mitigates the risk pool impact of this change and the downstream hardships for consumers who purchase insurance without, or with limited, subsidies who would bear the cost of rising premiums. While there is a risk of adverse selection by the minority of consumers with projected annual household income at or below 150 percent FPL who would not be eligible for a zero-dollar plan, such adverse selection is projected to increase premiums by only 3 to 4 percent absent IRA subsidies, and therefore the benefits of this policy in increased access to coverage for low-income consumers outweighs the risk of premium increases for higher income consumers.

Given that the risks of premium increases and adverse selection are challenging to predict, we will work to ensure that any effects of these risks are minimal by continuing to promote strong enrollment on the Exchanges through outreach and advertising efforts.

Comment: A few commenters cautioned against the increased frequency and availability of SEPs, and overall eligibility enforcement, stating that the 150 percent FPL SEP currently exists alongside too many other similar SEPs, such as the Medicaid Unwinding SEP and the Loss of MEC SEP.

Response: We acknowledge and understand commenters' concerns that increasing the availability and frequency of SEPs makes it harder for Exchanges to enforce eligibility, and that too many similar SEPs exist concurrently. The policy goal of the 150 percent FPL SEP is to ensure that lower-income consumers are able to enroll in affordable Exchange coverage without remaining uninsured for potentially long periods of time by having to wait to enroll in coverage during the annual Open Enrollment period. As stated above, consumers with annual household income at or below 150 percent FPL are likely to not have access to other coverage, such as employer-sponsored coverage. Such consumers would generally not be eligible for other SEPs, such as the Newly Eligible for APTC or CSRs SEP (§ 155.420(d)(6)(i–ii)), which applies only to those currently enrolled in coverage, or the loss of minimum essential coverage SEP (§ 155.420(d)(1)), which would require them to have already been enrolled in minimum essential coverage such as Medicaid or CHIP (but not short-term limited duration plans). Additionally, consumers with annual household income at or below 150 percent FPL

may be unlikely to seek out Exchange coverage during the annual open enrollment period due to low health literacy or a fear of the inability to pay, especially because their incomes tend to fluctuate. Therefore, for this population, the existence of the 150 percent FPL SEP provides an additional pathway into Exchange coverage that otherwise would be unavailable.

Comment: One commenter urged HHS not to finalize the proposed policy, stating it is unlawful. The commenter urged HHS instead to repeal the 150 percent FPL SEP policy.

Response: We do not agree with commenters that the 150 percent FPL SEP is unlawful. As discussed in prior rulemaking, section 1311(c) of the ACA requires the Secretary to establish the minimum uniform enrollment periods across all Exchanges; and section 1321(a) of the ACA provides broad authority for the Secretary to issue regulations setting standards to implement the statutory requirements related to Exchanges, QHPs, and other standards under title I of the ACA.²⁴²

18. Termination of Exchange Enrollment or Coverage (§ 155.430)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82584), we proposed to add § 155.430(b)(1)(iv)(D) to permit enrollees on Exchanges using the Federal platform to retroactively terminate their enrollment in a QHP through the Exchange²⁴³ when the enrollee enrolls in Medicare Parts A or B (including enrollment in Parts A or B through a Medicare Advantage plan)²⁴⁴ retroactively effective to the day before the date Medicare coverage begins. We also proposed making implementation of this proposal optional for State Exchanges. We are finalizing this proposal with three modifications: (1) we are limiting retroactive termination of QHP coverage to no earlier than the later of (a) the day before the first day of coverage under Medicare Parts A or B, and (b) the day that is 6 months before retroactive termination of QHP coverage is requested; (2) we are not permitting retroactive termination under § 155.430(b)(i)(iv)(D) of stand-alone dental plans (SADPs); and (3) we are allowing HHS to elect whether to

implement this provision for Exchanges using the Federal platform. We are also finalizing the proposal to be optional for State Exchanges.

Currently, we do not permit enrollees in Exchanges on the Federal platform to retroactively terminate QHP coverage due to retroactive enrollment in other coverage, including Medicare. When coverage is retroactively terminated, claims submitted during the period of terminated coverage will be reversed by the QHP issuer and become the responsibility of the enrollee, who must ensure claims are submitted by the health provider to the new insurance provider, if coverage is effective retroactively.²⁴⁵ State law would generally require that QHP issuers refund the enrollee any premiums paid during the months in which coverage is retroactively terminated.

Generally, consumers who become eligible for Medicare once they turn 65 can enroll prospectively, and those who are enrolled in Exchange coverage can normally terminate coverage prospectively so that there is no overlap between the two. In accordance with § 155.430(d)(2)(iii), Exchange enrollees may request same-day or prospective termination of coverage,²⁴⁶ and Exchange communications instruct enrollees to terminate coverage once they learn they will be enrolled in other coverage to avoid an overlap. Exchange enrollees approaching their 65th birthday also receive communications from the Exchange advising them that they will be ineligible for APTC if they enroll in Medicare and instructing them to terminate Exchange coverage if they do not wish to have an overlap between the two. However, there are scenarios in which a consumer may retroactively enroll in Medicare Parts A or B coverage. For example, consumers can become eligible for retroactive Medicare Parts A and B due to retroactive eligibility for SSDI benefits, in which

²⁴⁵ Providers are generally required to submit claims to Medicare no later than 12 months after the date of service. However, in situations where Medicare Part A or B entitlement did not exist at the time service was furnished, or the beneficiary receives notice of Medicare Part A or B entitlement after the date of service, the 12-month limit may be extended for 6 months following the month in which the beneficiary receives notice of Medicare Part A or Part B entitlement. CMS. (rev. 2023, Jan. 19). *Medicare Claims Processing Manual*, 100–04, Chapter 1, Section 70.7.2 “Retroactive Medicare Entitlement.” <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c01.pdf>.

²⁴⁶ Although this regulation permits QHP enrollees to request prospective terminations, limitations in operations in the Exchanges on the Federal platform limit the ability of one enrollee in an enrollment group to end their coverage prospectively when the other enrollees in the group intend to remain enrolled.

²⁴² 86 FR 53438

²⁴³ When an enrollee retroactively terminates QHP coverage, State law generally requires that the premiums paid in the months for which coverage is retroactively terminated be refunded by the QHP issuer.

²⁴⁴ References throughout this provision to Medicare Parts A and B include Part C Medicare Advantage plans, which provide Parts A and B benefits.

case the consumer may enroll in Medicare Parts A and B beginning with the 25th month of SSDI entitlement (that is, receipt of the SSDI benefit). If the SSA determines the consumer to be eligible more than 25 months back, the consumer will receive Medicare Part A automatically beginning with the 25th month of SSDI entitlement and will have the option of enrolling in Part B Medicare retroactive to the 25th month of SSDI entitlement (though they also have the choice to enroll in Part B prospectively). In addition, when a consumer has not been automatically enrolled in Medicare Part A and applies for Medicare Part A after their 65th birthday, their entitlement to Part A begins (that is, when coverage starts) up to 6 months prior to the date of the application but no sooner than the consumer's 65th birthday.

Because consumers who retroactively enroll in Medicare Parts A or B may not be able to avoid an overlap in coverage by prospectively terminating their Exchange coverage, we believe it is appropriate to allow them to retroactively terminate Exchange coverage. Allowing consumers to request retroactive terminations in this scenario ensures they can minimize an overlap between Exchange and Medicare coverage and avoid paying premium unnecessarily (if the consumer owes premium after the application of APTC). However, we note that consumers would not be required to request a retroactive termination and could maintain both Exchange and Medicare coverage if they wish. Consumers who enroll in Medicare retroactively are not categorically excluded from PTC eligibility for the period of retroactive coverage, and thus may not be required to repay APTC for the months of overlap when they file their taxes, in accordance with 26 CFR 1.36B-2(c)(2)(iv); however, a QHP enrollee receiving APTC who is voluntarily requesting and is granted a retroactive QHP termination relieves the government of subsidizing two forms of coverage, as the APTC is recouped for the terminated QHP coverage months.

Although it is also possible for consumers to become retroactively eligible for Medicaid, and have an unavoidable overlap with Exchange coverage, we continue to believe it is appropriate to limit the applicability of this provision in the Exchanges on the Federal platform to Medicare. We previously allowed retroactive terminations of Exchange coverage due to enrollment in Medicaid, CHIP, and the BHP, but removed this option for the FFEs in the 2019 Payment Notice (83 FR 16930). This option was retained for

State Exchanges and SBE-FPs, which as previously mentioned are more closely integrated into their State-administered Medicaid programs. In response to commenters who opposed this change, we noted that although consumers in these cases may wish to recoup premiums paid during the period of overlapping coverage, there is significant risk that providers who participate in the consumer's Exchange coverage do not participate in Medicaid, CHIP, or BHP, which would leave the consumer with unexpected out-of-pocket costs. However, because Medicare is accepted by many, if not most, providers, it is less likely that a retroactive QHP disenrollment would leave consumers responsible for claims incurred during the period of retroactive Medicare enrollment.

We note that in the FFEs and SBE-FPs, caseworkers have system-based evidence of both QHP and Medicare eligibility dates and would be able to verify that an enrollee requesting retroactive termination is enrolled in Medicare and approve retroactive requests. This would ensure that enrollees cannot retroactively terminate their QHP coverage for other, unauthorized reasons such as low utilization of coverage, which could create an adverse selection risk. We also note that, similar to retroactive Medicaid enrollment, a consumer's retroactive enrollment in Medicare will not cause the consumer, when filing taxes for the year of coverage, to have to repay APTC for the months in which the consumer, due to the retroactive Medicare enrollment, is enrolled in both a QHP with APTC and Medicare. See 26 CFR 1.36B-2(c)(2)(iv).

Because Medicare generally does not provide coverage for dental services, there is no overlap in services with an SADP when an enrollee retroactively enrolls in Medicare, as there is with a QHP, and we therefore clarify that requests for retroactive coverage under this provision are limited to QHPs. Allowing retroactive termination of SADPs would create a much greater risk of uncovered claims, since dental claims that were reversed by an issuer would likely not be covered under Medicare Parts A or B. However, we clarify that, due to the requirement that consumers must enroll in a QHP in order to enroll in an SADP, requests for retroactive termination of QHP coverage, which also involve prospective termination of the QHP, will result in prospective termination of SADP coverage.

Finally, in recognition of the challenges associated with retroactively adjusting coverage for preceding years, we proposed to require that enrollees

must request retroactive termination of coverage within 60 days of the date they retroactively enroll in Medicare (that is, the date the enrollment occurs, not the Medicare coverage effective date).

We requested comments on this proposal. Specifically, we requested comment on whether the public benefits of this proposal to honor an enrollee's choice, recoup APTC for duplicative coverage, and protect the individual market risk pool outweighs the risk that an enrollee would be left with uncovered claims for the overlapping period. We also requested comment on the best way to ensure that enrollees have the necessary information to make an informed decision about whether to retroactively terminate coverage. In the proposed rule we noted that if this proposal is finalized, we intended to monitor the impact to minimize harm to consumers. We also sought comment on whether this provision should be mandatory for State Exchanges, rather than optional, and if so, how State Exchanges would verify retroactive Medicare enrollment dates.

After consideration of comments and for the reasons outlined in the proposed rule and in our responses to comments, we are finalizing the proposal to permit enrollees on Exchanges using the Federal platform and in State Exchanges to retroactively terminate their enrollment in a QHP through the Exchange when the enrollee enrolls in Medicare Parts A or B retroactively with the following modifications: (1) we are making explicit that our reference to enrollment in Medicare Parts A or B includes enrollment through a Medicare Advantage plan; (2) retroactive termination of QHP coverage under this provision is limited to earlier than the later of (a) the day before the first day of coverage under Medicare Part A or B or a Medicare Advantage plan, and (b) the day that is 6 months before retroactive termination of QHP coverage is requested; (3) we are not permitting retroactive terminations for SADPs; and (4) we are allowing HHS to elect whether to implement this provision for Exchanges using the Federal platform.

As noted in the proposed rule (88 FR 82585), Exchanges on the Federal platform have system-based evidence of both QHP and Medicare eligibility dates and can verify Medicare enrollment. In addition, as noted in our response to commenters, we intend to explore ways to ensure that consumers are aware of the consequences of choosing to retroactively terminate coverage and are able to make an informed decision. Finalizing that this policy is at the option of the Exchanges on the Federal platform provides time to ensure these

processes are in place prior to effectuation of this provision. We also are finalizing the proposal to make implementation of this proposal optional for State Exchanges. Prior to implementation, we intend to provide advance notice to issuers and other interested parties through interested party webinars and published guidance such as the Federally-facilitated Exchange Enrollment Manual. We summarize and respond to public comments received on the proposal below.

Comment: Several commenters expressed support for the proposal, stating that it would be beneficial for consumers by allowing them to recoup premiums and avoid coordination of benefits issues, and would also decrease administrative burden on Exchanges and save the Federal Government money in recouped APTC. A few commenters indicated that this flexibility is especially important for certain groups of enrollees, such as those with disabilities and consumers who must pay premiums for Medicare Part A, for whom the ability to recoup QHP premiums is especially beneficial. Two State Exchange commenters stated that they had implemented this policy and had improved the consumer experience. An additional State Exchange and State Department of Insurance argued that this policy would give State Exchanges the flexibility to improve the consumer experience. One commenter stated that this proposal was important because consumers on the FFEs often have difficulty getting the correct termination date when transitioning to off-Exchange coverage such as Medicare.

Response: We agree that these changes will benefit consumers by allowing them to recoup premiums for Exchange coverage that overlaps with retroactive enrollment in Medicare and will benefit the Exchanges by allowing the government to recoup APTC for the period of retroactive termination. We also agree that these changes may be especially beneficial to certain groups of enrollees, such as those with disabilities, for whom recouping premium and avoiding coordination-of-benefit issues is particularly important. As noted by some commenters, it will also give State Exchanges the ability to improve the consumer experience by allowing retroactive terminations when desired by the enrollee. Lastly, although this proposal will enhance the consumer experience by enabling consumers to request retroactive termination of coverage when they retroactively enroll in Medicare, this proposal would not apply to consumers

who become eligible for Medicare prospectively, and thus, is unlikely to impact the experience of most enrollees transitioning from Exchange to Medicare coverage.²⁴⁷ We will continue to explore ways to improve the consumer experience for enrollees transitioning from Exchange to other coverage, including Medicare.

Comment: A few commenters opposed the proposal, stating that it would lead to confusion among enrollees because claims for services provided during the retroactive termination period would not be covered, and could lead to providers going unpaid if the service is not covered by Medicare or is furnished by a provider who does not participate in Medicare or Medicare Advantage. Several other commenters, while not opposing the proposal, expressed concerns that enrollees would not fully understand the implications of retroactively terminating coverage, including the reversal of claims by the QHP issuer and the impact on APTC. A few additional commenters stated that if payment rates for services were lower under Medicare than the QHP issuer, providers may attempt to bill enrollees for the difference. A few other commenters stated that this proposal could create problems regarding out-of-network claims implicated under the No Surprises Act, which would be subject to independent dispute resolution. One commenter requested that if the proposal is finalized, HHS create guidance materials for consumers to ensure they understand the potential benefits and drawbacks of retroactively terminating coverage in this scenario, including potential responsibility for claims reversed by the QHP issuer, and the fact that this scenario does not implicate APTC reconciliation.

Response: We believe it is important to minimize confusion among consumers who retroactively enroll in Medicare about the consequences of a decision to retroactively terminate Exchange coverage, and we intend to explore ways to ensure that enrollees have the necessary information to make an informed decision. In addition, we intend to closely monitor the impact of this provision after implementation and may make changes in the future if necessary to minimize harm to consumers, such as providing additional information on the factors consumers should consider before making the decision to retroactively terminate QHP

coverage. As noted elsewhere, because Medicare is accepted by many, if not most, providers, we expect that claims made during the period of retroactive enrollment will be covered by the Medicare Fee-For-Service (FFS) program if the individual enrolls in the FFS program. However, there may be cases in which claims are not covered by Medicare or a Medicare Advantage plan and become the responsibility of the consumer. We intend to explore ways to ensure consumers are aware of this potential outcome so they can make informed decisions. We emphasize that retroactively terminating Exchange coverage is at the option of the consumer, and consumers who retroactively enroll in Medicare could choose to maintain QHP coverage.

Regarding the potential for Medicare beneficiaries²⁴⁸ to be billed directly by providers and suppliers²⁴⁹ when Medicare's payment rates are lower than those of the QHP issuer, we note there are several Medicare regulations that prohibit providers and suppliers from directly billing beneficiaries for amounts other than the applicable Medicare deductible and coinsurance.²⁵⁰ In addition, in cases where a provider is not contracted with a Medicare Advantage plan, the provider would still be required to accept the amount they would have received under traditional Medicare as payment in full, and would be prohibited from billing the enrollee for the difference between the QHP and Medicare Advantage plan rates. Where providers are contracted with a Medicare Advantage plan, the provider is typically prohibited by the terms of their contract from balance billing the enrollee. Thus, in general, we anticipate that enrollees will not be balance billed, even when there is a difference between the payment rates of the old and new plans. As noted above, we will explore ways to ensure consumers are able to make an informed decision. In addition, as noted in the preamble to this provision, Medicare permits providers to submit claims more than 12 months after the date of service when an enrollee retroactively enrolls in Medicare, which minimizes the risk that providers will not be paid for claims for services provided during the retroactive period. Finally, regarding the No Surprises Act, we note that in the event

²⁴⁸ The term "beneficiaries" is used here to align with Medicare regulations, which generally use this term rather than the term "enrollee."

²⁴⁹ 42 CFR 400.202 defines the terms "provider" and "supplier," the latter of which includes physicians.

²⁵⁰ See 42 CFR 424.55, 414.48, and 489.21, and part 489, subpart C.

²⁴⁷ Enrollees who attempt to end Exchange coverage prospectively but receive an incorrect termination due to a technical error may already be allowed to retroactively terminate coverage under § 155.430(b)(1)(iv)(A).

QHP coverage is retroactively terminated pursuant to § 155.430(b)(1)(iv)(D), any claims for items or services furnished during the retroactive period would be ineligible for the independent dispute resolution under the No Surprises Act because the item or service would no longer be furnished with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.²⁵¹

Comment: A few commenters opposed the proposal, stating that it could increase the administrative burden on issuers, who would be required to recoup claim payments and reconcile enrollment information with the FFEs, and impact issuers' risk adjustment and payment integrity operations. One of these commenters also suggested that the proposed policy would ultimately lead to allowing retroactive terminations of QHP coverage for retroactive Medicaid enrollment. A few commenters also expressed concern that the proposal did not limit the number of months for which an enrollee can request retroactive terminations. Some of these commenters requested that retroactive terminations be limited to 6 months, even in cases where the consumer's Medicare coverage began more than 6 months retroactively, to limit the administrative burden on issuers to recoup claims and refund premiums. One of these commenters also stated that a 6-month limit would align with the 6-month extension to the 12-month limit to submitting claims to Medicare after the date of service.

Response: Although we recognize that QHP issuers may, in some cases, have difficulty recovering claims payments once coverage is retroactively terminated, they are generally entitled to do so. However, we agree that, because recovery of claims may be especially difficult for longer periods of retroactive termination, it is appropriate to place a limit on retroactive QHP terminations and are finalizing in this policy that requests for retroactive termination of QHP coverage are limited to no earlier than the later of (a) the day before the first day of coverage under Medicare Part A or B, and (b) the day that is 6 months before retroactive termination of QHP coverage is requested. One common retroactive enrollment scenario occurs when consumers first enroll in Medicare Part A or B after their 65th birthday, and whose entitlement to Part A starts up to 6 months prior to the date of enrollment (but no sooner than the consumer's 65th

birthday). In this case a 6-month limit on requests for retroactive coverage would still allow these consumers to retroactively terminate QHP coverage back to the date of Medicare entitlement if the retroactive termination was requested on the same day as the Medicare enrollment. Although other consumers, such as those who enroll in Medicare retroactively due to SSDI entitlement, may not be able to retroactively terminate QHP coverage back to the date of Medicare entitlement if it occurs more than 6 months before the request for QHP retroactive termination, these consumers will still be able to receive up to 6 months of relief from paying double premiums. We believe this limit appropriately balances granting enrollees retroactive termination of coverage when desired, while not excessively burdening issuers, who must attempt to recoup claims payments whenever coverage is retroactively terminated.

Although providers must generally submit claims to Medicare no later than 12 months after the date of service, in certain situations where Medicare Part A or B entitlement did not exist at the time service was furnished and the beneficiary receives notice of retroactive Medicare Part A or B entitlement after the date of service, the 12-month limit may be extended through the last day of the 6th calendar month following the month in which the beneficiary receives notice of Medicare Part A or Part B entitlement.²⁵² Thus, this 6-month limit on retroactive QHP terminations is not necessary to ensure that providers are able to resubmit claims to Medicare and receive payment, and the risk that providers will not be paid for claims for services provided during the retroactive period is minimized.

For the comment raising potential concerns about impacts to risk adjustment from retroactive termination of coverage, we note that the EDGE server data collection requirements have always mandated that issuers of risk adjustment covered plans provide the most recent enrollment data for the applicable benefit year.²⁵³ This most recent enrollment data would include any retroactive changes in enrollment, and will have the same impact on an issuer's risk adjustment data submission whether the retroactive enrollment changes are initiated by the issuer, Exchange, or enrollee.

²⁵² See 42 CFR 424.44

²⁵³ 45 CFR 153.710. See the EDGE Server Business Rules (ESBR) Version 24.0 (December 2023). https://regtap.cms.gov/reg_library.php?i=3765.

Comment: A few commenters argued that allowing retroactive terminations in this scenario could increase the risk of adverse selection and lead to higher premiums for enrollees.

Response: We do not believe that implementation of this provision is likely to increase the risk of adverse selection or lead to higher premiums for enrollees. As we discussed in the preamble to this provision, we have the ability to verify Medicare enrollment and ensure that retroactive termination of coverage is limited to those who are enrolled in Medicare, and not consumers seeking retroactive termination due to low utilization of coverage, which could create an adverse selection risk. Although consumers with greater numbers of claims may be less likely to retroactively terminate QHP coverage, we note that in general the population of consumers who are eligible for Medicare already tend to have a high number of medical expenses and claims, and we do not expect that this policy will increase the risk of adverse selection or increase premiums. Lastly, we expect the population of enrollees who request retroactive termination of QHP coverage under this provision to be a small percentage of the overall enrolled population, and thus we do not expect it to have a noticeable impact on the overall Exchange, including the risk pool.

Comment: Several commenters, while not expressing support for or opposition to the proposal, expressed concern that it would be difficult for QHP issuers to recoup payments for services provided during the retroactive termination period, especially pharmaceutical, emergency room, and out-of-country claims, which may not be possible to recoup. Another commenter requested that, if the proposal is finalized, HHS consider reimbursing health plans at the commercial rate for any pharmaceutical expenses incurred during the retroactive termination period. Lastly, one commenter questioned how pharmaceutical claims would be handled for the retroactive termination period if the consumer did not enroll in Medicare Part D.

Response: Although we recognize that QHP issuers may, in some cases, have difficulty recovering claims payments once coverage is retroactively terminated, they are generally entitled to do so. As noted in a previous response, to limit the burden on issuers to recoup claims payments, we are also finalizing this proposal to limit retroactive termination of QHP coverage to no more than 6 months from the date that retroactive termination is requested.

²⁵¹ See section 2799A-1(c)(1)(A) of the PHS Act.

Furthermore, we also note that issuers must, in certain circumstances, recoup payment for medical or pharmaceutical claims, under the retroactive terminations allowed by current regulation. Because the number of consumers who retroactively enroll in Medicare and elect to retroactively terminate QHP coverage is limited, we do not expect this provision to significantly increase the number of claims for which issuers must recoup payment. Although it may be difficult for issuers to recoup payment for certain types of claims, such as pharmaceutical claims, we do not believe it is appropriate to reimburse issuers for these unrecoverable claims, nor is there authorization for us to do so. We note that issuers are, generally, still entitled to seek reimbursement from providers for claims that are reversed. In addition, we expect that consumers who retroactively enroll in traditional Medicare Parts A or B, but not a stand-alone Part D plan, will evaluate whether retroactively terminating QHP coverage is appropriate, given the likelihood that the costs for any pharmaceutical claims will become the consumer's responsibility. We also note that some Medicare Advantage plans include Part D prescription drug benefits, and enrollees in these Medicare Advantage plans may be able to have these claims resubmitted by the provider to the new plan. As noted elsewhere, we intend to explore ways to convey this information to consumers.

Comment: A few commenters recommended requiring State Exchanges to adopt this proposal, one of whom stated that all Medicare enrollees, regardless of their State of residence, should have this option available to them. Several commenters recommended making this proposal optional for State Exchanges, a few of whom argued that States were best positioned to evaluate their insurance markets and determine whether, and how, to implement this proposal. One State Exchange commenter indicated that it allows consumers who enroll in Medicare Parts A or B up to 6 months to request retroactive termination of QHP coverage and requested that HHS allow States to exceed the 60-day requirement proposed in the rule. Another State Exchange commenter noted that implementation of this proposal would require updates to enrollment and eligibility systems and manual verification of Medicare eligibility, and therefore may impose financial or operational burdens on issuers, who would be required to reverse claims and refund premiums.

This commenter also requested that, if State Exchanges are required to implement the proposal, that the effective date be delayed so State Exchanges have additional time to implement this policy.

Response: Based on the comments we received from State Exchanges, which indicate that States have adopted different policies with regard to allowing consumers who retroactively enroll in Medicare to retroactively terminate QHP coverage, we believe it is appropriate to make adoption of this provision optional for State Exchanges. We agree with commenters who argued that States are best positioned to determine how to implement this proposal, given the difficulties of explaining to consumers how to decide whether to retroactively terminate QHP coverage, and the need to update enrollment and eligibility systems. In addition, State Exchanges may not have access to the same systems-based evidence of Medicare enrollment as the Exchanges on the Federal platform, which may make verification of retroactive Medicare enrollment more difficult. Because we are finalizing this rule to make implementation optional for State Exchanges and for HHS with respect to Exchanges that use the Federal platform, we do not believe it is necessary to delay the effective date of this provision.

Comment: A few commenters expressed support for the proposal and requested that it also be applied to enrollees who retroactively enroll in Medicaid or CHIP. Some of these commenters indicated that this was especially important given the ongoing process of Medicaid unwinding and the number of consumers being inappropriately disenrolled, in addition to the need to reinstate consumers who successfully challenge a denial of Medicaid eligibility and where there are delays in processing Medicaid applications. One of these commenters also requested that CMS publish data on the number of children enrolled in QHPs who are retroactively enrolled in Medicaid and CHIP, and that CMS issue guidance to States on how consumers who were inappropriately disenrolled from Medicaid or CHIP can be reimbursed for expenses.

Response: We recognize that consumers who are retroactively enrolled in other government programs such as Medicaid, CHIP, or the BHP, may also wish to retroactively terminate QHP coverage to eliminate an overlap in coverage and recoup QHP premiums. However, as we stated in the proposed rule and above, we do not believe it is appropriate to extend this provision to

these enrollees because providers who participate in the consumer's Exchange coverage may not participate in Medicaid, CHIP, or BHP, increasing the risk that the consumer would be left with unexpected out-of-pocket costs. Because Medicare is accepted by many, if not most, providers, enrollees who retroactively enroll in Medicare and terminate Exchange coverage are less likely to become solely responsible for reversed claims. The comments regarding publication of Medicaid and CHIP enrollment data and reimbursement for consumers who are inappropriately disenrolled are outside the scope of this proposal, and we have not included substantive responses in this final rule.

Comment: One commenter expressed support for the proposal and requested that CMS allow all QHP enrollees who retroactively enroll in Medicare to retroactively terminate coverage, regardless of whether the Medicare enrollment was prospective or retroactive, or at least allow States to implement this. This commenter stated that it is especially important given the difficulty many FFE consumers have with the process of transitioning to off-Exchange coverage, where it is necessary to call the Call Center on the day the new coverage begins to end FFE coverage. Another commenter, who opposed the proposal, recommended that HHS allow "pre-terminations" for enrollees who become eligible for Medicare, so that they do not have to call the Marketplace Call Center to terminate QHP coverage on the day Medicare coverage begins.

Response: We recognize that consumers who are transitioning to off-Exchange coverage such as Medicare may, at times, have difficulty ending QHP coverage on the appropriate date. We are working to improve this process in the Exchanges on the Federal platform so that all enrollees have the option to terminate coverage prospectively when transitioning to off-Exchange coverage such as Medicare. However, we do not believe it is appropriate to extend this provision to all QHP enrollees who transition to Medicare. As we note in the preamble to this provision, consumers generally have the opportunity to enroll in Medicare prospectively, and Exchange enrollees approaching their 65th birthday receive communications from the Exchange advising them that they will be ineligible for APTC if they enroll in Medicare and instructing them to terminate Exchange coverage if they do not wish to have an overlap between the two. Furthermore, we note that many enrollees in Exchanges on the Federal

platform already have the ability to prospectively terminate coverage either online through their *HealthCare.gov* account or by calling the Marketplace Call Center.²⁵⁴ Lastly, we note that consumers who attempt to end Exchange coverage and are given an incorrect coverage termination date due to a technical error may already receive retroactive terminations to correct the error, per § 155.430(b)(1)(iv)(A). We will continue to explore ways in which we can improve the consumer experience for those who are transitioning from Exchange to Medicare coverage.

Comment: Several commenters requested that HHS clarify or provide guidance on certain aspects of this proposal. A few commenters requested that HHS clarify whether issuers would have to refund APTC and premium payments for the months of retroactive coverage that are terminated. One of these commenters also asked HHS to provide guidance to issuers on how to handle changes in cost-sharing for consumers for the period of retroactive coverage termination. A third commenter requested guidance on how the proposal would impact the Medicare requirement to timely file claims within 12 months of the date of service. Several commenters asked that HHS provide operational guidance to issuers on how retroactive terminations under this provision should be handled and recommended that HHS promote alignment between the Exchanges and Medicare to ensure seamless transitions for consumers. Lastly, one commenter requested guidance on whether issuers would be liable for claims made during the 60-day window available to consumers to decide whether to retroactively terminate coverage.

Response: As with other retroactive terminations, issuers would be required to refund APTC to the government when an enrollee requests retroactive termination of coverage due to retroactive Medicare enrollment, and State law generally requires that issuers refund premiums as well. Once coverage is retroactively terminated, enrollees are responsible for contacting providers to ensure that any claims made during the retroactive period are resubmitted to Medicare, and differences in cost-sharing become the responsibility of enrollees, providers, and Medicare, as applicable. Although providers must generally submit claims to Medicare no later than 12 months after the date of service, in certain

situations where Medicare Part A or B entitlement did not exist at the time service was furnished and the beneficiary receives notice of retroactive Medicare Part A or B entitlement after the date of service, the 12-month limit may be extended through the last day of the 6th calendar month following the month in which the beneficiary receives notice of Medicare Part A or Part B entitlement.²⁵⁵ We also intend to provide guidance to issuers on how to process these retroactive terminations of coverage. As noted elsewhere in our response to comments, we intend to continue to work to improve the consumer experience for enrollees transitioning from Exchanges on the Federal platform to Medicare coverage. Lastly, with regard to the 60-day window, we note that this window is merely the amount of time consumers have to request a retroactive termination of coverage once they retroactively enroll in Medicare (the 60 days is from the date the consumer enrolls, not the effective date of coverage). Issuers are only responsible for claims to the extent that the enrollee remains in coverage, and if coverage is retroactively terminated, the issuer is generally entitled to recover payment for claims made during the period of retroactivity.

Comment: One commenter requested that HHS clarify that the proposal would not apply to SADPs, since Medicare Parts A and B generally do not provide dental benefits. This would ensure that SADP issuers are not required to recoup claims payments or refund premiums, and that enrollees must still terminate their SADP prospectively.

Response: As noted in the preamble to this provision, because Medicare generally does not provide coverage for dental services (although Medicare Advantage plans may include dental benefits as supplemental benefits), there is generally no overlap in coverage with an SADP when an enrollee retroactively enrolls in Medicare, as there is with a QHP. Therefore, we agree that it is appropriate to limit application of this provision to retroactive termination of QHP coverage. We clarify in this final rule that requests for retroactive coverage under this provision are limited to QHPs, and we have finalized this proposal to prevent retroactive termination of SADP coverage when a consumer retroactively enrolls in Medicare. Allowing retroactive termination of SADPs would create a greater risk of uncovered claims, since dental claims that were reversed by an issuer would likely not be covered

under Medicare Parts A or B (although they may be covered as a supplemental benefit under a Medicare Advantage plan). However, we clarify that, on Exchanges on the Federal platform, due to the operational requirement that consumers must enroll in a QHP in order to enroll in an SADP, requests for retroactive termination of QHP coverage will result in prospective termination of SADP coverage.

19. Establishment of Exchange Network Adequacy Standards (§ 155.1050)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82585), we proposed to require that State Exchanges and SBE-FPs establish and impose quantitative time and distance QHP network adequacy standards that are at least as stringent as the FFEs' time and distance standards established for QHPs under § 156.230. We also proposed that State Exchanges and SBE-FPs be required to conduct quantitative network adequacy reviews prior to certifying any plan as a QHP, consistent with the reviews conducted by the FFEs under § 156.230. We further proposed to require State Exchanges and SBE-FPs permit issuers that are unable to meet the specified time and distance network adequacy standards to participate in a justification process after submitting their initial network adequacy data to account for variances and potentially earn QHP certification. In addition, we proposed a framework for granting State Exchanges and SBE-FPs an exception to the proposed quantitative network adequacy standards and review requirements if we determine that the Exchange applies and enforces quantitative network adequacy standards that are different from the FFEs' but ensure a level of access to providers that is as great as that ensured by the FFEs' network adequacy standards established for QHPs under § 156.230. Finally, we proposed to mandate that State Exchanges and SBE-FPs require all issuers seeking QHP certification to submit information to the State Exchange or SBE-FP about whether network providers offer telehealth services.

Understanding that some State Exchanges or SBE-FPs may need to promulgate regulations to comply with the proposed provisions requiring State Exchanges and SBE-FPs to impose quantitative network adequacy standards and conduct quantitative network adequacy reviews, as well as the requirement related to QHP issuer submission of telehealth information, we proposed that these provisions would be effective for plan years

²⁵⁴ As noted by commenters, limitations in operations in the Exchanges on the Federal platform prevent one enrollee in an enrollment group from ending coverage prospectively when the other enrollees in the group intend to remain enrolled.

²⁵⁵ See 42 CFR 424.44.

beginning on or after January 1, 2025, to accommodate the time it may take for a State Exchange or SBE-FP to come into compliance. We stated in the proposed rule that we are of the view that strong network adequacy time and distance standards across all Exchanges would enhance consumer access to quality, affordable care through the Exchanges. We refer readers to the proposed rule (88 FR 82586 through 82587) for a detailed background discussion of HHS' network adequacy policy and the network adequacy proposals.

a. Network Adequacy Standards and Reviews Across Exchanges

In the proposed rule (88 FR 82587), we stated that network adequacy is a key factor affecting consumers' access to care. We explained that while the FFEs impose uniform network adequacy standards across the States they serve that require QHP issuers to meet quantitative metrics, a similarly uniform network adequacy standard does not exist for States served by State Exchanges and SBE-FPs. Indeed, we further explained that these circumstances prompted the National Association of Insurance Commissioners to develop the NAIC Health Benefit Plan Network Access and Adequacy Model Act (Model Act).²⁵⁶ The Model Act includes recommendations for qualitative network adequacy standards to which States could hold their issuers accountable and that require submission of access plans. We noted, however, that the Model Act does not specify what constitutes network adequacy, and, currently, only a few State Exchanges and SBE-FPs have adopted the full Model Act, resulting in the lack of a strong floor for network adequacy standards among State Exchanges and SBE-FPs.

We noted in the proposed rule (88 FR 82587) that State Exchanges and SBE-FPs currently have a mix of network adequacy policies in place, and approximately 25 percent of those fail to impose any quantitative standard. Quantitative network adequacy standards can be monitored relatively easily and applied objectively and may include standards that measure provider-to-enrollee ratios, time and distance, or appointment wait times.²⁵⁷ On the other hand, a qualitative

approach to network adequacy typically articulates a broad, general standard of adequacy and typically grants regulators or insurers discretion to determine how to measure compliance.²⁵⁸ State regulators using this approach may require issuers to simply articulate how they determine and measure adequacy in their networks.²⁵⁹ Once regulators approve an issuer's network adequacy plan using this approach, they then typically let issuers self-monitor their own compliance.²⁶⁰ As opposed to conducting routine audits or requiring periodic reports of compliance, State regulators usually rely on consumer complaints to highlight situations that might require investigation.²⁶¹

We stated in the proposed rule that, based on our experience conducting network adequacy reviews and regulating QHPs, as well as feedback from interested parties, including the many commenters who requested in the 2023 Payment Notice (87 FR 27334) that HHS extend Federal network adequacy standards to State Exchanges in future rulemaking, we are now of the view that no matter the State in which a QHP is offered, some quantitative analysis is necessary for an Exchange to objectively monitor network adequacy and determine whether a QHP provides enrollees in that State with access to an adequate network of providers.

Moreover, we stated that the proliferation in recent years of QHP issuers with narrower provider networks raises several consumer protection concerns. QHPs with narrower networks may lack access to specific provider specialties in-network, resulting in significant out-of-pocket expenses for consumers who must seek care out-of-network or resulting in consumers forgoing care to avoid these expenses. We noted that we have also been made aware, through communications with interested parties, of issues faced by consumers where in-network emergency physicians and mental health providers are in limited supply or, in the case of in-network emergency physicians, not available at in-network hospitals. Additionally, we stated that the proliferation of narrower networks risks consumers being enrolled in plans whose networks do not have sufficient capacity to serve them or whose providers are too geographically dispersed to be reasonably accessible.

Therefore, we proposed (88 FR 82587) to establish a national floor of

quantitative network adequacy standards and network adequacy reviews. We stated in the proposed rule that although a number of State Exchanges and SBE-FPs have taken meaningful steps towards ensuring the adequacy of QHP networks, we are of the view that every Exchange should apply quantitative network adequacy standards and conduct a thorough review and analysis of issuer compliance with these standards to effectively evaluate the adequacy of QHP networks in order to ensure that all consumers, regardless of which State they live in, have timely access to providers to manage their health care needs.

b. Proposals Related to State Exchange and SBE-FP Network Adequacy Standards and Reviews

i. Quantitative Network Adequacy Time and Distance Standards

For plan years beginning on or after January 1, 2025 and future plan years, we proposed that State Exchanges and SBE-FPs must (1) establish and impose quantitative time and distance network adequacy standards for QHPs that are at least as stringent as standards for QHPs participating on the FFEs under § 156.230; and (2) conduct reviews of a plan's compliance with those quantitative network adequacy standards prior to certifying any plan as a QHP, consistent with the manner in which the FFEs review the network adequacy of plans under § 156.230. For purposes of this proposed policy, we stated in the proposed rule that "at least as stringent as" means time and distance standards that use a specialty list that includes at least the same specialties as our provider specialty lists and time and distance parameters that are at least as short as our parameters. We explained that States would be permitted to implement network adequacy standards that are more stringent than those performed by the FFEs under § 156.230. In other words, States could use a specialty list that is broader than our specialty lists, but it must include all the provider specialties included in our lists. Similarly, we explained that the time and distance parameters could also be narrower than our parameters, meaning they could require shorter time and/or distances, but they cannot be less demanding than our time and distance parameters.

In the proposed rule, we stated that quantitative time and distance standards help strengthen QHP enrollees' timely access to a variety of providers to meet their health care needs, which in turn helps ensure that enrollees can receive

²⁵⁶ Health Benefit Plan Network Access and Adequacy Model Act. (2015, 4th Quarter). https://www.nh.gov/insurance/legal/documents/naic_model_act_network_adequacy.pdf.

²⁵⁷ Hall, Ginsburg. (2017, Sep.). A Better Approach to Regulating Provider Network Adequacy. <https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf>.

²⁵⁸ Id.

²⁵⁹ Id.

²⁶⁰ Id.

²⁶¹ Id.

health care services without unreasonable delay. Additionally, we stated that quantitative time and distance standards, when varied by county type, provide a useful assessment of whether QHPs provide reasonable access to care and a more comprehensive evaluation of the adequacy of QHPs' networks.

In the 2023 Payment Notice (87 FR 27322), we adopted time and distance standards that the FFEs would use to assess whether plans to be certified as QHPs in the FFEs meet network adequacy standards. The proposed provider specialty lists for time and distance standards for PY 2023 were informed by prior HHS network adequacy requirements, consultation with interested parties, and other Federal and State health care programs, such as Medicare Advantage and Medicaid. The provider specialty lists that were finalized for PY 2023 covered more provider types than previously evaluated under FFE standards so that QHP networks would be robust, comprehensive, and responsive to QHP enrollees' needs. In the proposed rule (88 FR 82588), we stated that we believe these provider specialty lists promote access to a variety of provider types and, as a result, strengthen consumer access to health care services without unreasonable delay. To establish a national floor for quantitative network adequacy standards, we proposed that the provider specialty list that State Exchanges and SBE-FPs use must include, at a minimum, the providers in the provider specialty lists for the FFEs that were applicable to PY 2023. Those lists are included in the preamble of this final rule, in Tables 9 and 10.

Consistent with the standards for the FFEs, and to strengthen QHP enrollees' timely access to a variety of providers to meet their health care needs, we proposed that State Exchanges and SBE-FPs' time and distance standards would be calculated at the county level and vary by county designation. We proposed that State Exchanges and SBE-FPs would be required to use a county type designation method that is based on the population size and density parameters of individual counties. We further stated that under our proposal, the time and distance standards State Exchanges and SBE-FPs would establish and impose would apply to the provider specialty lists contained in the proposed rule (Tables 9 and 10 in the preamble of this final rule). We explained that to count towards meeting the time and distance standards, individual and facility providers listed in Tables 9 and 10 would have to be appropriately

licensed, accredited, or certified to provide services in their State, as applicable, and would need to have in-person services available.

TABLE—INDIVIDUAL PROVIDER SPECIALTY LIST FOR TIME AND DISTANCE STANDARDS

| Individual 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 10—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) |

TABLE 10—FACILITY SPECIALTY LIST FOR TIME AND DISTANCE STANDARDS—Continued

| Facility specialty types |
|--|
| Inpatient or Residential Behavioral Health Facility Services |
| Mammography |
| Outpatient Infusion/Chemotherapy |
| Skilled Nursing Facilities |
| Surgical Services (Outpatient or ASC) |
| Urgent Care |

We stated in the proposed rule that the county-specific time and distance parameters that QHPs would be required to meet would be detailed in future guidance, namely, the annual CMS Letter to Issuers in the Federally-facilitated Exchanges. We stated that we would consider industry standards in developing these standards.

ii. Quantitative Network Adequacy Reviews

For plan years beginning on or after January 1, 2025, we proposed (88 FR 82590) that State Exchanges and SBE-FPs be required to conduct quantitative network adequacy reviews prior to QHP certification, and that they conduct them consistent with network adequacy reviews conducted by the FFEs under § 156.230. Specifically, we proposed that State Exchanges and SBE-FPs would be required to conduct, prior to QHP certification, quantitative network adequacy reviews to evaluate compliance with requirements under § 156.230(a)(1)(ii) and (iii), and (a)(2)(i)(A), while providing QHP certification applicants the flexibilities described under § 156.230(a)(2)(ii) and (a)(3) and (4). We stated in the proposed rule that under this proposal, State Exchanges and SBE-FPs would be prohibited from accepting an issuer's attestation as the only means for plan compliance with network adequacy standards. We further proposed that State Exchanges and SBE-FPs would make available to SADP applicants the limited exception available to SADPs under § 156.230(a)(4) pursuant to which SADPs may not be required to meet FFE network adequacy standards under § 156.230(a)(4), for the same reasons we made this exception available in the FFEs in the 2024 Payment Notice (88 FR 25878 through 25879). This exception is not available to medical QHP issuers.

iii. Quantitative Network Adequacy Review Justification Process

In the proposed rule (88 FR 82590), we acknowledged that State-specific challenges may necessitate exceptions, and so we proposed to require State Exchanges and SBE-FPs to permit issuers that are unable to meet the specified standards to participate in a justification process after submitting their initial data to account for variances, consistent with the processes specified under § 156.230(a)(2)(ii) and (a)(3) and (4). We noted that State-specific challenges could include barriers beyond an issuer's control, such as provider supply shortages or topographic barriers.

We stated in the proposed rule that the issuer would include this justification as part of its QHP application and describe 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. We further stated that the issuer would be required to provide information as requested by the State Exchange or SBE-FP to support this justification. We also explained that State Exchanges and SBE-FPs would be required to review the issuer's justification to determine whether making such health plan available through the Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates as specified under § 156.230(a)(3). We further explained that in making this determination, the factors State Exchanges and SBE-FPs could consider include whether the exception is reasonable based on circumstances such as the local availability of providers and variables reflected in local patterns of care. We stated that if the State Exchange or SBE-FP determines that making such health plan available through its Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates, it could then certify the plan as a QHP.

iv. Exception Process for State Exchanges and SBE-FPs

In the proposed rule (88 FR 82590), we stated that we are aware that some States Exchanges employ robust, quantitative network adequacy standards that differ from those used by the FFEs, but still ensure that QHPs provide consumers with reasonable, timely access to practitioners and facilities to manage their health care needs, consistent with the ultimate aim

of these proposals. Accordingly, we proposed a framework for granting exceptions to the requirements that State Exchanges and SBE-FPs establish and impose network adequacy time and distance standards for QHPs that are at least as stringent as the standards applicable to QHPs in FFEs and conduct quantitative network adequacy reviews that are consistent with those carried out by the FFEs under § 156.230. We proposed that HHS could grant State Exchanges and SBE-FPs an exception if it determines that the Exchange applies and enforces quantitative network adequacy standards that are different from the FFEs' but ensure reasonable access as defined under § 156.230. We also proposed that the exception would be available only to State Exchanges and SBE-FPs that conduct quantitative reviews of network adequacy prior to certifying plans as QHPs. We further proposed that Exchanges seeking to employ alternative network adequacy standards would be required to submit an exception request, in a form and manner specified by HHS, and to support their exception request with evidence-based data demonstrating that such standards ensure access as defined under § 156.230.

For example, we explained that if a State were to provide quantitative evidence that their network adequacy time and distance standards that measure access by service types provide consumers with equal access to providers as the Federal network adequacy standards under § 156.230 that measure access by provider types, we may grant the respective State's request for an exception from measuring access by provider types. Additionally, we explained that if a State were to use different county type designations than the five county type designations that we use to assess QHP time and distance standards at the county level (that is, Large Metro, Metro, Micro, Rural, CEAC), we would consider the respective State's request for an exemption from using the same five county type designations only if the State were to provide evidence that their alternative county type designations provide consumers with equal access to providers as the Federal network adequacy standards under § 156.230. We stated that alternative quantitative network adequacy standards that we would review for potentially qualifying for the exemption must be supported by evidence-based data, demonstrating that such standards provide enrollees with a level of access to providers that is equal to or greater than that ensured by the

FFE network adequacy standards under § 156.230.

Although we proposed to establish minimum standards related to network adequacy in the proposed rule, we solicited comment on how States may be able to develop a combination of data-driven quantitative and qualitative standards, developed with input from interested parties, to assess network adequacy. In the 2020 Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care final rule (85 FR 72754, 72802), we provided States the flexibility to develop quantitative network adequacy standards for determining network adequacy. In that rule, we noted that in some situations, time and distance may not be the most effective type of standard for determining network adequacy and that some States have found that the time and distance analysis produces results that may not accurately reflect provider availability. For example, a State that has a heavy reliance on telehealth in certain areas of the State may find that a health care provider-to-enrollee ratio is more useful in measuring meaningful access to all services without unreasonable delay, as the time it would take the enrollee, and the distance the enrollee would have to travel, to access the provider in-person could be well beyond applicable time and distance standards, but the enrollee may still be able to easily and quickly access many different providers on a virtual basis (85 FR 72802). In the proposed rule, we sought comment on how we should administer the process for Exchanges to apply for these exceptions, including the appropriate timelines, and the data that would be required to be submitted as part of the exception request. We also sought comment on how we should evaluate the provider access offered by QHP issuers in a State that requests an exception to establish and impose quantitative network adequacy standards that are different from the FFEs', whether and how to measure the access provided by those different standards over time, and how long an approved exemption should last.

In the proposed rule, we stated that to ensure compliance with these proposed quantitative time and distance QHP network adequacy standards and review requirements, we would coordinate with State Exchanges and SBE-FPs to provide technical assistance to support their compliance with the requirements of this policy and work with them should it be necessary to remedy any gaps in compliance. However, we stated that if a State Exchange or SBE-FP fails to comply with these standards, we

could seek to take remedial action under our authorities related to Exchange program integrity.

c. Proposal Related to QHP Reporting on Telehealth Services

We proposed (88 FR 82591) to require State Exchanges and SBE-FPs to require that all issuers seeking certification of plans to be offered as QHPs submit information to the respective State Exchanges or SBE-FPs about whether network providers offer telehealth services. We proposed that this requirement would be applicable beginning with the QHP certification cycle for PY 2025. We stated in the proposed rule that 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. We also stated that this information could be relevant to State Exchange and SBE-FP analysis of whether a QHP meets network adequacy standards. We noted that this proposal is not intended to suggest that telehealth services would be counted in place of in-person service access for the purpose of State Exchange and SBE-FP issuers meeting time and distance network adequacy standards for PY 2025. We explained that while we acknowledge the growing importance of telehealth, we want to ensure that telehealth services do not reduce the availability of in-person care.

We explained that for the purpose of this proposal, telehealth encompasses professional consultations, office visits, and office psychiatry services delivered through technology-based methods, including virtual check-ins, remote evaluation of pre-recorded patient data, and inter-professional internet consultations. We noted that, currently, for issuers in FFEs to comply with telehealth reporting standards, issuers must indicate whether each provider offers telehealth with the options “Yes,” “No,” or “Requested information from the provider, awaiting their response.” We proposed that State Exchanges and SBE-FPs would be required to impose this requirement on issuers when issuers submit provider information.

We sought comment on this proposal, including comments on how we might incorporate telehealth availability into network adequacy standards in future plan years.

d. Additional Network Adequacy Standards

To reduce burden on State Exchanges and SBE-FPs that are not yet conducting quantitative network adequacy reviews, we did not propose

that State Exchanges and SBE-FPs enforce appointment wait time standards or that State Exchanges and SBE-FPs ensure that the provider network of each QHP meets applicable standards specified in § 156.230(b) through (e). However, we sought comment to inform any potential future enforcement of appointment wait time standards as well as the standards specified in § 156.230(b) through (e) and stated that we looked forward to capturing a wide range of perspectives on these topics from various interested parties. We stated that we were especially interested in comments about how State Exchanges and SBE-FPs may enforce quantitative network adequacy standards for appointment wait times, as well as the impact enforcing these standards may have on issuers and consumers.

We also sought comment on our proposal for State Exchanges and SBE-FPs to establish and impose quantitative time and distance QHP network adequacy standards that are at least as stringent as the FFEs’ time and distance standards established for QHPs under § 156.230 and to conduct quantitative network adequacy reviews, prior to QHP certification, that are consistent with the reviews conducted by the FFEs under § 156.230, including comment on whether we should amend § 156.230 in addition to § 155.1050 to directly apply the same standards applicable to issuers on FFEs to issuers in State Exchanges and SBE-FPs for plan years beginning on or after January 1, 2025.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these proposals with a clarification to the exception process and a modification to require implementation for plan years beginning on or after January 1, 2026.

First, under § 155.1050(a)(2)(i)(A), we are finalizing that for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must establish and impose quantitative time and distance network adequacy standards for QHPs that are at least as stringent as standards for QHPs participating on the FFEs under § 156.230(a)(2)(i)(A).

Second, we are finalizing that, for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must conduct quantitative network adequacy reviews prior to certifying any plan as a QHP, consistent with the reviews conducted by the FFEs under § 156.230. Specifically, we are finalizing at § 155.1050(a)(2)(i)(B) that, for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs

must conduct network adequacy reviews to evaluate a plan’s compliance with network adequacy standards under § 156.230(a)(1)(ii), (a)(1)(iii), and (a)(2)(i)(A) prior to certifying any plan as a QHP, while providing QHP certification applicants the flexibilities described under § 156.230(a)(2)(ii) and (a)(3) and (4).

Third, we are finalizing § 155.1050(a)(2)(ii) to provide that, for plan years beginning on or after January 1, 2026, HHS may grant an exception to the requirements described under § 155.1050(a)(2)(i) to a State Exchange or SBE-FP that demonstrates with evidence-based data, in a form and manner specified by HHS, that (1) the Exchange applies and enforces alternate quantitative network adequacy standards that are reasonably calculated to ensure a level of access to providers that is as great as that ensured by the Federal network adequacy standards established for QHPs under § 156.230(a)(1)(iii), (a)(2)(i)(A), and (a)(4); and (2) the Exchange evaluates whether plans comply with applicable network adequacy standards prior to certifying any plan as a QHP. In this final rule, for this exception process, we are clarifying that, for (1) above, the Exchange will need to demonstrate that it applies and enforces alternate quantitative network adequacy standards that are reasonably calculated to ensure a level of access to providers that is as great as that ensured by the Federal network adequacy standards established for QHPs under § 156.230(a)(1)(iii), (a)(2)(i)(A), and (a)(4), and not § 156.230 generally, to reinforce that issuers on the State Exchanges and SBE-FPs do not need to comply with the appointment wait time standards under § 156.230(a)(2)(i)(B) under this policy.

Lastly, we are finalizing § 155.1050(a)(2)(i)(C) to provide that, for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must require that all issuers seeking certification of a plan as a QHP submit information to the Exchange reporting whether or not network providers offer telehealth services.

In preparation for PY 2026, we will begin communicating and coordinating with State Exchanges and SBE-FPs through the provision of technical assistance. Specifically, during PYs 2024 and 2025, we will work closely with State Exchanges and SBE-FPs on their plans to comply with these network adequacy requirements for plan years beginning on or after January 1, 2026.

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

Comment: Many commenters expressed support for the proposal that State Exchanges and SBE-FPs: (1) establish and impose quantitative time and distance network adequacy standards for QHPs that are at least as stringent as standards for QHPs participating on the FFEs under § 156.230(a)(2)(i)(A); and (2) conduct reviews of a plan's compliance with those quantitative network adequacy standards prior to certifying any plan as a QHP, consistent with the manner in which the FFEs review the network adequacy of plans under § 156.230.

Response: We appreciate the commenters' support for this proposal.

Comment: Many commenters expressed general support for the creation of a Federal floor for network adequacy standards or standardization of network adequacy standards across States. Commenters indicated that the imposition of standardized quantitative time and distance network adequacy requirements across States, particularly in States that do not currently impose quantitative time and distance network adequacy requirements or that impose requirements that are less stringent than the FFEs', is valuable because it increases access to providers and services. Commenters stated that the imposition of these requirements will do so by for example, decreasing disparities in access across States, and requiring States that have not implemented quantitative network adequacy standards to do so. One commenter also stated that "the establishment of stringent network adequacy standards is critical in ensuring continual access to high-quality dental care and incentivizing fair negotiations between insurers and dental providers during the network contracting process." Some of these commenters suggested alternatives to the proposed approach such as suggesting that the floor be qualitative in nature, that it be methods-based and not metrics-based, and that CMS work with State Exchanges and SBE-FPs to harmonize standards across States rather than extending the FFE network adequacy standards as a national floor.

Response: We appreciate the support for our proposals and agree with the benefits raised by commenters. We are finalizing these policies as proposed with a modification to the implementation date and a clarification to the exception process, as previously discussed. While we appreciate commenters suggesting a qualitative approach or a methods-based one,

which we believe may refer to approaches that impose standards that only require States or issuers to have processes in place to ensure network adequacy, we believe quantitative network adequacy standards, unlike qualitative or other methods-based approaches, can be monitored relatively easily and applied objectively. By contrast, qualitative or other methods-based approaches to network adequacy typically articulate a broad, general standard of adequacy and grant regulators or insurers discretion to determine how to measure compliance. State regulators using these approaches may require issuers to attest to meeting the network adequacy standards or allow the issuers to self-monitor compliance with the standards in a different way. As opposed to conducting routine audits or requiring periodic reports of compliance, State regulators using these approaches usually also rely on consumer complaints to highlight situations that might require investigation. Based on our experience conducting network adequacy reviews and regulating QHPs, as well as feedback from interested parties, we are of the view that no matter the State in which a QHP is offered, some quantitative analysis is necessary for an Exchange to objectively monitor network adequacy and determine whether a QHP can provide enrollees access to an adequate network of providers.

Additionally, harmonizing network adequacy standards across States would prevent States from enforcing quantitative network adequacy standards that are more stringent than the FFEs' standards or from using the exception process under § 155.1050(a)(2)(ii) to enforce standards that they determined are in the best interest of their consumers. We are of the view that setting the FFEs' quantitative time and distance network adequacy standards as a national floor strikes an appropriate balance of providing States with these important flexibilities while also ensuring that all consumers, regardless of which State they live in, have timely access to providers to manage their health care needs.

Comment: Many commenters offered recommendations about additional provider and facility specialty types that should be subject to the time and distance standards, such as academic cancer centers, essential community hospitals, substance use disorder treatment providers, and reproductive health providers, as well as recommendations about changes to the time and distance metrics such as

changes to the number of minutes/miles associated with time and distance standards for certain specialties.

Response: We are not inclined to add additional provider types to the individual and facility provider specialty lists for time and distance standards at this time. The provider specialty lists we proposed are the same lists we finalized for FFE issuers in the 2023 Payment Notice (87 FR 27325). Those specialty lists were informed by prior HHS network adequacy requirements, consultation with interested parties, and other Federal and State health care programs, such as Medicare Advantage and Medicaid, and those lists covered more provider specialty types than previously evaluated under FFE standards so that QHP networks would be robust, comprehensive, and responsive to QHP enrollees' needs. We continue to believe that those provider specialty lists promote access to a variety of provider types and, as a result, strengthen consumer access to health care services without unreasonable delay. Until we have more experience with the impact of the specialty lists, we finalize in this rule on QHP issuers in State Exchanges and SBE-FPs, adding additional providers to the specialty lists would be premature and may impose burdens on QHP issuers that we have not fully evaluated. Therefore, at this time, we do not believe that it is appropriate to include additional provider types in these specialty lists.

Our time and distance metrics for network adequacy are based on Medicare Advantage standards and were designed with careful consideration of other network adequacy standards, including those of individual States, accrediting entities, and Federal health care programs. Until we can more fully assess the impact of the time and distance standards, we finalize in this rule on QHP issuers in State Exchanges and SBE-FPs, we believe that modifying those standards would also be premature and may impose burdens on QHP issuers that we have not fully evaluated. We will further research commenters' recommended changes to our time and distance metrics as well as their implications and may consider them in future rulemaking.

Comment: Many commenters also opposed the proposal that State Exchanges and SBE-FPs (1) establish and impose quantitative time and distance network adequacy standards for QHPs that are at least as stringent as standards for QHPs participating on the FFEs under § 156.230(a)(2)(i)(A); and (2) conduct reviews of a plan's compliance with those quantitative network

adequacy standards prior to certifying any plan as a QHP, consistent with the manner in which the FFEs review the network adequacy of plans under § 156.230. Commenters stated that States are best informed about local context factors that should be considered in network adequacy standards and reviews such as provider shortages, provider quality, innovative delivery methods, and geographic constraints. Commenters also noted that the proposal has the potential for creating conflicting or duplicative regulations and increasing administrative burden on States and issuers.

Response: For the reasons explained in the proposed rule (88 FR 82587 through 82588), we continue to believe that requiring State Exchanges and SBE-FPs to establish and impose quantitative time and distance network adequacy standards for QHPs that are at least as stringent as the FFEs' and conduct reviews of plan compliance with those quantitative network adequacy standards consistent with the manner in which the FFEs review plan network adequacy will create an effective national baseline for network adequacy standards and help provide consumers, regardless of which State they live in, with reasonable, timely access to providers and facilities to manage their health care needs.

We acknowledge commenters' concerns that our network adequacy proposal may create conflicting or duplicative regulations and increase administrative burden on States Exchanges, SBE-FPs, and their issuers. We believe that finalizing these proposals with a modification to require implementation for plan years beginning on or after January 1, 2026, will provide States an opportunity to revise their regulations to ensure there are no conflicting or duplicative regulations. This modification may also lessen the administrative burden of this policy on State Exchanges, SBE-FPs, and their issuers by providing them more time to come into compliance with these new requirements.

In the proposed rule (88 FR 82590), we acknowledged that State-specific factors, such as provider supply shortages, topographic barriers, or other barriers beyond an issuer's control, may necessitate exceptions to these requirements, and this network adequacy policy permits State Exchanges and SBE-FPs to consider those factors as they conduct network adequacy reviews prior to plan certification. Specifically, this final rule extends flexibility to State Exchanges and SBE-FPs to permit issuers that are

unable to meet the specified standards to participate in a justification process after submitting their initial data to account for variances, consistent with the processes specified under § 156.230(a)(2)(ii) and (a)(3) and (4). The issuer would include this justification as part of its QHP application and describe 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. State Exchanges and SBE-FPs will be required to review the issuer's justification to determine whether making such health plan available through the Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates as specified under § 156.230(a)(3). In making this determination, the factors State Exchanges and SBE-FPs could consider include local context factors that the commenters reference and may envision, such as whether the exception is reasonable based on circumstances such as the local availability of providers and variables reflected in local patterns of care. If the State Exchange or SBE-FP determines that making such health plan available through its Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates, it could then certify the plan as a QHP.

Comment: Several commenters urged CMS to delay implementation of the proposed network adequacy standards to allow States sufficient time to assess whether their network adequacy standards comply with the proposed requirements or need modification, and for issuers offering QHPs through State Exchanges and SBE-FPs to modify their networks to comply with the new national floor for network adequacy standards.

Response: In the proposed rule, we proposed that the new network adequacy standards that State Exchanges and SBE-FPs must establish and impose would be applicable for plan years beginning on or after January 1, 2025. We understand, however, the desire expressed by some commenters to delay the implementation of this proposal, and we acknowledge that compliance with the network adequacy standards finalized in this rule may require States to review and modify their network adequacy standards and processes. In response to these concerns, CMS is finalizing that the new network adequacy standards for State Exchanges and SBE-FPs will apply to plan years beginning on or after January

1, 2026. In preparation for PY 2026, we will begin communicating and coordinating with State Exchanges and SBE-FPs through the provision of technical assistance. Specifically, during PYs 2024 and 2025, we will work closely with State Exchanges and SBE-FPs on their plans to comply with these network adequacy requirements for plan years beginning on or after January 1, 2026.

Comment: Several commenters requested clarification about whether the proposed network adequacy policies would apply when it is the State Department of Insurance, and not the State Exchange or SBE-FP, conducting the network adequacy reviews.

Response: When establishing a State Exchange or SBE-FP through the Exchange Blueprint approval process under § 155.105, a State must attest to its capacity to ensure QHPs' compliance with market reform rules, applicable regulations, and guidance, as well as its capacity to ensure QHPs' ongoing compliance with QHP certification requirements.²⁶² As part of this process, a State must inform CMS that network adequacy activities will be completed by the Exchange or an Exchange's designee through contract, agreement, or other arrangement. Regardless of whether a State intends to designate some entity other than the Exchange to perform network adequacy activities, under § 155.1050(a), Exchanges are ultimately responsible for ensuring QHP network adequacy. This proposal does not alter a State's ability to designate an entity other than the Exchange to perform network adequacy reviews, nor does it alter any existing agreements a State Exchange or an SBE-FP may have entered into with State regulatory entities, including State Departments of Insurance, to perform network adequacy reviews or other QHP certification functions. We clarify that the State Exchanges and SBE-FPs may continue current relationships with entities they have designated to undertake QHP certification functions under their approved Exchange Blueprint, including network adequacy reviews, and that all network adequacy reviews, including reviews conducted by an Exchange's designee, must meet the requirements of the network adequacy policies finalized in this rule under new § 155.1050(a)(2).

Comment: Most commenters were supportive of the proposal to make a justification process available for issuers in State Exchanges and SBE-FPs that

²⁶² Blueprint for Approval of State-Based Health Insurance Exchanges, section III, part C. 4.0. <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/cms-blueprint-application.pdf>.

cannot meet the FFEs' time and distance standards and urged CMS to work with State Exchanges and SBE-FPs to closely scrutinize submitted justifications and ensure that issuers' justifications would only be accepted if truly valid.

Response: We appreciate the commenters' feedback. This final rule requires State Exchanges and SBE-FPs to review the issuer's justification to determine whether making such health plan available through the Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates as specified under § 156.230(a)(3). In making this determination, the factors State Exchanges and SBE-FPs could consider include State-specific factors, such as provider supply shortages, topographic barriers, or other barriers beyond an issuer's control. Upon publication of this rule, we will begin communicating and coordinating with State Exchanges and SBE-FPs through technical assistance, in preparation for PY 2026, including on best practices to review and approve or deny issuer-submitted justifications.

Comment: Several commenters opposed the limited exception for SADPs because they believe that SADPs should be held accountable for access to dental providers in the same manner as medical QHPs.

Response: We acknowledge the commenters' concerns. In the 2024 Payment Notice (88 FR 25875), we finalized a limited exception to the provider network requirement for SADP issuers that sell plans in areas where it is prohibitively difficult for the issuer to establish a network of dental providers; this exception is not applicable to medical QHP issuers at this time.²⁶³ Under this exception, an area is considered "prohibitively difficult" for an SADP issuer to establish a network of dental providers based on attestations from State Departments of Insurance in States with at least 80% of their counties classified as CEAC, that at least one of the following factors exists in the area of concern: a significant shortage of dental providers, a significant number of dental providers unwilling to contract with Exchange issuers, or significant geographic limitations impacting consumer access to dental providers. We are extending the limited SADP exception to SADP issuers on State Exchanges and SBE-FPs to ensure that consumers residing in all States where it is prohibitively difficult for the issuer to establish a network of dental providers have access to dental plans. As we explained in the 2024 Payment

Notice, this limited exception follows logically from how the requirements in sections 1311(c)(1)(B) and (C) of the ACA that plans ensure a sufficient choice of providers apply in the unique SADP context. If creating a network of dental providers is prohibitively difficult for SADPs in certain areas in State Exchange or SBE-FP States, it is foreseeable that there may be some areas where SADPs could not be Exchange-certified, which then risks there being no SADPs in that area and thus no choice of dental providers through SADPs at all. Thus, in this limited context, requiring that SADP issuers in State Exchanges and SBE-FPs establish a dental provider network would defeat the purpose of section 1311(c)(1)(B) and (C) the ACA to ensure that enrollees have a sufficient choice of providers.

Comment: Most commenters supported the availability of an exception process for State Exchanges and SBE-FPs and urged CMS to review these exception requests quickly and to clearly identify the criteria for acceptance.

Response: We appreciate the commenters' support for the exception process. Upon publication of this rule, we will begin communicating and coordinating with State Exchanges and SBE-FPs through technical assistance in preparation for PY 2026. In reviewing exception requests, we will seek to determine whether the State has the requisite statutory, regulatory, and/or sub-regulatory authority to review all QHPs applying for QHP certification in the State for network adequacy as well as the requisite authority to review all QHPs for compliance with time and distance standards using the same specialty lists as detailed in the 2023 Payment Notice (87 FR 27324 through 27326) (set forth at Tables 9 and 10 of this preamble to this final rule).

We will also seek to determine whether the State conducts quantitative reviews of time and distance standards for QHP network adequacy using issuer-submitted data for all plans applying for QHP certification and whether the State's quantitative review of time and distance standards for QHP network adequacy includes parameters that are at least as short as those listed in the 2023 Letter to Issuers²⁶⁴ for the specialty types listed in Tables 9 and 10 of this preamble to this final rule. Lastly, we will seek to determine whether the State's quantitative review of time and distance standards occurs prior to plan certification and whether

the review includes a justification process for plans that do not meet the network adequacy standards.

Before PY 2026, we will also review the information provided by State Exchanges and SBE-FPs to support their exception request. This information may include materials such as guidance documents or templates that describe the State's methodology for reviewing issuer-submitted quantitative data to assess compliance with QHP network adequacy standards, information about the frequency and timeline for network adequacy reviews for QHP issuers in the State, information regarding the State's justification process for issuers not yet meeting the network adequacy standards, and information regarding any compliance review processes the State utilizes to follow up with issuers that complete the justification process.

Comment: Many commenters expressed support for the proposal to require collection of information about which providers offer telehealth services and one commenter recommended that issuers be required to ensure that a percentage of care available in their network is available via telehealth services.

Response: We appreciate the support from these commenters. In the proposed rule, we noted that this proposal is not intended to suggest that telehealth services would be counted in place of in-person service access for the purpose of meeting network adequacy time and distance standards for PY 2025. While we acknowledge the growing importance of telehealth, we want to ensure that telehealth services do not reduce the availability of in-person care. More research would be needed before we could analyze whether counting telehealth is appropriate for purposes of a QHP meeting network adequacy time and distance standards.

Comment: A few commenters expressed opposition to the collection of information about which providers offer telehealth services indicating that the proposed rule underestimated the burden of this proposal, and that the information would not capture the availability of telehealth services.

Response: We believe that the telehealth reporting standards, pursuant to which issuers in State Exchanges and SBE-FPs must indicate whether each network provider offers telehealth services with the options "Yes," "No," or "Requested information from the provider, awaiting their response," would not require extensive administrative time to gather. Approximately half of the parent companies of issuers on the State Exchanges and over two thirds of the

²⁶⁴ 2023 Letter to Issuers in the Federally-facilitated Exchanges: <https://www.cms.gov/files/document/2023-draft-letter-issuers-508.pdf>.

²⁶³ See § 156.230(a)(4).

parent companies of issuers on SBE-FPs offer Medicare Advantage plans, and Medicare Advantage offers a telehealth credit for network adequacy. Therefore, many more issuers on State Exchanges and SBE-FPs likely already have access to this information. We also believe that 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 directories. For these reasons, we estimate that any additional burden resulting from the requirement that QHP issuers report whether each network provider is furnishing telehealth services would be minimal.

We stated in the proposed rule (88 FR 82591, 82638 through 82639) that this data would be for informational purposes, would be intended to help inform the future development of telehealth standards, and would not be displayed to consumers. We believe that the above-described telehealth reporting standards support these objectives by providing State Exchanges and SBE-FPs with a general picture regarding the availability of telehealth services in their State. Additionally, at this time, since this data will not be displayed to consumers, it is not necessary for State Exchanges and SBE-FPs to collect more granular telehealth data from their issuers.

Comment: One commenter recommended delaying collection of telehealth information to allow the development of more efficient ways for issuers to collect that information from providers.

Response: We acknowledge this concern and will require compliance with this network adequacy requirement for plan years beginning on or after January 1, 2026. Upon publication of this rule, we will begin communicating and coordinating with State Exchanges and SBE-FPs through technical assistance in preparation for PY 2026. Notably, we collect the same telehealth information from QHP issuers in the FFEs, and all those issuers have successfully submitted it each plan year.

Comment: Many commenters recommended that CMS extend the FFEs' appointment wait time standards to State Exchanges and SBE-FPs, citing that it would further provide consumers with reasonable, timely access to practitioners and facilities to manage their health care needs. Many commenters also sought information on appointment wait time standards and operations, such as the use of secret shopper surveys to assess compliance with these standards.

Response: As we explained in the proposed rule (88 FR 82591), to reduce burden on State Exchanges and SBE-FPs that are not yet conducting quantitative network adequacy reviews, we did not propose, at this time, that State Exchanges and SBE-FPs enforce appointment wait time standards or that State Exchanges and SBE-FPs ensure that the provider network of each QHP meets applicable standards specified in § 156.230(b) through (e). We will monitor the implementation of these network adequacy standards in State Exchanges and SBE-FPs and consider whether applying the FFEs' appointment wait time standards to issuers in State Exchanges and SBE-FPs in future plan years is warranted. Additional information about appointment wait time standards will appear in the 2025 Letter to Issuers and will only apply to issuers in the FFEs in PY 2025.

We thank commenters for their feedback on these issues and will take their comments into consideration in future rulemaking.

E. 45 CFR 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 2025 Benefit Year (§ 156.50)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82591), for the 2025 benefit year, we proposed to retain the 2024 benefit year FFE user fee rate of 2.2 percent of total monthly premiums and an SBE-FP user fee rate of 1.8 percent of the total monthly premiums.

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

fees can be used for.²⁶⁵ OMB Circular A-25 provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public.

a. FFE User Fee Rates for the 2025 Benefit Year

Based on estimated costs, enrollment (including anticipated establishment of SBE-FPs or shifts to State Exchanges in certain States in which FFEs or SBE-FPs currently are operating), and premiums for the 2025 benefit year, we proposed a 2025 user fee rate for all participating FFE issuers of 2.2 percent of total monthly premiums.

Section 156.50(c)(1) provides that, to support the functions of FFEs, an issuer offering a plan through an FFE must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE. Issuers seeking to participate in an FFE in the 2025 benefit year will receive two special benefits not available to issuers offering plans in State Exchanges: (1) the certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. For the 2025 benefit year, issuers participating in an FFE will receive special benefits from the following Federal activities:

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

Activities performed by the Federal Government that do not provide issuers participating in an FFE with a special benefit are not covered by the FFE user fee. We expect that the user fee rates we finalize provide adequate funding for each of the special benefits issuers participating in an FFE receive. For a description of how estimates for costs are developed and a full description of how the proposed 2025 benefit year FFE

²⁶⁵ See Circular No. A-25 Revised. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>.

user fee rate was developed see the proposed rule (88 FR 82591 through 82592).

We noted in the proposed rule that if any events significantly changed our estimates around costs, premiums, or enrollment projections between the proposed rule and the final rule, we may modify the FFE and SBE–FP user fee rates that were proposed.

b. SBE–FP User Fee Rates for the 2025 Benefit Year

We proposed to charge issuers offering QHPs through an SBE–FP a user fee rate of 1.8 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP for the 2025 benefit year.

In § 156.50(c)(2), we specify that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE–FP. We expect that the user fee rates we finalize will provide adequate funding for each of the special benefits issuers participating in an SBE–FP will receive. See the proposed rule (88 FR 82592 through 82593) for a full description of how the user fee rate for SBE–FPs is calculated, special benefits to issuers using the SBE–FP, and how the proposed 2025 benefit year SBE–FP user fee rate was developed.

As previously mentioned in this section, we also noted in the proposed rule that if any events significantly change our estimates around costs, premiums, or enrollment projections between the proposed rule and the final rule, we may modify the FFE and SBE–FP rates that were proposed.

We sought comment on the proposed 2025 FFE and SBE–FP user fee rates.

After the proposed rule was published, we revised our enrollment projections as a result of newly available data based on the 2024 Open Enrollment (OE) that occurred between November 2023 and January 2024. In particular, during the 2024 OE cycle, there were more plan selections than expected, which resulted in an increase in our enrollment projections.²⁶⁶ After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments below,

and as a result of our revised enrollment projections, we are finalizing for the 2025 benefit year a user fee rate for all issuers offering QHPs through an FFE of 1.5 percent of the monthly premium charged by the issuer for each policy under plans where enrollment is through an FFE and a user fee rate for all issuers offering QHPs through an SBE–FP of 1.2 percent of the monthly premium charged by the issuer for each policy under plans where enrollment is through an SBE–FP. We note that we establish FFE and SBE–FP user fee rates annually using the latest data and assumptions available at the time to calculate our projections around costs, premiums, and enrollment. Furthermore, FFE and SBE–FP user fee rates in future years will be recalculated using the latest data available at the time, and will take into consideration any changing assumptions, such as any change in the status of the enhanced premium tax credits established by the ARP and extended by the IRA which are currently expected to expire at the end of the 2025 benefit year.

Comment: Several commenters supported our proposal to retain FFE and SBE–FP user fee rates at 2.2 percent and 1.8 percent, respectively, of total monthly premiums for benefit year 2025. Other commenters disagreed with the proposed user fee rates and requested that HHS increase the user fee rates. Several of these commenters requested that HHS increase the user fee rates to improve Exchange functions and requested that HHS increase funding for education and outreach, assisters, and *HealthCare.gov*.

Response: Due to revising our projections between the proposed and final rules based on newly available data, we are finalizing a lower FFE user fee rate at 1.5 of total monthly premiums and a lower SBE–FP user fee rate at 1.2 percent of total monthly premiums for the 2025 benefit year. We revised our enrollment projections based on newly available data as the result of the 2024 OE. During this OE period, there were more plan selections than we projected when calculating the proposed 2025 user fee rates, which resulted in an increase in our enrollment projections. As we discussed in the proposed rule (88 FR 82591 through 82593), 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 2025 benefit year and are not solely a reflection of the total expenses estimated to operate and maintain the FFE, Federal platform, and SBE–FP

operations. We note that the amount collected under these user fee rates will ensure adequate funding for all user fee eligible Exchange and Federal platform functions.

Accordingly, we are finalizing user fee rates of 1.5 percent of monthly premiums charged by issuers for each policy under plans offered through an FFE and 1.2 percent of monthly premiums charged by issuers for each policy under plans offered through an SBE–FP. We will continue to calculate the FFE and SBE–FP user fee rate annually in a manner that ensures sufficient funding for operations, ensuring that consumers' needs are met and consumer education and outreach, assisters, and *HealthCare.gov* are appropriately funded.

We will also continue to examine cost estimates for the special benefits provided to issuers offering QHPs on the FFEs and SBE–FPs and will continue to establish user fee rates that are reasonable and necessary to fully fund user fee eligible Exchange operation costs.

Comment: A few commenters stated that HHS should adopt a PMPM user fee structure, stating that administrative costs do not track with premium changes and a PMPM user fee would avoid higher fee amounts based solely on premium increases.

Response: We 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. We note that we propose and finalize user fee rates each benefit year and can adjust the user fee rates to avoid higher fee amounts based solely on premium increases. Therefore, should administrative costs not trend with premium changes, we do not believe that such a trend would necessarily justify a PMPM user fee cost structure. Additionally, in accordance with Circular A–25,²⁶⁷ issuers are charged the user fee in exchange for receiving special benefits beyond those that accrue to the general public. Setting the user fee as a percent of premium ensures that the user fee generally aligns with the business generated by the issuer as a result of participation in an FFE or the Federal platform. However, we will continue to engage with interested parties regarding how the FFE and SBE–FP user fee policies can best support consumer access to affordable, quality health insurance coverage

²⁶⁶ For additional information, see <https://www.cms.gov/newsroom/fact-sheets/marketplace-2024-open-enrollment-period-report-final-national-snapshot>.

²⁶⁷ See Circular No. A–25 Revised. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>.

through the Exchanges that use the Federal platform.

Comment: One commenter appreciated the increased transparency around user fees, and encouraged additional transparency in the methodology used to set the user fee rates, as well as how user fees support HHS' policy goals for the Exchanges. The same commenter recommended greater transparency in how the user fee rates are determined and requested enumerated costs of providing Federal eligibility and enrollment platform service and infrastructure to each State.

Response: We provided additional information in the 2024 Payment Notice proposed rule (87 FR 78272 through 78274) explaining the impact of stable contract cost estimates, the enhanced PTC subsidies in section 9661 of the ARP being extended in section 12001 of the IRA through the 2025 benefit year, anticipated effects of the IRA on enrollment, and States transitioning from FFEs or SBE-FPs to State Exchanges, as well as the enrollment impacts of section 1332 State innovation waivers. This methodology was also used to develop the 2025 benefit year FFE and SBE-FP user fee rates. Additionally, we note that while there are certain functions that HHS has historically allocated to individual entities, most costs are not currently mapped to usage by State or individual transaction. 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 in the proposed rule, 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 States, 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.

2. State Selection of EHB-Benchmark Plans for Plan Years Beginning On or After January 1, 2026 (§ 156.111)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82593), we proposed to revise the standards for the State selection of EHB-benchmark plans at § 156.111 for benefit years beginning on

or after January 1, 2027, to: consolidate the options for States to change EHB-benchmark plans at § 156.111(a); revise the scope of benefit requirements at § 156.111(b)(2); and amend § 156.111(e)(3) to require States to submit a formulary drug list as part of its application to change EHB-benchmark plans only if the State is seeking to change its prescription drug EHB. We refer readers to the proposed rule (88 FR 82593) for a discussion of the statutory and regulatory background relating to these proposals.

As we explained in the proposed rule, nine States have changed their EHB-benchmark plans since 2018 by complying with the requirements at § 156.111.²⁶⁸ We stated in the proposed rule that based on interactions with these States and feedback received in response to the EHB RFI,²⁶⁹ we understand that certain aspects of the process to change EHB-benchmark plans may impose unanticipated difficulty on and create confusion for States. We stated that we understand there are concerns that the typicality standard, as implemented, is a burdensome way to ensure a State's EHB-benchmark plan selection is equal in scope to a typical employer plan. In addition, we stated that, in limiting EHB-benchmark plan selections, we understand that the generosity standard may also impede the ability of States to select an EHB-benchmark that is equal in scope to the benefits provided under a typical employer plan in the State, which we understand States often find have become more generous over time. We further stated that we understand that requiring States to submit a formulary drug list to HHS as part of the documentation required under § 156.111(e) can be particularly onerous when a State is not seeking to change its prescription drug EHBs. We refer readers to the proposed rule (88 FR 82593 through 82597) for further discussion or our proposals and related rationale.

As a result of that feedback, we proposed changes to § 156.111, as discussed in the following subsections. We also sought comment on the effective date of these changes.

After consideration of comments and for the reasons outlined in our response to comments, we are changing the

effective date of the changes we are finalizing to § 156.111 (as further discussed in the sections below). Specifically, we are finalizing the proposed revisions to § 156.111 so that they will be effective for benefit years beginning on or after January 1, 2026, rather than benefit years beginning on or after January 1, 2027, as was proposed.

Comment: Many commenters noted that the proposed amendments to § 156.111 would first impact plans for benefit years beginning on or after January 1, 2027, which is later than the proposed effective dates for other amendments to regulations pertaining to the EHB (§§ 155.170(a)(2) and 156.122(a)(3)(i)(E)). Commenters requested aligning the effective dates across these proposals so that the revisions to § 156.111 would become effective at the same time to minimize confusion. Some commenters requested that CMS finalize an earlier effective date than 2027 so that States that are considering submitting applications to change EHB-benchmark plans in 2024, for effectiveness starting with benefit years beginning on or after January 1, 2026, may utilize the proposed flexibilities a year earlier in order to provide consumers with improved EHBs a year earlier.

Response: We are persuaded by commenters that suggested finalizing an earlier effective date for the revisions to § 156.111. We agree with commenters that an earlier effective date may allow States to take advantage of changes to § 156.111 a year earlier, so that consumers may in turn realize improvements to their State's EHB-benchmark plan a year earlier, which we expect to result in improved health outcomes. We had proposed the original January 1, 2027 effective date with the understanding that a later effective date would reduce burden and confusion for States that might be preparing applications for submission on May 1, 2024 that would take effect for benefit years beginning on or after January 1, 2026. We did not want to finalize an effective date that may materially disrupt those applications. However, having reviewed and considered comments, we are now persuaded that an earlier effective date would not cause material disruption to these applications. Indeed, it appears that States interested in submitting applications to change EHB-benchmark plans by May 1, 2024 prefer the finalization of an earlier effective date. We understand that States intending to submit an application by May 1, 2024, have already started that process and have made assumptions based on the policy in current § 156.111. We are

²⁶⁸ For more information on the changes States have made to their EHB-benchmark plans, see <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb>.

²⁶⁹ For example, see <https://www.regulations.gov/comment/CMS-2022-0186-0270>; <https://www.regulations.gov/comment/CMS-2022-0186-0412>; and <https://www.regulations.gov/comment/CMS-2022-0186-0559>.

sympathetic to these concerns and note that nothing in the revised § 156.111 finalized in this rule prohibits such States from submitting an application by May 1, 2024.

Therefore, we are finalizing the proposed revisions to § 156.111 so that they will be effective for benefit years beginning on or after January 1, 2026. We are otherwise finalizing the revisions to § 156.111 as proposed, as described in the sections that follow.

a. Consolidating the State EHB-Benchmark Plan Options

We proposed to consolidate the choices for States to change their EHB-benchmark plan by revising § 156.111(a) to add a new paragraph (a)(2) which would simply state that, subject to paragraphs (b), (c), (d), and (e) of § 156.111, for plan years beginning on or after January 1, 2027, a State may change its EHB-benchmark plan by selecting a set of benefits that would become the State's EHB-benchmark plan. We stated that the language at current § 156.111(a) would be redesignated as § 156.111(a)(1) and would be revised to provide that this paragraph applies to plan years beginning on or after January 1, 2020 through December 31, 2026. Further, we stated that the language currently at § 156.111(a)(1) through (3) would be redesignated as § 156.111(a)(1)(i) through (iii).

Under 42 CFR 440.347, Medicaid ABPs authorized under section 1937 of the Act are required to meet EHB standards. Similarly, under 42 CFR 600.405, in States that elect to operate a BHP, the standard health plans must meet EHB standards. We explained in the proposed rule that the changes to State EHB-benchmark plan options would also be applicable to States when choosing an EHB-benchmark plan used to define EHBs in a Medicaid ABP or BHP standard health plan.

We sought comment on the proposal to consolidate State EHB-benchmark plan options under § 156.111(a).

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed, though for the reasons described earlier, we are finalizing this change for plan years beginning on or after January 1, 2026, rather than for plan years beginning on or after January 1, 2027, as was proposed. We summarize and respond to public comments received on the proposed consolidation of State EHB-benchmark plan options under § 156.111(a) below.

Comment: Many commenters supported the proposal to consolidate

State EHB-benchmark plan update options at § 156.111(a), citing their belief that this simplification would reduce confusion and burden (for example, cost and time) for States seeking to update their EHB-benchmark plans. In turn, commenters also noted that enabling States to more easily and, perhaps therefore more frequently, update their EHB-benchmark plans could result in expanded coverage for, among other things, maternity care, substance use disorder care, obesity care, and chronic disease management. Finally, commenters also suggested that, if States can more easily and frequently update their EHB-benchmark plans as a result, in part, of the proposed consolidation, EHB-benchmark plans may more closely align to currently available typical employer plans, consistent with the statutory linkage between EHB-benchmark plans and typical employer plans.

Response: As noted earlier in this final rule, CMS has previously received feedback from State regulators suggesting that the current EHB-benchmark plan update process can be confusing and burdensome. We proposed to consolidate the options for EHB-benchmark plan updates at § 156.111(a) with this feedback in mind and appreciate commenters' indication that they see this policy as achieving the goals of making the EHB-benchmark plan update process easier to understand and undertake.

Comment: Several commenters opposed the proposal to consolidate State EHB-benchmark plan update options at § 156.111(a). However, commenters opposing the proposed consolidation spoke about their opposition to the proposed changes to the EHB-benchmark plan update process more generally—they did not raise specific concerns regarding consolidation. For example, one opposing commenter stated that the current EHB-benchmark plan update process is working well and strikes an effective balance between ensuring consumers have access to needed coverage, while also allowing States to make updates responsive to the needs of their constituents. Thus, the commenter did not believe the proposed updates, including to § 156.111(a), should be finalized as proposed, but did not identify any specific legal or operational issues that might result from the proposed consolidation.

Response: While we appreciate this feedback, we do not agree that the current EHB-benchmark plan update process is adequately streamlined, given the feedback discussed earlier from States indicating that the current

requirements are both difficult to understand and cumbersome to implement.

b. Scope of Benefit Requirements

We proposed to revise the scope of benefit requirements at § 156.111(b)(2) for plan years beginning on or after January 1, 2027, with corresponding proposed revisions to the actuarial requirements at § 156.111(e)(2). Specifically, we proposed at § 156.111(b)(2)(ii) that a State's new EHB-benchmark plan would be required to provide a scope of benefits that is equal to the scope of benefits of a typical employer plan in the State, and that the scope of benefits of a typical employer plan in the State would be defined as any scope of benefits that is as or more generous than the scope of benefits in the State's least generous typical employer plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), and as or less generous than the scope of benefits in the most generous typical employer plan in the State (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), among the typical employer plans currently defined at § 156.111(b)(2)(i)(A) and (B). We proposed to remove the generosity standard currently at § 156.111(b)(2)(ii). We also proposed a technical clarification to the language regarding supplementation at § 156.111(b)(2)(i), which currently states that a State's new EHB-benchmark plan must "provide a scope of benefits equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan" (emphasis added), to state that a State's EHB-benchmark plan must provide a scope of benefits equal to the scope of benefits provided under a typical employer plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)).

Under 42 CFR 440.347, Medicaid ABPs authorized under section 1937 of the Act are required to meet EHB standards. Under 42 CFR 600.405, in States that elect to operate a BHP, the standard health plans are required to meet EHB standards. We explained in the proposed rule that the changes to State EHB-benchmark plan requirements would also be applicable to States when choosing an EHB-benchmark plan used to define EHBs in a Medicaid ABP or a BHP standard health plan.

We sought comment on the proposals to revise the typicality standard at § 156.111(b)(2)(i), remove the generosity standard at § 156.111(b)(2)(ii), make corresponding edits to § 156.111(e)(2), and make a technical revision to the language regarding supplementation at § 156.111(b)(2)(i).

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed though, for the reasons described earlier, we are finalizing these changes for plan years beginning on or after January 1, 2026, rather than for plan years beginning on or after January 1, 2027. We summarize and respond to public comments received on these proposals below.

Comment: A majority of commenters supported the proposal to amend the typicality standard at § 156.111(b)(2)(i). These commenters affirmed that moving from a typicality standard under which States must identify a typical employer plan option that exactly matches the value of their proposed EHB-benchmark plan to an approach that sets a lower and upper boundary on the value of a typical employer plan will reduce the time and cost for assessing the value of individual typical employer plan options. Moreover, commenters expressed their belief that a range-based approach to typicality will provide States with additional flexibility to design innovative, responsive EHB-benchmark plans without the artificial constraint of matching with exact precision the value of a specific typical employer plan option.

Commenters indicated that the decreased burden and increased flexibility provided by the updates to the typicality standard will incentivize States to contemplate EHB-benchmark plan updates more frequently to keep pace with both the needs of their consumers and the evolving scope of benefits typically provided by employer plans. Commenters noted this is a particularly desirable outcome, given that only nine States have updated their EHB-benchmark plans to date, and many of those changes have been modest.

Commenters noted that, in light of the reduced costs and time States must allocate to update their EHB-benchmark plan under the proposed change, States may consequently be able to devote more of their attention and energy towards assessing the most optimal package of benefits to provide under their new EHB-benchmark plan, including through more robust public engagement efforts.

Response: We appreciate these commenters' confirmation of our assertion that the revised typicality standard will be conceptually and operationally more straightforward and less burdensome. We share commenters' interest in supporting States to contemplate EHB-benchmark plan updates as often as may be necessary to best meet the needs of their consumers, without needing to satisfy unnecessary or excessively burdensome typicality requirements.

Comment: A few commenters opposed the proposed updates to the typicality standard under at § 156.111(b)(2)(i). Commenters indicated their concern that the proposed changes could threaten the connection between the statutory requirements for typicality set forth by the ACA and the regulatory framework implementing these requirements. Commenters also expressed that a more flexible approach to typicality could expose the Federal Government to increased costs to the extent EHB-benchmark plans are more frequently updated with additional benefits. Commenters noted that such changes would necessitate greater Federal outlays in the form of additional Federal expenditure on subsidization of plan premiums through APTCs.

Response: We do not agree that the adjustments proposed to the typicality standard would erode the implementation of the ACA typicality requirement in the EHB-benchmark plan update process. We believe that the new typicality standards will strike an appropriate balance between easing State burden and ensuring that the scope of benefits considered EHB stays closely aligned to the scope of benefits typically provided by employers. Specifically, the typicality standard has previously required that States identify a single typical employer plan option offering an equivalent scope of benefits to the scope of the proposed EHB-benchmark plan, which has required States to: (1) analyze many typical employer plan benefit offerings until a match is identified (which could require both significant time and cost to the State), and/or (2) require States to offer a set of benefits as EHB that they believe is not as well suited to the needs of their population in order to achieve an exact scope of benefits that matches the scope of benefits offered by one specific typical employer plan, rather than, for example, selecting an EHB-benchmark plan that offers a scope of benefits that is greater than that offered by one typical employer plan, but not as great as the next-most-generous typical employer plan. Under the amended

typicality standard, States may need to only assess the value of two typical employer plans: the least generous and the most generous. This means that States can avoid additional time and cost for actuarial assessment. And, once States have identified the least and most generous typical employer plan options, they then have the flexibility to select an EHB-benchmark plan with a scope of benefits that falls anywhere along the continuum between the scope of the least and most generous plans. Further, we reiterate that the revised typicality standard maintains both a floor and a ceiling on the generosity of benefits considered EHB, which serves to ensure States can, at most, increase the scope of benefits provided by their EHB-benchmark plan to match, or be more generous than, to the extent supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided by the most generous typical employer plan. As such, Federal expenditures in the form of APTC are constrained to increase, at most, only as much as typical employer plans are also increasingly generous over time, which has always been the case under the typicality standard at § 156.111.

Comment: A majority of commenters also supported the removal of the generosity standard at § 156.111(b)(2)(ii), explaining that removing the generosity standard will make the EHB-benchmark plan update process easier to understand, less burdensome to execute, and more adaptable to the needs of each State's population. Commenters also explained that the elimination of the generosity standard will ensure that States can better incorporate in EHB-benchmark plans any changes to the scope of benefits in typical employer plans since 2017.

Commenters noted that, with the updates to the typicality standard and the elimination of the generosity standard, the scope of benefits provided by the most generous typical employer plan can now reflect the scope of benefits provided by the most generous large group typical employer plan. Commenters indicated that large group plans are more generous than the other plan options available for use in a State's typicality analysis, such that the updates to these policies taken together will provide States the opportunity to provide a potentially more generous package of EHB through their EHB-benchmark plan than they could previously.

Commenters suggested that by eliminating the generosity standard, States can better incorporate benefits

that consider the health care needs of diverse segments of the population as EHB. Commenters note this is of particular importance given the evolution of new approaches to address gaps in care for members of marginalized communities and those who have traditionally experienced inequitable health outcomes.

Several commenters opposed the proposed removal of the generosity standard at § 156.111(b)(2)(ii). These commenters suggested that removing the generosity standard could allow the scope of benefits in EHB-benchmark plans to outpace the scope of benefits provided by typical employer plans. Further, some commenters asserted, without the generosity standard, there would be no constraints on how generous a State could elect to make its EHB-benchmark plan and allow a State to manipulate the EHB-selection process to impermissibly expand the scope of benefits beyond what the ACA intended. Specifically, a few commenters expressed concern that, in conjunction with the proposed change at § 155.170 with regard to State-mandated benefits included in the EHB-benchmark plan, removing any constraint on EHB-benchmark plan generosity would enable States to subvert the requirement to defray the costs of mandated benefits, simply by adding all existing and future mandated benefits to their benchmark plan. Commenters expressed concerns about coverage becoming potentially unaffordable for consumers and costly for the Federal Government, in the form of increased APTCs.

Response: In the proposed rule (88 FR 82596), we acknowledged that the proposed removal of the generosity standard would also establish an upper bound for State EHB-benchmark plan selections that better tracks with the scope of benefits in typical employer plans as they change over time. We agree with commenters that larger group plans tend to be more representative of typical employer plans as they change over time, especially given that since small group health plans are required to provide the EHB, it may be less appropriate to rely on the scope of benefits in small group plans to assess the benefits typically provided in employer plans. Evidence also suggests that the generosity of larger group employer plans has moderately increased since the passage of the ACA. We also believe that, in conjunction with the more flexible range-based approach to typicality, a higher available upper bound for EHB-benchmark plan generosity will allow States greater flexibility to ensure EHB-

benchmark plans reflect evolving standards of care and are well-positioned to address long-standing health disparities.

We disagree with commenters' assertion that removing the generosity standard will jeopardize the connection between the EHB-benchmark plan update process and the ACA's typicality requirement. The typicality standard, which this rule amends but does not eliminate, ensures that EHB-benchmark plans cannot offer a scope of benefits that is more generous than the scope of benefits provided by the most generous typical employer plan available for comparison, except to the extent supplementation is required to provide coverage within each EHB category at § 156.110(a). As such, we believe that commenters' concern about affordability are largely disproportionate to the meaningful but modest increases the proposed changes represent to the range of plan generosity available to States when seeking to update their EHB-benchmark plans.

Nevertheless, we understand commenters' concerns that the amendments to §§ 155.170 and 156.111 could technically allow States to game the scope of benefits of the available typical employer plans in the State by mandating the coverage of benefits in large group market plans in the State. While we recognize this as a technical possibility available to States, we are not concerned that will in occur in practice. Based on our experience working with States and their selection of EHB, we understand that States are already motivated to minimize the cost impacts of additional benefit coverage in all markets, and thus do not believe it likely that States would impose benefit mandates on their large group markets solely to manipulate the typical employer plans available for comparison when seeking to change their EHB-benchmark plan. For those States that do enact benefit mandates on large group markets, our expectation is that States do so in order to improve the coverage of benefits in such plans to accommodate changes in medical evidence and scientific advancement, and not to specifically subvert Federal guidelines for changing EHB-benchmark plans. This is especially the case given that, in our experience, State legislatures typically enact mandated benefits on large group market plans with little consideration for their impact on EHB. In any event, commenters did not provide any insight on how one might distinguish between a State mandate on large group market plans designed to improve coverage in such plans and a mandate designed to allow

the State to game the scope of benefits of the available typical employer plans in the State.

We believe that States understand that it is implicit that applications must be submitted in good faith, and that States may not submit applications in good faith if a State mandates the coverage of specific benefits in large group market plans with the specific intent to manipulate the scope of benefits of the available typical employer plans. We are likely to suspect that a State may be gaming its typical employer plans if it enacts a mandate for the coverage of specific benefits in large group market plans and soon thereafter seeks to add similar benefits to its EHB-benchmark plan by utilizing a large group market plan that is impacted by the State's mandate as the most generous typical employer plan. We caution States that attempt to update EHB-benchmark plans in this manner that, pursuant to § 156.111(b)(2)(ii)(B)(1) and (4) as finalized in this rule, a large group typical employer plan must, among other things, belong to a product that has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State and be from a plan year beginning after December 31, 2013. We interpret that these provisions work together to mean that, while a State can select a recent large group market plan as a typical employer plan, enough time must pass between the effective date of the coverage of all large group market plans in the State for the State to make a determination that the selected plan's product has at least 10 percent of total enrollment of the five largest large group health insurance products in the State. This means a State cannot select a large group plan with an effective date that begins in the first months of the year that the State submits an application to change EHB-benchmark in May. Thus, from a timing perspective, States are not able to select a large group typical employer plan that is effective in the same year or that may be effective in a year following the year the State submits an EHB-benchmark plan application. Given this operational constraint, at this time, we do not believe it is necessary to propose a cooldown period that would prevent a State from using a large group market plan that is impacted by a State's recent benefit mandate as the most generous typical employer plan, but will consider such a cooldown period for potential future rulemaking if necessary. In addition, we clarify the interaction between the amendments to § 156.111 and the amendment to § 156.122 that

codifies that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB. As explained in the proposed rule and in the preamble of this final rule addressing § 156.122, when the amendment to § 155.170 is read in conjunction with the proposed amendment to § 156.122, any prescription drug that an issuer covers in excess of the State's EHB-benchmark plan is EHB *unless* there is a State mandate requiring such coverage. Accordingly, a State that mandates the coverage of prescription drugs in excess of a State's EHB-benchmark plan cannot consider coverage of the excess drugs as EHB for purposes of completing the actuarial analyses required under § 156.111(e).

Comment: One commenter asserted that any changes to a State's EHB-benchmark plan should also apply to the process by which a State selects a benchmark plan used to determine EHBs in a Medicaid ABP or a standard health plan in the BHP.

Response: In accordance with implementing Medicaid regulations found at 42 CFR 440.347, ABPs must contain EHB coverage in accordance with the requirements set forth at 45 CFR part 156. Similarly, BHP regulations at 42 CFR 600.405, require standard health plan coverage to include, at a minimum, EHB as described under §§ 156.110 and 156.122 regarding prescription drugs. Therefore, the amendments to § 156.111 will impact how States define EHBs that apply to the ABPs and the BHP, as we explained in the proposed rule.

c. Drug Formularies

We proposed to revise § 156.111(e)(3) to require States to submit a formulary drug list as part of their documentation provided to change EHB-benchmark plans only if the State is seeking to change its prescription drug EHB. Currently, we require States to submit a formulary drug list if the State is selecting its EHB-benchmark plan using the option at current § 156.111(a)(3), even if the State is not seeking to change its prescription drug EHB. We stated in the proposed rule that we understand that creation and submission of this formulary drug list creates a significant amount of burden for the State. Since we can carry over the State's existing prescription drug EHB, as defined under § 156.122, without substantial input from the State if the State is not seeking to change its prescription drug EHB, we proposed to revise § 156.111(e)(3) as specified to reduce the burden on States.

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed though, for the reasons described earlier, we are finalizing this change for plan years beginning on or after January 1, 2026, rather than for plan years beginning on or after January 1, 2027, as was proposed. We summarize and respond to public comments received on this proposal below.

Comment: Several commenters supported the proposal to require States to submit formulary drug lists as part of an EHB-benchmark plan update application only if the State is seeking to adjust its prescription drug EHB. Commenters indicated that requiring such submission even in the absence of any intended prescription drug EHB changes was unnecessarily burdensome and created an additional hurdle for States seeking to update their EHB-benchmark plans. Conversely, commenters suggested that removing this requirement except in cases where States are seeking to change their prescription drug EHB would facilitate easier and more frequent EHB-benchmark plan updates.

Response: We agree with commenters' assessment that requiring a formulary drug list even in cases where States are not seeking to change their prescription drug EHB is unnecessary, and a poor use of a State's resources. We also agree that reducing the barriers for States seeking to update their EHB-benchmark plans, in this way and others, may enable States to take up more frequent EHB-benchmark plan updates.

Comment: A few commenters opposed the proposal to require formulary drug lists only in cases where States seek to change their prescription drug EHB. However, these commenters did not articulate a specific objection to this proposal. Rather, for example, some of these commenters more generally asked that CMS retain the prior policy while also seeking to provide detailed assistance to support States as they endeavor to update their EHB-benchmark plans.

Response: We continue to believe, as was affirmed by supporting commenters, that requiring States to submit a formulary drug list even when they do not seek changes to their prescription drug EHB creates burdens that can be removed without negative impact to the comprehensiveness of an EHB-benchmark plan application. As such, we believe that removing this requirement will reduce the cost and time needed for States to apply to update their EHB-benchmark plans

while maintaining rigorous standards for the quality of such applications.

3. Provision of EHB (§ 156.115)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82597), we proposed to remove the regulatory prohibition at § 156.115(d) on issuers from including routine non-pediatric dental services as an EHB.

In the EHB Rule, we finalized at § 156.115(d) that issuers of a plan offering EHB may not include, among other services and benefits, routine non-pediatric dental services as an EHB, even if the State's current EHB-benchmark plan includes such services as covered benefits. Section 1302(b)(2) of the ACA directs the Secretary, in defining the EHB, to ensure that they are equal in scope to the benefits provided under a typical employer plan. In the proposed EHB Rule (77 FR 70644), in support of the prohibition at § 156.115(d), we stated that routine non-pediatric dental services are not typically included in the medical plans offered by employers and are often provided as excepted benefits by the employer. In the proposed rule, we explained that we now believe a more natural reading of Section 1302(b)(2) of the ACA is one that considers all the benefits typically covered by employers. This means EHB should be equal in scope to the benefits provided under a typical employer plan, regardless of whether such benefit is historically considered a non-excepted "health benefit" or whether such benefit is "typically covered" by an employer's major medical plan. Given that oral health has a significant impact on overall health and quality of life,²⁷⁰ and several commenters on the EHB RFI²⁷¹ advocated for non-pediatric dental EHB coverage, we proposed specifically to remove the regulatory prohibition on issuers from including routine non-pediatric dental services as an EHB. We sought comment on whether similar changes should be proposed with regard to routine non-pediatric eye exam services and long-term/custodial nursing home care benefits as well.

In the proposed rule, we stated it appears that routine non-pediatric dental services are commonly covered

²⁷⁰ Spanemberg, J.C., Cardoso, J.A., Slob, E.M.G.B., & López-López, J. (2019). Quality of life related to oral health and its impact in adults. *Journal of Stomatology, Oral and Maxillofacial Surgery*, 120(3), 234–239. <https://doi.org/10.1016/j.jormas.2019.02.004>.

²⁷¹ For example, see <https://www.regulations.gov/comment/CMS-2022-0186-0567>; <https://www.regulations.gov/comment/CMS-2022-0186-0586>; and <https://www.regulations.gov/comment/CMS-2022-0186-0626>.

as an employer-sponsored or other job-based benefit to a degree that warrants removing the prohibition on their provision as an EHB. We cited various sources to support this assertion, including KFF's 2019 Employer Health Benefits Survey results, which indicated that among firms offering health benefits in 2019, 59 percent of small firms (3–199 workers) and 92 percent of large firms (200 or more workers) offered a dental insurance program to their workers separate from the health plan(s).²⁷² We solicited comment on this understanding of the inclusion of routine non-pediatric dental services in employer-sponsored or other job-based benefits.²⁷³ Additionally, we stated that we believe prohibiting the inclusion of routine non-pediatric dental services as an EHB on the basis that they are not often covered by typical employer plans is a more restrictive reading of section 1302(b)(2) of the ACA than is warranted by a plain reading of the statute. Section 1302(b)(2) of the ACA states that, in defining the EHB, the Secretary shall ensure that the scope of the EHB is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary and as informed by a survey by the Secretary of Labor of employer-sponsored or other job-based coverage to determine the benefits typically covered by employers. We explained that in considering the benefits typically covered by employers, this statutory section does not require the Secretary to consider only those benefits provided in major medical plans. We further stated that it also does not require the Secretary to consider only those benefits that are strictly “health benefits,” if such a term excludes coverage of routine non-pediatric dental services. Therefore, we stated that we no longer believe the prohibition on non-pediatric dental services as an EHB is warranted. Accordingly, we proposed to remove the regulatory prohibition on including routine non-pediatric dental services as an EHB at § 156.115(d).

We explained in the proposed rule that removing the prohibition on issuers from including routine non-pediatric dental services as an EHB would remove

regulatory and coverage barriers to expanding access to routine non-pediatric dental benefits for those plans that must cover EHB. We further stated that this would allow States to work to improve adult oral health and overall health outcomes, which are disproportionately low among marginalized communities such as people of color and people with low incomes.²⁷⁴ We refer readers to the proposed rule (88 FR 82597 through 82598) for further discussion of the impact of oral health on overall health and quality of life.

We explained in the proposed rule that this proposed policy would also align with CMS' Oral Health Cross Cutting Initiative, which aims to implement policy changes and consider opportunities through existing authorities to expand access to oral health coverage.²⁷⁵ Additionally, we stated that it would align with the request of several commenters on the EHB RFI (87 FR 74097) for us to remove regulatory and coverage barriers to expanding access to routine non-pediatric dental care.

In the proposed rule, we emphasized that the removal of this prohibition would not, by itself, mean that routine non-pediatric dental services would be an EHB, even in States with an EHB-benchmark plan that currently describes routine non-pediatric dental services as a non-EHB covered benefit. We stressed that this proposal would not require any State to add such services as an EHB, nor would we consider any existing language regarding routine non-pediatric dental services in any State's current EHB-benchmark plan to have the effect of adding such services as an EHB. We stated that under this proposal, a State seeking to provide any routine non-pediatric dental services as an EHB would be required to update its EHB-benchmark plan to include such services as an EHB pursuant to § 156.111. We explained that if a State does not update its EHB-benchmark plan to add coverage of routine non-pediatric dental services as an EHB, then such services would not be an EHB, even if the current EHB-benchmark plan document includes routine non-pediatric dental services.

We explained in the proposed rule that under this proposal, we would expect States, in determining whether it

is appropriate to update their EHB-benchmark plan to add routine non-pediatric dental services as an EHB, to weigh the advantages of expanded dental services against the challenges of providing such services. We refer readers to the proposed rule (88 FR 82598) for further discussion.

We noted that while section 1302(b)(4)(F) of the ACA permits a medical QHP sold on the Exchange to omit coverage of pediatric dental EHB services if a SADP is offered through an Exchange,²⁷⁶ there is no statutory basis to extend this exception to routine non-pediatric dental services. Thus, we stated that plans subject to an EHB-benchmark plan that includes routine non-pediatric dental services as an EHB may not omit such coverage on the basis that a SADP already provides such coverage through an Exchange.

We explained that this proposal, if finalized, may impact plans that are not directly subject to the EHB requirements, such as self-insured group health plans and fully-insured group health plans in the large group market, that are required to comply with the annual limitation on cost sharing and restrictions on annual or lifetime dollar limits in accordance with applicable regulations with respect to such EHBs.²⁷⁷ We further explained that if a State updates its EHB-benchmark plan to add coverage of routine non-pediatric dental services as an EHB and the sponsor of a self-insured group health plan or fully-insured group health plan in the large group market selects that EHB-benchmark plan, any routine non-pediatric dental services covered by such a group health plan would generally be subject to the limitation on cost sharing and restrictions on annual or lifetime dollar limits. However, we stated that if the sponsors of such plans offer coverage of routine non-pediatric dental services through an excepted benefit under 26 CFR 54.9831–1(c)(3), 29 CFR 2590.732(c)(3), and 45 CFR 146.145(b)(3), including a limited-scope dental plan, that benefit is generally excepted from complying with the group market reforms, including the limitation on cost sharing and restrictions on annual or lifetime dollar limits.

Additionally, under 42 CFR 440.347, Medicaid ABPs authorized under section 1937 of the Act are required to

²⁷² KFF (2019, September 25). *2019 Employer Health Benefits Survey*. <https://www.kff.org/report-section/ehbs-2019-section-2-health-benefits-offer-rates/#figure217>.

²⁷³ Section 156.115(d) also currently prohibits routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, and non-medically necessary orthodontia as EHB. We did not propose to remove the prohibition on including such services as EHB in the proposed rule; however, we solicited comment on the extent to which employer-sponsored or other job-based benefits provide coverage for these services.

²⁷⁴ Northridge, M.E., Kumar, A., & Kaur, R. (2020). Disparities in Access to Oral Health Care. *Annual review of public health*, 41, 513–535. <https://doi.org/10.1146/annurev-publhealth-040119-094318>.

²⁷⁵ CMS. (n.d.) *Strategic Plan Cross-Cutting Initiatives*. <https://www.cms.gov/files/document/strategic-plan-overview-fact-sheet.pdf>.

²⁷⁶ See section 1311(d)(2)(B)(ii) of the ACA for more information on offering SADP benefits.

²⁷⁷ See parallel requirements to § 147.126 at 26 CFR 54.9815–2711, and 29 CFR 2590.715–2711. Additionally, section 2707(b) of the PHS Act, as added by the ACA, was incorporated by reference into section 9815 of the Internal Revenue Code and section 715 of ERISA.

meet EHB standards. Under 42 CFR 600.405, in States that elect to operate a BHP, the standard health plans are required to meet EHB standards. We explained that under this proposal, States would be permitted to include routine non-pediatric dental services as EHB for purposes of their ABPs or BHP standard health plans.

We sought comment on the proposal to revise § 156.115(d) to remove the regulatory prohibition on issuers from including routine non-pediatric dental services as an EHB, and whether other impacts should be considered, including the impact this proposal would have, if finalized, on health insurance coverage in the individual, small group, and large group markets, as well as self-insured plans.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision, as proposed, to remove the regulatory prohibition at § 156.115(d) on issuers from including routine non-pediatric dental services as an EHB. We also finalize that the changes at § 156.115(d) will be effective beginning with PY 2027. Pursuant to this effective date, if a State wants to add a routine non-pediatric dental benefit to its EHB-benchmark plan, the earliest it can do so is with the calendar year 2025 submission cycle, for applications due to CMS on or before May 7, 2025. Therefore, if CMS approves the application, then the changes would be effective in the State for plan years beginning on or after January 1, 2027. Further, we acknowledge that the annual limitation on cost-sharing for Exchange-certified stand-alone dental plans (SADPs), which is updated and published annually in the Letter to Issuers, is applicable to only to those services that are EHB and only to SADPs. We summarize and respond to public comments received on the proposed policy below.

Comment: A majority of commenters supported this proposal. Many of these commenters supported the proposal in part because of the important role oral health plays in overall health and/or quality of life. In particular, several commenters noted the important impact oral health has on chronic conditions including but not limited to diabetes, HIV/AIDS, and cancer. Several commenters also mentioned the importance of preventive care. A few commenters mentioned the connection between oral health and mental health. A few commenters also mentioned the importance of treating the “whole member.”

Response: We strongly agree with the commenters that oral health has a significant impact on overall health and quality of life.²⁷⁸ We prioritize the development and implementation of policies that promote the health and wellbeing of enrollees and will continue to direct our efforts towards improving overall health and quality of life. We also agree with commenters that it is crucial to treat the “whole member,” highlighting the importance of whole person health²⁷⁹ and the need for medical-dental integration.²⁸⁰ We also recognize the importance of preventive oral health care, the connection between oral health and chronic disease management, and the connection between oral health and mental health.

Comment: Many commenters supported this proposal because of its potential to improve oral health disparities and further health equity. More specifically, several commenters discussed the potential for improving low-income/economic disparities, rural disparities, racial disparities, and maternal health. On the other hand, one commenter disagreed that this proposal will lead to equitable access because of anticipated poor uptake by States.

Response: We strongly agree with the commenters who stated that this proposed policy has the potential to improve oral health disparities and achieve health equity. As we stated in the proposed rule (88 FR 82598), this amendment allows States greater flexibility to add benefits to improve non-pediatric oral health and overall health outcomes, which are disproportionately low among marginalized communities such as people of color and people with low incomes. Therefore, this policy will promote health equity by addressing non-pediatric oral health disparities and improving the health outcomes of vulnerable populations. We also agree with the specific oral health disparities that commenters highlighted—pertaining to economic disparities, rural disparities, racial disparities, and maternal health—which this policy can help address. We disagree with the comment that this policy will not lead to equitable access because of poor uptake by States, particularly in light of the other proposals finalized in this rule

to alleviate State burden in assessing the defrayal of State-mandated benefits and to change EHB-benchmark plans. Additionally, given the feedback we have received from States and relevant stakeholders on the EHB RFI and proposed 2025 Payment Notice, we believe States will add routine non-pediatric dental benefits as an EHB, and this will help reduce oral health disparities and improve health equity within these States' populations. This final policy provides States the option to add coverage of non-pediatric dental benefits as EHB and removes a barrier to this coverage that previously existed.

Comment: A few commenters requested to delay the finalization of this policy and requested the effective date be no sooner than PY 2027.

Response: We did not directly specify an effective date for this policy in the proposed rule; therefore, by default these changes would have become effective 60 days after the publication of the final rule in the **Federal Register**. We sought comment on the impact of this policy, acknowledging that issuers would need sufficient lead time in order to successfully operationalize it, and sought comment on whether other impacts should be considered. We acknowledged this policy is a departure from the prior policy and that issuers in States that choose to update their EHB-benchmark plan to include non-pediatric dental services may need to establish new networks of dental providers and address other operational needs to implement this change. Taking into consideration the comments received, we are finalizing that the changes at § 156.115(d) will be effective beginning with PY 2027. Pursuant to this effective date, a State seeking to add routine non-pediatric dental in PY 2027 would need to submit an EHB-benchmark plan application under § 156.111 by the EHB-benchmark plan update deadline of May 7, 2025, which would then be effective in the State for plan years beginning on or after January 1, 2027. We are finalizing this date with a change in the regulation text to account for this effective date.

We do not believe further delay of these changes is necessary. In PY 2024, approximately 9.9 percent of QHPs on the FFEs included coverage for some degree of routine non-pediatric dental services as non-EHB; thus, it is not unprecedented for health plans, including QHPs, to cover routine non-pediatric dental services as non-EHB. Accordingly, we expect that this experience will mitigate any operational challenges that States may face when adding such services as EHB.

²⁷⁸ Spanemberg, J.C., Cardoso, J.A., Slob, E.M.G.B., & López-López, J. (2019). Quality of life related to oral health and its impact in adults. *Journal of Stomatology, Oral and Maxillofacial Surgery*, 120(3), 234–239. <https://doi.org/10.1016/j.jormas.2019.02.004>.

²⁷⁹ <https://www.nccih.nih.gov/health/whole-person-health-what-you-need-to-know>.

²⁸⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6618181/>.

Further, State EHB-benchmark applications are due approximately 18 months before any change in EHB would be realized in plans. Before these applications are due, States have typically devoted several months or years interacting with interested parties in the State to understand what changes should be made to the EHB-benchmark plans, and what the impact of those changes would be. Thus, we expect ample time for issuers to operationalize the provision of routine non-pediatric dental services as EHB. Given that the finalization of this amendment would only begin to impact coverage beginning on January 1, 2027 in those States that might submit EHB-benchmark plan applications during the calendar year 2025 cycle, there will be sufficient lead time to allow issuers to build the infrastructure necessary to administer the routine non-pediatric dental benefits that States add as EHB. If a State is considering adding routine non-pediatric dental benefits as an EHB but believes it would be beneficial to take more time to assess the potential cost, operational, and other implications of the policy for their State, the State can wait to add this benefit to their EHB-benchmark plan until it is ready to do so.

Comment: The majority of commenters agreed with our reinterpretation in the proposed rule of the typical employer plan provision at section 1302(b)(2) of the ACA as one that considers all the benefits typically covered by employers, regardless of whether such benefit is historically considered a “health benefit” or whether such benefit is “typically covered” by an employer’s major medical plan or, for example, by a limited scope excepted benefits plan. As justification for their support of this reinterpretation, these commenters explained that the statutory text requires HHS to consider the benefits typically covered by employers in employer-sponsored coverage, without specifying whether that coverage is limited to the coverage provided in major medical plans. As a result, these commenters agreed that the previous interpretation was overly restrictive and unnecessarily denied access to basic and necessary services as EHB.

However, several commenters disagreed with HHS’s reinterpretation of this provision. These commenters asserted that the statutory text limits the EHB to those provided under a singular typical employer plan, and not all of the benefits provided by an employer under a combination of plans. Some of these commenters asserted that the ACA specifically excludes routine non-

pediatric dental services, routine non-pediatric eye exam services, and long-term/custodial nursing home care benefits from consideration as EHB. In these commenters’ view, HHS’s reinterpretation would impermissibly allow for the inclusion of any employer benefit as EHB, including employee assistance programs, short-term disability, critical illness, group life, legal assistance, and 401(k) benefits. These commenters also explained that, except for pediatric oral and vision services, all of the EHB categories explicitly mentioned in statute refer to benefits that have historically been considered “health benefits” that are typically covered under major medical plans and not excepted benefit plans. One commenter asserted that HHS’s reinterpretation would undermine statutory intent that the EHB be “essential benefits”, as it would include benefits that employers do not deem necessary to include in their major medical plan, but instead offer as a “voluntary add-on” for those employees who may desire them. Additionally, some commenters asserted that the majority of employers actively decide to provide routine dental services through a standalone dental plan rather than through a major medical plan.

Response: The ACA does not exclude routine non-pediatric dental services, routine non-pediatric eye exam services, and long-term/custodial nursing home care benefits from consideration as EHB; only the existing regulation at § 156.115(d), which this final rule now amends to remove the exclusion of routine non-pediatric dental services, prohibits health plans from covering such services as EHB. The statutory term “a typical employer plan” is ambiguous with regard to whether it references a single major medical plan, or the entire suite of benefits provided by the employer, and our updated interpretation is supported by the statutory directive for HHS to conduct a survey of employer-sponsored coverage to determine the benefits typically covered by employers without distinguishing whether this coverage is provided through one or more plans. Given this ambiguity, we do not agree with comments that the statutory text must be read to exclude coverage typically provided by employers through plans that are offered in addition to major medical coverage.

We disagree with commenters that employer-sponsored dental benefits cannot be considered an EHB simply because of the manner of the contractual arrangements by which employers provide benefits to their employees. The impact of routine dental care on overall

health and quality of life is not in question, nor is the fact that employers clearly view dental benefits as an essential part of the entire set of health benefits they provide for employees, given how many employers provide dental benefits to their employees.²⁸¹ That employers happen to provide those dental benefits through a separate contractual agreement seems a tenuous justification for prohibiting States from allowing adults to access as EHB something that can be as basic and impactful to overall health as routine dental care.

Further, we disagree with those commenters that claimed that employers have a choice whether to provide routine dental services through their major medical plan or through a standalone dental plan. We understand that, in many cases, the benefits that employers may select to cover for employees is contingent on the decisions made by health insurance companies on what benefits they want to make available for the employer’s selection.

We are not persuaded by commenters that insist the intent of the statute requires HHS to define the EHB in accordance with “benefits that have historically been considered a health benefit.” Many of the core tenets that support our modern understanding of health insurance as providing coverage of items and services are less than a hundred years old, and there is no universally understood set of essential items and services; even the ACA’s statutory text recognizes that HHS’s definition of the EHB need not be limited to the enumerated categories of EHB (“... the Secretary shall define the essential health benefits, except that such benefits shall include *at least* the following general categories and the items and services covered within the categories . . .” (emphasis added)).

The availability of benefits in health plans is always evolving. As a very limited example, consider that the very first health plans in the 1920s and 1930s only provided coverage for hospitalization, and coverage for professional services began later in the 1930s.²⁸² Psychiatric care first began to

²⁸¹ As these commenters pointed out, 91 percent of employers offer dental coverage that is separate from the coverage provided through their health plans. Source: Gary Claxton, Matthew Rae, Aubrey Winger, and Emma Wager, Employer Health Benefits: 2023, Kaiser Family Foundation, 2023, page 55 (<https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2023-Annual-Survey.pdf>).

²⁸² Institute of Medicine (US) Committee on Employment-Based Health Benefits; Field MJ, Shapiro HT, editors. Employment and Health Benefits: A Connection at Risk. Washington (DC):

be covered following World War II.²⁸³ Then, the first efforts to create parity between health benefits and mental health benefits began during President John F. Kennedy's administration with the requirement of the Federal Employees Health Benefits Program (FEHBP) to cover psychiatric illnesses at a level equivalent to general medical care.²⁸⁴ Benefits for the elderly, retired people, and those with disabilities or low-income became available through Medicare and Medicaid in the 1960s. Coverage for treatment of substance use disorders rose to prominence in the 1970s and 1980s. Medicare began covering hospice care in the early 1980s, the Emergency Medical Treatment and Active Labor Act (EMTALA) was passed in 1986, and Medicare Parts C and D were introduced in the early 2000s before the ACA was passed in 2010.²⁸⁵ These are just some of the examples of how benefits have expanded over the years, especially when such expansions have accounted for changes in medical evidence or scientific advancement. We therefore disagree with commenters' statement that there exists a set of "benefits that have historically been considered a health benefit" and disagree with commenters' concerns that it is unreasonable or unprecedented to now include routine non-pediatric dental care in this evolution.

Regardless of how one interprets statutory text, one intent of the ACA with regard to the EHB is clear—that enrollees should have access to a minimum set of benefits that take into account the health care needs of diverse segments of the population.²⁸⁶ Given that routine dental services consist of relatively basic items and services rendered by licensed dentists and allied health professionals to improve the health of an individual, it is reasonable for a State to determine that the provision of such benefits among this minimum set of benefits as EHB is necessary to accommodate the health care needs of its population.

We also note that commenters opposing the policy made no argument regarding the treatment of *non-routine* non-pediatric dental care, such as treatment for natural teeth or dental prostheses as a result of an injury, which are not currently prohibited as

EHB by § 156.115(d). Such non-routine dental benefits have long been included as EHB, given that they are among the covered benefits described in the vast majority of EHB-benchmark plans. Thus, it is hardly unprecedented for at least some non-pediatric dental benefits to be covered as EHB by health insurance plans.

Comment: One commenter explained that HHS's reinterpretation of the typical employer plan provision conflicts with the typicality standard at § 156.111(b)(2) that limits the plans available for the typicality analysis to major medical plans. This commenter also asserted that the proposal failed to grapple with the reliance interests engendered by the interpretation that the "typical employer plan" is a major medical plan.

Response: In the 2019 Payment Notice, we added § 156.111 to give States additional options for changing EHB-benchmark plans and implemented the typicality standard with an actuarial approach. As implemented, the typicality standard requires the State's proposed EHB-benchmark plan to provide a scope of benefits equal to the scope of benefits provided under a typical employer plan, in accordance with section 1302(b)(2) of the ACA. At § 156.111(b)(2) we selected as the specified examples of a typical employer plan: the selecting State's 10 base-benchmark plan options established at § 156.100 and available for the selecting State's selection for the 2017 plan year, and a set of large group health insurance plans in the State, provided certain requirements are met under current § 156.111(b)(2)(i)(B)(1)–(4). In order for a State to select one of these large group health insurance plans as the typical employer plan for the typicality standard, the following requirements must be met: (1) the plan must have at least 10 percent of the total enrollment of the five largest large group health insurance products in the State; (2) the plan must provide minimum value, as defined under § 156.145; (3) the plan's benefits must not be excepted benefits, as established under § 146.145(b) and § 148.220; and (4) the benefits in the plan must be from a plan year beginning after December 31, 2013.

In the 2019 Payment Notice (83 FR 17012), we stated that "a State's EHB-benchmark plan may not have the exact same benefits and limits as the typical employer plan the State identifies under this policy." However, this actuarial approach, which restricts the range of typical employer plans to which an EHB-benchmark plan can be compared, coupled with the requirement that the EHB-benchmark plan cover items and

services in each of the 10 specified categories of EHB, assures that the scope of benefits of the EHB-benchmark plan is equal to that of a typical employer plan.

Restricting the set of group health plans for the typicality standard to major medical plans merely establishes this actuarial benchmark for State EHB selections in a manner that balances State flexibility, ease of implementation, and a limitation on the range of what can be considered a typical employer plan.

When we originally implemented § 156.115(d) to prohibit issuers from covering routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, and non-medically necessary orthodontia as EHB, we did so based on a finding that "they are not typically included in medical plans offered by a typical employer." However, this finding did not conclude that such benefits are never included in such plans. In addition, such a finding only justifies the prohibition of designating certain benefits as EHB; it does not prohibit a State from including such benefits in their typicality analysis, to the extent such benefits are present among the set of typical employer plans designated by HHS. Put another way, nothing in regulation prohibits a State from including the quantitative value of routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia in its typicality analysis. Rather, we simply did not include non-major-medical benefits in the selected range of typical employer plans for ease of comparability.

Comment: Many commenters supported this proposal because it promotes State flexibility. One commenter explained that they are supportive of proposals that offer additional flexibility to States and allow States to make decisions that best meet the needs of consumers. Another commenter explained that determining exactly which dental benefits should include EHB protections should be based on State needs and preferences. Several other commenters believed HHS should require all States to include routine non-pediatric dental benefits as an EHB, potentially in the ambulatory or preventive services EHB categories. These commenters argued that given HHS's interpretation of non-pediatric dental services as commonly included as part of typical employer-sponsored plans, adding non-pediatric dental benefits as a required coverage category under EHB is the logical next step.

National Academies Press (US); 1993. 2, Origins and Evolution of Employment-Based Health Benefits. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK235989/>.

²⁸³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2950754/>.

²⁸⁴ *Id.*

²⁸⁵ <https://www.kff.org/wp-content/uploads/2011/03/5-02-13-history-of-health-reform.pdf>.

²⁸⁶ See section 1302(b)(4)(C) of the ACA.

Response: We agree with the commenters who mentioned that this proposal promotes State flexibility. This proposal aligns with CMS' State-based approach to EHB-benchmark plans and the ability for States to update them, in that, like any other benefit, States would have the option to add routine non-pediatric dental services as an EHB. We stress that the finalization of this proposal does not require any State to add such services as an EHB, nor would we consider any existing language regarding covered routine non-pediatric dental services in any State's current EHB-benchmark plan to have the effect of automatically adding such services as an EHB without further State action. We are therefore not adopting those commenters' suggestions to require the coverage of routine non-pediatric dental services as an EHB.

Comment: Many commenters raised potential operational impacts associated with States adding routine non-pediatric dental as EHB. Several commenters expressed that such an addition would present operational difficulties, including establishing new administrative and IT capabilities, and developing networks of dental providers. A few commenters expressed concern over issues with Current Dental Terminology (CDT) codes (for example, issuers' lack of experience with or infrastructure working with CDT codes, which may lead to cost concerns, additional premiums, and an overall increase in health care spending). A few commenters also requested to delay the finalization of this policy and requested the effective date be no sooner than PY 2027. A few commenters expressed concern regarding the impact on stand-alone dental premiums sold on the Exchange if routine non-pediatric dental benefits were to be included in a State's EHB-benchmark plan, and potential disparities between dental plan premiums on- versus off-Exchange. Moreover, many commenters questioned the impact this policy would have on other Federal provisions, including but not limited to provisions addressing: AV, MLR, network adequacy, APTC, and the premium adjustment percentage index (PAPI). One commenter suggested a separate dental MLR for dental EHB.

Response: We acknowledge the operational concerns raised by commenters. As we stated in the proposed rule (88 FR 82598), we expect States to weigh the advantages of expanded dental services against the challenges of providing such services. We also acknowledged the need for States to consider that issuers may need to establish new networks of dental

providers and that some plans may not currently have infrastructure or experience working with CDT codes. We agree that, for health plans that do not directly reimburse using dental codes, the transition to new coding would require investments in technology, staff, and internal expertise. We also agree this may lead to additional premiums and an overall increase in health care spending. However, as we emphasized in the proposed rule, a contract arrangement with issuers of stand-alone dental plans to administer these services is an option that issuers could pursue, which could mitigate some of the need to establish new administrative and IT capabilities. We emphasize that for States planning to update their EHB-benchmark plan to include routine non-pediatric dental benefits, it will be up to those States to work with issuers and other interested parties to determine to what extent operational challenges exist and whether it is feasible to overcome such challenges. In addition, any State considering the addition of such benefits should specifically seek feedback from interested parties on operational challenges as part of the public notice and an opportunity for public comment requirement at § 156.111(c).

We do not disagree with commenters that this policy may be disruptive to those issuers in States that add routine non-pediatric dental services as EHB; indeed, the intent of this policy was to effect a change in the availability of high-priority, high-impact, and relative low-cost benefits as EHB in order to improve the overall health of large segments of the population, and we cited several of these challenges in the proposed rule. We are sympathetic to the upfront costs that may be incurred by issuers to create the infrastructure necessary to administer routine dental benefits, or to contract with third parties to administer such a benefit on the health plan's behalf. However, we believe action is justified given the likelihood that it results in significant public health improvements. In addition, we expect States to take these burdens into account in determining whether to add routine non-pediatric dental services as EHB.

We also do not agree with the commenters' concerns regarding this amendment's impact on stand-alone dental premiums sold on the Exchange if a State adds routine non-pediatric dental benefits as EHB, and potential disparities between dental plan premiums on- versus off-Exchange. Under §§ 146.145(b)(3) and 148.220(b)(1), limited-scope dental

plans are considered excepted benefits that are not required to provide the EHB. Thus, if a State adds routine non-pediatric dental benefits as EHB, stand-alone dental plans are not required to cover such benefits, whether on- or off-Exchange.

We also acknowledge the commenters that questioned the impact this policy will have on other Federal provisions, including but not limited to provisions addressing AV, MLR, network adequacy, APTC, and PAPI. This final provision will not affect these programs any differently than any other benefits that a State adds to its EHB-benchmark plan, since States that seek to add routine non-pediatric dental services will need to adhere to the same requirements for updating their EHB-benchmark plans as they would for other benefits. We do encourage States adding routine non-pediatric dental services to ensure that issuers' networks include sufficient dental providers so that enrollees can access the benefit.

Comment: A few commenters explained that the risk profile of adults seeking dental care poses challenges for issuers, including the potential for adverse selection. This commenter expressed that enrollees could delay care until they have coverage, seek care for expensive procedures, and then drop coverage when the work is complete.

Response: We do not foresee that adverse selection will be a significant problem and would like to emphasize that the ACA has established means to help prevent unchecked adverse selection, including the risk adjustment program, premium subsidies, and limited enrollment windows. Specifically, enrollees must enroll during open enrollment or a special enrollment period. There is nothing specific or unique to dental coverage that would cause an enrollee to drop coverage midyear, other than possible pent-up demand for services due to the fact that coverage as EHB was previously not possible. However, based on prior experience under the ACA, and given that States will have to make difficult and careful decisions regarding which benefits to add given the regulatory requirements for EHB-benchmark plan updates, we do not believe that the addition of benefits will cause significant adverse selection. Additionally, adverse selection has not been a significant concern in prior EHB-benchmark plan applications.

Comment: A few commenters argued that CMS should allow for standalone non-pediatric dental plans to provide benefits as EHB on the Exchanges.

Response: Although we appreciate commenters' request to allow

standalone non-pediatric dental plans to provide benefits as EHB and to permit such plans on the Exchanges, as explained in the proposed rule, there is no statutory authority to do so. While section 1302(b)(4)(F) of the ACA permits a medical QHP sold on the Exchange to omit coverage of pediatric dental EHB services if an SADP is offered through an Exchange,²⁸⁷ there is no statutory basis to extend this exception to routine non-pediatric dental services. Non-pediatric dental services would fall under ambulatory patient services, § 1302(b)(1)(A), and not pediatric services, § 1302(b)(1)(J). Thus, plans subject to an EHB-benchmark plan that include routine non-pediatric dental services as an EHB may not omit such coverage on the basis that a standalone dental plan already provides such coverage through an Exchange.

Comment: Many commenters noted cost impacts to consider when implementing this proposal. More specifically, many commenters expressed cost concerns, including the cost impacts the proposal could have on networks. Commenters noted this includes outsized impacts on small group health plans. These commenters explained that this proposal could result in issuers leaving the market. A few commenters expressed concerns over lack of cost controls if non-pediatric dental is an EHB. For example, these commenters expressed concern that no annual or lifetime coverage limits would apply to non-pediatric dental services if they were to be added as an EHB, which could drive up prices. One commenter noted that increased costs would have implications for QHPs in the individual and small group markets, including making it more difficult to offer standalone dental benefits at a price that is attractive to consumers, making QHPs with embedded dental benefits less affordable for consumers who do not qualify for a premium subsidy, and increasing the cost of Federal subsidies. Another commenter encouraged CMS to carefully weigh the benefit of expanded access to routine non-pediatric dental benefits versus the impact increased premiums may have on coverage retention. On the other hand, a few commenters mentioned the positive impact this policy could have on reducing health care costs. A few commenters explained how routine dental care may yield downstream savings in overall health care expenditures given its potential to impede disease burden. Another commenter also explained how

emergency room department visits are very costly, and how if oral health problems are diverted to local dentist offices, large savings would ensue.

Response: We acknowledge the cost concerns raised by commenters, including the cost impacts it could have on networks. As we stated in the proposed rule (88 FR 82598), we expect States to weigh the advantages of expanded dental services against the challenges of providing such services. We also mentioned that States should consider the ability of plans to add such services as an EHB, which, as with pediatric oral care, may require plans to establish new networks of dental providers. Moreover, we mentioned that given the potential need for plans to establish new networks of dental providers, issuers could comply with this policy by contracting with issuers of standalone dental plans to administer these services, as long as it is seamless to the enrollee. This contracting arrangement would not be required, but it is permitted as an option. Furthermore, we agree with the commenters who stated that this policy would reduce health care costs by yielding downstream savings in overall health care expenditures and reducing costly emergency room department visits for dental care. We believe that the required public comment period that States must have when proposing to update their EHB-benchmark plans will become even more important considering this policy change. We also encourage States to work with issuers and other affected parties in their States before, during, and after applying to change their EHB-benchmark plan. Despite the prohibition on annual and lifetime dollar limits for benefits that are EHB and that States can choose how comprehensive the routine non-pediatric dental EHB will be, we are not swayed that this final policy will significantly increase premiums, and consequently, meaningfully increase Federal outlays, given that States' ability to increase benefit generosity is limited pursuant to the policy finalized at § 156.111(b)(2)(i). As we finalized in this final rule at § 156.111(b)(2)(i), we are revising the typicality standard so that the scope of benefits of a typical employer plan in a State would be defined as any scope of benefits that is *as or more generous* than the scope of benefits in the State's least generous typical employer plan, and *as or less generous* than the scope of benefits in the State's most generous typical employer plan. Therefore, a State interested in adding routine non-pediatric dental services as an EHB may

need to consider removing and/or adjusting other benefits to make room for the non-pediatric dental services to fit into the scope of benefits within the State, to ensure the scope of benefits falls within the typicality range.

Comment: A few commenters responded to our solicitation for comment on the potential impact of this proposed policy on health insurance coverage in the large group and self-insured markets and on grandfathered plans. A few of these commenters expressed concern over the unintended cost impacts this policy would have on these groups, given that the prohibition in PHS Act section 2711 on imposing annual and lifetime dollar limits on EHB also generally applies to self-insured group health plans, large group market health plans, and grandfathered health plans. In particular, one commenter expressed concern that the proposal may have an outsized impact on employer-sponsored coverage that may be subject to greater than anticipated costs, given such coverage is not subject to risk adjustment. Another commenter expressed concern that increasing costs for those employers that do choose to include non-pediatric dental benefits in their major medical plans is not a desirable result.

Response: Self-insured group health plans, large group market health plans, and grandfathered group and individual health insurance coverage are not required to provide coverage of EHB. Accordingly, even where a State updates its EHB-benchmark plan to include routine non-pediatric dental coverage as EHB, self-insured group health plans, large group market health insurance coverage, and grandfathered plans would not be required to cover such services. We also note that, as highlighted in the preamble to the proposed rule, if a sponsor of a self-insured group health plan, large group market health insurance coverage, or grandfathered plan offers coverage of routine non-pediatric dental services through an excepted benefit under 26 CFR 54.9831-1(c)(3), 29 CFR 2590.732(c)(3), and 45 CFR 146.145(b)(3), including a limited-scope dental plan, that benefit is generally excepted from complying with the group market reforms, including the annual limitation on cost sharing and restrictions on annual or lifetime dollar limits. Therefore, a self-insured group health plan, large group market health insurance coverage, or grandfathered plan may only be impacted by the finalization of this policy if it covers routine non-pediatric dental services. For the purpose of the prohibition in PHS Act section 2711 on imposing

²⁸⁷ See section 1311(d)(2)(B)(ii) of the ACA for more information on offering SADP benefits.

annual and lifetime dollar limits on EHB, a plan or issuer that is not required to provide EHB must define EHB in a manner consistent with an EHB-benchmark plan selected by a State in accordance with § 156.111, including coverage of any additional required benefits that are considered EHB consistent with § 155.170(a)(2).²⁸⁸ Therefore, a plan sponsor could select an EHB-benchmark plan in a State that has not chosen to update its EHB-benchmark plan to include routine non-pediatric dental services as EHB.

However, section 2707(b) of the PHS Act requires all non-grandfathered group health plans, including non-grandfathered self-insured and non-grandfathered insured small and large group market health plans, to limit cost sharing imposed by the plan on EHB in accordance with the annual limitation on cost sharing, and section 2711(a)(1)(A) and (B) of the PHS Act generally prohibits all group health plans and group or individual health insurance coverage from establishing annual or lifetime dollar limits on the dollar value of EHB for any participant, beneficiary, or enrollee.²⁸⁹ Previous guidance has stated that the Departments interpret PHS Act section 2707(b) as requiring all non-grandfathered group health plans to comply with the annual limitation on out-of-pocket maximums described in section 1302(c)(1) of the ACA,²⁹⁰ and that the Departments will consider self-insured group health plans or large group market health plans to have used a permissible definition of EHB under section 1302(b) of the ACA if the definition is one that is authorized by the Secretary of HHS.²⁹¹

Thus, for purposes of compliance with PHS Act sections 2707(b) and 2711, as applicable, a self-insured group health plan, large group market health insurance coverage, or grandfathered plan that selects an EHB-benchmark plan from a State that has updated its EHB-benchmark plan pursuant to this finalized policy to include routine non-pediatric dental services as an EHB would be required to treat routine non-pediatric dental services as EHB as they would with any other benefit that is an EHB in the selected benchmark plan.

However, if the selected plan is from a State that has not updated its EHB-benchmark plan to include routine non-pediatric dental services as EHB, then those plans and issuers would not be required to treat routine non-pediatric dental services as EHB for purposes of complying with the annual limitation on cost sharing in PHS Act section 2707(b) or the prohibition in PHS Act section 2711 on imposing annual and lifetime dollar limits on EHB, as applicable, even if such benefits appear in the EHB-benchmark plan. As we stated in the proposed rule (88 FR 82598), we would not consider any existing language regarding routine non-pediatric dental services in any State's current EHB-benchmark plan to have the effect of adding such services as an EHB. Rather, States interested in covering routine non-pediatric dental services as EHB must proactively update their EHB-benchmark plans pursuant to § 156.111 to add such benefits.

We acknowledge that this policy could impact non-grandfathered self-insured group health plans, and large group market health insurance coverage that cover routine non-pediatric dental benefits with respect to their compliance with the annual limitation on cost sharing and this policy could impact all such plans, as well as grandfathered health plans, with respect to the prohibition on annual or lifetime dollar limits; however, we believe the advantages of this policy outweigh the disadvantages. Particularly, we believe the advantages—including improving access to routine non-pediatric dental care, reducing oral health disparities, improving health equity, and improving overall health and quality of life in these markets—are worth the potential cost or operational impacts to health plans.

Comment: Several commenters agreed with the proposal to remove the prohibition on including routine non-pediatric dental services as EHB. These commenters noted that the proposal would also apply to Medicaid ABPs and BHP standard health plans.

Response: We appreciate these comments and agree with their understanding of the applicability of this amendment to Medicaid ABPs and BHP standard health plans.

Comment: Several commenters responded to our solicitation for comment on whether similar changes should be proposed regarding the removal of the prohibition at § 156.115(d) on issuers from including routine non-pediatric eye exam services and long-term/custodial nursing home care benefits. Several commenters also responded to our solicitation for comment on our updated understanding

on the inclusion of routine non-pediatric dental services in employer-sponsored or other job-based benefits. As we stated in the proposed rule (88 FR 82597), our updated understanding is that routine non-pediatric dental services are commonly covered as an employer-sponsored or other job-based benefit to a degree that warrants removing the prohibition on their provision as an EHB.

Response: For the reasons described in this section, we are finalizing removing routine non-pediatric dental services from the list of benefits at § 156.115(d) that a plan cannot include as EHB. As for the remaining list of benefits in § 156.115(d), we appreciate these comments and will continue to consider them for potential future rulemaking.

4. Prescription Drug Benefits (§ 156.122)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82599), we proposed revisions to certain EHB prescription drug benefit requirements at § 156.122, and requested comments on a possible future policy proposal, as further discussed below.

a. Classifying the Prescription Drug EHB

In the proposed rule, we requested information to confirm or further expand our understanding of the risks and benefits associated with replacing the reference to the USP MMG with a reference to the USP DC as a means of classifying the drugs required to be covered as EHB under § 156.122(a)(1). We thank commenters for their feedback and will take these comments into consideration if we pursue potential updates for future benefit years through notice and comment rulemaking.

b. Coverage of Prescription Drugs as EHB

We proposed to amend § 156.122 to codify that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB. We stated that, as a result, they would be subject to the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits, unless the coverage of the drug is mandated by State action and is in addition to EHB pursuant to § 155.170, in which case the drug would not be considered EHB. When § 155.170 is read in conjunction with the proposed amendment to § 156.122, this means that any prescription drug that an issuer voluntarily covers in excess of the minimum number of drugs required to be covered under the State's EHB-benchmark plan is EHB *unless* there is

²⁸⁸ 26 CFR 54.9815–2711(c)(2), 29 CFR 2590.715–2711(c)(2), and 45 CFR 147.126(c)(2).

²⁸⁹ The provisions of PHS Act section 2711 apply to both grandfathered and non-grandfathered health plans, except the annual dollar limits prohibition does not apply to grandfathered individual health insurance coverage.

²⁹⁰ FAQs Part XII, Q2 (February 20, 2013); see also the EHB Rule (78 FR 12835 through 12837).

²⁹¹ FAQs Part XVIII, Q2 (January 9, 2014); see also the 2019 Payment Notice (83 FR 17013).

a State mandate requiring such coverage.

In the EHB Rule (78 FR 12845), in response to commenter concerns regarding how plans must address new prescription drugs that come onto the market during the course of a plan year pursuant to § 156.122, we stated that while plans must offer at least the greater of one drug for each USP category and class or the number of drugs in the EHB-benchmark plan, plans are permitted to go beyond the number of drugs offered by the EHB-benchmark plan without exceeding EHB. We clarified in the preamble of the 2016 Payment Notice (80 FR 10749) in a discussion of requirements related to § 156.122(c) that this meant that if the plan is covering drugs beyond the number of drugs covered by the EHB-benchmark, all prescription drugs in excess of the drug count standard at § 156.122(a) are considered EHB, such that they are subject to EHB protections and must count towards the annual limitation on cost sharing.

In the proposed rule, we stated that we believed that this policy as noted in both the EHB Rule and preamble of the 2016 Payment Notice was clearly understood by issuers until we received comments in response to the EHB RFI that included a significant number of requests from interested parties to clarify this policy in rulemaking. In addition, a small number of commenters in response to the EHB RFI noted concerns regarding some plans that have stated that some prescription drugs in excess of the drug count standard at § 156.122(a) are not EHB and have developed programs to provide some drugs as “non-EHB,” outside of the terms of the rest of the coverage. We sought comment regarding how widespread these practices are.

To resolve these concerns, we proposed to amend § 156.122 to add paragraph (f), which would explicitly state that prescription drugs in excess of the EHB-benchmark plan are considered EHB. We stated that, to the extent that a health plan covers prescription drugs, in any circumstance, in excess of the EHB-benchmark plan, these drugs would be considered an EHB and would be required to count towards the annual limitation on cost sharing. We explained that this policy would apply unless the coverage of the drug is mandated by State action and is in addition to EHB pursuant to § 155.170, in which case the drug would not be considered EHB.

We noted that we had been made aware of a few plans within the individual and small group markets that have either developed or are offering programs that provide some drugs as

“non-EHB.” We stated that, as we had only recently begun receiving comments from interested parties regarding this issue, we did not believe that there are a large number of plans that offer these types of programs; however, we sought comment regarding how widespread these programs are.

We sought comment on this proposal. After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision with a technical edit to the regulation text to clarify the entire scope of cost-sharing requirements that apply to these prescription drugs. In the proposed rule, we proposed that the prescription drugs in excess of those covered by a State’s EHB-benchmark plan are considered EHB, and thus subject to both the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits. The proposed regulation text at § 156.122(f), however, referenced the annual limitation on cost sharing at § 156.130 as the only applicable cost-sharing requirement. We are finalizing the regulation text to reflect that prescription drugs in excess of those covered by a State’s EHB-benchmark plan are considered EHB, and thus subject to both the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits.

We summarize and respond below to public comments received on the proposal to amend § 156.122 to codify that prescription drugs in excess of those covered by a State’s EHB-benchmark plan are considered EHB such that they are subject to EHB protections, including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits, unless the coverage of the drug is mandated by State action and is in addition to EHB (in which case the drug would not be considered EHB). We also point readers to the preamble discussion above of § 155.170 regarding defrayal of State-mandated benefits, in which we clarified that a covered benefit in a State’s EHB-benchmark plan is considered an EHB even if mandated by State action after 2011.

Comment: A majority of commenters supported the proposal to amend § 156.122 to codify that prescription drugs in excess of those covered by a State’s EHB-benchmark plan are EHB. Several of these commenters expressed concern with any drugs being designated as “non-EHB” and noted that this was in conflict with HHS’ longstanding policy that covered prescription drugs in excess of the minimum drug count standard at § 156.122(a)(1) are still EHB. A few

commenters believed that the proposed rule did not explicitly state that issuers cannot designate certain drugs as “non-EHB” and encouraged HHS to further clarify that drugs cannot be classified as such and be in compliance with the regulation. Some commenters expressed concern that copay maximizers²⁹² and alternative funding programs²⁹³ are working with issuers and PBMs to designate drugs as “non-EHB,” and when a drug is no longer a covered benefit and EHB, even if it is theoretically available through a copay maximizer or alternative funding program, consumers lose State and Federal protections such as the annual limitation on cost sharing, the restriction on annual and lifetime dollar limits, and protection against exposure to discriminatory benefit designs. Some commenters also noted that these copay maximizers and alternative funding programs argue that specialty drugs are not required to be covered under the ACA, and that all specialty drugs can therefore be excluded.

In response to our request for comment regarding how widespread programs to provide some drugs as non-EHB are, a few commenters noted that these types of programs have been identified more frequently in self-insured group health plans and large group market health plans.

Response: We are finalizing this proposal to amend § 156.122 as proposed. As stated in this rule, given the prevalence of these programs, we are concerned that consumers lose important protections if a covered drug is no longer considered EHB. The impacts of these practices, including additional out-of-pocket costs and loss of consumer protections, justify the finalization of this policy.

²⁹² With a copayment maximizer, select drugs are categorized as non-EHBs, allowing plans to exclude drug manufacturer assistance payments from counting toward the patient’s deductible and out-of-pocket limitation. Zuckerman AD, Schneider MP, Dusetzina SB. Health Insurer Strategies to Reduce Specialty Drug Spending—Copayment Adjustment and Alternative Funding Programs. *JAMA Intern Med.* 2023;183(7):635–636. *Doi:10.1001/jamainternmed.2023.1829.*

²⁹³ Under alternative funding programs, payers exclude some or all specialty drugs, such as some used for cancer, arthritis, psoriasis, and hemophilia, from their defined benefit. Patients are then referred to a third-party organization contracted by the plan’s PBM to identify alternative funding options to obtain these excluded drugs, typically manufacturer patient assistance programs or other charitable assistance. When patients fail to meet the established criteria for manufacturer assistance, PBMs may reconsider drug coverage or, in some circumstances, source the medication from a pharmacy outside the U.S. at a lower cost. As a result, patients may face delays in starting a medication or may not be able to obtain the drug at all. *Id.*

We first stated that prescription drugs in excess of the minimum drug count do not exceed EHB in the EHB Rule (78 FR 12845), which was finalized over a decade ago, and we made clear in the 2016 Payment Notice (80 FR 10817) that “if the plan is covering drugs beyond the number of drugs covered by the benchmark, all of these drugs are EHB and must count towards the annual limitation on cost sharing.” In the proposed rule, we proposed to codify that, to the extent that a health plan covers prescription drugs, in any circumstance, in excess of the EHB-benchmark plan, these drugs would be considered EHB and would be required to count towards the annual limitation on cost sharing, unless the coverage of the drug is mandated by State action and is in addition to EHB pursuant to § 155.170, in which case the drug would not be considered EHB. Consequently, we now clarify that this interpretation means that issuers subject to the requirement to cover EHB will be considered to be failing to provide EHB if they do not treat those drugs as EHB, including by subjecting them to the annual limitation on cost sharing, by not applying annual or lifetime dollar limits, and by factoring them in the availability of APTCs, unless the drugs are mandated by State action. We agree with commenters’ concerns that coverage is diminished if a drug is no longer considered EHB. For example, a plan might designate certain drugs as “non-EHB,” but indicate that the member can obtain coverage of such drugs so long as they enroll into a third-party program. If the member declines to enroll in the program or fills a prescription for a “non-EHB” drug outside of the program, they risk assuming responsibility for cost sharing that does not count towards the member’s deductible or annual limitation on cost sharing.

From an operational perspective, it is not apparent on what basis issuers make distinctions between covered drugs that are EHB and “non-EHB,” including at what point certain drugs become “too costly” for the plan to consider them EHB. Further, it is not apparent that issuers are capable of readily explaining the rationale behind designations of “non-EHB” for specific drugs to consumers in advance of their enrollment in the plan. Even if an issuer is capable of explaining that rationale and providing any amount of notice to affected consumers in advance of their enrollment, we believe it is unreasonable to expect enrollees to be able to understand the complicated impacts that getting coverage for

specific “non-EHB” drugs would have on enrollee out-of-pocket costs and consumer protections. This is especially true considering that those drugs most likely to be designated as “non-EHB” are drugs that are more likely to be prescribed for members of particularly vulnerable segments of the population.²⁹⁴ The fact that the consumers that would be most affected by allowing drug coverage as “non-EHB” would be most negatively impacted by additional out-of-pocket costs and loss of consumer protections is further justification for the finalization of this policy.

We also find unpersuasive the argument that issuers may classify drugs as specialty drugs or apply another similar label and thus designate them as “non-EHB.” We have not defined “specialty drug” for the purposes of EHB and formulary standards; rather, issuers must meet the formulary requirements at § 156.122. Accordingly, while the ACA does not explicitly identify specialty drugs within the category of prescription drugs that must be covered, the ACA also does not provide for a blanket exclusion from the EHB coverage requirement for such drugs, and therefore the requirements under § 156.122 apply to such drugs. Additionally, although EHB standards do not prohibit issuers from designating certain drugs as “specialty” drugs or tiering them as such if non-discriminatory, we believe it would be difficult, if not impossible, for an issuer to remove all drugs it currently deems “specialty” from the formulary and still be in compliance with § 156.122.

Comment: Some commenters stated that HHS lacks the statutory authority to include prescription drugs covered by plans in excess of those covered by a State’s EHB-benchmark plan as EHB.

Response: Section 1302(b)(1) authorizes HHS to define the EHB, including items and services within the prescription drug category at § 1302(b)(1)(F). In this rule, we are exercising this authority to further define the prescription drugs that are considered EHB, which is clearly within HHS’s statutory authority to define the EHB.

Comment: Some commenters stated that the final rule should make clear whether this policy applies to large group market and self-funded plans and suggested that it should. Conversely, several commenters urged HHS to clarify that this policy, if adopted,

would not apply to self-insured and large group market plans. These commenters expressed concern that if the rule is extended to large group market and self-funded group health plans, it would be disruptive to formulary design, and plans may be forced to eliminate certain prescription drugs from their formularies due to increased plan costs. One commenter requested that if the policy were to apply to large group market and self-funded plans, the government provide a cost estimate to reflect the projected impact.

Response: The proposed rule primarily addressed the application of this policy with respect to issuers of non-grandfathered individual and small group market plans subject to the requirement to provide EHB. We are finalizing this proposal as proposed. This final rule does not address the application of this policy to large group market health plans and self-insured group health plans. While health insurance issuers offering non-grandfathered coverage in the individual and small group market are required to cover EHBs, self-insured group health plans and large group market health plans are not required to cover any EHBs. However, to the extent self-insured group health plans and large group market health plans cover EHBs, such plans must comply with the annual limitation on cost sharing under PHS Act section 2707(b) and annual and lifetime limit prohibitions under PHS Act section 2711, as applicable, with respect to those benefits.²⁹⁵ HHS shares interpretative jurisdiction with the Department of Labor and the Department of the Treasury (collectively, the Departments) of the relevant requirements that are included in PHS Act sections 2707 and 2711, which are adopted by reference into the Employee Retirement Income Security Act (ERISA) through section 715 of ERISA and into the Internal Revenue Code (Code) through section 9815 of the Code. The Departments understand the questions raised by commenters with respect to large group market health plans and self-insured group health plans and intend to address the applicability of this policy to those plans in future notice-and-comment

²⁹⁴ Assessment of racial and ethnic inequities in copay card utilization and enrollment in copay adjustment programs. J Manag Care Spec Pharm. 2023 Sep;29(9):1084–1092. Doi: 10.18553/jmcp.

²⁹⁵ The provisions of PHS Act section 2707(b) apply to all non-grandfathered group health plans, including non-grandfathered self-insured and non-grandfathered insured small and large group market plans. The provisions of PHS Act section 2711 apply to both non-grandfathered and grandfathered group health plans and group or individual health insurance coverage, except the annual limits prohibition does not apply to grandfathered individual health insurance coverage.

rulemaking. Specifically, the Departments intend to propose rulemaking that would align the standards applicable to large group market health plans and self-insured group health plans with those applicable to individual and small group market plans, so that all group health plans and health insurance coverage subject to sections 2711 and 2707(b) of the PHS Act, as applicable, would be required to treat prescription drugs covered by the plan or coverage in excess of the applicable EHB-benchmark plan as EHB for purposes of the prohibition of lifetime and annual limits and the annual limitation on cost sharing, which would further strengthen the consumer protections in the ACA.

Comment: A few commenters asserted that the proposal may impact the viability of copay maximizer programs, which could cause enrollee cost sharing and plan premiums to increase, particularly for cost sharing related to specialty drugs. One commenter stated that these programs maximize the value of coupons to benefit the patient, taxpayers, and plan sponsors, and bring manufacturers to the table to negotiate on fair prices, particularly for self-insured plans, and urged HHS to consider this proposed policy change in the context of the broader policy debates related to manufacturers' use of copay coupons and copay assistance programs.

Response: As noted above, this policy was first stated in the EHB Rule in 2013 and addressed again in the 2016 Payment Notice and so we disagree that codification of a long-standing policy should cause significant changes for plans in the individual and small group markets. We will consider copay maximizer programs, as relevant, in any subsequent policy making about drug manufacturer assistance programs.

Comment: Some commenters noted that the policy may impact issuers' ability to manage prescription drug costs, which may lead to increased premiums and cost sharing. Commenters suggested that HHS consider whether the risk adjustment methodology appropriately supports this policy, and whether issuers may need additional benefit design flexibilities or other assistance to help contain costs. One commenter encouraged HHS to carefully consider how this policy change may inappropriately benefit manufacturers by encouraging them to increase list prices for certain drugs.

Response: We encourage issuers to continue to exceed minimum drug count requirements and remind them of P&T committee obligations at § 156.122(a)(3)(iii). Based on our review

of formularies as part of QHP certification and as part of the form review for direct enforcement States, it is our understanding that issuers routinely exceed minimum requirements when developing formularies. We expect P&T committees to exercise sound decision-making and balance cost considerations with consumer needs. We share commenters' concerns about the increasing cost of prescription drugs in general. Therefore, we hope that drug manufacturers will negotiate with issuers and PBMs so that additional drugs can be included in formularies. Additionally, since this policy does not change the current treatment of prescription drugs in the individual and small group markets, codifying this policy will not impact the risk adjustment methodology.

Comment: Some commenters recommended that HHS monitor unintended consequences of this policy, if finalized as proposed, such as a potential decrease in the breadth of formularies beyond what is required by current regulation.

Response: We intend to monitor the breadth of formularies and will consider whether further regulation is warranted. However, we also note that this policy has been in place since at least the 2016 Payment Notice, so this is not a new interpretation. As noted in the proposed rule, we do not believe that the designation of drugs as "non-EHB" is currently pervasive in the individual and small group markets. Further, this provision is intended to operate in tandem with the other regulatory requirements at § 156.122, which impose other standards for prescription drug coverage. In particular, we highlight the requirements at § 156.122(a)(3)(iii), which place requirements on P&T committees to, among other things, ensure that formularies cover a range of drugs across a broad distribution of therapeutic categories and classes and provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

Comment: One commenter requested clarification on how the proposed amendment to "Additional Required Benefits (45 CFR 155.170)" will impact the proposed amendment to § 156.122. The commenter noted that, as proposed, it appears there would be an exception to the codification in § 156.122 that prescription drugs in excess of the EHB-benchmark plan are considered EHB if a drug is mandated by State action and considered in addition to EHB pursuant to the defrayal standards at § 155.170.

The commenter stated that this outcome appears to conflict with the proposed amendment to § 155.170(a)(2) which would provide that drug benefits covered in a State's EHB-benchmark plan would not be considered in addition to EHB and maintain its status as EHB.

Response: Pursuant to the finalized policy at § 155.170, any prescription drug that is covered in a State's EHB-benchmark plan is EHB, even if there is a State mandate requiring that specific drug to be covered. When read in conjunction with our clarification at § 156.122, this means that any prescription drug that an issuer voluntarily covers in excess of the State's EHB-benchmark plan is EHB *unless* there is a State mandate requiring such coverage.

c. Pharmacy and Therapeutics Committee Standards

For plan years beginning on or after January 1, 2026, we proposed to amend § 156.122 to provide that the P&T committee must include a consumer representative.

In the 2016 Payment Notice (80 FR 10749), we required plans providing EHB to establish P&T committees to review and update plan formularies in conjunction with the USP MMG. At § 156.122(a)(3)(i), we require P&T committees to: (a) have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees; (b) consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health care professionals who are licensed to prescribe drugs; (c) prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists; and (d) require at least 20 percent of its membership to have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer.

We noted in the proposed rule that many of the P&T committee requirements are also found in the Principles of a Sound Drug Formulary System, which was first developed in September 1999 by a coalition of national organizations representing health care professionals, government, and business leaders and later adopted in 2000 by the Academy of Managed Care Pharmacy (AMCP), Alliance of Community Health Plans, American Medical Association, American Society of Health-Systems Pharmacists, Department of Veterans Affairs, Pharmacy Benefits Management Strategic Healthcare Group, National

Business Coalition on Health, and U.S. Pharmacopeia.²⁹⁶ We further noted that since that time, best practices for P&T committees have matured throughout the health care system. In 2019, AMCP convened a group of thought leaders, clinicians, academics, patient advocacy organizations, payer organizations, and members of the pharmaceutical industry to consider P&T committee best practices in today's evolving health care system.²⁹⁷ Specifically, the group provided perspectives on: (a) P&T committee composition and relevant interested parties, (b) evaluation of emerging evidence for formulary decisions and recommendations around training of P&T committee members, and (c) characteristics and best practices of successful committees.

While a P&T committee is usually composed of actively practicing physicians, pharmacists, and other health care professionals, forum participants stated that a well-structured committee should also include patient representation since it provides additional insight into the patient perspective regarding the practical use of therapies and effects on quality-of-life outcomes, which can be a helpful component of the formulary evaluation process. Additionally, participants noted that the patient perspective should be considered a key voice in formulary decisions as they are directly affected by P&T committee decisions and can assist the committee in better understanding the value of different treatments and medications for patients.

We stated in the proposed rule that while we are aware that the inclusion of consumers in the P&T committee process is not common, it has been observed in different health care systems. We noted that one example of this practice includes the Uniform Formulary Beneficiary Advisory Panel (UFBAP), which provides independent advice and recommendation on the development of the TRICARE Uniform formulary.²⁹⁸ Members of the UFBAP include nongovernmental organizations and associations that represent the

views and interests of a large number of eligible covered beneficiaries, contractors responsible for the TRICARE retail pharmacy program, contractors responsible for the national mail-order pharmacy program, and TRICARE network providers. We further noted additional examples of States that include clinicians such as physicians, pharmacists, and other specialists along with consumer or patient representatives as members of their respective P&T committees, including Pennsylvania,²⁹⁹ Connecticut,³⁰⁰ and New York.³⁰¹

We explained in the proposed rule that P&T committee decisions have the power to impact a consumer's overall quality of life and encompass important elements of care and cost for the consumer. Therefore, we proposed to add paragraph (a)(3)(i)(E) to § 156.122 to update P&T membership standards to require the P&T committee to include a consumer representative as part of its membership for plan years beginning on or after January 1, 2026. In addition, we proposed to specify at § 156.122(a)(3)(E)(1) through (4) membership standards for consumer representatives. Specifically, we stated that the consumer representative would be required to represent the consumer perspective as a member of the P&T committee and would be required to have an affiliation with and/or demonstrate active participation in consumer or community-based organizations. We stated that some examples of these types of organizations include those that are representative of a community, or significant segments of a community, that provide educational or related direct services to individuals in the community, and organizations that protect consumer rights via advocacy, research, or outreach efforts. We explained that as a P&T committee member, the consumer representative would assume responsibility for highlighting and addressing any potential risks and benefits to consumers that could result from P&T committee actions. In addition, we explained that an affiliation with and/or

active participation in a consumer or community-based organization would provide the consumer representative with the necessary background to represent consumers' perspectives. We further stated that if the proposed rule were finalized as proposed, issuers would also be required to select a consumer representative who has experience in the analysis and interpretation of complex data and is able to understand its public health significance, bearing in mind that one of the duties as a member of a P&T committee would include thoughtful consideration of clinical criteria, such as drug safety and efficacy data, when making a recommendation about products under review. We further stated that this individual would also be required to have no fiduciary obligation to a health facility or other health agency and no material financial interest in the rendering of health care services. We explained that this conflict-of-interest standard is intended to ensure that, as a member of the P&T committee, the consumer representative is free from financial interests or other relationships that could compromise the objectivity of committee members as they perform their duties. We also noted that nothing in this proposal would prevent the P&T committee from defining additional membership standards pertaining to the position of consumer representative.

We stated in the proposed rule that we believe the proposed addition of § 156.122(a)(3)(i)(E) would ensure that the consumer experience with a disease or condition is considered in the design of formulary benefits. We explained that consumer representatives would offer insights into real consumer experiences unknown to P&T committees, which would educate the committee on consumer challenges related to medication use and assist the committee in exploring solutions to these challenges during the formulary development process. We also noted that broader inclusion of perspectives on the P&T committee would align with other groups, including the AMCP.

We sought comment on these proposals. We stated that the consumer representative, as a member of the P&T committee, would be subject to the conflict-of-interest standards as specified in § 156.122(a)(3); however, we stated we were interested in comments regarding whether we should further define additional membership standards for the consumer representative. In particular, we sought comments on the qualifications necessary to serve as a consumer representative on a P&T committee, to

²⁹⁶ Hawkins, B., ed. (2011). Principles of a sound drug formulary system. Best Practices for Hospital and Health System Pharmacy: Positions and Guidance Documents of ASHP. American Society of Health-System Pharmacists. <https://www.ashp.org/-/media/assets/policy-guidelines/docs/endorsed-documents/endorsed-documents-principles-sound-drug-formulary-system.pdf>.

²⁹⁷ AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics (P&T) Committee Practices: What's Next? (2020). *J Manag Care Spec Pharm*, 26(1), 48–53. <https://doi.org/10.18553/jmcp.2020.26.1.48>.

²⁹⁸ Charter: Uniform Formulary Beneficiary Advisory Panel. <https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Pharmacy-Operations/BAP>.

²⁹⁹ The Pennsylvania Department of Human Services Pharmacy and Therapeutics Committee. See <https://www.dhs.pa.gov/about/DHS-Information/Pages/Stakeholders/Pharmacy-Committee.aspx>.

³⁰⁰ The Connecticut Medical Assistance Program Pharmaceutical and Therapeutics Committee. See https://www.cga.ct.gov/current/pub/chap_319v.htm#sec_17b-274d and https://www.ctdssmap.com/CTPortal/Portals/0/StaticContent/Publications/CT_PT_COMMITTEE_BYLAWS_v2.pdf.

³⁰¹ New York State Department of Health Drug Utilization Review (DUR). See https://www.health.ny.gov/health_care/medicaid/program/dur/docs/board_membership.pdf.

include if the representative should have a clinical background, have served as a representative of organizations with a regional or Statewide constituency, or have been involved in activities related to health care consumer advocacy, including issues affecting individual and small group market enrollees. We also sought comment on whether the current conflict-of-interest provision is sufficient as applied to this proposed role, or whether the consumer representative role should be subject to additional conflict-of-interest standards. We sought comment on whether a consumer representative should have a background for more than one condition or disease to sufficiently represent the concerns of a diverse population. Additionally, we sought comment on the number of consumer representatives who should be included on a committee and if that number should be directly proportional to the size of the committee. We also recognized that a requirement to develop additional P&T committee standards, solicit for applicants for this new position, and provide any necessary training to new members would require lead time for States, issuers, and pharmacy benefit managers to implement and we sought comment on the proposed timing for implementation.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision with the following modifications: (1) we are making a change to § 156.122(a)(3)(i)(E) introductory text, § 156.122(a)(3)(i)(E)(1), and § 156.122(a)(3)(i)(E)(2) to replace “consumer” with “patient”; (2) we are amending § 156.122(a)(3)(i)(E) introductory text to include the term “at minimum one” to reflect that at least one patient representative is required, and that additional patient representatives may serve on a P&T committee; (3) we are modifying § 156.122(a)(3)(i)(E)(2) to broaden the experience requirement to serve as a patient representative by requiring that the patient representative have relevant experience or participation in patient or community-based organizations; (4) we are modifying § 156.122(a)(3)(i)(E)(3) to broaden the clinical requirement to serve as a patient representative by requiring that the patient representative be able to demonstrate the ability to integrate data interpretations with practical patient considerations; (5) we are adding § 156.122(a)(3)(i)(E)(5) to reflect an education requirement to serve as a patient representative in which the patient representative is

required to have a broad understanding of one or more conditions or diseases, associated treatment options, and research; and (6) we are adding § 156.122(a)(3)(i)(E)(6) to require the patient representative to disclose financial interests on their conflict-of-interest statements. Disclosed financial interests must include all interests with any entity that would benefit from decisions regarding plan formularies as well as specific information about these financial interests, such as the nature of the relationship and the value of the financial interest. We summarize and respond below to public comments received on the proposal to amend § 156.122 to provide that the P&T committee must include a consumer representative.

Comment: Two commenters encouraged CMS to amend the language of § 156.122(a)(3)(i)(E) to use the term “patient representative” as opposed to “consumer representative.” Both commenters noted that patient-centered approaches aim to ensure clinical care meets patients’ needs and preferences, which is different from a consumer orientation, which calls on patients to be prudent purchasers of medical care.

Response: We agree that the term “consumer representative” may not accurately represent the full scope of the insight that such a representative offers to a P&T committee and may not be primarily associated with a patient-centered role. We acknowledge that the use of the term “consumer” to some, may be more closely associated with purchases and consumption. However, we believe the proposed rule was clear in our intention that the term “consumer representative” did not limit the scope of this representative’s role to only “consumer” concerns. As discussed in the preamble, this representative will serve on a P&T committee to provide additional insight into the patient perspective regarding the practical use of therapies and effect on quality-of-life outcomes as part of the formulary evaluation process and assist the committee in better understanding the value of different treatments and medications for patients. We also did not intend to require the representative and the P&T committee to make overly technical distinctions between “consumer” and “patient” concerns, when both are necessary for this representative to ensure that the experience of people with a given disease or condition is considered in the design of formulary benefits which should help the committee better understand the challenges of those impacted related to medication use as well as assist the committee in

exploring solutions to these challenges during the formulary development process. Nevertheless, we agree with commenters that the term “patient representative” is a more appropriate term in this context. As such, we are finalizing this proposal with a change to replace “consumer” with “patient” at § 156.122(a)(3)(i)(E) introductory text and § 156.122(a)(3)(i)(E)(1) and (2).

Comment: We received many comments in response to our request for comments (88 FR 82602) regarding whether we should further define additional membership standards for the patient representative in this rule, including what qualifications and conflict-of-interest standards may be necessary to effectively implement the proposal. One commenter urged CMS to require that the patient representative have clinical experience. One commenter noted that while a clinical background should be encouraged, it should not be required, as it could exclude highly qualified patient representatives who have other expertise to contribute, such as from experience in public or community health, health care policy development, or administration. Additionally, one commenter noted that limiting the position to only those with a clinical background may negatively impact the value of adding patients’ voices to these committees. Two commenters recommended that the patient representative have a background in one or more conditions or diseases. Conversely, several commenters argued that the addition of a member without medical and scientific training to offer meaningful input on committee decisions would significantly and negatively impact the scientific rigor of P&T committee discussions, which are aimed to develop prescription drug formularies.

Finally, a few commenters recommended that the patient representative should function in an advisory or non-voting capacity. Two commenters suggested that patient representatives serving on the P&T committees must have clinical experience to have voting rights. One commenter recommended that patient representatives meet existing P&T committee membership criteria or be barred from voting rights.

Response: First, we are finalizing our proposal with modification to include an additional standard at § 156.122(a)(3)(i)(E)(5) to require the patient representative to have a broad understanding of one or more conditions or diseases, associated treatment options, and research. In the proposed rule, we specifically sought

comment on what the qualifications may be necessary to serve as a patient representative on a P&T committee, including whether the representative should have a clinical background and whether the patient representative should have a background for more than one condition or disease to sufficiently represent the concerns of a diverse population. Although we agree with commenters that while a clinical background can be beneficial for a patient representative, this need not be a regulatory requirement for the patient representative, as their role on the committee is to provide insights from a patient perspective and not necessarily with a clinical background.

Additionally, we do not agree that the addition of a patient representative to a P&T committee will hinder the quality of scientific exchange that occurs between members of the committee. The addition of a patient representative is meant to enhance the committee's ability to make well-informed decisions by incorporating the perspectives and experiences of the individuals directly affected by pharmaceutical and therapeutic choices. The inclusion of this member role will promote transparency, accountability, and a more patient-centered approach to health care.

However, we agree with commenters that noted that a patient representative should have background knowledge related to more than one condition or disease to sufficiently represent the concerns of a diverse population. Background knowledge of a given condition or disease can include but is not limited to information about the causes, symptoms, risk factors, diagnostic methods, available treatments, and potential outcomes associated with a specific medical condition or disease. The addition of the standard at § 156.122(a)(3)(i)(E)(5) will ensure that the patient representative is able to effectively communicate and collaborate with other clinically focused committee members as a result of the requirement that they have a foundational knowledge related to the treatment and management of a more than one condition or disease while also representing the needs and experiences of patients.

We disagree that patient representatives should function in an advisory role or non-voting capacity or that the voting rights of a patient representative be dependent upon clinical experience. Unlike members of the P&T committee who serve in a clinical capacity, such as the physician, pharmacist, or nurse, the patient representative is included as a member

of the P&T committee to serve in a non-clinical capacity to offer insight into real patient experiences that P&T committees may be unaware of that would help the committee better understand patient challenges related to medication use as well as assist them in exploring solutions to these challenges during the formulary development process. Additionally, in States where P&T committees already include patient representatives, such as Pennsylvania, Connecticut, and New York, which include clinicians along with consumer or patient representatives, voting rights are extended to all members. We are not aware of States that require P&T committees to include patient representatives where those members are not afforded voting privileges. These examples demonstrate to us that, once a qualified candidate has been identified to serve as a patient representative and becomes a member of the P&T committee, this member should be granted voting privileges like all other committee members who meet member requirements and fulfill the duties associated with their role.

Comment: A few commenters recommended that the number of patient representatives should be proportional to the size of the P&T committee, to help ensure adequate patient representation. Conversely, a few commenters recommended that, if finalized, the requirement should be to include only one patient representative on the P&T committee.

Response: We appreciate the commenters' suggestions, but we will not revise the regulatory text to require additional patient representatives at this time because we want to ensure that plans are able to successfully identify and incorporate at least one patient representative on their P&T committees without inflicting undue burden on issuers to implement this new requirement. We are finalizing a non-substantive revision to specify that a health plan must include "at minimum one" patient representative to allow health plans the ability to use additional patient representatives at their option. We will continue to monitor this requirement and may consider increasing the number of patient representatives required on a P&T committee in the future.

Comment: In the proposed rule, we noted that we were interested in comments regarding whether the current conflict-of-interest provision at § 156.122(a)(3) is sufficient as applied to the proposed role, or whether the patient representative role should be subject to additional conflict-of-interest standards. We received several

comments regarding how we should further define this membership standard in this rule. Several commenters stated that patient representatives attached to a patient or consumer advocacy organization may pose conflict-of-interest concerns as this could be an avenue for individuals affiliated, either explicitly or otherwise, with pharmaceutical manufacturers to gain representation on a P&T committee. Additionally, a few commenters recommended that CMS strengthen provisions to ensure that an individual has no link (direct or indirect) to a drug manufacturer. One commenter recommended that HHS collaborate with patient organizations and other interested parties to develop additional standards to appropriately safeguard against potential conflicts of interest and encouraged HHS to review resources from the NHC on best practices for integrating the patient voice into health care decision making.

Response: We acknowledge that the requirement that the patient representative have relevant experience or participation in patient or community-based organizations could result in financial conflicts of interest if, for example, the community-based organization the patient representative is affiliated with has a financial or material arrangement with pharmaceutical manufacturers. Additionally, we reiterate that the patient representative serves on the P&T committee to help the committee better understand the challenges of those impacted related to medication use as well as assist the committee in exploring solutions to these challenges during the formulary development process and should not be considered a role to be used by pharmaceutical manufacturers to gain representation on the P&T committee resulting in the prioritization of access over appropriate clinical evidence. We agree with commenters that the conflict-of-interest standards should include safeguards from inappropriate direct or indirect pharmaceutical manufacturer influence on P&T committee decisions and, as such, we are finalizing a new conflict-of-interest standard at § 156.122(a)(3)(i)(E)(6) that will require the patient representative to disclose financial interests on their conflict-of-interest statements. Disclosed financial interests must include all interests with any entity that would benefit from decisions regarding plan formularies as well as specific information about these financial interests, such as the nature of

the relationship and the value of the financial interest.³⁰²

Finally, we appreciate the suggestion to collaborate with patient organizations and interested parties to enhance standards and address potential conflicts of interest. We may consider developing additional standards to be applied to patient representatives on the P&T committee in the future and will consider such collaboration.

Comment: Several commenters recommended that CMS encourage alternative mechanisms for patient engagement with P&T committees, such as requiring annual training sessions for P&T committees that discuss the patient perspective, allowing existing members to attest to a consumer interest, requiring P&T committees to publish a plain language summary of the principles used to establish a formulary, or requiring issuers to hold consumer forums to capture patient feedback that can be shared with clinical teams.

Response: We do not believe that the alternative mechanisms suggested by commenters for patient engagement with P&T committees would be as effective as the addition of a patient representative to serve as a member of the P&T committee. The addition of this member to the P&T committee will offer the opportunity for members to be consistently engaged at every meeting in the discussion of topics related to patient experiences, patient challenges related to medication access and use, as well as exploring solutions to these challenges during the formulary benefit design process.

Comment: A few commenters expressed concerns that the criteria set forth for the patient representative in the proposed regulation are too stringent and will limit the ability of plans and issuers to recruit a qualified consumer representative if required to do so. One commenter noted that the requirement for a patient representative to have an affiliation with or participation in a consumer group should not be a strict standard given the difficulty that issuers may encounter identifying qualifying patient representatives. This same commenter also noted that it may be difficult to find patient representatives who are working or participating in consumer or community-based organizations that have sufficient experience to analyze, interpret, and understand the public health impact of complex scientific data. Additionally, the commenter recommended amending

the criteria to reflect the demands of the role to listen to interpretations of the data and be thoughtful in marrying those interpretations with the practical considerations that impact consumers. A few commenters recommended that HHS consider an exceptions process from meeting this standard for an issuer that makes a good faith effort but is unable to find a qualified consumer representative. Two commenters recommended that HHS allow adequate time for implementation of this policy, if finalized, for plans and issuers to locate and onboard new consumer representatives without delaying pressing P&T meetings and approvals.

Response: In general, we agree with commenters that requiring that the patient representative have an affiliation with and/or demonstrate active participation in consumer or community-based organizations is restrictive. We did not intend for this requirement to limit the ability of issuers to recruit a qualified patient representative. As noted in the preamble, we believe the inclusion of a patient representative on the P&T committee is necessary to ensure that the patient experience with a disease or condition is considered in the design of formulary benefits. While an affiliation with and/or the ability to demonstrate active participation in consumer or community-based organizations may be an ideal path for a candidate to have obtained the necessary experience to serve as a patient representative, we acknowledge that the relevant experience necessary to serve as a patient representative can also be obtained from working in roles that directly impact or support patient care and well-being. This could include positions in health care administration, patient advocacy, nursing, medical social work, or roles focused on improving patient experience and outcomes. We are amending § 156.122(a)(3)(i)(E)(2) to state that the patient representative must have relevant experience or participation in patient or community-based organizations. We believe that broadening the background experience necessary to serve as a patient representative will expand the pool of qualified candidates when searching for a patient representative to serve on the P&T committee which should further reduce any barriers for issuers to meet this requirement.

Further, we agree with commenters that requiring the patient representative to have experience in the analysis and interpretation of complex data and be able to understand its public health significance is also restrictive. The

background requirement as proposed may not easily be identified in candidates who only have relevant experience or participation in patient or community-based organizations unless they have additional background experience in interdisciplinary fields such as epidemiology, biostatistics, or data science where they would have gained the expertise needed to analyze and interpret complex data with a focus on public health significance. While this level of experience could be beneficial, we agree that it should not be a prerequisite for serving as a patient representative on a P&T committee considering that this member will serve in a non-clinical capacity to provide additional insight into the patient perspective regarding the practical use of therapies and effect on quality-of-life outcomes. We acknowledge that the proposed requirements may not accurately reflect the practical demands of the role and therefore may hinder issuer recruitment of qualified candidates to serve as a patient representative on the P&T committee, which was not our intent. However, we believe the patient representative should be able to demonstrate the ability to attentively consider data interpretations and thoughtfully integrate them with practical considerations affecting patients in order to help them contribute meaningfully to P&T committee member discussions and to assist the committee in better understanding the value of different treatments and medications for patients. Therefore, we are amending § 156.122(a)(3)(i)(E)(3) to require that the patient representative be able to demonstrate the ability to integrate data interpretations with practical patient considerations. We believe broadening this requirement will help to further assist issuers in identifying qualified candidates to serve as patient representatives.

In response to comments, we considered the establishment of an exception process should a health plan make a good faith effort and is unable to find a qualified candidate to serve as a patient representative. However, we are concerned that if we allow an exception process, this may incentivize some issuers to identify loopholes to obtain an exception to the rule and not make a meaningful attempt to comply with the requirements set forth to seek out a qualified candidate to serve as a patient representative on the P&T committee. Not implementing an exception process ensures consistent application of the policy, minimizes potential loopholes, and maintains a

³⁰² Department of Health and Human Services. Office of Inspector General. Gaps in Oversight of Conflicts of Interest In Medicare Prescription Drug Decisions. March 2013. <https://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf>.

clear and standardized approach for all issuers.

As noted above, we are finalizing this policy with modifications to broaden certain requirements to further assist issuers in identifying qualified candidates to serve as patient representatives. We recognize the challenges that plans and issuers may encounter while recruiting a qualified candidate to serve as a patient representative. However, several States currently include at least one patient representative as a member of their P&T committee which indicates that these committees were able to identify qualified candidates who are willing to serve in this role. We encourage issuers to reach out to their State should they experience challenges while making a good faith effort to identify a qualified candidate to serve as a patient representative and comply with this new requirement, as the State is responsible for the oversight and enforcement of the P&T committee standards.

Comment: One commenter encouraged CMS to consider including additional flexibility to account for the possibility that health plan P&T committees already include patient representatives. The commenter also recommended that CMS allow for the flexibility to combine consumer representative positions under State requirements that may already be in place so that one or more consumer advocates can advocate for both Medicaid and commercial health plan members.

Response: We do not believe that the requirement for health plans in the non-grandfathered individual and small group market to include a patient representative materially conflicts with any existing State requirements on these markets. No commenter identified any existing State requirements related to similar P&T committee membership standards, which comports with our own research of any potential conflicts in this space. Thus, we do not believe it is necessary to revise the proposal to accommodate any such potential conflicts. To the extent any may exist, we expect to work closely with any State regulators and provide technical assistance to affected health plans to ensure that P&T committee membership standards come into compliance with this rule with minimal burden. In addition, to the extent a health plan in these markets currently voluntarily has a patient representative on its P&T committees, we expect such health plans to ensure that any existing patient representatives meet the minimum

membership standards imposed by this rule.

Comment: One commenter recommended that CMS maintain the ability for issuers to include additional standards for consumer representatives noting that issuers should have the flexibility to establish criteria to demonstrate the individual's ability to participate on the P&T committee and standards to handle conflicts of interests.

Response: As noted in the proposed rule, nothing in this proposal would prevent the P&T committee from defining additional membership standards pertaining to the position of patient representative.

5. Publication of the 2025 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 (86 FR 24238), we publish the premium adjustment percentage, the required contribution percentage, and maximum annual limitations on cost sharing and reduced maximum annual limitation on cost sharing in guidance annually starting with the 2023 benefit year. We note that these parameters are not included in this rulemaking, as we did not propose to change the methodology for these parameters for the 2025 benefit year. Instead, on November 15, 2023, we published these 2025 benefit year parameters in guidance in accordance with our 2022 Payment Notice regulations.³⁰³

6. Standardized Plan Options (§ 156.201)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82603), HHS proposed to exercise its authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to make minor updates to the standardized plan options for PY 2025. Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA for, among other things, the offering of QHPs through such Exchanges.

Specifically, we proposed to make minor updates to the plan designs for PY 2025 to ensure these plans have AVs within the permissible *de minimis* range

for each metal level. We proposed to otherwise maintain continuity regarding the approach to standardized plan options finalized in the 2023 and 2024 Payment Notices. Our proposed updates to plan designs for PY 2025 were detailed in Tables 12 and 13 in the proposed rule. We did not propose to amend § 156.201. We refer readers to the proposed rule (88 FR 82603 through 82604) for background discussion regarding our proposed approach to standardized plan options, and to the preambles of the 2023 and 2024 Payment Notices discussing § 156.201 (87 FR 27310 through 27322 and 88 FR 25847 through 25855, respectively) for a detailed discussion regarding the approaches to standardized plan options finalized in those Payment Notices.

We proposed this approach for several reasons. In the proposed rule (88 FR 82604), we explained that we intended to continue to require FFE and SBE-FP issuers to offer standardized plan options in large part due to continued plan proliferation, which has only increased since the standardized plan option requirements were finalized in the 2023 Payment Notice. We stated that, in light of this continued plan proliferation, it is increasingly important to continue to attempt to streamline and simplify the plan selection process for consumers on the Exchanges. We explained that we believe these standardized plan options continue to play a meaningful role in that simplification by reducing the number of variables that consumers must consider when selecting a plan option, making it easier for consumers to compare available plan options.

More specifically, we stated that with these standardized plan options, consumers continue to be able to more easily consider meaningful factors, such as networks, formularies, and premiums, when selecting a plan. We stated that we further believe these standardized plan options include several distinctive features, such as enhanced pre-deductible coverage for several benefit categories and copayments instead of coinsurance rates for a greater number of benefit categories, that will continue to play an important role in reducing barriers to access, combatting discriminatory benefit designs, and advancing health equity.

We explained that including enhanced pre-deductible coverage for these benefit categories (specifically, primary care visits, specialist visits, speech therapy, occupational and physical therapy, and generic drugs at all metal levels, with an increasing number of benefit categories exempt at

³⁰³ <https://www.cms.gov/files/document/2025-papi-parameters-guidance-2023-11-15.pdf>.

higher metal levels) ensures consumers are more easily able to access these services without first meeting their deductibles. Additionally, we explained that using copayments instead of coinsurance rates for a greater number of benefit categories reduces the risk of unexpected financial expenses sometimes associated with coinsurance rates.

Furthermore, we proposed to maintain a high degree of continuity with many aspects of the standardized plan option policy finalized in the 2024 Payment Notice to reduce the risk of disruption for all involved interested parties, including issuers, agents, brokers, States, and enrollees. We stated that we believe making major departures from the methodology used to create the standardized plan options finalized in the 2023 and 2024 Payment Notices could result in drastic changes in these plan designs that may create undue burden for interested parties. For example, we noted that if the standardized plan options that we create vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost sharing for services they rely

upon differs substantially from the previous year. We stated that we ultimately believe consistency in standardized plan options is important to allow issuers and enrollees to become accustomed to these plan designs.

We sought comment on our proposed approach to standardized plan options for PY 2025. Additionally, we sought comment on requiring issuers offering QHPs in individual market State Exchanges to offer, in a future plan year, some version of standardized plan options, while not necessarily subjecting them to the full scope of standardized plan option requirements applicable to issuers offering QHPs through the FFEs or SBE-FPs under § 156.201.

In particular, we sought comment on requiring issuers offering QHPs in individual market State Exchanges that are not already required to offer standardized plan options under State requirements to offer some version of standardized plan options, even if these plan designs differ from the requirements of those included in the applicable Payment Notice for that plan year. We also sought comment on requiring States that intend to transition

their Exchange model type from an FFE or SBE-FP to a State Exchange to require their issuers to offer standardized plan options as one condition of this transition. As such, we stated that we were particularly interested in comments from individual market State Exchanges that do not currently require QHP issuers to offer standardized plan options, States with an FFE or SBE-FP Exchange model type that intend to transition their Exchange model type to a State Exchange, and issuers offering QHPs through such Exchanges.

We explained that while we recognize that State Exchanges are generally best positioned to set the requirements that serve the nuances of their respective individual markets, we underscored the benefits of offering at least some version of standardized plan options, which we discussed in greater detail in the preamble discussion of § 156.201 in the 2023 Payment Notice (87 FR 27316). We also explained that we believe the fact that over half of all State Exchanges currently require issuers to offer standardized plan options in one form or another suggests that they, too, see value in standardized plan options.

TABLE 11—2025 STANDARDIZED OPTIONS SET ONE (FOR ALL FFE AND SBE-FP ISSUERS, EXCLUDING ISSUERS IN DELAWARE, LOUISIANA, AND OREGON)

| | Expanded Bronze | Standard Silver | Silver 73 CSR | Silver 87 CSR | Silver 94 CSR | Gold | Platinum |
|--|-----------------|-----------------|---------------|---------------|---------------|---------|----------|
| Actuarial Value | 63.81% | 70.01% | 73.09% | 87.33% | 94.14% | 78.06% | 88.04% |
| Deductible | \$7,500 | \$5,000 | \$3,000 | \$500 | \$0 | \$1,500 | \$0 |
| Maximum Out-of-Pocket Limitation | \$9,200 | \$8,000 | \$6,400 | \$3,000 | \$2,000 | \$7,800 | \$4,300 |
| Emergency Room Services | 50% | 40% | 40% | 30% | * 25% | 25% | * \$100 |
| Inpatient Hospital Services (Including Mental Health & Substance Use Disorder) | 50% | 40% | 40% | 30% | * 25% | 25% | * \$350 |
| Primary Care Visit | * \$50 | * \$40 | * \$40 | * \$20 | * \$0 | * \$30 | * \$10 |
| Urgent Care | * \$75 | * \$60 | * \$60 | * \$30 | * \$5 | * \$45 | * \$15 |
| Specialist Visit | * \$100 | * \$80 | * \$80 | * \$40 | * \$10 | * \$60 | * \$20 |
| Mental Health & Substance Use Disorder Outpatient Office Visit | * \$50 | * \$40 | * \$40 | * \$20 | * \$0 | * \$30 | * \$10 |
| Imaging (CT/PET Scans, MRIs) | 50% | 40% | 40% | 30% | * 25% | 25% | * \$100 |
| Speech Therapy | * \$50 | * \$40 | * \$40 | * \$20 | * \$0 | * \$30 | * \$10 |
| Occupational, Physical Therapy | * \$50 | * \$40 | * \$40 | * \$20 | * \$0 | * \$30 | * \$10 |
| Laboratory Services | 50% | 40% | 40% | 30% | * 25% | 25% | * \$30 |
| X-rays/Diagnostic Imaging | 50% | 40% | 40% | 30% | * 25% | 25% | * \$30 |
| Skilled Nursing Facility | 50% | 40% | 40% | 30% | * 25% | 25% | * \$150 |
| Outpatient Facility Fee (Ambulatory Surgery Center) | 50% | 40% | 40% | 30% | * 25% | 25% | * \$150 |
| Outpatient Surgery Physician & Services | 50% | 40% | 40% | 30% | * 25% | 25% | * \$150 |
| Generic Drugs | * \$25 | * \$20 | * \$20 | * \$10 | * \$0 | * \$15 | * \$5 |
| Preferred Brand Drugs | \$50 | * \$40 | * \$40 | * \$20 | * \$15 | * \$30 | * \$10 |
| Non-Preferred Brand Drugs | \$100 | \$80 | \$80 | \$60 | * \$50 | * \$60 | * \$50 |
| Specialty Drugs | \$500 | \$350 | \$350 | \$250 | * \$150 | * \$250 | * \$150 |

* Benefit category not subject to the deductible.

TABLE 12—2025 STANDARDIZED OPTIONS SET TWO (FOR ISSUERS IN DELAWARE AND LOUISIANA)

| | Expanded bronze | Standard silver | Silver 73 CSR | Silver 87 CSR | Silver 94 CSR | Gold | Platinum |
|--|-----------------|-----------------|---------------|---------------|---------------|---------|----------|
| Actuarial Value | 63.81% | 70.01% | 73.10% | 87.36% | 94.37% | 78.10% | 88.07% |
| Deductible | \$7,500 | \$5,000 | \$3,000 | \$500 | \$0 | \$1,500 | \$0 |
| Maximum Out-of-Pocket Limitation | \$9,200 | \$8,000 | \$6,400 | \$3,000 | \$2,000 | \$7,800 | \$4,300 |
| Emergency Room Services | 50% | 40% | 40% | 30% | * 25% | 25% | * \$100 |
| Inpatient Hospital Services (Including Mental Health & Substance Use Disorder) | 50% | 40% | 40% | 30% | * 25% | 25% | * \$350 |
| Primary Care Visit | * \$50 | * \$40 | * \$40 | * \$20 | * \$0 | * \$30 | * \$10 |
| Urgent Care | * \$75 | * \$60 | * \$60 | * \$30 | * \$5 | * \$45 | * \$15 |

TABLE 12—2025 STANDARDIZED OPTIONS SET TWO (FOR ISSUERS IN DELAWARE AND LOUISIANA)—Continued

| | Expanded bronze | Standard silver | Silver 73 CSR | Silver 87 CSR | Silver 94 CSR | Gold | Platinum |
|--|-----------------|-----------------|---------------|---------------|---------------|---------|----------|
| Specialist Visit | * \$100 | * \$80 | * \$80 | * \$40 | * \$10 | * \$60 | * \$20 |
| Mental Health & Substance Use Disorder Outpatient Office Visit | * \$50 | * \$40 | * \$40 | * \$20 | * \$0 | * \$30 | * \$10 |
| Imaging (CT/PET Scans, MRIs) | 50% | 40% | 40% | 30% | * 25% | 25% | * \$100 |
| Speech Therapy | * \$50 | * \$40 | * \$40 | * \$20 | * \$0 | * \$30 | * \$10 |
| Occupational, Physical Therapy | * \$50 | * \$40 | * \$40 | * \$20 | * \$0 | * \$30 | * \$10 |
| Laboratory Services | 50% | 40% | 40% | 30% | * 25% | 25% | * \$30 |
| X-rays/Diagnostic Imaging | 50% | 40% | 40% | 30% | * 25% | 25% | * \$30 |
| Skilled Nursing Facility | 50% | 40% | 40% | 30% | * 25% | 25% | * \$150 |
| Outpatient Facility Fee (Ambulatory Surgery Center) | 50% | 40% | 40% | 30% | * 25% | 25% | * \$150 |
| Outpatient Surgery Physician & Services | 50% | 40% | 40% | 30% | * 25% | 25% | * \$150 |
| Generic Drugs | * \$25 | * \$20 | * \$20 | * \$10 | * \$0 | * \$15 | * \$5 |
| Preferred Brand Drugs | * \$50 | * \$40 | * \$40 | * \$20 | * \$5 | * \$30 | * \$10 |
| Non-Preferred Brand Drugs | \$100 | \$80 | \$80 | \$60 | * \$10 | * \$60 | * \$50 |
| Specialty Drugs | \$150 | \$125 | \$125 | \$100 | * \$20 | * \$100 | * \$75 |

* Benefit category not subject to the deductible.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed approach with respect to standardized plan options, as proposed. Our finalized plan designs for PY 2025 are detailed in Tables 11 and 12 of this final rule and reflect no changes to the plan designs in Tables 12 and 13 of the proposed rule. We summarize and respond to public comments received on the proposed approach to standardized plan options below.

Comment: Many commenters supported continuing to require FFE and SBE–FP QHP issuers to offer standardized plan options. These commenters explained that with continued plan proliferation, the risk persists that consumers may experience plan choice overload as they attempt to navigate the plan selection process. Commenters explained that these standardized plan options continue to play an important role in streamlining the plan selection process by reducing the number of variables consumers must consider when selecting a plan that best fits their unique health care needs.

In particular, commenters explained that standardizing the cost sharing parameters for these plans allows consumers to focus on other important plan attributes, such as networks, formularies, quality ratings, and premiums, when selecting a plan. This in turn allows consumers to ensure the health plan they ultimately select has a network that includes providers important to them, a formulary that includes critical prescription drug coverage, and quality ratings that meet consumers' desired standards. Commenters further explained that promoting informed decision-making reduces the risk of plan choice overload, suboptimal plan selection, and

unexpected financial harm for those consumers least able to afford it.

Several commenters also supported the continuation of differential display of these standardized plan options on *HealthCare.gov* to further facilitate the plan selection process. These commenters explained that continuing to differentially display these plans would help make it easier for consumers to make meaningful comparisons of available plan options. Several commenters also recommended making “additional enhancements” to choice architecture and the user experience on *HealthCare.gov* to further streamline consumer decision-making.

Response: We agree that standardized plan options continue to serve as one important facet of HHS' multifaceted strategy of reducing the rate of plan proliferation, the risk of plan choice overload, the frequency of suboptimal plan selection, and incidences of unexpected financial harm for consumers. We believe that continuing to require issuers to offer these standardized plan options, reducing the non-standardized plan option limit, introducing the non-standardized plan option limit exceptions process (which is described in more detail in section III.E.7 of the preamble of this final rule), continuing to differentially display these standardized plan options on *HealthCare.gov*, and enhancing choice architecture and the user experience on *HealthCare.gov* represent a comprehensive approach to improving Exchange coverage.

Regarding the comments recommending that we make “additional enhancements” to choice architecture and the user experience on *HealthCare.gov* to further streamline consumer decision-making, the commenters did not specify, and we are unsure, what they mean by “additional enhancements.” However, as noted

earlier, we agree that enhancing choice architecture and the user experience on *HealthCare.gov* will help improve Exchange coverage, including by streamlining consumer decision-making, and we will consider additional ways to do so in the future.

Comment: Several commenters opposed continuing to require issuers to offer these standardized plan options. These commenters explained that continuing to subject issuers to these requirements inhibits issuer innovation in plan designs. These commenters explained that issuers are most familiar with the unique health care needs of their enrollees and that they should therefore be given the leeway to design plans that meet these needs. Several of these commenters also recommended the cessation of the differential display of these standardized plan options, explaining that these plans should not be given preferential treatment over non-standardized plan options.

Response: We disagree that continuing to require issuers in the FFEs and SBE–FPs to offer standardized plan options will inhibit issuer innovation in plan design, even with the reduction in the non-standardized plan option limit described in more detail in section III.E.7 of the preamble to this final rule. This is because, in PY 2025 and subsequent plan years, issuers will be permitted to offer two non-standardized plan options per product type, metal level, inclusion of dental and/or vision benefit coverage, and service area, as well as additional non-standardized plan options per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, so long as these additional plans substantially benefit consumers with chronic and high-cost conditions and meet the other criteria for the exceptions process finalized in this rule, as

explained in more detail in section III.E.7 of the preamble to this final rule.

We believe the fact that issuers continue to be permitted to offer these non-standardized plan options ensures that consumers will continue to have access to a sufficiently broad range of plan designs that meet their diverse needs and that issuers can continue to offer innovative plan designs. We further believe that continuing to require issuers to offer standardized plan options, reducing the non-standardized plan option limit, and introducing an exceptions process for this limit strikes an appropriate balance between limiting the risk of plan choice overload while simultaneously continuing to permit issuers a sufficient degree of flexibility to offer innovative plan designs.

Further, we reiterate that issuers are not limited in the number of standardized plan options they may offer, meaning issuers continue to retain the ability to offer standardized plan options with different benefit packages, networks, and formulary variations, so long as they conform to the required cost sharing parameters for these plans.

Finally, differential display of these standardized plan options on *HealthCare.gov* does not result in the preferential display of standardized plan options over non-standardized plan options, and we believe that this differential display strikes an appropriate balance between facilitating the plan selection process while still allowing consumers the opportunity to consider all available non-standardized plan options. The form of differential display currently employed on *HealthCare.gov* distinguishes standardized plan options from non-standardized plan options by assigning standardized plan options a visual icon and a corresponding label. That form of differential display also permits consumers to filter all available plan choices to see only standardized plan options. However, consumers must actively choose to employ this filter.

Furthermore, this form of differential display does not elevate standardized plan options to the top of the sorting feature over non-standardized plan options such that they would always be the first plans that consumers see regardless of premium, as would be done if standardized plan options were preferentially displayed. Thus, although standardized plan options are distinguished from non-standardized plan options, the form of differential display currently employed on *HealthCare.gov* allows consumers to easily see and compare all available

plan options, including non-standardized plan options.

Comment: Many commenters supported our approach to the design of these standardized plan options for PY 2025. Specifically, commenters supported maintaining a high degree of continuity in these plan designs year over year to reduce the risk of unnecessary disruption for enrollees and issuers. Commenters explained that drastically modifying the plan designs from year to year could result in avoidable financial harm if the cost sharing for benefits that consumers depend upon increases unexpectedly, which may result in consumers forgoing obtaining medical care and, consequently, experiencing poorer health outcomes.

Response: We agree that maintaining a high degree of continuity in our standardized plan options from year to year is desirable for several reasons. Specifically, we agree that having consistent year-to-year plan designs allows enrollees to become better acquainted with these plans, increasing both consumer understanding and financial certainty. We also agree that drastically modifying the plan designs from year to year could result in avoidable financial harm if the cost sharing for benefits that consumers depend upon increases unexpectedly, which could also result in consumers forgoing obtaining medical care. Although we believe that, today, the benefits that may arise from making major modifications to these plan designs are outweighed by the risk that doing so could result in undue burden for issuers and enrollees, we may consider making major modifications to the design of these standardized plan options in future rulemakings if our assessment changes.

Comment: Several commenters made specific recommendations regarding particular aspects of the standardized plan options. Specifically, several of these commenters recommended lowering the maximum out-of-pocket values in these plan designs. We clarify that in this context, a plan's "maximum out-of-pocket" value refers to the plan's specific annual limitation on cost sharing value. These commenters explained that a high maximum out-of-pocket limitation on cost sharing places unreasonable burden on consumers with chronic and high-cost conditions. These commenters also explained that lowering the maximum out-of-pocket limitation on cost sharing values for these plans would advance health equity by reducing the amount that consumers from disadvantaged populations, whom commenters

explained are disproportionately affected by chronic and high-cost conditions, must pay for the treatment of these conditions.

Several commenters also recommended lowering the deductibles and expanding pre-deductible coverage to include additional benefit categories. These commenters explained that high deductibles often act as an obstacle that prevents consumers from obtaining the health care they need. These commenters further explained that lowering the deductibles for these plans and expanding pre-deductible coverage would reduce barriers to access to health care, reducing the risk of consumers forgoing obtaining medical care and, consequently, experiencing poorer health outcomes.

Several commenters supported the decision to continue including copayments instead of coinsurance rates for a range of benefit categories within these plan designs. Several of these commenters recommended expanding the use of copayments to apply to a greater number of benefit categories. These commenters explained that utilizing copayments instead of coinsurance rates increases financial certainty for consumers when they obtain the health care they need. Other commenters recommended standardizing the cost-sharing parameters for additional benefit categories not already standardized within these plan designs to further enhance plan comparability and reduce financial uncertainty. Several commenters recommended including health savings account (HSA)-compliant high-deductible health plan (HDHP) designs in each of these sets of standardized plan options.

Response: We acknowledge that high maximum out-of-pocket limitation on cost sharing values, high deductibles, and limited pre-deductible coverage can sometimes act as barriers that prevent consumers, including those with chronic and high-cost conditions, from obtaining the health care they need. We also acknowledge that coinsurance rates can potentially increase consumer uncertainty regarding how much particular services may cost.

However, due to AV constraints arising from the permissible *de minimis* range restriction for each metal level in accordance with § 156.140(c)(2), we are unable to substantially lower the maximum out-of-pocket limitation or deductible values, expand pre-deductible coverage to include additional benefits, or include copayments as the form of cost sharing for a broader range of benefit categories without a corresponding increase in the

AV of each plan. Making some combination of these modifications would increase the generosity of these plans, potentially to the point of each plan's AV exceeding the permissible *de minimis* range for its respective metal level. Furthermore, even if making some combination of these changes resulted in an AV within the permissible *de minimis* range for each metal level, there would still be a corresponding increase in premiums that would render these plans costlier for consumers and potentially uncompetitive.

Finally, we note that although it may be possible to make some combination of these modifications to these plan designs while maintaining an AV near the floor of the *de minimis* range for each metal level, doing so would require a corresponding increase in cost sharing for other benefits or subjecting additional benefits to the deductible to offset this increase in generosity. Since the benefits that we have exempted from the deductible as well as the benefits for which we have reduced cost sharing are some of the most frequently utilized benefits, we believe that the disadvantages of subjecting these benefits to the deductible or increasing the cost sharing for these benefits would outweigh the benefit that may arise from exempting other benefits from the deductible or reducing cost sharing for other benefits. Those disadvantages include risks that these plans would become uncompetitive and that consumers would forego obtaining medical services covered by these frequently utilized benefits which would be newly subject to the deductible or have increased cost sharing.

We also note that we are not standardizing the cost sharing for additional benefit categories beyond those already included in these plan designs since EHB-benchmark plans vary significantly by State, and we do not wish to standardize the cost sharing for benefits that issuers may not be required to offer in particular States. We also note that we have not included an HSA-eligible HDHP in these sets of plan designs due to decreased enrollment in these plans in the last several plan years, which suggests they may be less competitive and in-demand than traditional health insurance plans.

We thus declined to include HSA-eligible HDHPs in these sets of plan designs because our approach is to design standardized plan options that reflect the most popular QHPs offered through the Exchanges (87 FR 27319). We also declined to include an HSA-eligible HDHP in these sets of plan designs because we have not included

these types of plans in the sets of standardized plan options for PY 2023 or PY 2024, and we want to maintain a high degree of continuity with the standardized plan option policies and designs finalized in the 2023 and 2024 Payment Notices. However, we note that QHP issuers in the FFEs and SBE-FPs continue to be permitted to offer HSA-eligible HDHPs as non-standardized plan options, if so desired.

Comment: Many commenters supported expanding the requirement for issuers to offer standardized plan options to also apply to State Exchange issuers in a future plan year. Several of these commenters supported requiring all State Exchange issuers to offer some version of standardized plan options—including those issuers that are offering QHPs through already-established State Exchanges and are not currently subject to such a requirement. Other commenters supported requiring States that intend to transition their Exchange model type from an FFE or SBE-FP to a State Exchange to require their issuers to offer standardized plan options as a condition of that transition, while exempting issuers that are currently offering QHPs through State Exchanges and are not currently subject to such a requirement.

Many commenters pointed to the fact that many State Exchange issuers are already required to offer standardized plan options, which commenters argued demonstrates the utility of standardized plan options. These commenters further explained that the benefits of standardized plan options should not be limited to consumers purchasing health insurance coverage through FFEs and SBE-FPs—and instead, that these benefits should also be extended to consumers purchasing health insurance coverage through State Exchanges. Several of these commenters explained that the trend of plan proliferation that has been present in the FFEs and SBE-FPs for several years has also been present in many State Exchanges. These commenters thus explained that HHS should employ the same measures to address plan proliferation in State Exchanges that it utilizes in the FFEs and SBE-FPs.

Conversely, many commenters opposed requiring State Exchange issuers to offer some version of standardized plan options in a future plan year. Some of these commenters opposed expanding this requirement to all State Exchange issuers, while others only opposed expanding this requirement to State Exchange issuers not already subject to such a requirement. Other commenters only opposed expanding this requirement to

State Exchange issuers as a condition of a State transitioning its Exchange model type from an FFE or SBE-FP to a State Exchange in a future plan year.

These commenters explained that expanding this requirement to apply to State Exchange issuers would unnecessarily constrain a State's flexibility in operating its Exchange. These commenters highlighted the importance of the flexibility inherent to the State Exchange model type as one of the primary factors that motivates States to pursue this model type. These commenters further explained that requiring State Exchange issuers to offer some version of standardized plan options would make it more difficult for issuers to tailor health plans to meet the unique needs of each State's population. These commenters also explained that State regulators' and issuers' experience with and insight into their respective individual markets makes them uniquely suited to determine whether standardized plan options fit the health care coverage needs of their consumers.

Response: We acknowledge the potential advantages and disadvantages of expanding the requirement that QHP issuers offer standardized plan options to State Exchange issuers, including the advantages and disadvantages of expanding this requirement to all State Exchange issuers not already subject to such a requirement, as well as the advantages and disadvantages of expanding this requirement only to issuers that offer QHPs through an Exchange that transitions from an FFE or SBE-FP to a State Exchange in a future plan year.

Consistent with our rationale for not expanding the requirement that QHP issuers offer standardized plan options to State Exchange issuers in the 2023 Payment Notice (87 FR 27311), we continue to believe that expanding this requirement to State Exchange issuers would unnecessarily constrain a State's flexibility in operating its Exchange. We further continue to believe that State Exchanges' experience with and insight into their respective individual markets makes them uniquely suited to determine whether standardized plan options fit the health care coverage needs of their consumers and, if so, how those plans should be designed. 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 note that we will consider the potential advantages and disadvantages of expanding the requirement that QHP issuers offer standardized plan options to State Exchange issuers, including the advantages and disadvantages of expanding this requirement to all State Exchange issuers not already subject to such a requirement, as well as the advantages and disadvantages of expanding this requirement only to issuers that offer QHPs through an Exchange that transitions from an FFE or SBE-FP to a State Exchange in a future plan year. These considerations may inform our approach in any future rulemaking regarding standardized plan options.

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

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82606), HHS proposed to exercise its authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to amend § 156.202 by adding paragraphs (d) and (e) to introduce an exceptions process that would allow issuers to offer additional non-standardized plan options per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent plan years, if issuers demonstrate that these additional non-standardized plans have specific design features that would substantially benefit consumers with chronic and high-cost conditions. Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA for, among other things, the offering of QHPs through such Exchanges.

In the 2024 Payment Notice (88 FR 25855 through 25865), we finalized requirements limiting the number of non-standardized plan options that issuers of QHPs can offer through Exchanges on the Federal platform (including SBE-FPs) to four non-standardized plan options per product network type (as described in the definition of “product” at § 144.103), metal level (excluding catastrophic plans), inclusion of dental and/or vision benefit coverage, and service area for PY 2024, and two for PY 2025 and subsequent plan years. In the 2025 Payment Notice proposed rule, we did not propose to amend these non-

standardized plan option limits at § 156.202(a) through (b).

In the 2024 Payment Notice, we explained that we phased in this limit over 2 plan years (instead of adopting the limit of two in PY 2024) primarily to decrease the risk of disruption for both issuers and enrollees and to provide increased flexibility to issuers. We explained that many commenters supported adopting a more gradual approach in which the number of non-standardized plan options that issuers can offer is incrementally decreased over a span of 2 plan years, instead of adopting a limit of two for PY 2024. We referred readers to the preamble of the 2024 Payment Notice discussing § 156.202 (88 FR 25855 through 25865) for more detailed discussion of our approach to non-standardized plan option limits for PY 2024 and related background.

As a result of the limit on the number of non-standardized plan options that issuers can offer through the Exchanges being reduced from four in PY 2024 to two in PY 2025, in the proposed rule (88 FR 82607), we estimated (based on then-current PY 2024 plan offering data) that the weighted average number of non-standardized plan options available to each consumer would be reduced from 67.3 in PY 2024 to approximately 41.7 in PY 2025. We also estimated that the weighted average total number of plans, including both standardized and non-standardized plan options, available to each consumer would be reduced from 91.8 in PY 2024 to approximately 66.2 in PY 2025.³⁰⁴

Furthermore, in the proposed rule, we estimated that approximately 28,275 of the total 109,229 non-standardized plan option plan-county combinations³⁰⁵ (25.9 percent) would be discontinued as a result of this limit in PY 2025. Relatedly, based on trended enrollment data from PY 2023 (which we relied on for purposes of this estimate because PY 2024 enrollment data was unavailable when we finalized the proposed rule), we estimated that approximately 1.78 million of the 14.94 million enrollees on

the FFEs and SBE-FPs (11.9 percent) would be affected by these discontinuations in PY 2025.

However, based on updated PY 2024 plan offering and enrollment data, we now estimate that the weighted average number of non-standardized plan options available to each consumer will be reduced from 71.4 in PY 2024 to approximately 48.5 in PY 2025. Additionally, we estimate that the weighted average total number of plans, including standardized and non-standardized plan options, available to each consumer will be reduced from 99.5 in PY 2024 to approximately 76.6 in PY 2025.

Furthermore, based on this updated data, we estimate that approximately 27,660 of the total 87,620 non-standardized plan option plan-county combinations (31.6 percent) will be discontinued as a result of this limit in PY 2025. Relatedly, we estimate that approximately 1.43 million of the 16.34 million enrollees on the FFEs and SBE-FPs (8.7 percent) will be affected by these discontinuations in PY 2025.

In the proposed rule (88 FR 82607), we proposed an exceptions process at new § 156.202(d) and (e) that would permit FFE and SBE-FP issuers to offer more than two non-standardized plan options per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent plan years, if issuers demonstrate that these additional non-standardized plans beyond the limit at § 156.202(b) have specific design features that would substantially benefit consumers with chronic and high-cost conditions. We further proposed that issuers would not be limited in the number of exceptions permitted per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, so long as they meet specified criteria.

Specifically, we stated in the proposed rule that pursuant to proposed § 156.202(d), issuers would be permitted to offer more than two non-standardized plan options if these additional plans’ cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer’s other non-standardized plan option offerings in the same product network type, metal level, and service area.

³⁰⁴ The weighted average total number of plans available to each consumer was 107.8 in PY 2022, prior to the introduction of standardized plan option requirements, and 113.6 in PY 2023, the first year that standardized plan option requirements were introduced.

³⁰⁵ Plan-county combinations are the count of unique plan ID and FIPS code combinations. This measure was used because a single plan may be available in multiple counties, and specific limits on non-standardized plan options or specific dollar deductible difference thresholds may have different impacts on one county where there are four plans of the same product network type and metal level versus another county where there are only two plans of the same product network type and metal level, for example.

We stated that the reduction could not be limited to a part of the year, or an otherwise limited scope of benefits. Instead, we stated that issuers would be required to apply the reduced cost sharing for these benefits any time the covered item or service is furnished. For example, we explained that an issuer could not reduce cost sharing for the first three office visits or drug fills and then increase it for remaining visits or drug fills. Furthermore, we stated that issuers would be prohibited from conditioning reduced cost sharing for these benefits on a particular diagnosis. That is, we stated that although the benefit design would have reduced cost sharing to address one or more articulated conditions, the reduced cost sharing must be available to all enrolled in the plan who receive the service(s) covered by the benefit.

We explained in the proposed rule that no other plan design features (such as the inclusion of additional benefit coverage, different provider networks, different formularies, or reduced cost sharing for benefits provided through the telehealth modality) would be evaluated under this exceptions process, meaning no other differences in plan design features would allow issuers to be excepted from the limit to the number of non-standardized plan options offered per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area.

Additionally, we stated in the proposed rule that, as part of this exceptions process, issuers would be required, under proposed § 156.202(e), to submit a written justification in a form and manner and at a time prescribed by HHS that provides additional details and explains how the particular plan design the issuer desires to offer above the non-standardized plan option limit of two satisfies the proposed standards for receiving an exception to this limit—namely, how the particular plan would substantially benefit consumers with chronic and high-cost conditions. We noted that we would provide issuers with a justification form upon publication of the final rule and when the QHP templates for the applicable plan year are released.

We proposed that this justification form would ask the issuer to (1) identify the specific condition(s) for which cost sharing is reduced, (2) explain which benefits would have reduced annual enrollee cost sharing (as opposed to reduced cost sharing for a limited number of visits) for the treatment of the specified condition(s) by 25 percent or more relative to the cost sharing for the

same corresponding benefits in an issuer's other non-standardized plan offerings in the same product network type, metal level, and service area, and (3) explain how the reduced cost sharing for these services pertains to clinically indicated guidelines for treatment of the specified chronic and high-cost condition(s).

Additionally, we stated that to allow the Exchange adequate time to review these justification forms, issuers would need to submit their QHP application in a form and manner and at a time specified by us. We further stated that we anticipated requesting that issuers submit QHP applications for non-standardized plan options that exceed the two-plan limit by the QHP certification Early Bird deadline.

We proposed to allow exceptions only for plans that meet the previously described requirements for benefits pertaining to the treatment of conditions that are chronic and high-cost in nature. We clarified that, for purposes of this standard, chronic conditions are those that have an average duration of one year or more and require ongoing medical attention or limit activities of daily living, or both.³⁰⁶ We also clarified that, for purposes of this standard, high-cost conditions are those that account for a disproportionately high portion of total Federal health expenditures. We noted that the four chronic and high-cost conditions included in the prescription drug adverse tiering for PY 2025 (specifically, hepatitis C virus, HIV, multiple sclerosis, and rheumatoid arthritis) are examples of conditions that we would consider to be chronic and high-cost in nature for purposes of this standard.

However, for purposes of this standard, we clarified that we would also consider additional conditions to be chronic and high-cost in nature. We stated that additional representative examples of conditions that we would consider to be chronic and high-cost in nature for purposes of this proposal include Alzheimer's disease, kidney disease, osteoporosis, heart disease, diabetes, and all kinds of cancer. We further stated that examples of conditions that we would not consider chronic and high-cost in nature would be those that are generally acute in nature, including bronchitis, the flu, pneumonia, strep throat, and respiratory infections.

We proposed this approach for several reasons. Considering that chronic and

high-cost conditions (including the examples previously discussed) affect a comparatively low number of consumers, we stated that we anticipated that a significant portion of the non-standardized plan options that may be discontinued due to having comparatively lower rates of enrollment among each issuer's portfolio of offerings could potentially be those that have plan design features that benefit consumers with these chronic and high-cost conditions (such as plans with some combination of enhanced pre-deductible coverage for relevant services, reduced cost sharing for relevant benefits, lower maximum out-of-pocket limitations, lower deductibles, more comprehensive provider networks with more specialized providers, more generous formularies with more specialized medications, higher AVs, and higher premiums).

We explained in the proposed rule (88 FR 82608) that even with comparatively lower rates of enrollment, these non-standardized plan options can still fulfill an important role in addressing chronic and high-cost conditions, which are responsible for a disproportionate amount of health care expenditures.³⁰⁷ Thus, we stated that this proposed exceptions process could play an important role in enhancing the quality of life for those affected by these conditions, combatting health disparities, advancing health equity, and reducing health care expenditures. We further stated that introducing such an exceptions process while also reducing the non-standardized plan option limit to two for PY 2025 would balance the dual aims of reducing the risk of plan choice overload while simultaneously ensuring that truly innovative plan designs that may benefit consumers with chronic and high-cost conditions can continue to be offered.

We stated in the proposed rule that not limiting the number of permitted exceptions per issuer, product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area (instead of allowing exceptions for only two such plans, for example) would ensure that issuers are not restricted in the number of innovative plans they can offer. We noted that this would in turn help ensure that a greater portion of consumers with chronic and high-cost conditions have access to plans that reduce barriers to access to care for

³⁰⁶ National Center for Chronic Disease Prevention and Health Promotion. *About Chronic Diseases*, July 21, 2022, <https://www.cdc.gov/chronicdisease/about/index.htm>.

³⁰⁷ Waters, H., & Graf, M. (2018). *The Cost of Chronic Disease in the U.S.* Milken Institute. <https://milkeninstitute.org/sites/default/files/reports-pdf/ChronicDiseases-HighRes-FINAL2.pdf>.

services critical to the treatment of their conditions.

We further stated in the proposed rule (88 FR 82608), that although issuers would not be limited in the number of exceptions they may be granted under this proposal, we anticipated that most issuers would determine that the burden of creating and certifying additional non-standardized plans intended to benefit a comparatively small population of consumers would outweigh the benefit of doing so. We noted that we also previously solicited comments on innovative plan designs, such as in the 2024 Payment Notice proposed rule.

We stated that in response to this comment solicitation, we received only two examples of plan designs that commenters considered to be innovative in nature: plan designs that have reduced cost sharing for benefits provided through telehealth, and plan designs that have reduced cost sharing for services and medications related to the treatment of diabetes (such as in the form of insulin). We clarified that the former example (reduced cost sharing for benefits provided through the telehealth) would not qualify for this exceptions process, while the latter example (reduced cost sharing for benefits related to the treatment of diabetes) could potentially qualify for this exceptions process, if the specified criteria are met.

Regardless, we stated that given that we only received two examples of plan designs that particular issuers considered to be innovative in nature, we did not anticipate that issuers would seek to have a substantial number of non-standardized plan options excepted from the non-standardized plan option limit. As a result, we explained that we did not anticipate this proposal would result in an increased risk of plan choice overload for consumers interested in plans with better benefits for qualifying conditions.

We stated in the proposed rule (88 FR 82608), that permitting exceptions solely based on whether a non-standardized plan option has reduced cost sharing of 25 percent or more for benefits pertaining to the treatment of chronic and high-cost conditions, as opposed to considering other factors (such as specialized networks, specialized formularies, or specialized benefit packages), is appropriate since the current standardized plan option requirements do not limit issuers in the number of standardized plan options they can offer per product network type, metal level, or service area.

However, we noted that standardized plan option requirements do not permit

issuers to deviate from the specified cost sharing parameters for standardized plan options—meaning issuers would not be able to offer standardized plan options with reduced cost sharing of 25 percent or more for the treatment of specific conditions if the benefit category's cost sharing does not comply with the specified standards. Thus, we noted that under the current standardized plan option framework, issuers already have the flexibility to offer specialized provider networks, formularies, and benefit packages (including those that decrease barriers to access for the treatment of chronic and high-cost conditions—such as by including additional specialized providers, prescription drugs, or benefits) as standardized plan options.

We further stated that the cost sharing difference threshold of 25 percent or more is appropriate since we have observed that cost sharing differences below this threshold represent normal variation within a particular metal level, while differences at or above this threshold are more often associated with cost sharing differences between different metal levels. We do not believe that a difference in a cost sharing amount that is of the same magnitude as normal variation within a particular metal level (specifically, less than 25 percent) would warrant being excepted from the non-standardized plan option limit.

We noted that under this proposed exceptions process, if additional plans were permitted to be offered in excess of the limit of two non-standardized plan options, in accordance with the guaranteed availability requirements at § 147.104(a), these plans would also be required to be made available on the same basis to consumers without these chronic and high-cost conditions. Further, we emphasized that these plans would be prohibited from discriminating in accordance with the nondiscrimination requirements at §§ 147.104(e), 156.125, and 156.200(e).³⁰⁸ We noted that to meet these non-discrimination requirements, these plans would be required to apply preferential cost sharing to all enrolled in the plan, without regard to diagnosis.

Furthermore, although we acknowledged that non-standardized plan options excepted under this

³⁰⁸ The nondiscrimination requirements at § 147.104(e) apply to health insurance issuers offering non-grandfathered group or individual health insurance coverage, and their officials, employees, agents, and representatives. The nondiscrimination requirements at § 156.200(e) apply to QHPs in the individual and small-group markets, and the nondiscrimination requirements at § 156.125(b) apply to issuers providing EHB.

proposal would primarily benefit consumers with chronic and high-cost conditions, we stated that a sufficiently satisfactory range of both non-standardized and standardized plan options currently exist that are primarily intended for consumers without chronic and high-cost conditions. As a result, we explained that we were not concerned that any risk of discrimination created by this exceptions process would negatively impact consumers, including but not limited to consumers with chronic and high-cost conditions.

We sought comment on this proposed approach. Specifically, we sought comment on the proposed exceptions process, and whether there should be any exceptions at all to the limit on the number of non-standardized plan options that issuers can offer through the Exchanges. In addition, we noted that we were particularly interested in comments on the following topics: whether exceptions should be permitted only for a specific set of chronic and high-cost conditions as opposed to any chronic and high-cost condition; whether there are other plan attributes we should consider outside of sufficiently differentiated cost sharing, such as the inclusion of alternative payment models or sufficiently differentiated benefits, networks, or formularies; the specific difference threshold for these cost-sharing amounts, including whether a threshold higher or lower than 25 percent would be more appropriate; the specific components of the justification form that issuers would be required to submit; the deadline for issuers to submit the materials necessary for us to consider whether non-standardized plan options should be excepted from the limit; and whether we should require that non-standardized plan options excepted from the limit be visually differentiated from other non-standardized plan options not excepted from the limit—such as by differentially displaying these excepted plans on *HealthCare.gov*, or by requiring these excepted plans to adopt a particular plan marketing name that accurately conveys how these plans would substantially benefit consumers with chronic and high-cost conditions (for example, by requiring that an excepted plan that reduces cost sharing for the treatment of diabetes have a corresponding plan marketing name related to diabetes).

We also sought comment on other ways to balance the dual aims of reducing the risk of plan choice overload while simultaneously ensuring that truly innovative plan designs that

may benefit consumers with chronic and high-cost conditions can continue to be offered. Specifically, we sought comment on whether we should limit the number of exceptions available such that issuers are only permitted to offer one or several additional plans pursuant to the proposed exceptions process above the limit of two non-standardized plans—as opposed to not limiting the number of exceptions permitted per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision with the following modifications. In particular, we are finalizing at new § 156.202(d)(1) that a 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions will be evaluated at the level of total out-of-pocket costs for the treatment of the chronic and high-cost condition for a population of enrollees with the relevant chronic and high-cost condition.

In addition, we are moving the requirement that the reduction in cost sharing must not be limited to a part of the year, or an otherwise limited scope of benefits, from § 156.202(d) in the proposed regulation text to § 156.202(d)(2) in the final regulation text. We are also moving the requirement that the reduction in cost sharing for these benefits cannot be conditioned on a consumer having a particular diagnosis from § 156.202(d) in the proposed regulation text to § 156.202(d)(3) in the final regulation text.

We are also finalizing at new § 156.202(d)(4) that the required reduction in cost sharing only applies to the standard variant of the plan for which an issuer seeks an exception, and not to the income-based cost-sharing reduction plan variations required by § 156.420(a), nor to the zero and limited cost-sharing plan variations required by § 156.420(b). In addition, we are finalizing at new § 156.202(d)(5) that issuers are limited to one exception per

product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, for each chronic and high-cost condition. We are also moving the requirement that the chronic and high-cost conditions that may qualify an issuer for this exception will be determined by HHS from § 156.202(d) in the proposed regulation text to § 156.202(d)(6) in the final regulation text.

Furthermore, we are modifying the regulation text describing requirements related to the written justification issuers will be required to submit to utilize this exceptions process at § 156.202(e)(1) through (3), to more accurately reflect how the reduction in cost sharing will be evaluated under this exceptions process. Finally, we are adding a requirement at § 156.202(e)(4) for issuers to submit a corresponding actuarial memorandum demonstrating the underlying actuarial assumptions made in the design of the plan the issuer is requesting to except, which includes a confirmatory actuarial opinion. These modifications are discussed in greater detail later in this section.

In addition, we note that we no longer anticipate requesting that issuers submit exception requests and accompanying justification forms by the QHP certification Early Bird deadline. Instead, we anticipate that the exception request and justification form submission deadline for issuers seeking to utilize this exceptions process will be the initial submission deadline for QHP certification applications, aligning the exception request deadline with the submission deadlines for QHP certification applications for standardized and non-standardized plan option offerings.

We also clarify that the example included in the 2024 Payment Notice that illustrated issuer flexibility to vary the inclusion of dental and/or vision benefit coverage in accordance with § 156.202(c) under the non-standardized plan option limits at § 156.202(a) through (b) failed to distinguish between the adult and pediatric dental benefit coverage categories.

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

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

We affirm that issuers continue to retain this flexibility for PY 2025. Thus, under the non-standardized plan option limit of two for PY 2025, if an issuer desires to offer the theoretical maximum number of plans, and if that issuer varies the inclusion of dental and/or vision benefit coverage in these plans in accordance with the flexibility provided for at § 156.202(c)(1) through (3), that issuer could offer a theoretical maximum of 16 plans in a given product network type, metal level, and service area in the manner demonstrated in Table 13. Furthermore, if an issuer offers QHPs with two product network types (for example, HMO and PPO), that issuer could offer a theoretical maximum of 32 plans in a given metal level and service area in the manner demonstrated in Table 13.

TABLE 13—ISSUER FLEXIBILITY UNDER THE NON-STANDARDIZED PLAN OPTION LIMIT OF TWO FOR PY 2025 AND SUBSEQUENT YEARS

| Plan | Network type | Cost sharing structure | Adult dental | Pediatric dental | Adult vision |
|---------|--------------|------------------------|--------------|------------------|--------------|
| 1 | HMO | A | | | |
| 2 | HMO | A | Covered | | |
| 3 | HMO | A | | Covered | |
| 4 | HMO | A | | | Covered |
| 5 | HMO | A | | Covered | Covered |
| 6 | HMO | A | Covered | | Covered |

TABLE 13—ISSUER FLEXIBILITY UNDER THE NON-STANDARDIZED PLAN OPTION LIMIT OF TWO FOR PY 2025 AND SUBSEQUENT YEARS—Continued

| Plan | Network type | Cost sharing structure | Adult dental | Pediatric dental | Adult vision |
|----------|--------------|------------------------|--------------|------------------|--------------|
| 7 | HMO | A | Covered | Covered | |
| 8 | HMO | A | Covered | Covered | Covered |
| 9 | HMO | B | | | |
| 10 | HMO | B | Covered | | |
| 11 | HMO | B | | Covered | |
| 12 | HMO | B | | | Covered |
| 13 | HMO | B | | Covered | Covered |
| 14 | HMO | B | Covered | | Covered |
| 15 | HMO | B | Covered | Covered | |
| 16 | HMO | B | Covered | Covered | Covered |
| 17 | PPO | C | | | |
| 18 | PPO | C | Covered | | |
| 19 | PPO | C | | Covered | |
| 20 | PPO | C | | | Covered |
| 21 | PPO | C | | Covered | Covered |
| 22 | PPO | C | Covered | | Covered |
| 23 | PPO | C | Covered | Covered | |
| 24 | PPO | C | Covered | Covered | Covered |
| 25 | PPO | D | | | |
| 26 | PPO | D | Covered | | |
| 27 | PPO | D | | Covered | |
| 28 | PPO | D | | | Covered |
| 29 | PPO | D | | Covered | Covered |
| 30 | PPO | D | Covered | | Covered |
| 31 | PPO | D | Covered | Covered | |
| 32 | PPO | D | Covered | Covered | Covered |

Below, we summarize and respond to public comments received on the proposed non-standardized plan option limit exceptions process and the related issues we sought comment on.

Comment: Many commenters supported introducing an exceptions process that would allow issuers to offer non-standardized plan options exceeding the limit of two if the specified requirements are met. Several commenters explained that reducing the non-standardized plan option limit from four in PY 2024 to two in PY 2025 will cause issuers to discontinue plans with lower enrollment, which would likely be plans with designs that are attractive to a smaller number of enrollees that have relatively less common and high-cost health care needs. Commenters thus explained that many of the plans that would likely be discontinued would be those that benefit consumers with chronic and high-cost conditions. As such, commenters explained that permitting issuers to offer additional non-standardized plan options that provide targeted coverage specifically for medically complex populations with chronic and high-cost conditions supports health equity and allows for more targeted innovation by issuers, while still achieving the reduction in plan proliferation HHS has sought.

Many of these commenters noted that individuals with chronic and high-cost

conditions are especially price-sensitive, and that, relative to the average enrollee, these individuals often encounter significantly higher out-of-pocket costs associated with the higher rates of utilization of the services related to treatment of these conditions. Commenters thus explained that plans reducing cost sharing for these services would allow consumers to more easily obtain the medical care they need, resulting in improved patient outcomes. Commenters further explained that this exceptions process could play an important role in advancing health equity by reducing cost sharing for conditions that disproportionately affect disadvantaged populations. Commenters specifically cited diabetes, COPD, HIV, hepatitis C, and rheumatoid arthritis as chronic and high-cost conditions that could be effectively targeted by issuers under this exceptions process.

Conversely, many commenters opposed introducing an exceptions process. Several of these commenters explained that introducing an exceptions process that would allow issuers to exceed the non-standardized plan option limit would contradict the action HHS has taken to reduce the rate of plan proliferation. Additionally, many commenters explained that prioritizing the treatment of chronic and high-cost conditions does not

necessarily require HHS to permit issuers to offer additional non-standardized plans above the non-standardized plan option limit. They explained that plans could still be designed to include specialized benefits and cost sharing for those with chronic and high-cost health conditions within the non-standardized plan option limit.

Many commenters also explained that plans designed specifically to reduce cost sharing for services pertaining to the treatment of chronic and high-cost conditions are likely to involve trade-offs in the form of increasing cost sharing for other services. Commenters noted that consumers with chronic and high-cost conditions are still likely to experience other health needs and may be unlikely to realize a net benefit from the excepted plan if that plan precludes them from appropriately generous cost sharing for a broader set of services.

Response: We acknowledge that reducing the non-standardized plan option limit from four in PY 2024 to two in PY 2025 will cause issuers to discontinue plans, which will likely be those plans with lower rates of enrollment. We also acknowledge that these discontinued plans will likely be those with designs that are attractive to a smaller number of enrollees that have relatively less common and high-cost health care needs.

However, we agree that reducing the non-standardized plan option limit while simultaneously introducing a targeted exceptions process that will allow issuers to offer additional non-standardized plan options that substantially benefit consumers with chronic and high-cost conditions, including consumers who have relatively less common and high-cost health care needs, strikes an appropriate balance between reducing plan proliferation and the risk of plan choice overload while still permitting issuers a sufficient degree of flexibility to innovate as well as a sufficiently ensure a diverse range of plan offerings for consumers to select from.

We also agree that reducing cost sharing for benefits that pertain to the treatment of chronic and high-cost conditions will significantly reduce the total out-of-pocket costs for consumers with these conditions. We further agree that this reduction in out-of-pocket costs will allow consumers to more easily obtain the medical care they need, resulting in improved health outcomes. We also agree that improving health outcomes for consumers with chronic and high-cost conditions that disproportionately affect disadvantaged populations—including diabetes, COPD, HIV, hepatitis C, and rheumatoid arthritis—would advance health equity. Accordingly, we believe that the risk that these types of plans will be discontinued as a result of the reduction in the non-standardized plan option limit from four in PY 2024 to two in PY 2025 is sufficiently mitigated by the targeted exceptions process we are finalizing in this rule.

We also believe the criteria that we have set forth in the exceptions process finalized in this rule, such as requiring issuers to demonstrate that the additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions is at least 25 percent lower than the cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, and service area, ensures that any excepted plans will be meaningfully different from other non-standardized plan options. We also believe these criteria will ensure that this exceptions process will not be utilized as a means to simply offer duplicative non-standardized plan options similar to existing plan offerings. Furthermore, in the last several plan years, the majority of FFE and SBE-FP issuers have not offered plans that would have been eligible for this exceptions process.

Although it is our hope that issuers will take advantage of this exceptions process as a means of advancing health equity, we also anticipate that issuers will carefully consider applying for such exceptions in general, particularly given the stringent requirements of the exceptions process. Furthermore, we note, in particular, that under § 156.202(d)(5), issuers are limited to one exception per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, for each chronic and high-cost condition. Thus, we believe there will be a very limited increase in the number of non-standardized plan options as a result of this exceptions process, and that the risk of the exceptions process causing a meaningful increase in plan proliferation is very low.

We also recognize the importance of plans designed specifically to improve cost sharing for services pertaining to the treatment of chronic and high-cost conditions, and we acknowledge the trade-offs that will likely be required for issuers to create and maintain these plans—namely, increased cost sharing for other services. We also acknowledge that plans could still technically be designed to include specialized benefits and cost sharing for those with chronic and high-cost health conditions within the non-standardized plan option limit.

However, we note that the plans that will likely be discontinued as a result of the reduction in the non-standardized plan option limit for PY 2025 and subsequent years will be those tailored to appeal to a smaller segment of the population—such as those with chronic and high-cost conditions. Thus, we believe this targeted exceptions process will effectively counterbalance the impact that the reduction of this limit may have on these types of plans and the consumers who rely on them. Consumers without the chronic and high-cost conditions targeted by plans that are likely to be discontinued can continue to select among the many available plans that have broader appeal.

Comment: Several commenters recommended limiting the number of exceptions that each issuer may be permitted under this process. These commenters explained that the intent of the non-standardized plan option limit is to mitigate the risk of uncontrolled plan proliferation that leads to consumer confusion, and that to not limit the number of potential exceptions each issuer may receive would counteract this intent. Relatedly, many commenters expressed concern that the number of non-standardized plan

options in PY 2025 could exceed the number of non-standardized plan options in PY 2024 without a limit on the number of exceptions.

Conversely, several commenters opposed limiting the number of potential exceptions. These commenters stated that limiting the number of potential exceptions permitted for each issuer would unnecessarily restrict issuer innovation and may harm consumers who have a comparatively less common chronic and high-cost condition that issuers may choose to not target with this exceptions process, which could hinder efforts to advance health equity.

Response: In the proposed rule (88 FR 82609), we proposed that issuers would not be limited in the number of excepted plans they could offer but solicited comment on the utility of limiting the number of potential exceptions. We considered such a limitation at the time of the proposed rulemaking.

Upon consideration of comments, we share commenters' concerns that permitting an unlimited number of exceptions for each issuer runs counter to our goal of reducing the risk of plan proliferation, a non-standardized plan option policy goal we explained in the proposed rule (88 FR 82608). Without a limit on the number of exceptions permitted, issuers could choose to submit multiple exception requests for non-standardized plan options that reduce cost sharing for benefits pertaining to the treatment of the same chronic and high-cost condition—with minor or no differences between the benefits with reduced cost sharing, or with minor or no difference in the amount that cost sharing is reduced for these benefits.

For example, without a limit on the number of exceptions permitted, issuers could submit exception requests for two identical non-standardized plan options that reduce cost sharing for benefits pertaining to the treatment of diabetes—each of which reduce cost sharing for the same benefits by the same amount. We do not believe it would be in consumers' interest to permit issuers to offer both of these plans due to their duplicative nature. Specifically, we believe that permitting issuers to offer both of these plans creates significant risk of plan choice overload, which, as we noted in the proposed rule (88 FR 82608), we want to minimize. However, we also agree that limiting the total number of exceptions could harm consumers who have a comparatively less common chronic and high-cost condition that issuers may choose to not target with this exceptions process,

which would hinder efforts to advance health equity.

To balance these concerns, at § 156.202(d)(5), we are limiting issuers to one exception per chronic and high-cost condition, in each product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area. Under this limitation, one exception would be permitted for each separate non-standardized plan option that reduces cost sharing for benefits pertaining to the treatment of a different chronic and high-cost condition—so long as the specified requirements are met.

For example, if an issuer submits exception requests for three separate plans in a given product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area (such as one plan that reduces cost sharing for benefits pertaining to the treatment of diabetes, one plan that reduces cost sharing for benefits pertaining to the treatment of COPD, and one plan that reduces cost sharing for benefits pertaining to the treatment of hepatitis C), we would permit exceptions for each of these plans, assuming these plans meet all other certification and exception requirements.

However, under this limitation, multiple exceptions will not be permitted for separate plans that reduce cost sharing for benefits pertaining to the treatment of the same chronic and high-cost condition, regardless of whether these benefits with reduced cost sharing vary between the separate plans. Thus, under this limitation, for example, if an issuer submits two exception requests for two separate plans that have reduced cost sharing for benefits pertaining to the treatment of diabetes (and both plans reduce cost sharing for insulin), only one exception would be permitted. Similarly, if an issuer submits exception requests for two separate plans with reduced cost sharing for different benefits pertaining to the treatment of diabetes (with one plan reducing cost sharing for insulin, and the other reducing cost sharing for diabetic foot care, diabetic retinal exam, and diabetic lab testing), the issuer would be permitted only one exception.

We believe adopting this approach will ensure that issuers do not offer duplicative exceptions plans with only minor differences in cost sharing, and that the exceptions process will instead encourage issuers to focus on reducing cost sharing for the most impactful benefits pertaining to the treatment of particular chronic and high-cost conditions. We believe that these exceptions will be an important way for

issuers to further health equity and address pressing health needs in their service areas, and we believe that this limit will encourage issuers to focus their time and efforts on creating the strongest plan designs for these conditions as possible. We also believe this limit is congruent with existing market trends and will not impede issuers' ability to use non-standardized plan options to develop and offer the full desired scope of innovative plan designs.

Comment: Several commenters requested further clarification on the particular chronic and high-cost conditions eligible for consideration under this exceptions process.

Response: Similar to our stance in the proposed rule (88 FR 82608), we clarify that, for purposes of this standard, high-cost conditions are those that account for a disproportionately high portion of total Federal health expenditures. We note that the four chronic and high-cost conditions included in the prescription drug adverse tiering review for PY 2025 (specifically, hepatitis C virus, HIV, multiple sclerosis, and rheumatoid arthritis) are examples of conditions that we would consider to be chronic and high-cost in nature for purposes of this standard.

However, we note that we would also consider additional conditions to be chronic and high cost in nature for purposes of this standard. As we explained in the proposed rule (88 FR 82608), additional representative examples of conditions that we would consider to be chronic and high cost in nature include, but are not limited to, Alzheimer's disease, kidney disease, osteoporosis, heart disease, diabetes, and all kinds of cancer. Examples of conditions that we would not consider chronic and high cost in nature for purposes of this standard would be those that are generally acute in nature, including bronchitis, the flu, pneumonia, strep throat, and respiratory infections.

Comment: Several commenters recommended expanding the criteria considered in the exceptions process. Many commenters explained that the criteria included in the proposed exceptions process fail to consider the impact of different variations of benefit packages, provider networks, formularies, and the inclusion of telehealth services on the accessibility of services for individuals with chronic and high-cost conditions.

Several commenters thus recommended modifying the exceptions process to consider product ID, network ID instead of product network type, formulary ID, and inclusion of

telehealth services. One commenter recommended expanding the exceptions process criteria to allow issuers to offer plan design options with benefits tailored to address documented health disparities in underserved communities (such as non-standardized plan options that include benefits designed to improve access to "critical services," enhance the quality of care for "critical services," and/or lower out-of-pocket costs for "critical services," as well as provide access to wellness programs and promote native-language inclusivity to increase engagement and health literacy).

Response: While we agree that different benefit packages, provider networks, formularies, and the inclusion of telehealth services are all important factors that pertain to the treatment of chronic and high-cost conditions, we believe restricting eligibility for this exceptions process based solely on a reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions is the most appropriate approach. We believe the inclusion of those additional factors would compromise how precisely tailored the current standard is in ensuring that excepted plans indeed target the unique health care needs of consumers with high-cost and chronic conditions.

Specifically, considering these criteria in determining eligibility for an exception would allow issuers to slightly vary included provider IDs, formulary IDs, and the inclusion of telehealth services, which could result in these plans having a different product IDs, network IDs, formulary IDs and telehealth benefits while still failing to provide meaningfully different coverage between excepted plans. We do not believe that including one different provider in a plan's network, for example, should result in that plan being permitted an exception on that basis alone. We believe such an approach would weigh against our goals of reducing plan proliferation and choice overload (88 FR 82608).

In response to the commenter who recommended incorporating additional criteria to allow issuers to better address health disparities documented in underserved communities, we note that we continue to believe that the criteria that we will consider under § 156.202(d) in determining whether to grant an exception will help ensure that non-standardized plan options offered pursuant to this exceptions process are well-designed to address health disparities in underserved communities. As we explained in the proposed rule (88 FR 82608), we believe this

exceptions process could play an important role in combatting health disparities and supporting health equity. Furthermore, since we did not restrict the chronic and high-cost conditions potentially eligible for this exceptions process to a discrete list of conditions, we believe issuers will have sufficient flexibility to address health disparities in underserved communities through the exceptions process.

Relatedly, we believe that since members of underserved communities suffer from the type of chronic and high-cost conditions that may qualify an issuer for an exception at greater rates than the general population, and since this exceptions process permits issuers to offer innovative non-standardized plan options that include substantially reduced cost sharing for services related to treatment of those conditions, we believe the criteria considered under this exceptions process will improve this population's access to care and, subsequently, their health outcomes.

Finally, we note that issuers are not limited in the number of standardized plan options they can offer. Given this flexibility, issuers are permitted to offer different standardized plan options with different product IDs, network IDs, and formulary IDs, so long as they conform to the required cost-sharing parameters for these plans.

Comment: Many commenters noted the concern that permitting exceptions solely on the basis of a reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions could significantly impact risk pools and risk adjustment transfers—such as by attracting a higher number of enrollees with chronic and high-cost conditions into these plans, leading to a corresponding increase in actuarial risk insufficiently considered in the current structure and operation of HHS-operated risk adjustment program.

Response: We do not agree with commenters' concerns about the impact of these excepted plans on the risk pool and risk adjustment. First, issuers are not required to offer these excepted plans. Similar to what we explained in the proposed rule (88 FR 82608), we continue to anticipate that most issuers would determine that the burden of creating and certifying additional non-standardized plan options intended to benefit a comparatively small population of consumers would outweigh the benefit, meaning we do not anticipate a substantial number of exceptions requests. With a limited number of issuers requesting exceptions under this exceptions process, we anticipate a correspondingly limited impact on the risk pool. Second, these

excepted plans are subject to the *AV de minimis* range requirements under §§ 156.140, 156.200, and 156.400, meaning issuers are limited in the extent in which they can vary allowable cost sharing within these excepted plans.

Third, if an issuer does choose to offer an excepted plan, we believe the current structure and operation of HHS-operated risk adjustment program³⁰⁹ accounts for the actuarial risk associated with enrollment in these plans. This is because the chronic and high-cost conditions we anticipate issuers will target with this exception process are already accounted for in the HHS risk adjustment models under the hierarchical condition categories (HCCs) used in the models to assess an enrollee's actuarial risk,³¹⁰ and subsequent plan liability.

For example, HCC 01 (HIV/AIDS), HCC 118 (Multiple Sclerosis), and multiple HCCs for diabetes related diagnoses, HCC 19 (Diabetes with Acute Complications), HCC 20 (Diabetes with Chronic Complications), HCC 21 (Diabetes without Complication), and HCC 22 (Type 1 Diabetes Mellitus, add-on to Diabetes HCC 19–21) are payment HCCs that account for chronic and high-cost conditions targeted with this exceptions process. Therefore, we believe the current structure and operation of HHS-operated risk adjustment program sufficiently accounts for the risk that may arise from attracting a higher number of enrollees with chronic and high-cost conditions into these plans.

Lastly, these excepted plans are limited to the individual markets, and the HHS risk adjustment models are national models that are used in all States where the HHS-operated risk adjustment program applicable to the individual, small group, and merged markets is operated. These models are intended to reflect the relative national average costs for HCCs and have not been developed to account for specific State or market specific variation in plan liability. We have found, based on our experience in modeling, that the nationwide dataset is often necessary to ensure that we have adequate sample size and stability in our risk adjustment models, including the models' factors and coefficients. If an issuer offers excepted non-standardized plan options that attract a higher number of enrollees with chronic and high-cost conditions,

the issuer would receive credit for the increased actuarial risk as part the risk score and transfer calculations for the applicable benefit year.

Comment: Several commenters supported maintaining the 25 percent reduction in cost sharing as the difference threshold for the proposed exceptions process. These commenters explained that reducing this cost sharing difference threshold below 25 percent would make it difficult for consumers with chronic and high-cost conditions to obtain meaningful benefit from enrolling in an excepted plan. These commenters also explained that reducing the cost sharing difference threshold would allow issuers to offer non-standardized plan options that are not meaningfully different from existing offerings, which runs counter to the goal of reducing the rate of plan proliferation.

Conversely, several commenters expressed concern with the proposed cost sharing difference threshold. These commenters noted that it would be difficult to demonstrate a 25 percent reduction in cost sharing for benefits associated with the treatment of chronic and high-cost conditions while maintaining an AV for these plans within the permissible *de minimis* range for each metal level. Several commenters thus recommended reducing the cost sharing difference threshold, such as to 10 percent, to allow issuers to submit exception requests that more easily meet the required cost sharing difference threshold under the standard.

Response: We agree that reducing the cost sharing difference threshold to less than 25 percent may make it difficult for consumers with chronic and high-cost conditions to obtain meaningful benefit from enrolling in an excepted plan. As we explained in the proposed rule (88 FR 82608), we continue to believe that the cost sharing difference threshold of 25 percent or more is appropriate since we have observed that cost sharing differences below this threshold represent normal variation within a particular metal level, while differences at or above this threshold are more often associated with cost sharing differences between different metal levels.

Altogether, we do not believe that a difference in a cost sharing amount that is of the same magnitude as normal variation within a particular metal level (specifically, less than 25 percent) would warrant being excepted from the non-standardized plan option limit. We further agree that reducing the cost sharing difference threshold to below 25 percent may allow issuers to utilize this exceptions process to offer non-

³⁰⁹ Since the 2017 benefit year, HHS has operated the risk adjustment program for the individual, small group, and merged markets in all 50 States and the District of Columbia.

³¹⁰ See Tables 1 through 6 of this final rule.

standardized plans that are not meaningfully different from existing non-standardized plan offerings, which runs counter to our goal of reducing the rate of plan proliferation.

Finally, we note that it will be possible for issuers to reduce cost sharing for benefits pertaining to the treatment of a chronic and high-cost condition by at least 25 percent in these plans while maintaining AVs within the permissible *de minimis* range for each metal level, but doing so will require issuers to make deliberate and thoughtful decisions about their plan designs (such as prioritizing the benefits that will yield the greatest impact on cost sharing for the treatment of a given chronic and high-cost condition). We also believe that requiring issuers to make these deliberate and thoughtful decisions will increase the likelihood that non-standardized plan options offered under this exceptions process support our dual aims of ensuring that truly innovative plan designs that substantially benefit consumers with chronic and high-cost conditions continue to be offered and reducing the risk of plan choice overload.

Comment: Many commenters expressed concerns about our statement in the proposed rule that we anticipated requesting that issuers submit QHP applications for non-standardized plan options that exceed the two-plan limit by the QHP certification Early Bird deadline. These commenters cited difficulties incurred by issuers in designing plans that would comply with the requirements of this exceptions process in the time afforded between the publication of this final rule and the Early Bird submission deadline. Many commenters noted that constructing plans that would fulfill the exceptions process' criteria would require not only finalizing unique benefits coverage, including cost-sharing features, but would also require securing network agreements and conducting market reviews needed to bring the novel plan designs to market.

Many commenters also noted that, historically, the Early Bird submission deadline does not offer issuers sufficient time to conduct all these activities while meeting the individual market filing deadlines imposed by their respective States. Commenters explained that imposing too early a submission deadline would substantially reduce the likelihood that issuers would apply for exceptions, resulting in fewer non-standardized plan options targeting chronic and high-cost conditions being submitted for possible inclusion above the limit.

Several commenters also cited operational concerns related to interfacing with State Departments of Insurance that would make it difficult for issuers to be able to submit complete exception requests by the Early Bird deadline. In particular, many commenters noted that although it may be possible for issuers to submit exception requests by the Early Bird deadline, depending on the publication date of this final rule and related QHP certification materials, it would be difficult for State Departments of Insurance that transfer plan submission data to CMS on behalf of their respective issuers to do so prior to the Early Bird submission deadline.

This is because issuers in some States are required to first submit plan data to their State Department of Insurance before the State Department of Insurance transfers the plan submission data to CMS. This process may take several weeks to complete from beginning to end, which would effectively require issuers to submit complete plan portfolios—including these exception requests—to their State Departments of Insurance several weeks in advance of the Early Bird deadline, possibly only several weeks after the Payment Notice is published.

Accordingly, some commenters do not believe that it is feasible for State Departments of Insurance that transfer plan submission data to CMS on behalf of their respective issuers to do so prior to the Early Bird submission deadline.

Several commenters suggested alternatives to requiring issuers to submit QHP applications for non-standardized plan options that exceed the two-plan limit by the QHP certification Early Bird deadline. One commenter recommended that exception requests be approved or rejected in concept by CMS prior to the formal submission of the complete QHP certification application by the Initial Application Deadline. The commenter suggested that this approach would mitigate any operational burden imposed on the issuer while reducing the risks associated with coordinating with State Departments of Insurance and managing varying filing deadlines (such as issuers being unable to submit complete plan portfolios and exception requests to their State Departments of Insurance in advance of the Early Bird deadline). The commenter stated this approach would also allow CMS to provide feedback on the proposed excepted plan, helping to circumvent any quality assurance challenges (such as issuers formally submitting exception requests that do not meet the requirements of the exceptions process).

Response: We acknowledge the commenters' concerns with requesting that issuers submit QHP applications, including exception requests, for non-standardized plan options that exceed the two-plan limit by the QHP certification Early Bird deadline, and we agree with many of the points commenters made. Specifically, we agree that it would be difficult for issuers to compile a complete portfolio of plans, as well as related exception requests, only several weeks after the publication of the final rule in order to transfer this data to their State Departments of Insurance sufficiently in advance of the Early Bird deadline. We also agree that the Early Bird submission deadline may not offer issuers sufficient time to conduct all required activities while meeting the individual market filing deadlines imposed by their respective States.

As such, we anticipate that the exception request submission deadline for issuers will be the Initial Application Deadline for QHP certification, aligning the exception request submission deadline with the Initial Application Deadline for QHP certification applications for standardized and non-standardized plan option offerings. We note that the Initial Application Deadline for QHP certification for each plan year will continue to be communicated in sub-regulatory guidance. We believe adopting this approach will permit issuers sufficient time to finalize unique benefits coverage and cost sharing, secure network agreements, and conduct market reviews necessary to bring these novel plan designs to the market in a feasible timeframe. We also believe that adopting this approach obviates the need for CMS to approve or reject exception request materials in advance of the deadline for submitting a complete QHP certification application.

Comment: Several commenters suggested that interested parties should be given the opportunity to review and provide feedback on the application materials and justification forms.

Response: We agree that providing interested parties the opportunity to review and provide feedback on the exception request form is critical to ensuring the success of the implementation of this exceptions process. As such, we note that interested parties had the opportunity to review these materials in the 60-day PRA package associated with this rule

(CMS–10878).³¹¹ We encourage interested parties to review any future iterations of such materials in subsequent PRA packages when they are published. Finally, we note that we intend to solicit feedback on these forms in future interested party listening sessions.

Comment: Some commenters suggested that the proposed exceptions process be accompanied by additional functionalities on *HealthCare.gov* and DE entity non-Exchange websites to enable consumers to more easily identify non-standardized plan options that offer specialized cost sharing offerings intended to benefit the treatment of the corresponding chronic and high-cost conditions. Other commenters noted that differential display for non-standardized plan options that are offered pursuant to the exceptions process may confuse or overwhelm consumers with information that is not meaningful to them.

One commenter recommended imposing restrictions on mentioning specific chronic and high-cost conditions in the plan marketing names of non-excepted plans. The commenter noted that currently available QHPs that are marketed as being uniquely relevant to a certain chronic and high-cost condition may not actually provide substantial benefits to individuals seeking treatment for that condition. The commenter suggested that some plans with references to diabetes in their planned marketing names may fail to substantially reduce cost sharing for benefits related to diabetes treatment, for example. The commenter stated that, therefore, issuers should not be permitted to display a plan marketing name that markets a non-excepted QHP as if it had been approved under this exceptions process.

Response: We intend to explore the benefit and feasibility of requiring some form of visual differentiation of these excepted plans in the form of differential display on *HealthCare.gov*, in conjunction with our continued work on choice architecture. We will also consider whether any future differential display requirements related to excepted plans should also apply to DE entity non-Exchange websites. At this time, we are not finalizing any requirements for excepted or non-excepted plans related to particular plan marketing names, since both excepted and non-excepted plans are already subject to the plan marketing name requirements at § 156.225. We

encourage issuers offering excepted plans to adopt plan marketing names that reflect the chronic and high-cost condition for which the plan offers substantially reduced cost sharing, if so desired.

Comment: Several commenters requested clarification on the interaction between the reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions, deductibles, and annual limitations on cost sharing. Several commenters also requested clarification of how a 25 percent reduction in cost sharing for benefits pertaining to the treatment of a chronic and high-cost condition would be evaluated under this exceptions process.

Response: We clarify that deductibles and annual limitations on cost sharing (as well as their interactions with copayments and coinsurance rates) will be considered when evaluating the 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions under this exceptions process. We believe that excluding deductibles and annual limitations on cost sharing from consideration when evaluating the difference in cost sharing for relevant benefits would make accurate comparisons between the in-limit non-standardized plan option the issuer is using as a baseline and the non-standardized plan option the issuer is requesting to be excepted more difficult, since the cost sharing type (specifically, coinsurance rate or copayment subject to or exempt from the deductible) for the same benefit may differ between plans.

For example, without considering deductibles and annual limitations on cost sharing and their interactions with coinsurance rates and copayments when evaluating the 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions under this exceptions process, it would be difficult to assess whether the required reduction in cost sharing is achieved if the in-limit non-standardized plan option the issuer is using as a comparison has a coinsurance rate of 50 percent subject to the deductible as the form of cost sharing for a particular benefit, whereas the corresponding benefit in the non-standardized plan option the issuer requests to be excepted has a copayment of \$30 exempt from the deductible as the form of cost sharing. It would similarly be difficult to assess whether the required reduction in cost sharing is achieved if the two plans have different deductibles and/or annual limitations on cost sharing.

We also clarify that under new § 156.202(d)(1), a 25 percent reduction in cost sharing for benefits pertaining to the treatment of a chronic and high-cost condition will not be evaluated at the individual benefit level, but will instead be evaluated at the level of total out-of-pocket costs for the treatment of the particular chronic and high-cost condition for a population of enrollees with that particular chronic and high-cost condition.

This is because if we were to adopt an approach that evaluated this difference in cost sharing at the individual benefit level, issuers may reduce cost sharing for only one or several already relatively inexpensive or infrequently utilized benefits—which may technically meet the required difference in cost sharing threshold under the standard but may not actually meaningfully reduce cost sharing for enrollees with that chronic and high-cost condition. For example, if this difference in cost sharing were evaluated at the individual benefit category level, an issuer would be able to reduce cost sharing for a particular prescription drug used to treat a chronic and high-cost condition from a \$20 copay exempt from the deductible to a \$15 copay exempt from the deductible to meet the required cost sharing difference threshold under the standard. We do not believe this reduction in cost sharing would substantially benefit consumers with the relevant chronic and high-cost condition.

Thus, we believe evaluating the required difference in cost sharing at the level of total out-of-pocket costs for the treatment of the chronic and high-cost condition for a population of enrollees with the relevant chronic and high-cost condition represents a more comprehensive and holistic approach in ensuring that excepted plans substantially benefit consumers with chronic and high-cost conditions. As we explained in the proposed rule (88 FR 82607), one of our goals with the proposed exceptions process is to ensure that excepted plans substantially benefit consumers with chronic and high-cost conditions.

Consider the following hypothetical scenario as an illustration of how the 25 percent reduction in cost sharing for benefits pertaining to the treatment of a chronic and high-cost condition will be evaluated. In this scenario, an issuer desires to offer two non-standardized plan options per product network type, metal level, and inclusion of dental and/or vision benefit coverage. This issuer also desires to submit an exception request for an additional non-standardized plan option that reduces cost sharing for benefits pertaining to

³¹¹ <https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pralisting/cms-10878>.

the treatment of diabetes. As part of the request for the additional non-standardized plan option to be excepted, the issuer chooses one of its non-standardized plan options within the limit of two for PY 2025 in the same product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area to serve as a point of comparison. The issuer will utilize one of these non-standardized plan options within the limit of two for PY 2025 as the comparison for evaluating whether the required 25 percent reduction in cost sharing is achieved relative to the plan the issuer is requesting to except from the non-standardized plan option limit.

The cost sharing structure in the non-standardized plan option the issuer has chosen as the in-limit comparison includes a \$40 copayment exempt from the deductible for each primary care visit, an \$80 copayment exempt from the deductible for each podiatrist specialist visit, an \$80 copayment exempt from the deductible for each ophthalmologist specialist visit, and a 40 percent coinsurance rate exempt from the deductible for each utilization of laboratory services. The cost sharing structure in the non-standardized plan option that the issuer requests be excepted from the limit includes a \$20 copayment exempt from the deductible for each primary care visit, a \$70 copayment exempt from the deductible for each podiatrist visit, a \$70 copayment exempt from the deductible for each ophthalmologist visit, and a 20 percent coinsurance rate exempt from the deductible for each utilization of laboratory services, with the cost sharing for all other benefits remaining the same between both plans.

Under this exceptions process, the 25 percent reduction in cost sharing for benefits pertaining to the treatment of a chronic and high-cost condition will not be evaluated at the individual benefit category level (in this case, primary care visit, podiatrist specialist visit, ophthalmologist specialist visit, and laboratory services) between the in-limit non-standardized plan option the issuer is using as a point of comparison and the additional non-standardized plan option the issuer is requesting to have excepted from the limit. Rather, the required reduction in cost sharing will be evaluated at the level of total out-of-pocket costs for a representative treatment scenario for the relevant chronic and high-cost condition. In this hypothetical scenario, for example, a representative treatment scenario for the treatment of diabetes is comprised of four primary care visits, one podiatrist specialist visit, one ophthalmologist

specialist visit, and the utilization of laboratory services one time.

Under the cost sharing structure in the non-standardized plan option the issuer has chosen as an in-limit point of comparison, this representative treatment scenario would result in the enrollee paying the \$40 copayment exempt from the deductible for a primary care visit four times, amounting to \$160; the \$80 copayment exempt from the deductible for a podiatrist specialist visit one time; the \$80 copayment exempt from the deductible for an ophthalmologist specialist visit one time; and, assuming a total cost of \$200 for each utilization of laboratory services and a coinsurance rate of 40 percent exempt from the deductible for this service, one utilization of laboratory services amounting to \$80. Altogether, the total out-of-pocket costs for this representative treatment scenario under the cost-sharing structure in the non-standardized plan option the issuer has chosen as an in-limit point of comparison would amount to \$400.

Under the cost sharing structure in the non-standardized plan option that the issuer requests be excepted from the limit, the representative treatment scenario would result in the enrollee paying the \$20 copayment exempt from the deductible for a primary care visit four times, amounting to \$80; the \$70 copayment exempt from the deductible for a podiatrist specialist visit one time; the \$70 copayment exempt from the deductible for an ophthalmologist specialist visit one time; and, assuming a total cost of laboratory services of \$200 for each utilization of laboratory services and a coinsurance rate of 20 percent exempt from the deductible for this service, one utilization of laboratory services amounting to \$40. Altogether, the total out-of-pocket costs for this representative treatment scenario under the cost-sharing structure in the non-standardized plan option the issuer is requesting to be excepted from the limit would amount to \$260.

Thus, although there is not necessarily a 25 percent reduction when comparing each individual benefit category between these two plans, the standard would still be satisfied, so long as the overall cost sharing (in the form of total out-of-pocket costs, which takes into consideration maximum out-of-pocket limitations and deductibles) for a population of enrollees with diabetes will still be reduced by at least 25 percent under the excepted non-standardized plan option (which in this case would be \$260) compared to the non-standardized plan option being used as an in-limit point of comparison (which in this case would be \$400). We

note that an issuer seeking to utilize this exceptions process must demonstrate underlying actuarial assumptions in the required actuarial memorandum (which includes corresponding actuarial attestation) as part of the exception request that we explain later in this section of this final rule.

We are also making several changes to the requirements related to the written justification form that issuers will be required to submit to utilize this exceptions process at § 156.202(e)(1) through (3), to more accurately reflect how the reduction in cost sharing will be evaluated under this exceptions process and ensure that excepted non-standardized plan options have specific design features that will substantially benefit consumers with chronic and high-cost conditions, a goal we explained in the proposed rule (88 FR 82606). We also introduced new paragraph (4) to ensure that the form issuers submit adequately explains the underlying actuarial assumptions made in designing the proposed excepted plan.

In particular, under proposed § 156.202(e)(1), an issuer seeking to utilize this exception request process would have been required to identify the specific condition(s) for which cost sharing is reduced. However, under finalized § 156.202(e)(1), an issuer seeking to utilize this exceptions request process must identify the specific chronic and high-cost condition that their additional non-standardized plan option offers substantially reduced cost sharing for, in accordance with the definition of “cost sharing” at § 156.20.

We made this change to reflect the fact that each excepted non-standardized plan option should be tailored to the treatment of one chronic and high-cost condition, since we believe it will be both difficult and impractical for issuers to reduce cost sharing for benefits pertaining to the treatment of two or more chronic and high-cost conditions while maintaining AVs within the permissible *de minimis* range for each metal level within the same excepted plan design. This is because the required cost sharing reduction is 25 percent, and for an issuer to reduce the treatment-specific cost sharing for the treatment of two separate chronic and high-cost conditions within the same plan design would likely result in that plan having an AV exceeding the permissible *de minimis* range, or at least having an AV that would render the plan costly and uncompetitive at a minimum.

Under proposed § 156.202(e)(2), an issuer seeking to utilize this exception request would have been required to

explain which benefit(s) would have reduced annual enrollee cost sharing (as opposed to reduced cost sharing for a limited number of visits) for the treatment of the specified condition(s) relative to the same corresponding benefits in an issuer's other non-standardized plan offerings in the same product network type, metal level, and service area. However, this requirement would not have enabled accurate assessment of whether an excepted plan reduces cost sharing at the level of total out-of-pocket costs for the treatment of a particular chronic and high-cost condition, in accordance with § 156.202(d)(1).

As such, under finalized § 156.202(e)(2), an issuer seeking to utilize this exceptions process must identify which specific benefits in the Plans and Benefits Template are discounted to provide reduced treatment-specific cost sharing for individuals with the specified chronic and high-cost condition. These discounts must be relative to the treatment-specific cost sharing for the same corresponding benefits in the issuer's other non-standardized plan option offerings in the same product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area.

For the purposes of this standard, "treatment specific cost sharing" consists of the costs for obtaining services that pertain to the treatment of a particular chronic and high-cost disease—but not the costs for obtaining services that do not pertain to the treatment of the relevant condition. For example, costs for obtaining chemotherapy would not be considered treatment-specific cost sharing for a plan designed to address diabetes for the purposes of this standard. However, as an additional clarifying example, a primary care visit would pertain to the treatment of the diabetes to the extent that this visit entails the treatment of the relevant condition.

We also clarified in this paragraph (e)(2) that the issuer must identify all services for which the benefits substantially reduce cost sharing in the Plans and Benefits Template. These benefits must encompass a complete list of relevant services pertaining to the treatment of the relevant condition. For example, if an issuer intends to offer a plan that is designed to address diabetes, the issuer should list only the benefits with reduced cost sharing for services pertaining to the treatment of diabetes. We made these modifications to ensure that the written justification that issuers will be required to submit as part of this exceptions process

accurately explains how the excepted plan substantially reduces cost sharing at the level of total out-of-pocket costs for the treatment of a particular chronic and high-cost condition, in accordance with § 156.202(d)(1).

Under proposed § 156.202(e)(3), an issuer seeking to utilize this exceptions process would have been required to explain how the reduced cost sharing for these benefits pertain to clinically indicated guidelines for treatment of the specified chronic and high-cost condition(s). However, under finalized § 156.202(e)(3), an issuer seeking to utilize this exceptions process must explain how the reduced cost sharing for these services pertains to clinically indicated guidelines and a representative treatment scenario for treatment of the specified chronic and high-cost condition. We also clarified in this paragraph that the issuer must include any relevant studies, guidelines, or supplementary documents to support the application, as applicable. In addition, we clarified in this paragraph that for purposes of this standard, a representative treatment scenario is an annual course of treatment for a chronic and high-cost condition (for example, osteoporosis, diabetes, cancer).

We made this modification to ensure that each excepted non-standardized plan option is tailored to the treatment of one chronic and high-cost condition. We also made this modification to ensure that issuers would not be able to simply reduce cost sharing for one already relatively inexpensive or relatively infrequently utilized service by 25 percent or more to meet the standard, which could result in the plan failing to substantially benefit consumers with a chronic and high-cost condition. Instead, under the final requirement in this paragraph, issuers will be required to reduce cost sharing for a representative treatment scenario in order to reduce cost sharing for the treatment of that particular condition by 25 percent or more, which we believe ensures the plan would substantially benefit consumers with the relevant chronic and high-cost condition.

We also finalized new § 156.202(e)(4) requiring that issuers include a corresponding actuarial memorandum that explains the underlying actuarial assumptions made in the design of the plan the issuer is requesting to except. In this memorandum, an issuer must demonstrate how the benefits that are discounted to provide reduced treatment-specific cost sharing of at least 25 percent identified at § 156.202(e)(2) for the treatment of the condition identified at § 156.202(e)(1) under the excepted plan compare to the

identified in-limit offering in the same product network type, metal level, inclusion of dental and/or vision coverage, and service area.

We also clarified in this paragraph that this demonstration must specifically be in reference to the specific population that would be seeking treatment for the relevant condition and not the general population. We also clarified that this memorandum also must include an actuarial opinion confirming that this analysis was prepared in accordance with the appropriate Actuarial Standards of Practice and the profession's Code of Professional Conduct. We made these modifications to ensure issuers' exception requests accurately explain how the excepted plans substantially reduce cost sharing at the level of total cost sharing for the treatment of a particular chronic and high cost condition, which enables the assessment of whether the required difference in cost sharing is achieved in accordance with § 156.202(d)(1).

Comment: Several commenters requested clarification of how the cost sharing difference threshold applies when there is no cost sharing for a benefit under the in-limit non-standardized plan option the issuer is comparing against. These commenters noted that it is impossible to reduce cost sharing for a benefit in the excepted non-standardized plan option if the in-limit non-standardized plan option being utilized as a comparison already offers that benefit at no cost. These commenters recommended requiring that any proposed excepted non-standardized plan options being compared to an in-limit non-standardized plan option that offers a given benefit at no cost to the consumer also offer that benefit at no cost to the consumer.

Response: We acknowledge this concern, and we believe the approach we are adopting in which we evaluate the 25 percent reduction in cost sharing at the level of total out-of-pocket costs for benefits pertaining to the treatment of the particular chronic and high-cost condition for a population of enrollees with the particular chronic and high-cost condition—instead of evaluating the reduction in cost sharing at the individual benefit category level—sufficiently mitigates this concern.

This modification avoids requirements on issuers that would be unworkable, such as requiring the issuer to further reduce the cost sharing for a particular benefit in the excepted non-standardized plan option when there is no cost sharing for the benefit in the in-limit non-standardized plan option. For

example, if there is no cost sharing for primary care visits in the in-limit non-standardized plan option being utilized as a comparison, and there is similarly no cost sharing for primary care visits in the non-standardized plan option the issuer is requesting to be excepted, it would be impossible for the issuer to further reduce cost sharing for this benefit category in the excepted plan. However, so long as the total out-of-pocket costs for benefits pertaining to the treatment of the particular chronic and high-cost condition are reduced by 25 percent or more, the standard would be satisfied.

Comment: Several commenters recommended that the cost sharing difference threshold only be applied to the standard variant of the plan for which the issuer is seeking an exception and not to the income-based cost sharing reduction (CSR) variants or American Indian (AI)/Alaska Native (AN) limited or zero cost share variants. The commenter noted that it would be difficult for issuers to design plans with the necessary reduction in cost sharing in these plan variants while maintaining AVs within the permissible *de minimis* ranges due to the restricted *de minimis* ranges for these plan variants.

Response: We agree it would be difficult to reduce cost sharing by 25 percent for benefits pertaining to the treatment of chronic and high-cost conditions in the more generous income-based CSR variants and the AI/AN limited or zero cost share variants of excepted plans, due to the restricted AV *de minimis* range of these plans. This is because under the definition of “*de minimis* variation for a silver plan variation” at § 156.400, there is a –0 percentage point and +1 percentage point allowable AV *de minimis* variation for these plans—compared to a permissible AV *de minimis* variation of –2 percentage points and +2 percentage points for standard variants under § 156.140(c)(2), and a permissible AV *de minimis* range of –0 percentage points and +2 percentage points for individual market silver QHPs under § 156.200(b)(3).

Furthermore, since the AI/AN zero cost share variant at § 156.420(b)(1) eliminates cost sharing for all services, while the AI/AN limited cost share variant at § 156.420(b)(2) eliminates cost sharing on any item or service that is an EHB furnished directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization (each as defined in 25 U.S.C. 1603), or through referral under contract health services, cost sharing cannot be further reduced.

As such, we are finalizing at § 156.202(d)(4) that the reduced cost sharing requirement that excepted plans must meet only applies to the standard variant of the plan for which the issuer is seeking exception, and not to the income-based CSR plan variations required by § 156.420(a) or the zero and limited cost sharing plan variations required by § 156.420(b). We are making this change to ensure that issuers can achieve the required reduction in cost sharing between the non-standardized plan option the issuer chooses as an in-limit comparison and the non-standardized plan option the issuer requests to be excepted.

Comment: Several commenters requested additional clarification on how the proposed exceptions process would comply with existing guidance under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

Response: In general, MHPAEA and its implementing regulations apply to group health plans and health insurance issuers offering group or individual health insurance coverage that provide both medical and surgical benefits and mental health or substance use disorder benefits and require, in relevant part, that the financial requirements (such as coinsurance and copayments) 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 the same classification.³¹²

The regulations under MHPAEA set forth six classifications of benefits for applying the parity rules for financial requirements and treatment limitations.³¹³ Under MHPAEA regulations, a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of all medical/surgical benefits in the classification. If a type of financial requirement or treatment limitation does not apply to at

least two-thirds of medical/surgical benefits in a classification, it cannot apply to mental health or substance use disorder benefits in that classification. If the type of requirement or limitation does apply to at least two-thirds of medical/surgical benefits in a classification, the predominant level that may be applied to mental health or substance use disorder benefits in the classification is the one that applies to more than one half of medical/surgical benefits within the classification subject to the financial requirement or treatment limitation.³¹⁴ The determination of the portion of medical/surgical benefits subject to the financial requirement or treatment limitation is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year.

QHP issuers seeking to reduce cost sharing in non-standardized plans under the exceptions process will need to carefully evaluate whether and how designing a plan with reduced cost sharing for certain chronic or high-cost conditions can be achieved consistent with MHPAEA and its implementing regulations. Depending on the extent to which reducing cost sharing for medical/surgical benefits in a benefit classification (or any other design feature of the excepted plan) affects the results of the substantially all/predominant analysis under MHPAEA, the QHP issuer may not be permitted to impose the cost-sharing (or other unique) requirement on mental health or substance use disorder benefits in that classification, or may be required to reduce cost sharing for mental health and substance use disorder benefits in the classification, to ensure compliance with MHPAEA. Further, the issuer must comply in all other regards with applicable requirements under MHPAEA and its implementing regulations.

Comment: Several commenters requested further clarification on how the excepted plan designs would be consistent with the nondiscrimination standards, including the EHB nondiscrimination standards at § 156.125.

Response: As we explained in the proposed rule (88 FR 86208 through 88

³¹² Section 9812 of the Code, section 712 of ERISA, and section 2726 of the PHS Act. 26 CFR 54.9812–1, 29 CFR 2590.712, and 45 CFR 146.136 and 147.160.

³¹³ The six classifications of benefits are (1) inpatient, in-network; (2) inpatient, out-of-network; (3) outpatient, in-network; (3) outpatient, out-of-network; (4) emergency care; and (6) prescriptions drugs. In addition, sub-classifications are permitted for office visits, separate from other outpatient services. 26 CFR 54.9812–1(c)(2)(ii) and (c)(3)(iii); 29 CFR 2590.712(c)(2)(ii) and (c)(3)(iii); and 45 CFR 146.136(c)(2)(ii) and (c)(3)(iii).

³¹⁴ If no single level applies to more than one-half of medical/surgical benefits subject to a financial requirement or quantitative treatment limitation in a classification, the plan or issuer may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. 26 CFR 54.9812–1(c)(3)(i)(B), 29 CFR 2590.712(c)(3)(i)(B), and 45 CFR 146.136(c)(3)(i)(B).

FR 86209), if additional plans are permitted to be offered exceeding the limit of two non-standardized plan options, in accordance with the guaranteed availability requirements at § 147.104(a), these plans will also be required to be made available on the same basis to consumers without these chronic and high-cost conditions. Further, we emphasize that these plans will be prohibited from discriminating in accordance with the nondiscrimination requirements at §§ 147.104(e), 156.125, and 156.200(e). To meet these nondiscrimination requirements, these plans will be required to apply reductions in cost sharing to all enrolled in the plan, without regard to diagnosis. Furthermore, although we acknowledge that non-standardized plan options excepted under this proposal will primarily benefit consumers with chronic and high-cost conditions, we believe that a sufficiently satisfactory range of both non-standardized and standardized plan options currently exist that are primarily intended for consumers without chronic and high-cost conditions. As a result, we are not concerned that any risk of discrimination created by this exceptions process will negatively impact consumers, including but not limited to consumers with chronic and high-cost conditions.

Comment: Several commenters requested clarification on how enrollees affected by plan discontinuations arising from the reduction of the non-standardized plan option limit at § 156.202(b) will be re-enrolled into new plans.

Response: Similar to what we explained in the 2024 Payment Notice (88 FR 25856), we will continue to utilize the existing discontinuation notices and process as well as the current re-enrollment hierarchy at § 155.335(j) to ensure a seamless transition and continuity of coverage for enrollees affected by discontinuations.

8. CO-OP Loan Terms (§ 156.520)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82609), we proposed to amend § 156.520(f) to enable CMS to approve requests by CO-OP borrowers to voluntarily terminate their loan agreement with CMS, and thereby cease to constitute a qualified non-profit health insurance issuer (QNHII),³¹⁵ for the purpose of permitting the loan recipient to pursue innovative business plans that are not otherwise consistent

with the governance requirements and business standards applicable to a CO-OP borrower, provided certain conditions are met as described in this section.

Section 1322 of the ACA requires a CO-OP loan recipient, or qualified nonprofit health insurance issuer (QNHII), to be, among other things, an entity “substantially all of the activities of which consist of the issuance of qualified health plans in the individual and small group markets in each State in which it is licensed to issue such plans.”³¹⁶ This requirement is set forth in regulations which require that at least two-thirds of the policies or contracts for health insurance coverage issued by a CO-OP in each State in which it is licensed be qualified health plans offered in the individual and small group markets.³¹⁷

The ACA also mandates that a QNHII be subject to governance by “a majority vote of its members.”³¹⁸ Accordingly, § 156.515(b) imposes governance requirements for each CO-OP that include a requirement that the entity remain under member control, such that a majority of its directors are elected by a majority vote of the CO-OP’s members. A CO-OP “member” is an individual covered by a health insurance policy issued by a CO-OP.³¹⁹ A CO-OP’s voting members consist of all persons covered by health insurance policies issued by the CO-OP who are 18 years of age or older.³²⁰

Section 1322 of the ACA mandates that the Secretary require an entity receiving a CO-OP loan to enter into a loan agreement with the Secretary. The required loan agreement must obligate the borrower to “meet, and to continue to meet” the requirements of a QNHII, and “any other requirements contained in the agreement.”³²¹ No more is specified concerning the required contents of the loan agreement.³²² The requirement that a CO-OP be subject to a majority vote of its members is, accordingly, imposed by regulation, at § 156.515(b), as well as the CO-OP loan agreement. Specifically, Section 18.2 of the CO-OP loan agreement prohibits any “[o]rganizational [c]hange . . . that would result in . . . implementing a governance structure that does not meet

the governance standards codified at 45 CFR 156.515(b).”

We explained in the proposed rule that as a result of these requirements, a CO-OP cannot pursue new business arrangements that would impose a governance structure under which it is possible for a majority of directors to be elected by a majority vote of persons who are not covered by health insurance policies issued by the CO-OP. We further explained that a CO-OP also cannot enter into new business arrangements under which voting members need not be individuals covered by policies issued by the CO-OP. We stated that it is also not possible for a CO-OP to enter into a business plan under which potentially less than two-thirds of the company’s activities may consist of issuing qualified health plans.

In the proposed rule, we explained that the loan agreements currently in force only permit a CO-OP to initiate voluntary termination of its loan agreement on grounds that the loan recipient believes that it cannot create a viable and sustainable CO-OP.³²³ We noted that the inability to create a viable or sustainable CO-OP would consist of a failure to become or remain licensed as a health insurance company, a failure to qualify as a QHP issuer, or a failure to become or remain financially solvent. We explained that there is no avenue currently for a CO-OP to request to terminate its loan agreement for the purpose of pursuing new business ventures that involve a governance structure or business model inconsistent with CO-OP governance or operational standards.

We stated that, informed by 8 years of experience with business operations for the CO-OP program, we have become aware of opportunities that may be available to CO-OPs to terminate their loan agreement, cease to constitute a QNHII, and thus become able to pursue new opportunities that appear well-calculated to expand operations from regional areas within a State to Statewide operations, and also improve consumer access to other health insurance products, while remaining a non-profit, member-focused entity.

We therefore proposed to amend § 156.520(f) to add § 156.520(f)(2) which would enable CMS, in its sole discretion, to approve requests by CO-OP borrowers to voluntarily terminate their loan agreement with CMS, and thereby cease to constitute a QNHII, for the purpose of permitting the loan recipient to pursue innovative business plans that are not otherwise consistent

³¹⁶ 42 U.S.C. 18042(c)(1)(B).

³¹⁷ See § 156.515(c)(1).

³¹⁸ ACA section 1322(c)(3)(A); 42 U.S.C. 18042(c)(3)(A).

³¹⁹ See § 156.505.

³²⁰ See § 156.515(b)(1).

³²¹ 42 U.S.C. 18042(b)(2)(C).

³²² 42 U.S.C. 18042(b)(2)(C)(iii) contains specific prohibitions, and concomitant penalty, that are not relevant here.

³¹⁵ Section 1322 (c)(1)(B) of the ACA and 42 U.S.C. 18042(c)(1)(B) define a QNHII.

³²³ CO-OP loan agreement, section 16.1.1(a).

with the governance requirements and business standards of a CO-OP borrower, provided that (1) all outstanding CO-OP loans issued to the loan recipient are repaid in full prior to termination of the loan agreement, and (2) we believe granting the request would meaningfully enhance consumer access to quality, affordable, member-focused, non-profit health care options in affected markets. We proposed to move the current regulation text at § 156.520(f) to new § 156.520(f)(1).

As a general matter, we anticipated that plans could be deemed innovative and likely to enhance consumer access to quality, affordable, member-focused health care if they appear to be well-calculated to lead directly to marketing non-profit, member-focused health plans in new regions of a State, or to offer health plans on a Statewide basis for the first time, or to expand operations into new States, or to enhance consumer access to new non-profit products that are not qualified health plans. We noted that these examples of innovative business plans are illustrative, and not exclusive.

After consideration of comments, and for the reasons outlined in the proposed rule and our responses to comments below, we are finalizing this provision as proposed. We summarize and respond below to public comments received on the proposed amendments § 156.520(f).

Comment: Three commenters expressed support for the proposal to revise CO-OP regulations to permit CO-OP loan recipients to seek voluntary termination for the purpose of pursuing business opportunities that would not otherwise be available to a CO-OP. The commenters believed the proposal, if finalized, would potentially benefit consumers by improving access to non-profit, member-focused health care options in affected markets. One commenter acknowledged the proposal but did not articulate any position.

Response: We agree with commenters who believe the proposal could benefit consumers by making available potential business opportunities that can benefit consumers and are not otherwise feasible for a CO-OP to consider.

Comment: One commenter expressed uncertainty as to whether the proposal could have significant impact, since only three CO-OPs remain in operation.

Response: We acknowledge that three CO-OPs remain, operating across five States. Efforts to expand operations within a State, and to expand operations to new States, depend on several factors. While it is true that the population affected by the proposed regulation is

limited in the near-term, its impact over time could be significant since it will remove certain obstacles to business opportunities that could ultimately impact many consumers by improving access to non-profit, member-focused health care options.

9. Conforming Amendment to Netting Regulation To Include Federal IDR Administrative Fees (§ 156.1215)

In the HHS Notice of Benefit and Payment Parameters for 2025 proposed rule (88 FR 82510, 82610), we proposed conforming amendments to the payment and collections process set forth at § 156.1215 to align with the policies and regulations proposed in the Federal Independent Dispute Resolution Operations proposed rules (88 FR 75744). We proposed that the administrative fees for utilizing the No Surprises Act³²⁴ Federal IDR process charged to health insurance issuers that participate in financial programs under the ACA would be subject to netting as part of HHS' integrated monthly payment and collections cycle, assuming the policies related to HHS collection of the IDR administrative fees in the Federal Independent Dispute Resolution Operations proposed rules (88 FR 75744) are finalized.³²⁵

To implement this policy, we proposed to amend § 156.1215(b) to allow HHS to net payments owed to issuers and their affiliates³²⁶ operating under the same tax identification number (TIN) against amounts due to the Federal Government from the issuers and their affiliates operating under the same TIN for APTC, advance payments of and reconciliation of CSRs (as applicable), payment of FFE or SBE-FP user fees, HHS risk adjustment,

reinsurance, and risk corridors payments and charges, and administrative fees from these issuers and their affiliates for utilizing the Federal IDR process in accordance with § 149.510(d)(2). Additionally, we proposed to amend § 156.1215(c) to provide that any amount owed to the Federal Government by an issuer and its affiliates for unpaid administrative fees due to the Federal Government from these issuers and their affiliates for utilizing the Federal IDR process in accordance with § 149.510(d)(2), after HHS nets amounts owed by the Federal Government under these programs, would be the basis for calculating a debt owed to the Federal Government.

We sought comment on the proposed amendments to § 156.1215(b) and (c).

After consideration of comments and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing this provision as proposed. We summarize and respond below to public comments received on the proposed amendments to the payment and collections process at § 156.1215(b) and (c).

Comment: Some commenters opposed the proposal to allow HHS to net unpaid Federal IDR administrative fees with payments owed to issuers for certain other specified HHS ACA programs. Several of these commenters raised concerns regarding the proposal's impact on the current integrated payment and collections processes with a few of these commenters expressing concerns that modifying any payment and collections process prior to stabilizing the Federal IDR process could create substantial administrative burdens and unintended challenges for issuers. Additionally, some commenters expressed concern that without detailed accounting from HHS, netting would hinder issuers' ability to determine which disputes the administrative fee is being collected for and to which entities, who are involved in a dispute, the IDR administrative fee should be attributed. Finally, one commenter requested the netting process be delayed until issuers are required to pay the Federal IDR administrative fee directly to HHS.

Response: We are finalizing amendments to the payment and collections process set forth at § 156.1215 as proposed. We will not begin netting Federal IDR administrative fees until disputing parties are required to pay Federal IDR administrative fees directly to HHS, if the proposal in Federal Independent Dispute Resolution Operations proposed rules (88 FR 75744) is finalized.

³²⁴ The Consolidated Appropriations Act, 2021 (CAA) was enacted on December 27, 2020. Both title I, also known as the No Surprises Act, and title II (Transparency) of Division BB of the CAA amended chapter 100 of the Code, Part 7 of ERISA, and title XXVII of the PHS Act. Administrative fees are charged in accordance with 45 CFR 149.510(d)(2), 26 CFR 54.9816-8T(d)(2), and 29 CFR 2590.716-8(d)(2).

³²⁵ We stated in the 2025 Payment Notice proposed rule (88 FR 82610) that the effective date of any finalized proposal related to netting of amounts owed to the Federal Government from health insurance issuers for administrative fees for utilizing the No Surprises Act Federal IDR process would not be earlier than a time at which both the proposals related to the manner of administrative fee collection and netting proposed in the Federal Independent Dispute Resolution Operations proposed rule and the proposed amendments to § 156.1215 in this proposed rule are finalized.

³²⁶ "Affiliate" refers to any affiliated issuer that operates under the same taxpayer identification number as an issuer, such as when there are multiple Health Insurance Oversight System (HIOS) identifiers operating under the same taxpayer identification number. See the 2015 Payment Notice proposed rule (78 FR 72371).

To further explain this netting process, HHS will include amounts owed to the Federal Government from issuers and their affiliates operating under the same TIN for administrative fees for utilizing the Federal IDR process in accordance with § 149.510(d)(2) when netting payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal Government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of Federally-facilitated Exchange user fees, payment of State Exchanges utilizing the Federal platform user fees, and risk adjustment, reinsurance, and risk corridors payments and charges.

As part of this netting policy, we will also provide that any amount owed to the Federal Government by an issuer and its affiliates for unpaid administrative fees due to the Federal Government from these issuers and their affiliates for utilizing the Federal IDR process in accordance with § 149.510(d)(2), after HHS nets amounts owed by the Federal Government under these programs, would be the basis for calculating a debt owed to the Federal Government. Should the parallel related proposals related to the manner of the administrative fee collection and netting be finalized in the Federal Independent Dispute Resolution Operations proposed rules, we will work with issuers to prevent additional administrative burdens or unintended challenges for HHS and issuers in implementing this netting policy. Specifically, we intend to leverage our current integrated payment and collections process and reporting to simplify the implementation of this netting policy, to assist issuers in identifying debts owed through its current invoice process, and to keep issuers informed of updates to the integrated payment and collections processes.

Comment: One commenter recommended that if HHS finalizes the proposal to allow HHS to net unpaid IDR administrative fees with other HHS program funds owed to issuers, issuers should be allowed to file a request for reconsideration to contest errors, application of the relevant methodology, or mathematical errors with respect to

the amount of an IDR administrative fee by HHS.

Response: We do not believe that additional dispute processes, such as the appeal process under § 156.1220, are needed. If HHS were to directly collect IDR administrative fees, issuers will be able to dispute charges or raise issues, such as mathematical errors, under existing processes as provided in § 30.12. Accordingly, all issuers' invoices for all programs identified under § 156.1215 provide instructions for how issuers can submit a written dispute of their invoices and request that HHS review the determination of the debt. Under this process, issuers have the right to inspect HHS records related to the invoice and present evidence that all or part of their debt is not past due or not legally enforceable. Once a written request presenting the evidence is submitted to HHS, we review the determination of the debt and work with issuers to resolve any issues or inconsistencies.

IV. Collection of Information Requirements

Under the Paperwork Reduction F of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the 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 these issues for the following sections of this document that contain information collection requirements (ICRs). The public comments and our responses appear in this section, and in the applicable ICR sections that follow.

Comment: Regarding the Collection of Information requirements, one commenter stated that paperwork

burden and information collection estimates concentrate on the design of products such as forms without also devoting attention to recordkeeping requirements, training, and legitimate private sector concerns over exposure to new enforcement actions. The commenter suggested that CMS can minimize these problems by ensuring adequate implementation periods, proposing major changes that start from a common and familiar knowledge base, soliciting feedback more often than annually, closely examining the “regulatory sandbox” concept, and designing and promulgating “safe harbor” guidance for entities.

Response: We appreciate the commenter's general feedback on ways that HHS can continually improve the accuracy of its cost estimates. We emphasize that HHS adheres to the Administrative Procedure Act³²⁷ standards of notice and comment rulemaking and that HHS strives to estimate information collection burden as accurately as possible given the data available to inform its estimates, and incorporates feedback and input from interested parties, both through notice and comment rulemaking and informal feedback throughout the year.

A. Wage Estimates

To derive wage estimates, we generally use data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for the cost of fringe benefits and overhead) for estimating the burden associated with the ICRs.³²⁸ Table 14 presents the median hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

³²⁷ Public Law 79–404.

³²⁸ See May 2022 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oes_stru.htm.

TABLE 14—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

| Occupation title | Occupational code | Median hourly wage (\$/hr.) | Fringe benefits and overhead (\$/hr.) | Adjusted hourly wage (\$/hr.) |
|--|-------------------|-----------------------------|---------------------------------------|-------------------------------|
| Business Operations Specialist | 13–1000 | \$36.56 | \$36.56 | \$73.12 |
| Web and Digital Interface Designer | 15–1255 | 40.02 | 40.02 | 80.04 |
| Web Developer | 15–1254 | 37.78 | 37.78 | 75.56 |
| Compliance Officer | 13–1041 | 34.47 | 34.47 | 68.94 |
| Accountant and Auditor | 13–2011 | 37.50 | 37.50 | 75.00 |
| Management Analyst | 13–1111 | 45.81 | 45.81 | 91.62 |
| Chief Executive | 11–1011 | 91.12 | 91.12 | 182.24 |
| Computer Systems Analyst | 15–1211 | 49.15 | 49.15 | 98.30 |
| Financial Examiners (State Government, excluding schools and hospitals) .. | 13–2061 | 39.52 | 39.52 | 79.04 |
| Actuary (Member of American Academy of Actuaries) | 15–2011 | 54.80 | 54.80 | 109.60 |
| General and Operations Manager | 11–1021 | 47.16 | 47.16 | 94.32 |
| General Internal Medicine Physician | 29–1216 | 103.11 | 10.113 | 206.22 |
| Computer Programmers | 15–1251 | 47.02 | 47.02 | 94.04 |

B. ICRs Regarding Finalized Amendments to Normal Public Notice Requirements (31 CFR 33.112, 31 CFR 33.120 and 45 CFR Part 155.1312, and 45 CFR 155.1320)

We are finalizing amendments to the section 1332 waiver implementing regulations to set forth flexibilities related to State public notice requirements and post-award public participation requirements. Current regulations at 31 CFR 33.112 and 45 CFR 155.1312 specify State public notice and comment period and participation requirements for finalized section 1332 waiver requests, and 31 CFR 33.116(b) and 45 CFR 155.1316(b) specify the public notice and comment period and approval requirements under the accompanying Federal process.

However, this final rule does alter any of the requirements related to section 1332 waiver applications, compliance and monitoring, or evaluation in a way that would impose any additional costs or burdens for States seeking waiver approval or those States with approved waiver plans that have not already been captured in prior burden estimates. The Departments anticipate that implementing these provisions will not significantly change or decrease the associated burden currently approved under OMB control number: 0938–1389, expiration date: February 29, 2024.

We did not receive any comments on ICRs regarding the amendments to normal public notice requirements for section 1332 waivers.

C. ICRs Regarding Basic Health Program Regulations (42 CFR 600.320)

We are finalizing requirements at 42 CFR 600.320(c)(1) through (3) that a State operating a BHP must establish a uniform method of determining the effective date of eligibility for enrollment in a standard health plan which follows: (1) the Exchange

coverage effective date standards at 45 CFR 155.420(b)(1); (2) the Medicaid effective date standards at 42 CFR 435.915 exclusive of § 435.915(a); or (3) an effective date of eligibility of the first day of the month following the month in which BHP eligibility is determined. We are also adding 42 CFR 600.320(c)(4) which allows for a State to establish its own effective date of eligibility for enrollment policy subject to HHS approval. We note that only 42 CFR 600.320(c)(3) and (4) are newly finalized. The options under 42 CFR 600.320(c)(1) and (2) currently exist.

We estimate that the policies under 42 CFR 600.320(c)(3) and (4) will have no impact on the information collection burden. We note that any cost would be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

We sought comment on these assumptions.

We did not receive any comments in response to the burden estimates for this policy change. We are finalizing these estimates as proposed.

D. ICRs Regarding Election To Operate an Exchange After 2014 (45 CFR 155.106)

We are finalizing amendments to § 155.106(a)(2) to add new paragraphs (a)(2)(i) and (ii). Specifically, we are finalizing that as part of a State's activities for its establishment of a State Exchange, the State provide upon request, supplemental documentation to HHS detailing the State's implementation of its State Exchange functionality, including information regarding the State's ability to implement and comply with Federal requirements for operating an Exchange. Such supporting documentation would inform HHS's decision to approve or conditionally approve a State Exchange and could include, for example,

materials demonstrating progress toward meeting State Exchange Blueprint application requirements, documentation that details a State's plans to implement and meet the Exchange functional requirements as laid out in the State Exchange Blueprint application, or plans to engage in consumer assistance programs and activities. Additionally, we are finalizing the requirement that when a State submits its State Exchange Blueprint application to HHS for approval, the State must provide the public with notice and a copy of its State Exchange Blueprint application. Further, at some point following a State's submission of its State Exchange Blueprint application to HHS, a State must conduct at least one public engagement (such as a townhall meeting or public hearing), in a timeline and manner considered effective by the State, with concurrence from HHS, at which interested parties can learn about the State's intent to establish a State Exchange and the State's progress toward executing that transition. We are also finalizing the requirement that while a State is in the process of establishing a State Exchange and until HHS has approved or conditionally approved the State Exchange Blueprint application, the State conduct periodic public engagements at which interested parties can continue to learn about the State's progress towards establishing a State Exchange, in a timeline and manner considered effective by the State, with concurrence from HHS. These finalized requirements will impact States that are considering, or are in the process of, establishing a State Exchange for PY 2025 and subsequent years. We anticipate minimal burden on these States, as we believe they will have sufficient time to plan for such public-facing State Exchange

engagements and activities if not already in their plans.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

E. ICRs Regarding Adding and Amending Language To Ensure Web-Brokers Operating in State Exchanges Meet Certain HHS Standards Applicable in the FFEs and SBE-FPs (45 CFR 155.220)

We are finalizing amendments to § 155.220 to apply to web-brokers operating in State Exchanges, and consequently in State Exchanges, in both the Individual Market Exchanges and SHOPS, certain existing HHS standards governing web-brokers' use of non-Exchange websites to assist consumers with enrolling in QHPs and applying for APTC/CSRs in a manner that constitutes enrollment through the Exchange. The burden associated with these amendments includes costs for web-brokers assisting consumers in State Exchanges to meet the requirements in finalized § 155.220(n) and for State Exchanges related to the development and oversight of web-broker programs within their State. We anticipate that the same number of web-brokers operating in the Exchanges on the Federal platform (20) will also operate in the 5 State Exchanges and will be required to incur this burden for each of the 5 State Exchanges they may operate in. We estimate the relevant costs based on current Federal costs. These estimates are described below.

These amendments will impose burdens on web-brokers assisting consumers in State Exchanges for costs related to web-development to meet the finalized website display requirements to be extended to web-brokers operating in these State Exchanges and costs associated with creating and submitting audit documentation for the applicable Exchange's review. We solicited feedback from State Exchanges regarding these burden estimates and the number of web-brokers expected to participate in State Exchanges pursuant to this proposal. Although we have allowed certain flexibility for State Exchanges to tailor their web-broker program and establish their own standards with respect to operational readiness demonstrations by their web-brokers, we expect the costs can be reasonably estimated based on the Federal costs as follows.

We estimate it will take 5 hours for a Business Operations Specialist at an hourly rate of \$73.12 to implement the standardized disclaimers required under § 155.220(c)(3)(i)(A) and (G), along with

30 hours at an hourly rate of \$80.04 for a Web and Digital Interface Designer to modify the website to implement the standardized disclaimers across 5 State Exchanges. Therefore, for the standardized disclaimers under § 155.220(c)(3)(i)(A) and (G), we estimate each web-broker assisting consumers in State Exchanges will incur a cost of \$2,766.80 (5 hours × \$73.12 per hour + 30 hours × \$80.04 per hour). We estimate a cumulative burden of \$55,336 for the anticipated 20 web-brokers operating across the State Exchanges (\$2,766.80 × 20 web-brokers). Additionally, finalized new paragraph § 155.220(n)(1) allows State Exchanges the flexibility to add State-specific language to the standardized disclaimers, provided the additional language does not conflict with the HHS-provided standardized disclaimers. We solicited feedback from State Exchanges regarding how these flexibilities would impact these burden estimates.

Additionally, we anticipate it will take up to 100 hours at an hourly rate of \$80.04 for a Web and Digital Interface Designer to modify the website to implement and display the standardized QHP comparative information required under § 155.220(c)(3)(i)(A) (including the quality ratings assigned by HHS and enrollee satisfaction survey) across 5 State Exchanges. Therefore, for the display of the QHP comparative information on web-broker non-Exchange websites, we estimate each web-broker operating in State Exchanges will incur a cost of \$8,004 (100 hours × \$80.04 per hour). We estimate a cumulative burden of \$160,080 for the anticipated 20 web-brokers operating across the State Exchanges (\$8,004 × 20 web-brokers).

We anticipate it will take 25 hours for a Web and Digital Interface Designer at an hourly rate of \$80.04 to modify the website to display the APTC and CSR eligibility information required under § 155.220(c)(3)(i)(I) across 5 State Exchanges. Therefore, for changes related to implementation of the HHS minimum web-broker standards related to display of consumer APTC and CSR eligibility information, we estimate each web-broker operating in States with State Exchanges will incur a cost of \$2,001 (25 hours × \$80.04). We therefore estimate a cumulative burden of \$40,020 for the anticipated 20 web-brokers operating across the 5 State Exchanges (\$2,001 × 20 web-brokers). Additionally, as discussed in the proposed rule (88 FR 82560), we allow State Exchanges flexibility in how consumer eligibility information for APTC or CSRs is displayed on websites by web-brokers in

State Exchanges, at the discretion of the State Exchange on the display of that information. We solicited feedback from State Exchanges regarding how these flexibilities would impact these burden estimates.

Finalized paragraph § 155.220(c)(4)(iii) will extend certain downstream agent and broker requirements at § 155.220(c)(4)(i) that currently apply to web-brokers in FFE and SBE-FP States and govern the use of the web-broker's non-Exchange website by other agents or brokers assisting Exchange consumers to also apply to web-brokers, and their downstream agents and brokers in State Exchanges, and consequently to these State Exchanges. Under the finalized provision, web-brokers that permit other agents or brokers, through a contract or other arrangement, to use the web-broker's non-Exchange website to help an applicant or enrollee complete a QHP selection or complete the Exchange eligibility application will be required to meet the standards at § 155.220(c)(4)(i)(A), (B), (D), and (F) when assisting consumers in States with State Exchanges. This includes extension of requirements for web-brokers to verify that any agent or broker accessing or using the website is licensed in the State in which the consumer is selecting the QHP and has completed training and registration and has signed all required agreements with the applicable State Exchange. It will also require web-brokers to terminate the agent or broker's access to its website if the applicable State Exchange determines the agent or broker is in violation of the provisions described in this section and/or if the applicable State Exchange terminates any required agreement with the agent or broker. In addition, it will also extend a requirement for web-brokers to provide State Exchanges with a list of agents and brokers who enter into such a contract or other arrangement to use the web-broker's non-Exchange website, in a form and manner to be specified by the State Exchanges similar to the requirement in § 155.220(c)(4)(i)(A) for web-brokers in FFE and SBE-FP States to report the same information to HHS. We understand that web-brokers who work with and allow other agents and brokers to use the web-brokers' non-Exchange websites to assist Exchange consumers typically obtain and manage information on each of their downstream agents or brokers as part of an onboarding process. As a result, we expect web-brokers will already have the necessary data to provide a list to the applicable State Exchange of each of

the other agents or brokers that are allowed to use the web-brokers' non-Exchange websites to assist Exchange consumers. We estimate that it will take up to 240 hours at an hourly cost of \$94.04 for a computer programmer to perform the necessary programming to comply with these requirements in § 155.220(c)(4)(i)(A), (B), and (D), and 10 hours at an hourly cost of \$73.12 for a Business Operations Specialist to develop a listing of affiliated third-party agents and brokers across all 5 State Exchanges. Therefore, for changes related to implementation of these HHS minimum web-broker standards related to downstream agents or brokers, we estimate each web-broker operating in State Exchanges will incur a cost of \$23,300.80 per web-broker (($\$94.04 \times 240 \text{ hours}$) + ($\$73.12 \times 10 \text{ hours}$)). We estimate a cumulative burden of \$466,016 for an anticipated 20 web-brokers operating across the State Exchanges ($\$23,300.80 \times 20 \text{ web-brokers}$).

We estimate it will take 95 hours for a Business Operations Specialist at an hourly rate of \$73.12 to oversee and monitor compliance with the operational readiness requirements established by State Exchanges, as required by new § 155.220(n)(2) across 5 State Exchanges. Therefore, for compliance requirements, we estimate each web-broker operating in States with State Exchanges will incur a cost of \$6,946.40 ($95 \text{ hours} \times \73.12) for the finalized operational readiness requirements. We estimate a cumulative burden of \$138,928 for the anticipated 20 web-brokers operating across the 5 State Exchanges ($\$6,946.40 \times 20 \text{ web-brokers}$). These burden estimates are provided based on the estimates of the cost for DE entities to comply with the operational readiness requirements established by HHS. Finalized paragraph § 155.220(n)(2) will allow State Exchanges to define and establish the form and manner for their web-brokers to establish operational readiness. Although we anticipate State Exchanges would establish requirements similar to the requirements for demonstrating operational readiness to operate in the FFE or SBE-FPs, we solicited feedback from State Exchanges regarding how well these burden estimates reflect their anticipated requirements.

Therefore, we estimate each web-broker operating in all 5 State Exchanges will incur a one-time burden in PY 2025 of 505 hours at a cost of \$43,019. We estimate a cumulative burden of 10,100 hours at an estimated cost of \$860,380 for all 20 web-brokers operating across the 5 State Exchanges.

We sought comment on the number of State Exchanges that would be interested in establishing a web-broker program to allow web-brokers to host non-Exchange websites to assist Exchange consumers in their State and on the number of web-brokers interested in operating in those State Exchanges.

Finalized paragraph 155.220(n) will require State Exchanges to comply with the HHS standards described above and in the preamble. Finalized paragraph 155.220(n)(1) will allow State Exchanges the flexibility to add State-specific language to the standardized disclaimers provided the additional language does not conflict with the HHS-provided standardized disclaimers and provides flexibility in how consumer eligibility information for APTC or CSRs is displayed on websites by web-brokers in State Exchanges, at the discretion of the State Exchange on the display of that information. Finalized paragraph (2) under this new section will also require State Exchanges to establish the form and manner for their web-brokers to demonstrate operational readiness, which may include submission or completion of the same items addressed in § 155.220(c)(6)(i)–(v) to the State Exchanges, in the form and manner specified by the Exchange. The burden associated with these finalized changes includes costs for existing and future State Exchanges related to drafting new policy, updating standards, and potentially hiring additional staff to perform functions not currently being performed by the State Exchange, such as for drafting web-broker disclaimer language, drafting consumer-facing educational content, and engaging web-brokers in operational readiness, that will now incur new costs related to establishment of a web-broker program and ongoing monitoring of web-brokers to enforce the minimum HHS standards and any additional State-specific requirements.

We estimate the relevant costs based on current Federal costs as follows. We estimate that 5 States will opt to host a web-broker program for their State Exchanges. We anticipate the total burden associated with the State Exchanges developing the associated policies and procedures, including providing web-brokers with examples and technical assistance (including technical implementation guidance such as providing the quality ratings assigned and enrollee satisfaction survey data) to be up to 528 hours per State. This assumes 480 hours for a GS–13, Step 5 employee at an hourly rate of \$121.66 (the hourly wage rate for a GS–13, Step 5 employee in the Washington,

DC area,³²⁹ doubled to account for fringe benefits and overhead) and 48 hours for a GS–15, Step 5 employee at an hourly rate of \$169.10 (the hourly wage rate for a GS–15, Step 5 employee in the Washington, DC area,³³⁰ doubled to account for fringe benefits and overhead). In total, for the 5 State Exchanges anticipated to participate, we estimate a burden of 2,640 hours ($5 \text{ State Exchanges} \times 528 \text{ hours per State Exchange}$) at a cost of \$332,568 ($2,400 \text{ hours} \times \$121.66 + 240 \times \$169.10$).

We estimate it will take 40 hours each for the State Exchange equivalent of 2 GS–13, Step 5 employees at an hourly rate of \$121.66 (the hourly wage rate for a GS–13, Step 5 employee in the Washington, DC area,³³¹ doubled to account for fringe benefits and overhead) to complete initial documentation review related to all web-broker requirements pursuant to this finalized policy, for a total cost to State governments of \$9,732.80 ($2 \times 40 \text{ hours} \times \121.66) per State Exchange. We estimate it will take 8 hours for the equivalent of 1 GS–15, Step 5 employee at an hourly rate of \$169.10 (the hourly wage rate for a GS–15, Step 5 employee in the Washington, DC area,³³² doubled to account for fringe benefits and overhead) to provide managerial review and oversight, for a total cost to State governments of \$1,352.80 ($1 \times 8 \text{ hours} \times \169.10) per State Exchange. Additionally, we estimate the total burden for each State government for State contract and contractors ongoing reviews for oversight will include 1,087 hours at GS–12, Step 5 with an hourly rate of \$102.30 (the hourly wage rate for a GS–12, Step 5 employee in the Washington, DC area,³³³ doubled to account for fringe benefits and overhead) and 2,305 hours at GS–13, Step 5 with an hourly rate of \$121.66 (the hourly wage rate for a GS–13, Step 5 employee in the Washington, DC area,³³⁴ doubled to account for fringe benefits and overhead), and the total burden across all 5 States to be 16,960 hours. Therefore, we estimate a cost to each State governments of \$469,225.60, with a total estimated cost to State governments of \$2,346,128 ($5 \text{ States} \times \$469,225.60$). We sought comment from

³²⁹ OPM. (2023, January). *Salary Table 2023–DCB Incorporating the 4.1% General Schedule Increase and a Locality Payment of 32.49% For the Locality Pay Area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA Total Increase: 4.86%*. https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf.

³³⁰ *Id.*

³³¹ *Id.*

³³² *Id.*

³³³ *Id.*

³³⁴ *Id.*

State Exchanges on these burden estimates.

We recognize that some State Exchanges may utilize web-brokers already assisting consumers in the FFEs and SBE-FPs, and encourage State Exchanges to leverage web-broker operational readiness demonstrated to participate in the FFEs or SBE-FPs when possible, as to minimize the burdens on the State Exchanges and their web-brokers.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates with modifications to the estimated burden hours for web-brokers to implement the requirements associated with this policy. We summarize and respond to public comments received regarding this provision below.

Comment: One commenter suggested that the burden estimates could be substantially reduced if the State Exchanges leverage or choose to mirror the HHS requirements. This commenter noted concern that it is misleading to present a separate burden analysis for web-brokers and DE entities, as the majority of web-brokers are DE entities and the burden for complying with web-broker standards on top of EDE standards is minimal.

Response: We appreciate the comment that the burden estimates could be substantially reduced if the State Exchanges leverage the HHS requirements. Although we agree with this comment, the flexibilities afforded to State Exchanges as part of this finalized policy, particularly with regards to implementation of web-broker programs and requirements, present the possibility of significant differences between web-broker programs in different States while also establishing baseline consumer protections across the State Exchanges. We formulated these burden estimates to account for a possible scenario of varied web-broker program requirements across State Exchanges. However, we encourage State Exchanges to leverage the HHS requirements and believe the implementation costs for both State Exchanges and web-brokers may be substantially reduced if the State Exchanges leverage the HHS requirements. However, the assumption that States can save money by mirroring HHS standards assumes that all entities participating have complied and met the HHS standards, as verified by HHS, and ignores the possibility that entities may participate in a given State's web-broker or DE entity program as a net new entity, with no experience or documented compliance at the Federal

level. We carefully considered this commenter's feedback and reduced relevant burden estimates for requirements where we believe there is a high likelihood that State Exchanges will adopt the same requirements as the FFE. We disagree where the commenter suggested it is misleading to present a separate burden analysis for web-brokers and DE entities. Although the majority of DE entities are web-brokers, there exist some DE entities that are not web-brokers (for example, Issuer DE Technology Providers). For that reason, we believed it was important to provide a comprehensive burden estimate for participating in web-broker programs and DE entity programs. However, we acknowledge there is significant overlap between the requirements for web-brokers and DE entities, and, accordingly, have reduced the entity burden estimates for DE entities distinct from web-brokers. We note, however, given the State's requirements for a DE entity under § 155.221 may require a different burden for an entity to implement and comply with compared to the State's requirements for a web-broker under § 155.220.

Comment: One supporting commenter provided comments related specifically to the portion of the burden estimate regarding costs for State Exchanges to implement web-broker programs. This commenter noted that the cost estimates for States to implement this finalized proposal are overstated and fail to incorporate the potential cost savings and additional user fee revenues that States could realize through utilization of web-brokers, including reduced burdens on State call centers and State Exchanges. The commenter expressed concern that the burden estimates were based on salary information for Washington, DC, citing higher salaries for that locality as compared to employees in the majority of State Exchanges. This commenter requested clarification for how the estimated hours for contractor oversight of State Exchanges were determined.

Response: We acknowledge the concern that the burden estimates for State Exchanges to implement web-broker programs are overstated. As acknowledged above, this finalized policy provides flexibility to State Exchanges in their implementation of web-broker programs. These burden estimates account for the possibility that State Exchanges may implement web-broker programs differing from the FFE program. We encourage State Exchanges to leverage the HHS requirements when developing their web-broker programs and we anticipate that doing so would substantially reduce the burden for State

Exchanges to develop and implement these programs. In addition, we acknowledge the comment that web-broker programs may provide additional user fee revenues and cost savings to State Exchanges associated with reduced burdens on State call centers and State Exchanges. Although we acknowledge that there could be cost savings associated with implementing web-broker programs in State Exchanges, we have not conducted a detailed analysis on the cost savings associated with the implementation of web-broker programs in the FFE and, therefore, cannot quantify the extent of any such savings. Furthermore, these estimates are specific to defining the oversight policies and procedures, and the implementation of such oversight for web-brokers and DE entities under §§ 155.220 and 155.221; these estimates are not intended to calculate the total cost—or savings—for any given State to implement a web-broker or DE program, including the costs of developing and maintaining the technical infrastructure to maintain a web-broker and DE entity program. However, we do recognize the potential for savings and are open to feedback as we continue to work with our State partners on implementation of these programs. We acknowledge the concern regarding the use of Washington, DC, labor rates in calculating these burden estimates. In the absence of a national average pay scale, we acknowledge there will be variations in regional pay scales among State Exchanges, including some which may be higher or lower than the rates used to calculate these estimates. With regards to the estimates for contractor oversight of State Exchanges, we are clarifying that these estimates were calculated by mapping labor for the relevant requirements to GS categories based on the applicable FFE contractor support labor costs and hours for the applicable requirements and estimated number of entities. We acknowledge that any given State may experience a higher or lower cost for implementing these programs depending on the extent (that is, scope and frequency) of the State's oversight mechanisms, the scope of the State's specific requirements for these programs, and the general quality and compliance posture of web-brokers or DE entities intending to participate in the State.

Comment: One supporting commenter provided comments related to the portion of the burden estimate regarding costs for web-brokers to operate in State Exchanges. Specifically, this commenter provided detailed feedback on the estimated burden hours based on their

experience as a web-broker operating in the FFEs. This included feedback on the burden associated with implementing §§ 155.220(c)(3)(i)(A), 155.220(c)(3)(i)(G), 155.220(c)(3)(i)(I), 155.220(c)(4)(i)(A), 155.220(c)(4)(i)(B), 155.220(c)(4)(i)(D), and 155.220(n)(2).

Response: We appreciate the feedback on these burden estimates from a web-broker currently operating in the FFEs. We recognize the value of feedback from an entity with experience implementing the FFE program requirements and we carefully considered this feedback and have adjusted the burden estimates where applicable. In making these adjustments, we considered that the commenter has considerable experience operating in the FFE. As the commenter acknowledged, other web-brokers may have differing levels of technical expertise and capacity. We have accounted for the costs associated with implementing these requirements from the perspective of web-brokers with limited experience. However, we agree that the burden may be substantially lower for web-brokers with increased technical experience and capacity. In considering the feedback on these burden estimates, we note there were several assumptions made regarding the State Exchanges' provision of data to web-brokers (for example, the provision of QHP data and agent or broker registration data). These burden estimates account for a scenario where there may be variability between the format of data provided across State Exchanges. We encourage State Exchanges to leverage the data formats used in the FFEs and are committed to providing technical assistance to State Exchanges to facilitate such standardization.

F. ICRs Regarding Establishing Requirements for DE Entities Mandating HealthCare.gov Changes To Be Reflected on DE Entity Non-Exchange Websites Within a Notice Period Set by HHS (45 CFR 155.221(b))

As discussed in the preamble of this finalized rule, we are finalizing without modification but with technical changes additional language to § 155.221 requiring that, in FFE and SBE-FP States, would require DE entities to implement and prominently display website display changes made by HHS to *HealthCare.gov* by meeting standards communicated and defined by HHS within a time period set by HHS, unless HHS approves a deviation from those standards. within a time period specified by HHS, unless HHS approves a deviation.

Based on our experience with operating the DE program on the FFEs

and SBE-FPs over the past several years, we estimate that approximately three or fewer display changes will be required annually. We estimate that a total of 100 web-brokers and QHP issuers participating in DE in FFE and SBE-FP States will be required to comply with these requirements. These display changes may range from changes such as, but not limited to, relatively simple text-based updates to more complex display changes involving the website's backend display methodology or algorithms. We estimate approximately two simpler and one more complex display change annually. We estimate that it will take a Web and Digital Interface Designer 30 hours annually, at a cost of \$80.04 per hour, to implement these changes, at a total annual cost of approximately \$2,401.20 ($\80.04×30 hours) per web-broker or QHP issuer. We therefore estimate a total annual burden of 3,000 hours (30×100) at a cost of \$240,120 (3,000 hours \times \$80.04 per hour) for all applicable web-brokers and QHP issuers.

We recognize that system constraints may prevent DE entity non-Exchange websites from precisely mirroring the *HealthCare.gov* display approach, and that DE entities may have an idea for implementation that does not meet the standards defined by HHS but would effectively communicate the same information to consumers. We are finalizing that DE entities assisting consumers in FFE and SBE-FPs that intend to deviate from the standards defined by HHS will be required to submit a deviation request. Those requests will be subject to review by HHS in advance of implementation of any alternative display approaches.

Based on internal data, we estimate that 25 web-brokers and QHP issuers assisting consumers in FFE or SBE-FP States will submit a request to deviate from the standards defined by HHS annually. We estimate it will take a compliance officer approximately 3 hours annually, at a rate of \$68.94 per hour, to prepare and submit the request to deviate from the communicated standards, including preparing the rationale explaining the request. We therefore estimate the total annual burden for all web-brokers and issuers in completing and submitting a request to deviate to be approximately \$5,170.50 annually.

We do not expect this finalized policy to impose a new burden on EDE entities, as EDE entities are already following the process outlined in this finalized policy through the change request processes described in the Third-Party Auditor Guidelines.

Because the proposal to ensure DE entities assisting consumers in State Exchanges meet certain standards applicable in the FFEs and SBE-FPs at new § 155.221(j) was finalized, we estimate that DE entities may incur burden related to the website development needed to implement and prominently display changes made to State Exchange websites per the standards defined by the State Exchange. We anticipate that the web-development costs cited above will apply for each DE entity assisting consumers in State Exchanges. As described in the preamble, there may be burden associated with maintaining DE environments tailored to each States Exchanges' display requirements. However, based on our experience conducting oversight of DE entity non-Exchange websites assisting consumers in FFEs and SBE-FPs, it is our understanding that DE entities are familiar with and capable of tailoring website displays based on specific criteria and, as such, we anticipate entities are capable of tailoring website displays to the requirements of the State the consumer is seeking assistance in. We anticipate a total annual burden of \$247,358.70 for DE entities assisting consumers in States with State Exchanges associated with implementing display changes and submitting requests to deviate from the standards defined by the State Exchange across 5 State Exchanges, should the State Exchange elect to permit deviation requests. The total burden was calculated by multiplying the costs associated with implementing display changes among 20 DE entities expected to operate across 5 State Exchanges ($\$2,401.20 \times 5$ State Exchanges $\times 20$ DE entities) and adding this to the expected costs for 7 DE entities operating across 5 State Exchanges to submit requests to deviate from the standards defined by the State Exchanges ($\$206.82 \times 5$ State Exchanges $\times 7$ DE entities). If the State Exchange permits deviation requests, those requests will be subject to review by the State Exchange in advance of implementation of any alternative website displays. We sought comment on the burden of this proposal on DE entities planning to operate in State Exchanges.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates as proposed. We summarize and respond to public comment received regarding the requirements that *HealthCare.gov* or State Exchange website changes be implemented and prominently

displayed on DE entity non-Exchange websites within a time notice period set by HHS below.

Comment: One commenter noted they believe this proposal will propose little to no additional burden on most DE entities because it is believed that many of the applicable entities may already be complying with the proposed standards.

Response: We appreciate this comment and agree, as described above and in the proposed rule, that the majority of DE entities are already complying with the requirements associated with this policy because they are subject to the existing HHS-initiated change request practices outlined in the Third-Party Auditor Guidelines. However, we believe the provided burden estimates appropriately characterize the burden for the existing HHS-initiated change request process and for the expansion of this process to Classic DE entities and to DE entities operating in State Exchanges.

G. ICRs Regarding Ensuring DE Entities Operating in State Exchanges Meet Certain Standards Applicable in the FFEs and SBE-FPs (45 CFR 155.221)

We are finalizing amendments to § 155.221 to apply to DE entities operating in State Exchanges, and consequently State Exchanges that choose to implement a DE program, certain existing HHS standards applicable to DE entities assisting consumers with enrolling in QHPs and applying for APTC/CSRs in FFEs and SBE-FPs, in both the Individual Market Exchanges and SHOPS. We anticipate approximately 20 DE entities will operate in the 5 State Exchanges and will be required to incur this burden for each of the 5 State Exchanges they may operate in. The burden associated with these changes includes costs for DE entities assisting consumers in State Exchanges to meet the requirements described in finalized § 155.221(j) and for State Exchanges related to the development and oversight of DE programs within their State. We estimate relevant costs based on current Federal costs. These estimates are described below.

The burden associated with operating a DE program includes costs for DE entities related to web-development to meet the website display requirements being applied to DE entities operating in States with State Exchanges and costs for creating, storing, and submitting operational readiness documentation for Exchange review. Although these policies allow States certain flexibility for State Exchanges to tailor their DE program and establish their own standards with respect to operational

readiness demonstrations by their DE entities, including whether to require third-party audits of DE entities and to impose additional requirements beyond the proposed HHS minimum standards as they determine may be appropriate based on their operational or business needs, we expect the costs to reasonably be estimated based on the Federal costs as follows.

We estimate it will take 5 hours for a DE entity's Business Operations Specialist at an hourly rate of \$73.12 to implement the standardized disclaimer required under § 155.221(b)(2), along with 15 hours at an hourly rate of \$80.04 for a Web and Digital Interface Designer to modify the DE entity non-Exchange website to implement the standardized disclaimer across 5 State Exchanges. Therefore, for the standardized disclaimer under § 155.221(b)(2), we estimate each DE entity operating in State Exchanges that operate their own eligibility and enrollment platform will incur a burden of 20 hours at an estimated cost of \$1,566.20 (5 hours × \$73.12 per hour + 15 hours × \$80.04 per hour). We estimate the anticipated 20 DE entities will incur a cumulative burden of 400 hours at an estimated cost of \$31,324 (\$1,566.20 × 20 DE entities).

Costs related to demonstrating operational readiness at finalized § 155.221(j) will depend on the DE entity's desired enrollment pathway and the options made available by the State Exchange. Although we are allowing States the flexibility to establish operational readiness requirements, including the form and manner for their DE entities to demonstrate operational readiness, we encourage State Exchanges to leverage the existing items in § 155.220(b)(4)(i) and (ii) as the starting point for their operational readiness reviews. If State Exchanges leverage these items, we anticipate the burden associated with DE entity demonstration of operational readiness can be estimated based on the Federal costs as follows. We estimate it will take up to 360 hours for an Auditor at an hourly rate of \$75.00 to submit business audit documentation across 5 State Exchanges, and we estimate 1 DE entity will participate in a manner that would trigger this information collection, resulting in an estimated cost of \$27,000 per DE entity (360 hours × \$75.00). We estimate it will take up to 122 hours for an Auditor at an hourly rate of \$75.00 to submit security and privacy audit documentation across 5 State Exchanges, and we estimate 3 DE entities will participate in a manner that would trigger this information collection, resulting in an estimated cost

of \$9,150 per DE entity (122 hours × \$75.00). We estimate it will take 45 hours for a Business Operations Specialist to complete and submit a typical Enhanced Direct Enrollment (EDE) documentation package and related information across 5 State Exchanges at an hourly rate of \$73.12, and 15 DE entities will participate in a manner that will trigger this information collection, resulting in an estimated cost of \$3,290.40 per DE entity (45 hours × \$73.12). Therefore, for a DE entity to demonstrate operational readiness and compliance with applicable requirements to State Exchanges, we estimate each DE entity will incur a burden of up to 527 hours at an estimated cost of up to \$39,440.40 (360 hours × \$75.00 per hour + 122 hours × \$75.00 per hour + 45 hours × \$73.12), but many DE entities will incur a lower burden and cost due to not participating in a manner that would trigger some of these information collection costs. We estimate a cumulative burden of 1,401 hours at an estimated cost of \$103,806 for all applicable DE entities operating across the 5 State Exchanges (\$27,000 × 1 DE entities + \$9,150 × 3 DE entities + \$3,290.40 × 15 entities). We solicited feedback from State Exchanges with regards to the form and manner of documentation they would require DE entities to submit to demonstrate operational readiness, along with the estimated burden associated with those submissions.

We estimate it will take 100 hours for a Web and Digital Interface Designer at a rate of \$80.04 per hour to modify the DE entity's non-Exchange website to comply with the requirements to display and market QHPs offered through the Exchange, individual health insurance coverage, and any other products on at least three separate websites pages in accordance with §§ 155.221(b)(1) and (3) and (c) across 5 State Exchanges. Therefore, for these website display requirements, we estimate each DE entity operating in State Exchanges will incur an estimated cost of \$8,004 (100 hours × \$80.04 per hour). We estimate 8 DE entities will trigger this information collection with a cumulative burden of 800 hours at an estimated cost of \$64,032 across the State Exchanges (\$8,004 × 8 DE entities).

The burden associated with this change also includes costs for DE entities operating in State Exchanges with oversight of direct enrollment entity application assisters, as described in § 155.221(d) (citing § 155.415(b)), for those DE entities that opt to use these application assisters, when permitted by the applicable State Exchange and only to the extent permitted by applicable

State law. As described in the preamble, the requirements at §§ 155.415(b)(2) and (b)(3) are already applicable to DE entities operating in all Exchanges and therefore do not represent a new burden for DE entities. The extension of § 155.221(d) to DE entities operating in State Exchanges will require DE entities' application assisters to complete appropriate State-required training and registration in a manner specified by the State Exchange consistent with § 155.415(b)(1). We estimate that up to 1,000 application assisters will operate in each State Exchange that opts to implement a DE program and allows DE entity application assisters to assist Exchange consumers. Accordingly, we anticipate that 5,000 application assisters across an estimated 5 States will participate. We estimate the burden for 20 DE entities to comply with this requirement at 3 hours per assister for a total annual burden of 750 hours for a Compliance Officer at an hourly wage of \$68.94 for a total cost of \$51,705 per entity. We estimate a cumulative burden of 15,000 hours at an estimated cost of \$1,034,100 for 20 DE entities operating across the 5 State Exchanges ($51,705 \times 20$ entities).

Finalized paragraph § 155.221(j)(3) will extend requirements for DE entities assisting consumers in State Exchanges to implement and prominently display changes in a manner that is consistent with the display changes made by the State Exchange to the State Exchanges' website by meeting standards communicated and defined by the State Exchange within a time period set by the State Exchange, unless the State Exchange approves a deviation from those standards under the deviation request process it would be required to establish should the State Exchange elect to permit deviations. The costs associated with DE entities implementing this finalized policy in State Exchanges is discussed in the ICR section related to finalized paragraph § 155.221(b)(6).

Regarding finalized paragraph § 155.221(a) extending requirements under § 156.1230(a) to DE QHP issuers operating in State Exchanges, we do not anticipate any additional burdens for QHP issuers, beyond the estimated burdens for the website display requirements described above, to provide consumers with correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the Exchanges, and insurance affordability programs, or to refrain from marketing or conduct that is misleading, coercive, or discrimination based on race, color, national origin, disability, age, or sex.

Therefore, we estimate each DE entity operating in State Exchanges will incur a one-time burden in PY 2025 of up to 1,397 hours at a cost of up to \$100,715.60 for an overall total for all DE entities operating across the State Exchanges of up to 17,601 hours at an estimated cost of \$1,233,262 to comply with these finalized requirements. We sought comment on the burden of these requirements on DE entities planning to participate in State Exchanges. For the purposes of better determining burden estimates, we also sought comment on the number of State Exchanges that operate their own eligibility and enrollment platforms and would be interested in implementing a DE program in their State and on the number of DE entities interested in operating in those State Exchanges.

Finalized paragraph § 155.221(j) will require State Exchanges to comply with the FFE standards described above and in the preamble. § 155.221(j)(1) allows State Exchanges the flexibility to add State-specific information to the standardized disclaimer that does not conflict with the HHS-provided language. Finalized paragraph (2) under this new section also requires State Exchanges to establish the form and manner for their DE entities to demonstrate operational readiness and compliance with applicable requirements, in the form and manner specified by the Exchange. Finalized paragraph (3) will require State Exchanges establish requirements for their DE entities to implement and prominently display website changes in a manner that is consistent with display changes made by the State Exchange to State Exchanges' websites by meeting standards communicated and defined by the State Exchange within a time period set by the State Exchange. The burden associated with these finalized changes includes costs for State Exchanges related to drafting new policy, updating standards, and potentially hiring additional staff to perform functions not currently being performed by the State Exchange, such as for drafting DE entity program requirements and guidelines, including establishment of DE entity operational readiness programs, establishment of procedures related to defining and communicating standards for required display changes, establishment of any State-specific disclaimer text, and ongoing monitoring of DE entity compliance with applicable HHS standards and any additional State-specific requirements. DE entities operating in States transitioning off of the Federal Platform to a State Exchange

will likely have fewer costs as they should already be meeting the HHS minimum requirements. No State Exchange has implemented DE to date, so we are not able to provide precise costs estimates of the burden associated with these finalized changes for State Exchanges. However, we anticipate that operational costs related to establishing policies and adding staff in order to operate a compliant DE program under § 155.221 may be estimated based on Federal platform costs and will be added to the costs and burdens of transitioning to State Exchange.

We estimate that 5 States will opt to host a DE program for their State Exchanges. We anticipate the total burden associated with the State Exchanges developing the associated policies and procedures to be up to 528 hours per State. This assumes 480 hours for a GS-13, Step 5 employee at an hourly rate of \$121.66 (the hourly wage rate for a GS-13, Step 5 employee in the Washington, DC area,³³⁵ doubled to account for fringe benefits and overhead) and 48 hours for a GS-15, Step 5 employee at an hourly rate of \$169.10 (the hourly wage rate for a GS-15, Step 5 employee in the Washington, DC area,³³⁶ doubled to account for fringe benefits and overhead). In total, for the 5 State Exchanges anticipated to participate, we estimate a burden of 2,640 hours (5 State Exchanges \times 528 hours per State Exchange) at a cost of \$332,568 (2,400 hours \times \$121.66 per hour + 240 hours \times \$169.10 per hour).

Based on the Federal platform costs, we estimate it will take 60 hours each for the State Exchange equivalent of 2 GS-13, Step 5 employees at an hourly rate of \$121.66 (the hourly wage rate for a GS-13, Step 5 employee in the Washington, DC area,³³⁷ doubled to account for fringe benefits and overhead) to complete initial documentation review related to all DE entity requirements pursuant to this finalized policy, for a total cost to State governments of \$14,599.20 (2 employees \times 60 hours per employee \times \$121.66 per hour) per State Exchange. We estimate it will take 12 hours for the equivalent of 1 GS-15, Step 5 employee at an hourly rate of \$169.10 (the hourly wage rate for a GS-15, Step 5 employee in the

³³⁵ Office of Personnel Management. (2023, January). *Salary Table 2023-DCB Incorporating the 4.1% General Schedule Increase and a Locality Payment of 32.49% For the Locality Pay Area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA Total Increase: 4.86%*. https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf.

³³⁶ *Id.*

³³⁷ *Id.*

Washington, DC area,³³⁸ doubled to account for fringe benefits and overhead) to provide managerial review and oversight, for a total cost to State governments of \$2,029.20 (12 hours × \$169.10 per hour) per State Exchange. Additionally, we estimate the total burden for each State government for State contract and contractors ongoing reviews for oversight will include 1,631 hours for a GS–12, Step 5 employee with an hourly rate of \$102.30 (the hourly wage rate for a GS–12, Step 5 employee in the Washington, DC area,³³⁹ doubled to account for fringe benefits and overhead) and 3,458 hours for a GS–13, Step 5 employee with an hourly rate of \$121.66 (the hourly wage rate for a GS–13, Step 5 employee in the Washington, DC area,³⁴⁰ doubled to account for fringe benefits and overhead). We estimate a burden to each State government of 5,089 hours at an estimated cost of \$587,551.58 for State contracts and contractors ongoing reviews for oversight. Therefore, each State will incur a burden of 5,749 hours at an estimated cost of \$670,693.58 (\$66,513.60 + \$14,599.20 + \$2,029.20 + \$587,551.58) in total for these finalized policies, and all 5 States will incur a total burden of 28,745 hours at an estimated cost of \$3,353,468 (5 States × \$670,693.58). We sought comment from State Exchanges on these burden estimates.

We recognize that some State Exchanges may decide to utilize DE entities already assisting consumers in the FFEs and SBE–FPs and encourage State Exchanges to leverage DE operational readiness demonstrated to participate in the FFEs or SBE–FPs when possible, so as to help minimize burden on both the State Exchanges that operate their own eligibility and enrollment platform and their DE entities.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates with modifications to the burden hours and number of entities subject to these information collection requirements. We summarize and respond to public comments received regarding this provision below.

Comment: One commenter suggested that the burden estimates are inappropriately based on the premise that States will implement DE programs in the same manner as the FFEs. One commenter suggested that the burden estimates could be substantially reduced

if the State Exchanges leverage or choose to mirror the HHS requirements.

Response: We disagree with the comment that these burden estimates were inappropriately based on the premise that States will implement DE programs in the same manner as the FFEs. The nature of this policy requires a consideration of the baseline Federal consumer protection requirements, while accounting for the potential variation in the ultimate DE requirements determined by each State Exchange. These requirements will provide baseline consumer protections across the State Exchanges but also allows flexibility with regards to State Exchange implementation of DE requirements. Accordingly, States may implement more stringent or less stringent standards and oversight processes; these estimates intend to strike a balance between the Federal implementation and the varied hypothetical possibilities for a State's requirements and oversight process. We appreciate the comment that the burden estimates could be substantially reduced if the State Exchanges leverage the HHS requirements. We encourage State Exchanges to leverage the HHS requirements and believe the implementation costs for both State Exchanges and DE entities may be substantially reduced if the State Exchanges leverage the HHS requirements. However, we note the assumption that States can save money by mirroring HHS standards assumes that all entities participating have complied and met the HHS standards, as verified by HHS, and ignores the possibility that entities may participate in a given State's web-broker or DE entity program as a net new entity, with no experience or documented compliance at the Federal level. We have carefully considered this commenter's feedback and reduced relevant burden estimates for requirements where we believe there is a high likelihood that State Exchanges will adopt the same requirements as the FFE.

Comment: A few commenters provided comments related specifically to the portion of the burden estimate regarding costs for State Exchanges to implement DE programs. Both commenters noted that the cost estimates for States to implement this proposal are overstated and fail to incorporate the potential cost savings and additional user fee revenues that States could realize through utilization of DE entities, including reduced burdens on State call centers and State Exchanges. One commenter expressed concern that the burden estimates were

based on salary information for Washington, DC, citing higher salaries for that locality as compared to employees in the majority of State Exchanges. This commenter requested clarification for how the estimated hours for contractor oversight of State Exchanges were determined.

Response: We acknowledge the concern that the burden estimates for State Exchanges to implement DE programs are overstated. As acknowledged above, this policy provides flexibility to State Exchanges in their implementation of DE programs. These burden estimates account for the possibility that State Exchanges may implement DE programs differing from the FFE program. We encourage State Exchanges to leverage the HHS requirements when developing their DE programs and we anticipate that doing so would substantially reduce the burden for State Exchanges to develop and implement these programs. In addition, we acknowledge the comment that DE programs may provide additional user fee revenues and cost savings to State Exchanges associated with reduced burdens on State call centers and State Exchanges. Although we acknowledge that there could be cost savings associated with implementing DE programs in State Exchanges, we have not conducted a detailed analysis on the cost savings associated with the implementation of DE programs in the FFE and, therefore, cannot quantify the extent of any such savings. Furthermore, these estimates are specific to defining the oversight policies and procedures, and the implementation of such oversight for web-brokers and DE entities under § 155.220 and § 155.221; these estimates are not intended to calculate the total cost—or savings—for any given State to implement a web-broker or DE program, including the costs of developing and maintaining the technical infrastructure to maintain a web-broker and DE entity program. However, we do recognize the potential for savings and are open to feedback as we continue to work with our State partners on implementation of these programs. We acknowledge the concern regarding the use of Washington, DC, labor rates in calculating these burden estimates. In the absence of a national average pay scale, we acknowledge there will be variations in regional pay scales among State Exchanges, including some which may be higher or lower than the rates used to calculate these estimates. With regards to the estimates for contractor oversight of State Exchanges, we are clarifying that these estimates were calculated by

³³⁸ *Id.*

³³⁹ *Id.*

³⁴⁰ *Id.*

mapping labor for the relevant requirements to GS categories based on the applicable FFE contractor support labor costs and hours for the applicable requirements and estimated number of entities. We acknowledge that any given State may experience a higher or lower cost for implementing these programs depending on the extent (that is, scope and frequency) of the State's oversight mechanisms, the scope of the State's specific requirements for these programs, and the general quality and compliance posture of web-brokers or DE entities intending to participate in the State.

Comment: One supporting commenter provided comments related to the portion of the burden estimate regarding costs for DE entities to operate in State Exchanges. Specifically, this commenter provided detailed feedback on the estimated burden hours based on their experience as a DE entity operating in the FFEs. This included feedback on the burden associated with implementing § 155.221(j) and various web-broker requirements that are relevant to DE entities operating in the FFEs. This commenter suggested that the burden estimates should be limited to the number of primary EDE entities expected to participate in State Exchanges.

Response: We appreciate the feedback on these burden estimates from a DE entity currently operating in the FFEs. We recognize the value of feedback from an entity with experience implementing the FFE program requirements and we carefully considered this feedback and have adjusted the burden estimates where applicable. In making these adjustments, we considered that the commenter has considerable experience operating in the FFE. As the commenter acknowledged, other entities may have differing levels of technical expertise and capacity. We have accounted for the costs associated with implementing these requirements from the perspective of DE entities with limited experience. However, we agree that the burden may be substantially lower for DE entities with increased technical experience and capacity. In considering the feedback on these burden estimates, we note there were several assumptions made regarding the State Exchanges' provision of data to DE entities (for example, the provision of QHP data). These burden estimates account for a scenario where there may be variability between the format of data provided across State Exchanges. We encourage State Exchanges to leverage the data formats used in the FFEs and are committed to providing technical assistance to State Exchanges to facilitate such

standardization. We agree with the commenter's suggestion that the burden estimates should be limited to the number of primary EDE entities expected to participate in State Exchanges. We have adjusted the burden estimates to reflect the current number of primary entities operating in the FFEs and to account for the possibility of new primary DE entities entering the State Exchanges.

H. ICRs Regarding Failure To File and Reconcile Process (45 CFR 155.305(f)(4))

We are finalizing amendments to § 155.305(f)(4) to provide that when an enrollee or their tax filer is identified as having FTR status for one-year State Exchanges must either notify the tax filer directly, and alert them of their FTR status, or send informative notices to the enrollee or their tax filer that provide information on the APTC reconciliation requirement, and lets the recipient know that they are at risk of being determined ineligible for APTC without containing protected FTI. This requirement will ensure that State Exchanges provide notifications, similar to how Exchanges on the Federal platform do, and that tax filers on State Exchanges are adequately educated on the requirement to file and reconcile. This final rule will impact State Exchange FTR noticing processes for PY 2025 and subsequent years. For State Exchanges, FTR will be conducted in the same manner it had previously been conducted with respect to collection of information, with minimal changes to the language of the Exchange application questions necessary to obtain relevant information; as such, we anticipate that the finalized amendment will not impact the existing information collection requirements (OMB control number: 0938–1191) or burden for consumers.

Under previous FTR policy, State Exchanges were already required to notify tax filers identified as FTR at a minimum of once per year. As such, we do not anticipate this requirement increasing State Exchanges' burden of noticing beyond their existing FTR processes. We sought comment on these assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

I. ICRs Regarding Verification Process Related to Eligibility for Enrollment in a QHP Through the Exchange (45 CFR 155.315(e))

We are finalizing several revisions to § 155.315(e) that will allow Exchanges to accept consumer attestation of

incarceration status without further verification or, alternatively, to propose an alternative data source for incarceration verification for HHS approval. Exchanges that elect to verify incarceration status will continue to be required to use the DMI process if the data source provides a mismatch against the consumer attestation of incarceration status or other information provided by the applicant or in the records of the Exchange. Should a State Exchange choose to propose using an alternative electronic data source for verifying incarceration status, HHS will review such proposals for consistency with the finalized standard in § 155.315(e)(2).

Of the 18 State Exchanges (operating in 12 States and the District of Columbia) that have incarceration verification processes, 8 conduct incarceration verifications similar to the one used to date by Exchanges on the Federal platform, and 5 have connected to an individual State or local incarceration facility for verifications and have received approval to do so from HHS. Additionally, 3 States are currently in process of transitioning to State Exchanges for PY 2024 or beyond and may choose to connect to an alternative incarceration verification data source with HHS approval. Subtracting the 5 Exchanges with preexisting approvals, we anticipate 11 State Exchanges could connect to an alternative incarceration verification data source, should they assess that an alternative data source exists and want to continue verification of consumer incarceration status using it.

For the purposes of assessing whether an alternative data source should be used, we estimate that a Management Analyst will spend 20 hours, at an hourly rate of \$91.62, to synthesize a cost-benefit analysis regarding whether the Exchange should continue to verify incarceration status using an approved data source instead of accepting a consumer's attestation that they are not incarcerated. If the Exchange finds a viable alternative data source and determines that it should be used, we anticipate that a Business Operations Specialist will take about 2 hours, at an hourly rate of \$73.12, to submit a request for HHS approval. We also anticipate that it will take a Chief Executive equivalent for the Exchange 1 hour, at an hourly rate of \$182.24, to approve the paperwork for submission to request HHS approval of the alternative incarceration data source. In total, the assessment of whether the Exchange should continue to verify incarceration status using an alternative data source instead of accepting

consumer attestation will take 20 hours at a cost of \$1,832.40, and the process of approving and submitting a request for HHS approval will take 3 hours at a cost of \$328.48. Therefore, the total one-time burden for each Exchange that elects to verify incarceration status using an HHS-approved data source in 2025 will be 23 hours at a cost of approximately \$2,161, and the total burden across all 11 State Exchanges would be 253 hours at a cost of approximately \$23,770.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

J. ICRs Regarding Eligibility Redetermination During a Benefit Year (45 CFR 155.330(d))

We are finalizing amendments to § 155.330(d) to require that Exchanges periodically examine available data sources described in §§ 155.315(b)(1) and 155.320(b) to identify changes related to death of an applicant on whose behalf APTC or CSRs are being provided. The Exchanges have developed electronic data exchanges to support obtaining this information to determine the applicant's eligibility at the point of application and could reuse those data exchanges here. Consequently, we estimate costs associated with this requirement to be minimal.

However, State Exchanges not already conducting Death PDM with the required frequency or not deemed in compliance with the finalized PDM requirements will be required to engage in IT system development activity to communicate with these programs and act on enrollment data either in a new way, or in the same way more frequently. Thus, there may be additional associated administrative cost for these State Exchanges to implement the finalized PDM requirement.

Based on experience with other PDMs, for each State Exchange not already conducting Death PDM at least twice a year, we estimate that it will take 40 hours by a Computer Systems Analyst at an hourly rate of \$98.30 to implement this finalized provision, for a cost of \$3,932 per State Exchange. Therefore, for all 11 State Exchanges not currently meeting the finalized requirement, we estimate a total burden of 440 hours at a cost of \$43,252. We assume that this burden will be incurred primarily in 2025.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

K. ICRs Regarding Establishment of Exchange Network Adequacy Standards (45 CFR 155.1050)

The burden associated with subjecting QHP issuers in State Exchanges and SBE-FPs to time and distance standards as proposed at § 155.1050 is covered by the information collection currently approved under OMB control number 0938–1312 (CMS–10593). We note that we are also revising the information collection currently approved under OMB control number 0938–1415 (CMS–10803) regarding appointment wait time standards encompassed in previously finalized regulations at 45 CFR 156.230(a)(2)(B). We sought comment on these burden estimates. We did not receive any comments related to this collection.

Under § 155.1050(a)(2)(i)(A), we are finalizing that for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must establish and impose quantitative time and distance network adequacy standards for QHPs that are at least as stringent as standards for QHPs participating on the FFEs under § 156.230(a)(2)(i)(A).

Second, we are finalizing that, for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must conduct quantitative network adequacy reviews prior to certifying any plan as a QHP, consistent with the reviews conducted by the FFEs under § 156.230. Specifically, we are finalizing at § 155.1050(a)(2)(i)(B) that, for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must conduct quantitative network adequacy reviews to evaluate a plan's compliance with network adequacy standards under § 156.230(a)(1)(ii), (a)(1)(iii), and (a)(2)(i)(A) prior to certifying any plan as a QHP, while providing QHP certification applicants the flexibilities described under § 156.230(a)(2)(ii) and (a)(3) and (4). Under this policy, State Exchanges and SBE-FPs will be prohibited from accepting an issuer's attestation as the only means for plan compliance with network adequacy standards.

We are aware that some State Exchanges employ robust, quantitative network adequacy standards that differ from those used by the FFEs, but still ensure that QHPs provide consumers with reasonable, timely access to practitioners and facilities to manage their health care needs, consistent with the ultimate aim of these policies. Therefore, we are finalizing § 155.1050(a)(2)(ii) to provide that, for plan years beginning on or after January 1, 2026, HHS may grant an exception to the requirements described under

§ 155.1050(a)(2)(i) to a State Exchange or SBE-FP that demonstrates with evidence-based data, in a form and manner specified by HHS, that (1) the Exchange applies and enforces alternate quantitative network adequacy standards that are reasonably calculated to ensure a level of access to providers that is as great as that ensured by the Federal network adequacy standards established for QHPs under § 156.230(a)(1)(iii), (a)(2)(i)(A), and (a)(4); and (2) the Exchange evaluates whether plans comply with applicable network adequacy standards prior to certifying any plan as a QHP. In this final rule, for this exception process, we are clarifying that, for (1) above, issuers on the State Exchanges and SBE-FPs do not need to comply with the appointment wait time standards under § 156.230(a)(2)(i)(B).

Lastly, we are finalizing § 155.1050(a)(2)(i)(C) to provide that, for plan years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must require that all issuers seeking certification of a plan as a QHP submit information to the Exchange reporting whether or not network providers offer telehealth services.

We estimate that the total annual burden associated with State Exchanges and SBE-FPs establishing and imposing the finalized network adequacy standards, conducting the network adequacy reviews, collecting telehealth information from issuers seeking QHP certification, and submitting any exception to be up to 900 hours. Assuming the compliance officer average hourly rate of \$68.94 per hour, we estimate the cost of the data collection, operations, and maintenance pertaining to these requirements on each State Exchange and SBE-FP to be \$62,046 per year (900 hours × \$68.94 per hour). In total, for the 19 State Exchanges and 3 SBE-FPs anticipated to be operational in 2025, we estimate a burden of 19,800 hours (22 State Exchanges and SBE-FPs × 900 hours per Exchange) at a cost of \$1,365,012 (22 State Exchanges and SBE-FPs × 900 hours per Exchange × \$68.94 per hour).

We estimate that the burden for QHP issuers in State Exchanges and SBE-FPs to gather and submit the time and distance data, including any justification, to the respective State Exchanges or SBE-FPs will be 10 hours in total for each medical QHP issuer (a QHP issuer that is not an SADP issuer) and 2 hours in total for each SADP issuer submitted by a compliance officer at a rate of \$68.94 per hour. The 10-hour estimate includes the burden associated with the requirement that all issuers seeking QHP certification submit

information to the State Exchange or SBE-FP about whether network providers offer telehealth services.

Approximately half of the parent companies of issuers on the State Exchanges and over two thirds of the parent companies of issuers on SBE-FPs offer Medicare Advantage plans, and Medicare Advantage offers a telehealth credit for network adequacy. Therefore, many more issuers on State Exchanges and SBE-FPs likely already have access to this information. We also believe that 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 directories. For these reasons, we estimate that any additional burden resulting from the requirement that QHP issuers report whether each network provider is furnishing telehealth services would be minimal.

The requirement that all issuers seeking QHP certification submit information to the State Exchange or SBE-FP about whether network providers offer telehealth services will account for 3 of the total 10 hours we estimate for gathering and submitting the time and distance data to the respective State Exchange or SBE-FP for medical QHP issuers and 30 minutes of the total 2 hours we estimate for SADP issuers. We believe the cost estimates of 3 hours for medical QHP issuers and 30 minutes for SADP issuers to be a maximum and that the burden could be less to issuers that are already collecting telehealth data for other purposes.

We estimate that the total annual burden associated with QHP issuers in State Exchanges and SBE-FPs to gather and submit the time and distance and telehealth data to the respective State Exchanges or SBE-FPs for up to 149 medical QHP issuers in State Exchanges and SBE-FPs would be up to 1,490 hours (10 hours \times 149 medical QHP issuers). Assuming the compliance officer average hourly rate of \$68.94 per hour, we estimate that the cost of gathering and submitting this network adequacy data for an individual medical QHP issuer could be up to \$689.40 (10 hours \times \$68.94 per hour), and for all 149 medical QHP issuers in State Exchanges and SBE-FPs, up to \$102,720.60 (149 medical QHP issuers \times 10 hours per issuer \times \$68.94 per hour). We estimate that the total annual burden associated with this requirement for 89 SADP issuers in State Exchanges and SBE-FPs will be up to 178 hours (2 hours \times 89 SADP issuers). Assuming the compliance officer average hourly rate of \$68.94 per hour, we estimate that the

cost of gathering and submitting the network adequacy data for an individual SADP could be up to \$137.88 (2 hours \times \$68.94 per hour), and for all 89 SADP issuers in State Exchanges and SBE-FPs, up to \$12,271.32 (89 SADP issuers \times 2 hours per issuer \times \$68.94 per hour). We estimate the total annual burden associated with this finalized requirement across both medical QHP and SADP issuers in State Exchanges and SBE-FPs beginning in 2025 will be approximately \$114,992.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates as proposed. We summarize and respond to public comments received regarding the establishment of Exchange network adequacy standards policy below.

Comment: A few commenters expressed opposition to the collection of information about which providers offer telehealth services indicating that the proposed rule underestimated the burden of this proposal and that the information would not capture the availability of telehealth services.

Response: We believe that the telehealth reporting standards, pursuant to which issuers in State Exchanges and SBE-FPs must indicate whether each network provider offers telehealth services with the options “Yes,” “No,” or “Requested information from the provider, awaiting their response,” would not require extensive administrative time to gather. Approximately half of the parent companies of issuers on the State Exchanges and over two thirds of the parent companies of issuers on SBE-FPs offer Medicare Advantage plans, and Medicare Advantage offers a telehealth credit for network adequacy. Therefore, many more issuers on State Exchanges and SBE-FPs likely already have access to this information. We also believe that 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 directories. For these reasons, we estimate that any additional burden resulting from the requirement that QHP issuers report whether each network provider is furnishing telehealth services would be minimal.

We stated in the proposed rule (88 FR 82591, 82638 through 82639) that this data would be for informational purposes, would be intended to help inform the future development of telehealth standards, and would not be displayed to consumers. We believe that the above-described telehealth reporting

standards support these objectives by providing State Exchanges and SBE-FPs with a general picture regarding the availability of telehealth services in their State. Additionally, at this time, since this data will not be displayed to consumers, it is not necessary for State Exchanges and SBE-FPs to collect more granular telehealth data from their issuers.

L. ICRs Regarding the State Selection of EHB-Benchmark Plans for Plan Years Beginning On or After January 1, 2026 (45 CFR 156.111)

The existing OMB approval (0938–1174) PRA package, for which we are seeking a renewal for use beginning in March 2024, would remain in effect until the amendments to § 156.111 finalized in this rule would come into effect.

We are finalizing several revisions to § 156.111 that will reduce the burden associated with State selection of EHB-benchmark plans. For plan years beginning on or after January 1, 2026, we are finalizing revisions to the standards for State selection of EHB-benchmark plans at § 156.111 to consolidate the options for States to change EHB-benchmark plans at § 156.111(a); revisions to the scope of benefit requirements at § 156.111(b)(2); and revisions to § 156.111(e)(3) to require States to submit a formulary drug list as part of their application to change EHB-benchmark plans only if the State is seeking to change their prescription drug EHB. We are also finalizing revisions to the actuarial certification requirements at § 156.111 to reflect the finalized scope of benefit changes. The changes to § 156.111 will first be applicable during the EHB-benchmark plan selection cycle in 2024 and the anticipated reduction in burden to States will begin to be realized at that time.

The changes to § 156.111 will lead to an overall reduction in burden on States to change their EHB-benchmark plans in accordance with the revisions to § 156.111. The revisions to § 156.111 will remove the requirement that States report which option under § 156.111(a) they are using as a basis to change their EHB-benchmark plans, their methodology for confirming compliance with the generosity standard at current § 156.111(b)(2)(ii), and the submission of a formulary drug list under § 156.111(e)(3) unless the State is seeking to make changes to their prescription drug EHB. We will also change the information States submit to HHS to confirm compliance with the scope of benefit requirements at

§ 156.111(b)(2), for which we estimate an overall reduction in burden.

These policies will not change the number of documents States will be required to submit to change their EHB-benchmark plans under § 156.111(e)(3), unless the State is not seeking to make changes to its prescription drug EHB, in which case, the State will not be required to submit a formulary drug list as specified in § 156.111(e)(3). In addition, a response will not be required from all States under current § 156.111 and its finalized revisions. Only States choosing to modify the State's EHB-benchmark plan will need to submit this information to HHS.

Since finalizing the addition of § 156.111 in the 2019 Payment Notice, between one and three States have changed their EHB-benchmark plan each year between 2019 and 2023. While we anticipate that the finalized revisions to § 156.111 will reduce overall burden on States and incentivize more frequent changes to EHB-benchmark plans, we anticipate that at most 5 States will choose to make a change to their EHB-benchmark plans in any given year (15 States over 3 years within the authorization of this ICR).

To change an EHB-benchmark plan, a State currently provides confirmation that the State's EHB-benchmark plan selection complies with certain requirements, including those under § 156.111(a), (b), and (c). This information collection will be revised under the finalized policies in this rule. To comply with the finalized requirement, we estimate that a financial examiner will require 4 hours (at a rate of \$79.04 per hour) to fill out, review, and transmit a complete and accurate document. We estimate that it will cost each State approximately \$316.16 to meet the reporting requirement, with a total annual burden for all 5 States of 20 hours and an associated total cost of \$1,580.80.

Section 156.111(e)(2) currently requires States to submit an actuarial certification and associated actuarial report of the methods and assumptions when selecting options under § 156.111(a). Presently, before compiling this report, States must consider which of the options provided at current § 156.111(a) best facilitate their intended EHB-benchmark changes. This deliberation often involves both research and discussion within the State and between the State and HHS. The finalized consolidation of the options currently available at § 156.111(a) into one overarching approach for EHB-benchmark plan updates will eliminate the need for, and time spent by, States contemplating the merits of one option

or another. This actuarial certification and associated actuarial report must also demonstrate compliance with section § 156.111(b)(2)(i), which requires a State's EHB-benchmark plan to provide a scope of benefits that is equal in scope to the scope of benefits under one of the typical employer plans at § 156.111(b)(2)(i)(A) and (B). While the finalized revisions to § 156.111(b)(2)(i) will still require a State's EHB-benchmark plan to provide benefits that are equal in scope to the scope of benefits under a typical employer plan, they will also allow a State to select any scope of benefits that is as or more generous than the scope of benefits in the least generous plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), and as or less generous than the scope of benefits in the most generous plan in the State (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), among the plans currently defined at § 156.111(b)(2)(i)(A) and (B). We anticipate that these revisions will substantially reduce the burden on States to perform the required actuarial analyses. Under this revision, we anticipate that a State will typically only need to perform three actuarial analyses to determine the scope of benefits in the least and most generous plans among the plans currently defined at § 156.111(b)(2)(i)(A) and (B), and the scope of benefits in the State's new EHB-benchmark plan. Under current regulation, a State may need to perform an indeterminate number of actuarial analyses of the plans defined at § 156.111(b)(2)(i)(A) and (B) until the State identifies a plan with a scope of benefits equal to the State's EHB-benchmark plan. This revision will significantly reduce the likelihood that a State would need to perform as many actuarial analyses. Accordingly, we anticipate a reduction in the estimated burden on States to perform the actuarial analysis to confirm compliance with § 156.111(b)(2)(i).

This actuarial certification and associated actuarial report must also demonstrate compliance with § 156.111(b)(2)(ii), which currently requires a State's EHB-benchmark plan to not exceed the generosity of the most generous among a set of comparison plans. For benefit years beginning on or after January 1, 2026, we are finalizing the removal of this requirement and will revise this estimate to reflect a reduced burden on States that would no longer need perform the actuarial analyses

required to confirm compliance with § 156.111(b)(2)(ii).

The actuarial certification that will be collected under this ICR will be required to include an actuarial report that complies with generally accepted actuarial principles and methodologies. This estimate includes complying with all applicable actuarial standards of practice (ASOPs) (including ASOP 41 on actuarial communications). For example, ASOP 41 on actuarial communications includes disclosure requirements, including those that apply to the disclosure of information on the methods and assumptions being used for the actuarial certification and report. The actuarial certification for this requirement currently includes an attestation that the standard actuarial practices have been followed or that exceptions have been noted. The signing actuary is required to be a Member of the American Academy of Actuaries. These requirements will continue to apply with this finalized policy.

We estimate that an actuary, who is a member of the American Academy of Actuaries, will be required to complete 12 hours of work (at a rate of \$109.60 per hour) on average for § 156.111(e)(2). This will include the certification and associated actuarial report from an actuary to affirm, in accordance with generally accepted actuarial principles and methodologies that the State's EHB-benchmark plan must provide a scope of benefits that is equal to the scope of benefits provided under a typical employer plan. For these calculations, the actuary will need to conduct the appropriate calculations to create and review an actuarial certification and associated actuarial report, including minimal time required for recordkeeping. The precise level of effort for the actuarial certification and associated actuarial report under § 156.111(e)(2) will likely vary depending on the State's approach to its EHB-benchmark plan and this certification requirement, but we are estimating 12 hours of work for the actuary to complete the actuarial certification and associated report in this final rule in recognition that the definition of typical employer plan may require the actuary to determine whether the typical employer plan meets minimum value requirements. We estimate that it will cost each State approximately \$1,315.20 to meet this reporting requirement, with a total annual burden for all 5 States of 60 hours and an associated total cost of \$6,576.

We estimate that a financial examiner will require 1 hour (at a rate of \$79.04 per hour) to review, combine, and

electronically transmit these documents to HHS, as part of a State's EHB-benchmark plan submission. We estimate that each State will incur a burden of 1 hour with an associated cost of \$79.04 with a total annual burden for 5 States of 5 hours at associated total cost of \$395.20.

We require at § 156.111(e)(3) that each State seeking to make a change to its EHB-benchmark plan submit its new EHB-benchmark plan documents. The level of effort associated with this requirement could depend on the State's selection of the EHB-benchmark plan options under the regulation at § 156.111(a). However, for the purposes of this estimate, we estimate that it will require a financial examiner (at a rate of \$79.04 per hour) 12 hours on average to create, review, and electronically transmit the State's EHB-benchmark plan document that accurately reflects the benefits and limitations, resulting in a burden of 12 hours and an associated cost of \$948.48, with a total annual burden for all 5 States of 60 hours and an associated cost of \$4,742.40. This estimate of 12 hours will also include the burden necessary for a State to submit a formulary drug list for the State's EHB-benchmark plan in a format and manner specified by HHS, in accordance with § 156.111(e)(3). However, we are finalizing revisions to § 156.111(e)(3) in this final rule to require a State to submit this formulary drug list only if the State is changing the prescription drug EHB. We do not anticipate that all States would change prescription drug EHB, so we anticipate this burden will be lower for some States. To collect the formulary drug list, the State will be required to use the template provided by HHS and must submit the formulary drug list as a list of RxNorm Concept Unique Identifiers (RxCUIs).

Section 156.111(e)(4) requires a State to submit the documentation necessary to operationalize the State's EHB-benchmark plan. This reporting requirement includes the EHB summary file that is currently posted on CCIIO's website and is used as part of the QHP certification process and is integrated into HHS' IT Build systems that feeds into the data that is displayed on *HealthCare.gov*.³⁴¹ We estimate that it requires a financial examiner 12 hours, on average, (at a rate of \$79.04 per hour) to create, review, and electronically submit a complete and accurate document to HHS resulting in a burden

of 12 hours and an associated cost of \$948.48, with a total annual burden for all 5 States of 60 hours and an associated cost of \$4,742.40.

We estimate that the total number of respondent States would be 5 per year, for a total yearly burden of 205 hours³⁴² and an associated cost of approximately \$18,036³⁴³ to meet these reporting requirements.

We sought comment on these burden estimates.

We did not receive any comments on ICRs regarding the amendments to State selection of EHB-benchmark plans. We are finalizing these estimates as proposed.

M. ICRs Regarding Non-Standardized Plan Option Limits (45 CFR 156.202)

As was previously discussed in the preamble to this finalized rule, we are finalizing permitting issuers to offer non-standardized plan options in excess of the limit of two per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent years, if issuers demonstrate that these additional non-standardized plans beyond the limit at § 156.202(b) have specific design features that would substantially benefit consumers with chronic and high-cost conditions and meet other specified requirements.

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

We finalized several specifications for issuers seeking to utilize this exceptions process at § 156.202(d)(1) through (6). Specifically, at paragraph (d)(1), the 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions will be evaluated at the level of total out-of-

pocket costs for the treatment of the chronic and high-cost condition for a population of enrollees with the relevant chronic and high-cost condition. At paragraph (d)(2), the reduction must not be limited to a part of the year, or an otherwise limited scope of benefits. At paragraph (d)(3), the reduction in cost sharing for these benefits cannot be conditioned on a consumer having a particular diagnosis.

At paragraph (d)(4), the required reduction in cost sharing only applies to the standard variant of the plan for which an issuer seeks an exception, and not to the income-based cost-sharing reduction plan variations required by § 156.420(a), nor to the zero and limited cost sharing plan variations required by § 156.420(b). At paragraph (d)(5), issuers are limited to one exception per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, for each chronic and high-cost condition. At paragraph (d)(6), the chronic and high-cost conditions that may qualify an issuer for this exception will be determined by HHS. Refer to § 156.202 of the preamble to this rule for a more detailed discussion regarding these requirements.

Additionally, at § 156.202(e), an issuer that seeks to utilize this exceptions process is required to submit a written justification in a form and manner and at a time prescribed by HHS. At paragraph (e)(1), the written justification must identify the specific chronic and high-cost condition that its additional non-standardized plan option offers substantially reduced cost sharing for, in accordance with the definition of "cost sharing" at § 156.20.

At paragraph (e)(2), the written justification must identify which benefits in the Plans and Benefits Template are discounted to provide reduced treatment-specific cost sharing for individuals with the specified chronic and high-cost condition. These discounts must be relative to the treatment-specific cost sharing for the same corresponding benefits in the issuer's other non-standardized plan offerings in the same product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area. For the purposes of this standard, treatment specific cost sharing consists of the costs for obtaining services that pertain to the treatment of a particular chronic and high-cost disease—but not the costs for obtaining services that do not pertain to the treatment of the relevant condition. The issuer must identify all services for which the benefits substantially reduce cost sharing in the Plans and Benefits Template. These benefits must

³⁴¹ Information on Essential Health Benefits (EHB) Benchmark Plans. Accessed at <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html>.

³⁴² This is calculated as follows: (29 hours for the financial examiner + 12 hours for the actuary) × 5 States = 205 hours.

³⁴³ This is calculated as follows: (\$11,460.80 for the financial examiner + \$6,576.00 for the actuary) × 5 States = \$18,036.80.

encompass a complete list of relevant services pertaining to the treatment of the relevant condition.

At paragraph (e)(3), the written justification must explain how the reduced cost sharing for these services pertains to clinically indicated guidelines and a representative treatment scenario for treatment of the specified chronic and high-cost condition (and include any relevant studies, guidelines, or supplementary documents to support the application, as applicable). For the purposes of this standard, a representative treatment scenario is an annual course of treatment for a chronic and high-cost condition.

At paragraph (e)(4), the written justification must include a corresponding actuarial memorandum that explains the underlying actuarial assumptions made in the design of the plan the issuer is requesting to except. In this memorandum, an issuer must demonstrate how the benefits that are discounted to provide reduced treatment-specific cost sharing of at least 25 percent identified at § 156.202(e)(2) for the treatment of the condition identified at § 156.202(e)(1) under the excepted plan compare to the identified in-limit offering in the same product network type, metal level, inclusion of dental and/or vision coverage, and service area. This demonstration must specifically be in reference to the specific population that would be seeking treatment for the

relevant condition and not the general population. This memorandum must also include an actuarial opinion confirming that this analysis was prepared in accordance with the appropriate Actuarial Standards of Practice and the profession's Code of Professional Conduct.

In order for an issuer to complete the necessary documentation to submit a request to be excepted from the non-standardized plan option limit at § 156.202(b) in accordance with the requirements at § 156.202(d) through (e), we estimate that it will take an actuary (OES occupational code 15–2011) 5 hours annually at a median hourly cost of \$109.60 per hour (amounting to \$548 annually) to create a new plan design with sufficiently differentiated cost sharing and to set the premium rate for this plan; a general internal medicine physician (OES occupational code 29–1216) 2 hours annually at a median hourly cost of \$206.22 (amounting to \$412.44 annually) to complete the justification form for this exceptions process; and a general and operations manager (OES occupational code 11–1021) 10 hours annually at a median hourly cost of \$94.32 per hour (amounting to \$943.20 annually) to review and submit the justification form, including all required data, as part of an issuer's portfolio of plan offerings that it seeks certification of during QHP certification.

Altogether, we estimate a total burden of 17 hours at a cost of \$1,903.64 per

issuer annually to create a new non-standardized plan option that substantially benefits consumers with a chronic and high-cost condition, and to submit a request for that new non-standardized plan option to be excepted from the non-standardized plan option limit. We do not anticipate that issuers will seek to have more than one additional non-standardized plan option excepted from the limit. We further estimate that approximately 50 FFE and SBE-FP issuers (of the 228 issuers based on current PY 2024 plan offering data, amounting to approximately 22 percent) will request to be excepted from the non-standardized plan option limit in order to offer these additional plans annually, at a total burden of 850 hours and associated cost of \$95,182 for all issuers annually. We estimate that 50 issuers will submit a request to be excepted from the non-standardized plan option limit since we anticipate that most issuers would believe that the burden of creating and certifying additional plans intended to benefit a comparatively small population of consumers would outweigh the benefit of doing so.

We sought comment on these burden estimates.

We did not receive any comments on ICRs associated with non-standardized plan option limit exceptions.

N. Summary of Annual Burden Estimates for Finalized Requirements

TABLE 15—FINALIZED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

| Regulation section(s) | OMB Control No. | Number of respondents | Number of responses | Burden per response (hours) | Total annual burden (hours) | Labor cost of reporting (\$) | Total cost (\$) |
|----------------------------|-----------------|-----------------------|---------------------|-----------------------------|-----------------------------|------------------------------|-----------------|
| 45 CFR 155.1050 | 0938–XXXX | 22 | 22 | 900 | 19,800 | 1,365,012 | 1,365,012 |
| 45 CFR 155.220 | 0938–XXXX | 20 | 20 | 505 | 10,100 | 860,380 | 860,380 |
| 45 CFR 155.220 | 0938–XXXX | 5 | 5 | 4,008 | 20,040 | 2,346,128 | 2,346,128 |
| 45 CFR 155.221 | 0938–XXXX | 20 | 20 | 1,397 | 17,601 | 1,233,262 | 1,233,262 |
| 45 CFR 155.221 | 0938–XXXX | 5 | 5 | 5,749 | 28,745 | 3,353,468 | 3,353,468 |
| 45 CFR 155.221(b)(6) | 0938–XXXX | 100 | 100 | 33 | 3,125 | 245,290.50 | 245,290.50 |
| 45 CFR 155.221(b)(6) | 0938–XXXX | 20 | 20 | 165 | 3,105 | 247,358.70 | 247,358.70 |
| 45 CFR 155.315 | 0938–XXXX | 11 | 11 | 23 | 253 | 23,770 | 23,770 |
| 45 CFR 155.330(d) | 0938–XXXX | 11 | 11 | 40 | 440 | 43,252 | 43,252 |
| 45 CFR 156.111 | 0938–1174 | 5 | 5 | 41 | 205 | 18,036 | 18,036 |
| 45 CFR 156.202 | 0938–XXXX | 50 | 50 | 17 | 850 | 95,182 | 95,182 |
| Total | | 269 | 269 | 12,878 | 104,264 | 9,832,523 | 9,832,523 |

The following information collection requests will be submitted for OMB approval outside of this rulemaking, through separate **Federal Register** notices: Exchange requirements for web-brokers (§§ 155.220, 155.221, 155.315) and non-standardized plan options (§ 156.202).

V. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes several HHS risk adjustment updates, such as to use the 2019, 2020, and 2021 data for recalibration of the HHS risk adjustment models for benefit year 2025; to update and retain the AI/AN CSR adjustment factors for benefit year 2025 and beyond, unless changed through notice-

and-comment rulemaking; to establish the risk adjustment user fee for benefit year 2025; and to give HHS the authority to require corrective action plans for certain observations identified as a result of risk adjustment audits for the high-cost risk pool. The rule further finalizes State Exchange and agent, broker, web-broker, and DE entity standards; requiring State Exchanges and State Medicaid and CHIP agencies

to pay to access and use optional CSI data from the Hub for income verification; eligibility and auto re-enrollment standards; open enrollment period and special enrollment period standards; and permitting enrollees to retroactively terminate their enrollment in a QHP through the Exchange when the enrollee enrolls in Parts A or B Medicare retroactively effective to the date Medicare coverage begins. Additionally, the rule finalizes the FFE and SBE–FP user fee rates for the 2025 benefit year, as well as EHB-benchmark plan selection updates, other EHB updates, minor updates to the standardized plan options for PY 2025, an exceptions process for issuers to offer additional non-standardized plan options in excess of the limit of two for PY 2025, Consumer Operated and Oriented Plan (CO–OP) loan term revisions, and modifications to section 1332 waiver implementing regulations governing public hearing procedures.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled “Modernizing Regulatory Review” (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), 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). The April 6, 2023 Executive Order on Modernizing Regulatory Review ³⁴⁴ amends Section 3(f) of Executive Order 12866 to define a “significant regulatory action” as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of OMB’s Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in the Executive Order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for significant rules.

OMB’s OIRA has determined that this rulemaking is ‘significant’ as measured by the \$200 million threshold under section 3(f)(1). We have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these finalized regulations, and the Departments have provided the following assessment of their impact.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

As required by OMB Circular A–4 (available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf), we prepared an accounting statement in Table 16 showing the classification of the impact associated with the provisions of this final rule.

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 (including merged) health insurance markets and in Exchanges. We are unable to quantify all the benefits and costs of this final rule. The effects in Table 16 reflect 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 16 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers.

TABLE 16—ACCOUNTING TABLE

| Benefits: | Estimate | Year dollar | Discount rate | Period covered |
|--------------------------------------|-----------------------|-------------|-----------------|----------------|
| Annualized Monetized (\$/year) | \$25.79 million | 2023 | 7 percent | 2024–2028 |
| | 26.32 million | 2023 | 3 percent | 2024–2028 |

Quantitative:

- Annual cost savings to State Exchanges of approximately \$20,317,000 beginning in 2025 associated with the policy to permit Exchanges to accept consumer incarceration attestations without further verification.
- Annual cost savings to the Federal Government of approximately \$570,000 beginning in 2025 due to the policy to stop generating incarceration DMIs and thereby stop paying the PUPS annual maintenance and transaction fees for the purposes of verification incarceration status for QHP eligibility.
- Annual cost savings to the Federal Government of approximately \$12.5 million associated with the policy to conduct an additional Death PDM check annually beginning in 2025.

Qualitative:

- Increased State flexibility with respect to determining the effective date of eligibility for enrollment in a standard health plan for purposes of a BHP.

³⁴⁴ Executive Order 14094. <https://www.whitehouse.gov/briefing-room/presidential->

[actions/2023/04/06/executive-order-on-modernizing-regulatory-review/](https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/06/executive-order-on-modernizing-regulatory-review/).

TABLE 16—ACCOUNTING TABLE—Continued

- Improved transparency as a result of the requirement that States seeking to transition to a State Exchange must provide the public with a notice and copy of its State Exchange Blueprint application at the time of submission to HHS for approval, and conduct periodic public engagements whereby interested parties can learn about the State's intent to transition, as well as a State's progress toward transitioning. Although, historically, States that have transitioned to State Exchanges conducted some level of public engagements that would meet what has been finalized, they have done so voluntarily, so this policy will set a clear expectation moving forward for all States that intend to establish and operate a State Exchange.
- Improved consumer experience associated with the requirement that Exchange call centers must provide consumers with access to a live call center representative during the Exchanges' published hours of operations who must be able to assist consumers with submitting their application for QHP coverage. Although all current Exchanges meet this requirement, there may be States transitioning to State Exchanges in the future that would not consider offering live call center representatives in the absence of this finalized amendment. This policy will set a clear expectation moving forward for all States that intend to establish and operate a State Exchange.
- Improved consumer experience and access to accurate insurance information associated with the requirement that all Exchanges must have a centralized eligibility and enrollment platform on its website. Although all current Exchanges meet this requirement, there may be States transitioning to State Exchanges in the future that would not consider operating a centralized eligibility and enrollment platform in the absence of this finalized amendment. This policy will set a clear expectation moving forward for all States that intend to establish and operate a State Exchange.
- Increased transparency for agents, brokers, and web-brokers by specifying who will be reviewing their reconsideration requests.
- Improved consumer experience on non-Exchange websites by requiring DE entities to implement *HealthCare.gov* and State Exchange website display changes that enhance the consumer experience, simplify the plan selection process, and increase consumer understanding of plan benefits, cost-sharing responsibilities and eligibility for financial assistance.
- Reduced burdens and barriers to care for applicants as a result of the policy to permit Exchanges to accept incarceration attestations without further verification.
- Improved continuity of coverage for enrollees due to the requirement that Exchanges must automatically re-enroll enrollees in catastrophic coverage into QHP coverage for the coming plan year.
- Reduced consumer confusion and increased consumer access to assisters as a result of the requirement that State Exchanges generally must adopt an open enrollment period that begins on November 1 of the calendar year preceding the benefit year and ends no earlier than January 15 of the applicable benefit year, with the option to extend the open enrollment period beyond January 15.
- Reduced consumer confusion and coverage gaps due to the policy to align the effective dates of coverage after selecting a plan during certain special enrollment periods across all Exchanges.
- Reduced overlaps in coverage and premium payments for Exchange enrollees who retroactively enroll in Medicare Part A or B as a result of the policy to permit Exchange enrollees to retroactively terminate Exchange coverage back to the date in which they retroactively enroll in Medicare Part A or B, but no more than 6 months before the date that retroactive termination is requested.
- Reduced costs for States to perform actuarial analyses to confirm compliance of EHB-benchmark plans with scope of benefit requirements at § 156.111(b)(2).
- Reduced coverage barriers to expanding access to adult dental benefits, improved State flexibility to add benefits to improve adult oral health, and promotion of health equity associated with the policy to remove the prohibition on including routine non-pediatric dental services as an EHB.
- Increased issuer flexibility in plan design as a result of the finalized exceptions process to allow issuers to offer additional non-standardized plan options in excess of the limit of two per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, if specified requirements are met.
- Streamlined payments and collections processes and limited administrative burden for operating HHS programs due to the policy to align netting regulations at § 156.1215 with the policies proposed in the Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges proposed rule.

| Costs: | Estimate | Year dollar | Discount rate | Period covered |
|--------------------------------------|-----------------------|-------------|-----------------|----------------|
| Annualized Monetized (\$/year) | \$10.00 million | 2023 | 7 percent | 2024–2028 |
| | \$10.00 million | 2023 | 3 percent | 2024–2028 |

Quantitative:

- Cost to issuers being audited for high-cost risk pool payments of approximately \$25,078 to complete, submit to HHS, and implement corrective action plans for certain high-cost risk pool audit observations for each benefit year being audited, if required by HHS.
- One-time cost in PY 2025 to web-brokers operating in State Exchanges of approximately \$860,380 due to the policy to ensure agents, brokers, and web-brokers operating in these State Exchanges are meeting certain requirements applicable in the FFE and SBE-FPs.
- Costs to States of \$2,346,128 associated with the policy that agents, brokers, and web-brokers operating in State Exchanges meet certain requirements applicable in the FFEs and SBE-FPs.
- Costs to DE entities operating in FFE and SBE-FP States of approximately \$240,120 annually beginning in 2025 as a result of the requirement that DE entities implement and prominently display website changes in a manner that is consistent with display changes made by HHS to *HealthCare.gov* by meeting standards communicated and defined by HHS within a time period set by HHS, unless HHS approves a deviation from those standards.
- Costs to DE entities participating in State Exchanges of approximately \$247,359 annually beginning in 2025 associated with implementing display changes and submitting requests to deviate from the standards defined by the State Exchange.
- Costs to DE entities operating in FFE and SBE-FP States of approximately \$5,171 to submit a request to deviate from the display approach adopted by *HealthCare.gov* standards defined by HHS annually beginning in 2025.
- Costs to States of \$3,353,468 associated with the policy that DE entities operating in State Exchanges meet certain requirements applicable in the FFEs and SBE-FPs, including the costs for States associated with policy surrounding DE entities operating in State Exchanges regarding implementing display changes and reviewing associated deviation requests if the State Exchange permits deviations.
- One-time cost in PY 2025 to DE entities in State Exchanges of approximately \$1,233,262 to comply with the policy to add language to ensure DE entities operating in these State Exchanges are meeting certain requirements applicable in the FFE and SBE-FPs.
- One-time cost in PY 2025 to State Exchanges of \$23,770 to conduct an analysis of whether to accept consumer attestation of incarceration status or identify an alternative data source to verify incarceration status and to make changes to their eligibility systems and processes to either accept consumer attestation or use an alternative data source to verify incarceration status.

TABLE 16—ACCOUNTING TABLE—Continued

- One-time cost to HHS of \$2,557,077 in 2024 to build the structure and set up operations for the purposes of distinguishing costs of accessing CSI data through the VCI Hub service between the State Exchange and State Medicaid agency.
- Costs to States of \$867,539 in 2024 and \$1.7 million annually beginning in fiscal year 2025 associated with the administrative fee to account for any direct or indirect costs to HHS of making CSI income data accessed through the VCI Hub service available to Exchanges and State Medicaid and CHIP agencies.
- One-time cost to 1 to 3 States with State Exchanges that currently have one Hub connection shared between the State Exchange and Medicaid, of approximately \$3 to 6 million in 2024 (averaged to approximately \$4.5 million for purposes of this final rule) if they elect to build a second, separate Hub connection for the purposes of distinguishing costs of accessing CSI data through the VCI Hub service between the State Exchange and State Medicaid agency. Should any of these States elect to build a second Hub connection, the State will determine if the State Exchange or Medicaid agency will finance the implementation and operational costs associated with the second Hub connection.
- One-time cost in 2025 of approximately \$43,252 to 11 State Exchanges that are not currently meeting the requirement to conduct Death PDM at least twice a year.
- Costs to 5 States per year of approximately \$18,036 to comply with the policy regarding the State selection of EHB-benchmark plans.
- Costs to 50 issuers of approximately \$95,182 annually to complete the exceptions process in order to offer one additional non-standardized plan option in excess of the non-standardized option plan limit of two for PY 2025 and subsequent years.
- Costs to QHP issuers in State Exchanges and SBE-FPs of approximately \$114,992 annually beginning in 2025 associated with the network adequacy policies in this final rule.
- Costs to State Exchanges and SBE-FPs of approximately \$1,365,012 annually beginning in 2025 associated with the network adequacy policies in this final rule.
- Costs to HHS per year of approximately \$58,923 to conduct an additional check for deceased enrollees associated with the requirement that Exchanges must conduct periodic checks for deceased enrollees twice yearly and subsequently end deceased enrollees' QHP coverage beginning with the 2025 calendar year.
- One-time cost in 2025 of \$1,540,000 to HHS to modify the Federal platform's current incarceration verification processes for the purposes of verifying eligibility for QHP, and to update the Federal platform's system logic for HHS to stop sending incarceration verification requests to PUPS.

Qualitative:

- Increased costs for consumers annually, to the extent that the policies to address State-mandated benefits and the process to change EHB-benchmark plans incentivize States to update and modernize the EHB with additional benefits, including routine non-pediatric dental services. Such added benefits could lead to approximately a 1% increase in second lowest cost silver plan premiums in approximately 5 States annually, raising premium costs for consumers.
- Increased administrative burden to States and issuers to develop criteria used to select a consumer representative for the P&T committee, to create or revise standard operating procedures for the committee, as well as for any additional training.

| Transfers: | Estimate | Year dollar | Discount rate | Period covered |
|--------------------------------------|----------------------|-------------|-----------------|----------------|
| Annualized Monetized (\$/year) | \$1.42 billion | 2023 | 7 percent | 2024–2028 |
| | \$1.48 billion | 2023 | 3 percent | 2024–2028 |

Quantitative:

- Estimated transfers of costs from the Federal Government to States of approximately \$72 million to \$122 million per year beginning in 2024 (averaged to \$100 million for purposes of this final rule) by requiring State Exchanges and State Medicaid agencies to pay for their use of the optional CSI income data accessed through the VCI Hub service.
- Reduction in risk adjustment user fee transfers from issuers to the Federal Government of approximately \$11 million for benefit year 2025 compared to the prior benefit year.
- Reduction in FFE and SBE-FP user fee rates transfers from issuers to the Federal Government of approximately \$340 million for benefit year 2025 compared to the prior benefit year.
- Estimated increased APTC outlays from the Federal Government to issuers of \$2 billion to \$3 billion (averaged to \$2.5 billion for purposes of this final rule) annually beginning in 2026 associated with the policy to remove the limitation that the 150 percent FPL SEP be available only to a consumer whose applicable percentage, which is used to determine the amount of the consumer's premium not covered by APTC, is zero percent.

Qualitative:

- Increased APTC outlays from the Federal Government for APTC to the extent that the policies to address State-mandated benefits and the process to change EHB-benchmark plans incentivize States to update and modernize the EHB with additional benefits, including routine non-pediatric dental services. Such added benefits could lead to an estimated 1% increase in second lowest cost silver plan premiums in an estimated 5 States annually, necessitating increased outlays in the form of APTC.
- Increase in the overall absolute value of risk adjustment State transfers calculated under the State payment transfer formula of approximately 8 percent in Oklahoma, 2.5 percent in Alaska, 2 percent in Montana, and less than 0.5 percent in South Dakota and North Dakota as a result of the policy to recalibrate the CSR adjustment factors for AI/AN plan variant enrollees.

TABLE 17—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE HHS RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FISCAL YEAR 2025–2029, IN BILLIONS OF DOLLARS ³⁴⁵

| Year | 2025 | 2026 | 2027 | 2028 | 2029 | 2025–2029 |
|---|------|------|------|------|------|-----------|
| HHS Risk Adjustment and Reinsurance Program Payments | 8 | 9 | 10 | 10 | 10 | 47 |
| HHS Risk Adjustment and Reinsurance Program Collections | 9 | 10 | 10 | 10 | 10 | 49 |

Note: HHS risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time. Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: CBO and JCT's May 2023 Baseline Projections. Table 2. May 2023. <https://www.cbo.gov/system/files/2023-05/51298-2023-05-healthinsurance.pdf>.

1. Finalized Amendments to Normal Public Notice Requirements (31 CFR 33.112, 31 CFR 33.120, 45 CFR 155.1312, and 45 CFR 155.1320)

In this final rule, the Departments are finalizing modifications to the section 1332 waiver implementing regulations to set forth flexibilities in the public notice requirements and post-award public participation requirements for section 1332 waivers. However, this final rule does not alter any of the requirements related to section 1332 waiver applications, compliance and monitoring, or evaluation in a way that will create any additional costs or burdens for States submitting proposed waiver applications or those States with approved waiver plans that have not already been captured in prior burden estimates. The Departments are of the view that both States with approved section 1332 waivers and States that apply for section 1332 waivers will be minimally impacted or would benefit from reduced burden by these policy changes. The Departments anticipate that implementing these provisions will not significantly change the associated burden currently approved under OMB control number: 0938–1389, Expiration date: February 29, 2024. The Departments are of the view that section 1332 waivers help increase State innovation, which in turn lead to more affordable health coverage for individuals and families in States that consider implementing a section 1332 waiver program.

The Departments sought comment on these impacts and assumptions but did not receive any comments in response to the cost and benefit estimates for this policy. We are finalizing these estimates as proposed.

2. Increase State Flexibility in the Use of Income and Resource Disregards for Non-MAGI Populations (42 CFR 435.601)

Current 42 CFR 435.601(d) authorizes States to apply less restrictive methodologies than those that would otherwise be required to be considered in the individual's eligibility determination. Paragraph (d)(4) requires that the application of less restrictive methodologies by State Medicaid agencies be comparable for all persons within each Medicaid eligibility group. For example, if a State wants to apply an income disregard to an eligibility group serving individuals who are 65 years old or older, it must either agree to apply the income disregard to all

members of the eligibility group who are 65 years old or older or forego application of the disregard. We proposed to eliminate this requirement; however, as explained above, we are not finalizing the proposal at this time, and therefore, we are not finalizing the burden estimates included in the proposed rule.

3. Changes to the Basic Health Program Regulations (42 CFR 600.320)

Section 1331 of the ACA (42 U.S.C. 18051) requires the Secretary to establish a BHP, and section 1331(c)(4) specifically provides that a State shall coordinate the administration of, and provision of benefits under the BHP with other State programs. These finalized regulations build from previous BHP regulations to provide for options for BHP implementation and operations beginning with program year 2024.

In this final rule, we are finalizing the additional options for a State establishing a uniform method of determining the effective date of eligibility for enrollment in a standard health plan. We believe this finalized policy will provide additional flexibility for States when implementing their BHP. If the State chooses to follow either new effective date of eligibility for enrollment option, we believe this finalized policy will also benefit enrollees by providing coverage sooner than if the State were to follow the Exchange effective date of coverage option. We do not anticipate any costs to States because of this finalized policy, as we are only finalizing to provide other options by which a State could determine the effective date of eligibility for purposes of its BHP.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

4. HHS Risk Adjustment (45 CFR 153.320)

We are finalizing the recalibration of the HHS risk adjustment models for the 2025 benefit year using the 2019, 2020, and 2021 enrollee-level EDGE data. We believe that continuing to maintain the approach of blending (or averaging) 3 years of separately solved coefficients provides stability within the HHS-operated risk adjustment program and minimizes volatility in changes to risk scores from the 2024 benefit year to the 2025 benefit year. We also finalized continuing to apply a market pricing adjustment to the plan liability

associated with Hepatitis C drugs in the HHS risk adjustment models.

We are finalizing the recalibration of the CSR adjustment factors for AI/AN zero-cost sharing and limited cost sharing CSR plan variant enrollees for the 2025 benefit year, and to retain the finalized AI/AN CSR adjustment factors for all future benefit years unless changed through notice-and-comment rulemaking. We also finalized maintaining the current CSR adjustment factors for silver plan variant enrollees (70 percent, 73 percent, 87 percent, and 94 percent AV plan variants)³⁴⁶ for the 2025 benefit year and beyond, unless changed through notice-and-comment rulemaking. In addition, we affirm that for plan liability risk score calculations under the State payment transfer formula, we use the CSR adjustment factors that align with the AV of the plan. Thus, for unique State-specific plans that have higher plan liability than the standard silver plan variants (for example, CSR wrap-around and Medicaid-expansion plans), we will continue to apply the applicable CSR adjustment factor that corresponds to the plan's AV, as determined by HHS in consultation with the applicable State Departments of Insurance and other relevant State institutions.

We anticipate that changes to the AI/AN CSR adjustment factors will result in an increase in overall individual market risk pool HHS risk adjustment transfers under the State payment transfer formula in States with a sizable share of AI/AN enrollees. We anticipate that the finalized recalibration of the AI/AN CSR adjustment factors will increase transfer payments (or decrease transfer charges) to the issuers with the larger shares of the AI/AN subpopulation and increase transfer charges (or decrease transfer payments) under the State payment transfer formula for the issuers with smaller shares of the AI/AN subpopulation. Therefore, we anticipate that issuers with larger shares of AI/AN enrollees will have the ability to lower premium rates slightly, as the additional plan liability associated with AI/AN CSR recipients will be offset by the increase in HHS risk adjustment transfer payments (or decrease in transfer charges) to these issuers.

Based on internal analyses, the States with the highest proportion of AI/AN enrollees as a percentage of member months in the 2021 benefit year were Oklahoma (15 percent), Alaska (4 percent), Montana (2 percent), South

³⁴⁵ Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

³⁴⁶ See 83 FR 16930 at 16953; 84 FR 17478 through 17479; 85 FR 29190; 86 FR 24181; 87 FR 27235 through 27236; and 88 FR 25772 through 25774.

Dakota (2 percent), and North Dakota (1 percent). Based on internal analyses of 2021 enrollee-level EDGE data, we anticipate that the finalized recalibration of the AI/AN CSR adjustment factors would increase total transfers under the State payment transfer formula by 8 percent in Oklahoma, 2.5 percent in Alaska, 2 percent in Montana, and less than 0.5 percent in South Dakota and North Dakota. We further anticipate that these transfer impacts would result in modest decreases in premiums among issuers that enroll a high proportion of AI/AN consumers, as issuers with larger AI/AN enrollment will benefit from increased transfer payments (or decreased transfer charges) under the State payment transfer formula. We do not anticipate that States with a low proportion of AI/AN enrollees would experience a transfer or premium impact due to the very low number of enrollees (less than 1 percent) who would be impacted by the finalized recalibration of CSR adjustment factors for this population in those States.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

5. HHS Risk Adjustment User Fee for 2025 Benefit Year (45 CFR 153.610(f))

For the 2025 benefit year, HHS will operate risk adjustment in every State and the District of Columbia. As described in the 2014 Payment Notice (78 FR 15416 through 15417), HHS' operation of risk adjustment under section 1343 of the ACA on behalf of States is funded through a risk adjustment user fee. For the 2025 benefit year, we finalized using the same methodology to estimate our administrative expenses to operate the HHS risk adjustment program as was used in the 2024 Payment Notice. As discussed previously in this final rule, risk adjustment user fee costs for the 2025 benefit year are expected to increase from the prior 2024 benefit year estimates. However, in the proposed rule, we project higher enrollment than our prior estimates in the individual and small group (including merged) markets in the 2024 and 2025 benefit years due to the enhanced PTC subsidies provided for in section 9661 of the ARP³⁴⁷ and extended through the 2025 benefit year pursuant to section 12001 of the IRA.

We estimate that the total cost for HHS to operate the risk adjustment

program on behalf of all States and the District of Columbia will increase from \$60 million in 2024 to approximately \$66 million in 2025. However, we believe that the increased enrollment projections will more than offset the increased risk adjustment user fee costs, and therefore, we proposed that the finalized risk adjustment user fee will be reduced from the \$0.21 PMPM for the 2024 benefit year to \$0.20 PMPM for the 2025 benefit year. In the proposed rule, we expected that the finalized risk adjustment user fee for the 2025 benefit year would reduce the amount transferred from issuers of risk adjustment covered plans to the Federal Government by approximately \$3.5 million.

Since the proposed rule, we have further revised our enrollment projections used for the calculation of the risk adjustment user fee based on newly available data, and as result of that data, we are finalizing a lower 2025 benefit year risk adjustment user fee rate of \$0.18 PMPM than proposed. This 2025 benefit year final user fee rate will further reduce the amount transferred from issuers of risk adjustment covered plans to the Federal Government by approximately \$11 million.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

6. Audits and Compliance Reviews of Risk Adjustment Covered Plans (45 CFR 153.620(c))

We are finalizing amendments to § 153.620(c)(4) to require issuers of risk adjustment covered plans to complete, implement, and provide to HHS written documentation of any corrective action plans when required by HHS if a risk adjustment audit results in the inclusion of certain observations in the final audit report. Based on data from the 2018 benefit year high-cost risk pool audits, we estimate that each issuer audited may receive approximately 2 observations on average in future benefit years of high-cost risk pool audits where there is evidence of non-compliance with applicable Federal requirements, thereby triggering the finalized requirement for the issuer to take corrective action. We also estimate that it will take approximately 4 hours by a business operations specialist (at \$73.12 per hour), 2 hours by a compliance officer (at \$68.94 per hour), and 2 hours by a computer systems analyst (at \$98.30 per hour) to complete, implement, and provide documentation to HHS of a corrective action plan for 2

observations. This results in a total cost per issuer of \$626.96 (4 hours × \$73.12 per hour + 2 hours × \$68.94 per hour + 2 hours × \$98.30 per hour). We estimate that we may conduct high-cost risk pool audits for approximately 40 issuers for each benefit year. Therefore, the total estimated cost to issuers of risk adjustment covered plans for each benefit year being audited will be approximately \$25,078 (40 issuers × \$626.96 per issuer).

We sought comment on these burden estimates and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

7. Approval of a State Exchange (45 CFR 155.105)

We are finalizing the addition of a requirement that a State seeking to transition to a State Exchange must first operate an SBE-FP, meeting all requirements under § 155.200(f), for at least one plan year, including its first open enrollment period.

We do not anticipate this finalized policy will create an additional burden to the States that are currently transitioning to a State Exchange, since those States have already operated an SBE-FP for at least 1 year or will first be operating an SBE-FP. Since PY 2020, all States that have transitioned to a State Exchange have first transitioned to an SBE-FP for one or more plan years. Furthermore, based on our experience, the costs for a State to transition from an FFE to operating an SBE-FP are relatively low in comparison to the costs a State will incur to transition from an FFE, or an SBE-FP, to establishing a State Exchange. This is due to the significant investment of costs incurred in implementing and operating a State Exchange consumer-facing website, eligibility and enrollment technology platform, and associated eligibility and enrollment support infrastructure, such as the State Exchange's consumer call center technology and resources, that FFEs and SBE-FPs rely on HHS to provide. We also expect the impact and costs to States that are considering, or may consider, establishing a State Exchange in the future to be minimal because we believe there will be sufficient time to plan for operating an SBE-FP before operating a State Exchange.

We believe that one of the primary benefits of States operating an SBE-FP prior to implementing and operating a State Exchange lies in the investment of time and resources that a State transitioning to, and operating, an SBE-FP makes in the establishment of direct

³⁴⁷ Public Law 117–2.

relationships with their consumers, assisters, issuers, and other interested parties that will ultimately help in the successful implementation and operation of its State Exchange. Furthermore, we believe that the benefit of these activities to a State and its consumers and partners far outweigh the relatively low cost for the State to first transition to, and operate, an SBE-FP for at least one year before implementing and operating a State Exchange. We are also of the view that this policy will mitigate the significant risk and disruption, for consumers, assisters, issuers, and other interested parties, associated with a scenario where a State wishes to transition from an FFE to establishing and operating a State Exchange in a timeframe of less than a year or otherwise not in alignment with the timelines associated with the approval of a State Exchange specified in § 155.106.

We sought comment on these assumptions of the financial impact of this proposal on States that transition to an SBE-FP for at least one plan year before operating a State Exchange pursuant to this proposal.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

8. Election To Operate an Exchange After 2014 (45 CFR 155.106)

As discussed in the preamble, we are finalizing that a State, as part of its activities for its establishment of a State Exchange, provide upon request, supplemental documentation to HHS detailing the State's implementation of its State Exchange functionality, including information regarding the State's ability to implement and comply with Federal requirements for operating an Exchange. Such supporting documentation would inform HHS's decision to approve or conditionally approve a State Exchange and could include, for example, materials demonstrating progress toward meeting State Exchange Blueprint application requirements, documentation that details a State's plans to implement and meet the Exchange functional requirements as laid out in the State Exchange Blueprint application, or plans to engage in consumer assistance programs and activities.

We do not anticipate additional burden associated with this policy. The current State Exchange Blueprint application already includes requests for supporting documentation that a State is progressing toward meeting State Exchange Blueprint application requirements. As a result, this provision

codifies existing policy, which States currently comply with. Blueprint application. The information collection burden associated with this policy is already accounted for under approved OMB control number: 0938-1172, Expiration date: August 31, 2025.

Further, as discussed in the preamble, we are finalizing the requirement that when a State submits its State Exchange Blueprint application to HHS for approval, the State must provide the public with notice and a copy of its State Exchange Blueprint application. We are also finalizing the requirement that at some point following a State's submission of its State Exchange Blueprint application to HHS, a State must conduct at least one public engagement (such as a townhall meeting or public hearing), in a timeline and manner considered effective by the State, with concurrence from HHS, at which interested parties can learn about the State's intent to transition to a State Exchange and the State's progress toward effectuating that transition. We are also finalizing the requirement that while a State is making this transition and until HHS has approved or conditionally approved the State Exchange Blueprint application, a State conducts periodic public engagements at which interested parties can continue to learn about the State's progress toward finalizing its transition to a State Exchange, in a timeline and manner, either in-person or virtually, considered effective by the State.

We do not anticipate significant additional burden associated with these requirements, as States are currently required to submit a State Exchange Blueprint application to HHS for approval, and so the impact of sharing a copy of the submitted Exchange Blueprint application with the public using their website would be *de minimis*. Further, we believe that since States seeking to establish, or are in the process of establishing, a State Exchange for PY 2025 or in subsequent years would be given broad flexibility to design the public engagements in a manner that best suits their respective State, for meeting the interested party consultation requirement under § 155.130, that States will design their public engagements in a manner such that the additional burden incurred by the State would be minimal. The goal of the policy changes at § 155.106(a)(2)(ii) is to clearly state, for States that are seeking to establish State Exchanges, HHS' expectations of the State engaging with the public regarding its transition to a State Exchange, thus strengthening the transparency requirements of the State Exchange Blueprint review and

approval process. We believe this policy will help States that establish a State Exchange meet the consultation requirements of interested parties at § 155.130 during the period when the State is establishing a State Exchange, by formalizing a process whereby States and interested parties communicate about the State's establishment of a State Exchange throughout the transition process. As such, we believe the impact of this policy will be *de minimis*.

We sought comment on this burden estimate and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

9. Additional Required Benefits (45 CFR 155.170)

We are finalizing amendments to § 155.170(a)(2) to provide that benefits covered in a State's EHB-benchmark plan will not be considered in addition to EHB and thus will not be subject to defrayal by the State beginning with PY 2025. We believe that this revision will have a mixed effect on the cost to the Federal Government. In States that update EHB-benchmark plans to include benefits, the costs of which are currently being defrayed, the percentage of premium attributable to coverage of EHB for purpose of calculating APTC will increase and any increase remains subject to the typicality requirement in that section. In a State that enacts a mandate for a benefit that is currently covered in its EHB-benchmark plan, there will be no effect on Federal Government expense as the benefit was already included in the percentage of premium attributable to coverage of EHB for purpose of calculating APTC. States may choose to evaluate the overlap between mandates and EHB-benchmark-plans for benefits they are currently defraying the costs of but are not required to. Issuers may have to make modifications to their plan designs and plan filings to reflect any possible changes in designation of benefits as EHB because of this policy in the regular course of updating those annual materials. We do not anticipate an additional burden on States or issuers associated with this finalized policy.

We sought comment on this burden estimate and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

10. Consumer Assistance Tools and Programs of an Exchange (45 CFR 155.205)

As discussed in the preamble, we are finalizing the addition of minimum standards for Exchange call center operations, such that Exchanges, other than SBE-FPs and SHOP Exchanges that do not provide for enrollment in SHOP coverage through an online SHOP enrollment platform, meet the following additional requirements: their call center must provide consumers with access to a live call center representative during the Exchanges' published hours of operation and their live call center representatives must be able to assist consumers with submitting their Exchange application for QHP coverage.

We believe this policy will support the intent of sections 1311(d)(4)(B) and 1413(b)(1)(A)(ii) of the ACA by codifying the requirement that a consumer must be able to obtain live call center support with submitting an application for QHP coverage during reliable, published hours of operation. It is our presumption that speaking to a live representative will better aid in troubleshooting consumer Exchange application issues, provide a real time opportunity for a live representative to explain Exchange application terminology to a consumer, provide for a live representative to ensure the consumer provides the most correct information to the Exchange application (thereby alleviating unnecessary follow-up), and provide greater overall consumer satisfaction.

As stated in the preamble, we believe that all State Exchanges already meet these finalized minimum standards, and we know that the Exchanges on the Federal platform does as well. As such, we do not anticipate an additional burden associated with this finalized policy.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

11. Requirement for Centralized Exchange Eligibility and Enrollment Platform on the Exchange's Website (45 CFR 155.205(b) and 155.302(a)(1))

We are finalizing amendments to § 155.205(b)(4) to require that an Exchange operate a centralized eligibility and enrollment platform on the Exchange's website (or, for an SBE-FP, through the Federal eligibility and enrollment platform) such that the Exchange allows for the submission of the single, streamlined application for

enrollment in a QHP and insurance affordability programs by consumers, in accordance with § 155.405, through the Exchange's website and performs eligibility determinations for all consumers based on submissions of the single, streamlined application. Further, we are finalizing amendments to § 155.302(a)(1) to clarify that the Exchange, through the centralized eligibility and enrollment platform operated on the Exchange's website (or, for an SBE-FP, the Federal eligibility and enrollment platform) is the entity responsible for making all determinations regarding the eligibility for QHP coverage and insurance affordability programs regardless of whether an individual files an application for enrollment in a QHP on the Exchange's website, or on a website operated by an entity described under § 155.220, such as a web-broker defined at § 155.20, or a direct enrollment entity or QHP issuer described under § 155.221. This amendment to § 155.302(a)(1) will also clarify that only entities that an Exchange elects to contract with to operate its centralized eligibility and enrollment platform can perform this function on behalf of an Exchange and would prohibit Exchanges from solely relying on non-Exchange entities, including a web-broker (defined at § 155.20) or other entities under § 155.220 or § 155.221, from making such eligibility determinations on behalf of an Exchange.

We also are finalizing amendments to § 155.205(b)(5) to require that an Exchange operate a centralized eligibility and enrollment platform through the Exchange's website (or, for an SBE-FP, by relying on the Federal eligibility and enrollment platform) so that the Exchange (or, for an SBE-FP, the Federal eligibility and enrollment platform) meets the requirement under § 155.400(c) to maintain records of all effectuated enrollments in QHPs, including changes in effectuated QHP enrollments.

Since all Exchanges, including State Exchanges, SBE-FPs, and FFEs, currently provide access to a centralized eligibility and enrollment platform and process for consumers that they serve, and all Exchanges also currently perform all eligibility determinations through the operation of a centralized eligibility and enrollment platform on their websites, we believe the burden of this policy on Exchanges and interested parties will be minimal.

We sought comment on the assumptions and estimated impacts of this proposal.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

12. Adding and Amending Language To Ensure Web-Brokers Operating in State Exchanges Meet Certain HHS Standards Applicable in the FFEs and SBE-FPs (45 CFR 155.220)

We are finalizing amendments to § 155.220 to apply to web-brokers operating in State Exchanges, and consequently in State Exchanges, in both the Individual Market Exchanges and SHOPS, certain existing HHS standards governing use of web-brokers' non-Exchange websites to assist consumers with enrolling in QHPs and applying for APTC/CSRs in a manner that constitutes enrollment through an Exchange. As discussed in the preamble of this final rule, the finalized regulatory amendments will require these State Exchanges to draft policy, update standards, and potentially hire more staff to perform functions not currently being performed by the State Exchange as a result of applying the identified § 155.220 standards to web-brokers participating in State Exchanges. These changes will also require web-brokers hosting non-Exchange websites in these State Exchanges to perform web-development and oversight to ensure compliance with the HHS minimum standards this rulemaking finalized to extend to these web-brokers. These changes will also require web-brokers in State Exchanges who want to assist consumers with enrolling in QHPs and applying for APTC and CSRs to display standardized disclaimers, display QHP comparative information, display information pertaining to a consumer's eligibility for APTC or CSRs, to participate in operational readiness reviews and potentially maintain relevant documentation, and to extend downstream agent and broker requirements to web-brokers operating in State Exchanges. Although these policies allow States certain flexibility for State Exchanges to tailor their web-broker program (including the flexibility to add State-specific language to standardized disclaimers, provided the additional language does not conflict with the HHS-provided standardized disclaimers) and establish their own standards with respect to operational readiness demonstrations by their web-brokers, we expect the impact and costs to be reasonably-based on the impacts seen on the FFEs and SBE-FPs.

Although there will be some additional burden for web-brokers operating in State Exchanges, amounting to approximately \$43,019

per web-broker as discussed in the information collection requirements section of this final rule, we anticipate that some of these State Exchanges may utilize web-broker entities already participating in the FFEs and SBE-FPs, which will help provide administrative savings related to the approval process if the State Exchange does not impose additional State-specific requirements beyond the HHS minimum standards. We encourage State Exchanges to leverage web-broker operational readiness demonstrated for the FFEs and SBE-FPs when possible. Additionally, we expect those web-brokers already participating in the FFEs and SBE-FPs to be able to leverage their existing web-development work with additional burden and costs only required for tailoring the website display, operational readiness, and downstream agent and broker access to any State-specific requirements adopted by the applicable State Exchange. Additionally, as described in the accompanying ICR discussion, we anticipate an impact on State governments totaling \$2,346,128 for 5 States to opt to host a web-broker program for their State Exchange.

We estimate a total cumulative burden of \$860,380 associated with this policy for an estimated 20 web-brokers operating across the 5 State Exchanges. We anticipate these changes to extend certain HHS minimum standards governing web-broker participation in FFEs and SBE-FPs to also apply to State Exchanges and their web-brokers will be beneficial to consumers by establishing uniform, baseline requirements for agent, broker, and web-broker participation across all Exchange types. These finalized changes will allow State Exchanges to leverage the framework that has already been established and currently applies to FFEs and SBE-FPs, thereby decreasing the burden to these State Exchanges to establish such a program, while providing some flexibility for these State Exchanges to tailor the new requirements to include State-specific content (such as the updating disclaimer language to refer to the State Exchange website rather than the *HealthCare.gov* website). Additionally, these finalized changes will establish administrative and operational consistency throughout the Exchanges, which is beneficial to agents, brokers, and web-brokers by allowing them to expand their business into States with State Exchanges in a more streamlined fashion, as well as to Exchanges and their consumers.

We sought comment on these estimated impacts and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates with the modifications to the estimated burden hours for web-brokers to implement the requirements associated with this proposal. We summarize and respond to public comments received regarding this provision below.

Comment: One commenter noted that the burden estimates provided are overstated and fail to incorporate the potential cost savings and additional user fee revenues that States could realize through utilization of web-brokers, including reduced burdens on State call centers and State Exchanges.

Response: We acknowledge this comment and have modified the burden estimates incorporated within this regulatory impact analysis. Refer to the comment summary within this finalized proposal's ICR analysis for a detailed summary and response to this comment.

13. Ability of States To Permit Agents and Brokers and Web-Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (45 CFR 155.220(h))

As discussed in the preamble to this final rule, we are finalizing revisions to § 155.220(h) to specify that the CMS Administrator, a principal officer, will review agent, broker, and web-broker requests for reconsideration of HHS' decision to terminate their Exchange agreement(s) for cause. We are finalizing that the CMS Administrator's determination would be final and binding. We believe this policy will improve transparency for agents, brokers, and web-brokers by ensuring they know who will be responsible for handling these reconsideration decisions under § 155.220(h).

We sought comment on the estimates associated with this proposal.

We received only positive comments on this proposal, with commenters stating this would improve transparency and clarity in the regulation. We are finalizing these estimates as proposed.

14. Establishing Requirements for DE Entities Mandating *HealthCare.gov* Changes Be Reflected on DE Entity Non-Exchange Websites Within a Notice Period Set by HHS (45 CFR 155.221(b))

We are finalizing amendments to § 155.221 as proposed but with technical changes to require that DE entity non-Exchange websites assisting consumers in FFEs and SBE-FPs implement and prominently display website changes in a manner that is consistent with display changes made by HHS to *HealthCare.gov* by meeting

standards communicated and defined by HHS within a time period set by HHS, unless HHS approves a deviation from those standards. We are also finalizing the requirement that State Exchanges must implement a similar process to require their DE entities to implement and prominently display website changes in a manner that is consistent with display changes made by State Exchanges to the State Exchanges' websites by meeting standards communicated and defined by the State Exchanges within a time period set by the State Exchange, unless the State Exchange approves a deviation from those standards under the deviation request process it is required to establish should the State Exchange elect to permit deviation requests.

As discussed in the preamble of this final rule, this policy will require web-brokers and QHP issuers participating in DE in FFE and SBE-FP States to update their non-Exchange websites to implement and prominently display website changes in a manner that is consistent with display changes made by HHS to *HealthCare.gov* by meeting standards communicated and defined by HHS within a time period set by HHS. This requirement will provide those DE entities flexibility in their user interface graphic design, provided that their design complies with the standards defined by HHS. This requirement will also allow those DE entities to submit a deviation request for review and approval by HHS if they would like to implement a display that does not meet those standards. We anticipate an average of three or fewer required display changes annually, with the majority of changes being simpler website display changes that are relatively easy to implement. Furthermore, HHS will provide examples and associated disclaimer text with the release of any required website display changes pursuant to this finalized policy, and therefore, we expect the overall impact of these simple website display changes to be minimal. As described in the information collection requirements section of this final rule, we estimate a total cumulative annual burden of \$240,120 associated with the requirement for DE entity non-Exchange websites assisting consumers in FFEs and SBE-FPs to implement and prominently display website changes in a manner that is consistent with display changes made by HHS to *HealthCare.gov* and a burden of \$5,171 associated with completing and submitting a request to deviate from the *HealthCare.gov* display.

As discussed in the preamble for this final rule, we continue to support DE entities' use of innovative decision-support tools and user interface designs, and this policy is not intended to prohibit the implementation of display features beyond the baseline provided by *Exchange websites*. As such, there may be occasions where some web-brokers and QHP issuers participating in direct enrollment may have implemented the standards of the desired display before the change was made on *the Exchange website*. In these instances where the DE entity non-Exchange website is already meeting the minimum standards associated with the website display changes communicated by HHS pursuant to this requirement, the entity will not have to make any further website updates. We also anticipate approximately one more complex display change per plan year, potentially involving updates to backend UI algorithms and display methodologies. Although more complex display changes may represent additional burden for DE entities, we will ease the burden by providing them with examples of *the Exchange website's* display, technical implementation guidance (including Marketplace API (MAPI) or Public Use Files (PUF) data integration guidance), and technical assistance as needed. We anticipate that giving examples of a user interface design that meets HHS' standards will ease the burden of implementation as compared to solely providing HHS' standards and relying on DE entities to determine how to configure their websites to meet those standards.

Finalized § 155.221(j) will extend this new finalized DE entity non-Exchange website display requirement to require State Exchanges to require their DE entities to implement and prominently display website changes in a manner that is consistent with display changes made by State Exchanges to the State Exchanges' websites on their non-Exchange websites for purposes of assisting consumers with DE in QHPs offered through the Exchange in a manner that constitutes enrollment through the Exchange. This will require State Exchanges to establish requirements for DE entities operating in State Exchanges to reflect changes to the State Exchange website on their DE entity non-Exchange websites. This change will also require State Exchanges to establish processes for communicating and defining standards and for setting advance notice periods. We also encourage State Exchanges to consider the same factors (that is,

complexity of the change and the urgency with which the change must be implemented on the DE entity's non-Exchange website) when setting advance notice periods. Similarly, we encourage State Exchanges to provide DE entities operating in their States examples of the State Exchange display, and technical assistance, including technical implementation guidance, to ease the burden of required display changes.

We anticipate this requirement will benefit consumers by codifying and expanding our existing EDE HHS-initiated change request practices to apply to all DE entities and ensuring that all Exchange consumers receive consistent, clear, and accurate information in a timely fashion as they navigate the QHP selection and enrollment process. We are further of the view that this requirement will mitigate the risk that consumers receive different, and possibly confusing or misleading, information based on the platform they choose to utilize when enrolling in or applying for coverage. This requirement will help ensure consumers using the DE pathways benefit from policies we introduce to improve the *HealthCare.gov* website display, and in State Exchanges the State Exchange website, by enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process.

As discussed in the ICR for this requirement, the cumulative cost estimate as a result of the new finalized paragraph § 155.221(j)(3) will be approximately \$247,359 for 20 entities operating in the State Exchanges in the 2025 benefit year. This includes the estimated costs for entities that submit a request to deviate from the display approach adopted by the State Exchange website, should the State Exchange elect to permit deviation requests, which is estimated at a cost of approximately \$7,239 annually.

We sought comment on these estimated impacts.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

15. Ensuring DE Entities Operating in State Exchanges Meet Certain Standards Applicable in the FFEs and SBE-FPs (45 CFR 155.221)

We are finalizing amendments to § 155.221 to apply to DE entities operating in State Exchanges, and consequently State Exchanges that utilize DE entities, certain existing HHS standards applicable to DE entities assisting consumers with enrolling in

QHPs and applying for APTC/CSRs in FFEs and SBE-FPs, in both the Individual Market Exchanges and SHOPS.

As discussed earlier in this final rule, regulatory amendments will require these State Exchanges to draft policy, update standards, and potentially hire additional staff to perform functions not currently being performed by the State Exchange because of applying certain § 155.221 standards to the State. The amendments will also require DE entities participating in DE programs in State Exchanges to perform web-development to ensure compliance with the Federal minimum standards that this rulemaking finalized to extend to these DE entities, along with any State-specific requirements that may be adopted under the flexibility provided to State Exchanges in this rulemaking.

Although there will be additional burden for DE entities operating in State Exchanges, amounting to approximately \$100,716 per DE entity, as discussed in the information collection requirements section of this final rule, we anticipate that some of these State Exchanges may utilize DE entities already participating in the FFEs and SBE-FPs, which will help provide administrative savings related to the approval process under § 155.221(b)(4) if the State does not impose additional State-specific requirements beyond the HHS standards. We encourage State Exchanges to leverage DE operational readiness demonstrated for the FFEs and SBE-FPs when possible. Additionally, we expect those DE entities already participating in the FFEs and SBE-FPs to be able to leverage their existing web-development work with additional burden only required for tailoring the website display to any State-specific requirements adopted by the State Exchange (for example, updating website disclaimers to reference the State Exchange website rather than the *HealthCare.gov* website). Although these amendments allow States certain flexibility for State Exchanges to tailor their DE program and establish their own standards with respect to operational readiness demonstrations by their DE entities, including whether to require third-party audits of DE entities and to impose additional requirements beyond the proposed HHS minimum standards as they determine may be appropriate based on their operational or business needs, we expect the impact and costs to be reasonably based on the impacts seen on the FFEs and SBE-FPs. As described in the information collection requirements section, we anticipate a total cumulative burden of \$1,233,262

for DE entities in State Exchanges to comply with this policy to ensure DE entities operating in these State Exchanges are meeting certain requirements applicable in the FFEs and SBE-FPs. Additionally, we anticipate this policy will have an impact on State governments totaling \$3,353,468 for 5 States to opt to host a DE program for their State Exchange.

We anticipate that these finalized changes to extend certain minimum HHS standards governing DE entity participation in FFEs and SBE-FPs to also apply to State Exchanges will benefit consumers by establishing uniform, baseline requirements for DE entity participation across all Exchange types. These finalized changes will allow State Exchanges to leverage the framework that has already been established and currently applies to FFEs and SBE-FPs, thereby decreasing the burden to these State Exchanges to establish such a program, while providing some flexibility for these State Exchanges to tailor the applicable standards to include State-specific content. Additionally, this policy will establish administrative and operational consistency throughout the Exchanges, which benefits DE entities by allowing them to expand their business into States with State Exchanges with minimal costs and burdens. Consumers will also benefit by the expansion of entities and enrollment pathways available to assist with enrolling in health insurance coverage.

We sought comment on these estimated impacts and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates with modifications to the burden hours and number of entities subject to these information collection requirements. We summarize and respond to public comments received regarding this provision below.

Comment: A few commenters noted that the burden estimates provided are overstated and fail to incorporate the potential cost savings and additional user fee revenues that States could realize through utilization of DE entities, including reduced burdens on State call centers and State Exchanges.

Response: We acknowledge these comments and have modified the burden estimates incorporated within this regulatory impact analysis. Refer to the comment summary within this finalized proposal's ICR analysis for a detailed summary and responses to these comments.

16. Failure To Reconcile (FTR) Process (45 CFR 155.305(f)(4))

We are finalizing in connection with the FTR process described in § 155.305(f)(4) that Exchanges will be required to send notices to tax filers for the first year in which they failed to reconcile APTC as an initial warning to inform and educate tax filers that they need to file and reconcile, or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive year. If the Exchange cannot send the notice directly to the tax filer, or otherwise cannot send protected FTL, it may send a more general notice to an enrollee or their tax filer informing them of the APTC reconciliation requirement, along with other possible reasons they may be at risk of losing APTC eligibility.

Under this policy, Exchanges on the Federal platform will continue to send notices to tax filers for the year in which they have failed to reconcile APTC as an initial warning to inform and educate tax filers that they need to file and reconcile, or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive tax year. Our policy to codify this practice and require it of all Exchanges, including State Exchanges, to ensure that tax filers who have been determined to have FTR status for 1 year are adequately educated on the file and reconcile requirement, and have ample opportunity to address the issue and file and reconcile their APTC before they are determined to have FTR status for 2 consecutive years. We requested comment on how best to conduct outreach to tax filers who need more intensive assistance in understanding FTR status, including directing them to resources such as Navigator or Assistors that could help explain what they need to do to reconcile their APTC.

This policy will support compliance with the filing and reconciling requirement under 36B(f) of the Code and its implementing regulations at 26 CFR 1.36B-4(a)(1)(i) and (a)(1)(ii)(A), minimize the potential for APTC recipients to incur large tax liabilities over time, and support eligible enrollees' continuous enrollment in Exchange coverage with APTC by avoiding situations where enrollees become uninsured when their APTC is terminated. Additionally, this policy will better align State Exchanges' failure to reconcile processes with that of the Exchanges on the Federal platform.

We are aware of seven States that will operate their own State Exchange for PY 2025 and have not yet fully implemented the infrastructure to run FTR operations for plan years through

2024 due to the flexibility the Exchanges were given to temporarily pause FTR operations due to the COVID-19 PHE.

We sought comment on the estimated one-time costs for these States to fully implement the functionality and infrastructure to conduct FTR operations, and the estimated annual costs to maintain FTR operations.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

17. Verification Process Related to Eligibility for Enrollment in a QHP Through the Exchange (45 CFR 155.315(e))

Finalizing revisions to § 155.315(e) so that Exchanges can accept incarceration attestations without further verification and verify incarceration status using an HHS-approved data source only if they choose to will minimize administrative costs and burdens for Exchanges. Flexibility in verifying incarceration status for Exchanges will result in significant cost savings through not creating and processing incarceration DMIs. The current incarceration verification process resulted in a high number of DMIs, almost all of which are resolved in favor of the applicant and has been burdensome and costly for the Exchanges to implement. By revising the current incarceration verification process, this policy will also eliminate undue burdens and barriers to care for applicants, particularly formerly incarcerated people, a population comprised of a significant number of people with disabilities.³⁴⁸ Many documents that can prove incarceration status cannot be obtained without an unexpired proof of identity document, and most cannot be obtained without submitting non-refundable payments. Incarceration may inhibit one's financial savings, and formerly incarcerated individuals are less likely to secure employment.³⁴⁹ As discussed further in the information collection requirements section for this policy, we anticipate a one-time cost to 11 State Exchanges of approximately \$23,770 to conduct analyses to determine whether to accept consumer attestation of incarceration status or use an alternative data source to verify incarceration status and to submit such request to HHS, and make associated changes to their eligibility

³⁴⁸ Robert Apel, Gary Sweeten, The Impact of Incarceration on Employment during the Transition to Adulthood, Social Problems, Volume 57, Issue 3, 1 August 2010, Pages 448–479, <https://doi.org/10.1525/sp.2010.57.3.448>.

³⁴⁹ Id.

systems and processes to implement the option they choose.

From PY 2018 to 2019, there were 110,802 incarceration DMIs generated. In PY 2019, nearly 38,000 out of 78,000 applicants submitted documents to attempt to resolve the incarceration DMI. Conducting an intensive incarceration verification check through the DMI process for each DMI caused HHS to incur additional costs totaling about \$0.57 million per year for verification of incarceration along with the PUPS annual maintenance and transaction fees. The additional costs associated with generating incarceration DMIs include the costs to inform applicants of their DMI through their eligibility determination notice, and to process the DMI and any documentation mailed by the applicants. State Exchanges have likely incurred similar costs. Of the 13 State Exchanges (operating in 12 States and the District of Columbia) with incarceration verification processes, eight conduct incarceration verifications similar to those conducted by the Exchanges on the Federal platform. We estimate that incarceration DMI processing costs approximately \$9,561,000 annually across all eight of these State Exchanges. Of the 13 State Exchanges with incarceration verification processes, five State Exchanges connected to an individual State or local incarceration facility for verifications and fully process incarceration DMIs. These State Exchanges currently incur DMI processing costs, including costs associated with noticing the applicant of their DMIs and costs associated with DMI and appeals casework. Based on costs incurred by the Exchanges on the Federal platform to process DMIs, we estimate that incarceration DMI processing costs State Exchanges approximately \$7,171,000 annually across all 5 of these State Exchanges. Finally, 3 States are transitioning to State Exchanges. We anticipate their incarceration verification operations will cost approximately \$3,585,000 annually. In total, the costs to an anticipated 16 State Exchanges would be approximately \$20,317,000 annually if current policy continued.

By providing flexibility to Exchanges to verify incarceration status and allowing Exchanges to accept applicant attestations without verification, this policy will enable HHS and Exchanges to avoid incurring the aforementioned costs associated with DMI creation and processing. Exchanges will not have to invest resources into building data transfer connections with an alternative incarceration verification data source and will not have to invest in providing

DMI notices and support to applicants. Therefore, the cost savings to State Exchanges associated with this policy will be approximately \$20,317,000.

As previously mentioned, conducting an intensive incarceration verification check through the DMI process for each DMI caused HHS to incur additional costs totaling approximately \$570,000 per year for verification of incarceration along with the PUPS annual maintenance and transaction fees. While overall, this policy will reduce the burden and costs associated with incarceration verification operations and data sourcing, there will be a modest up-front cost of \$1,200,000 to HHS to modify the Federal platform's current incarceration verification processes for the purposes of verifying eligibility for QHP, and it will cost \$340,000 to update the Federal platform's system logic for HHS to stop sending incarceration verification requests to PUPS. Once these operations and noticing have stopped, no further costs will be incurred by HHS, or by Exchanges that opt to act on the flexibilities provided by this policy. In total, we anticipate a cost of \$1,540,000 to HHS because of this change. We reiterate that this cost will be overshadowed by the expected savings of approximately \$20,317,000 because of this policy.

We sought comment on these estimates.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

18. Verification Process Related to Eligibility for Insurance Affordability Programs (45 CFR 155.320)

We are finalizing amendments to § 155.320(c) by adding a new requirement at paragraph (c)(1)(iii) to require that State Exchanges pay for their utilization of the CSI data provided by the VCI Hub service to verify a tax household's attested annual income, or a Medicaid applicant's current household income, due to our reinterpretation of State Exchange and State Medicaid and CHIP agency use of the Hub to access and use the income data provided by the optional VCI Hub service as a State Exchange or a State Medicaid and CHIP agency function. We are finalizing that beginning on July 1, 2024, State Exchanges and State Medicaid and CHIP agencies will be required to pay for the costs of their use of the VCI Hub Service. We are also finalizing the proposal with a modification: rather than requiring States to pay in advance for their use of the VCI Hub Service, HHS will invoice

States on a monthly basis for their actual utilization of the CSI income data accessed through VCI Hub service, as well as an administrative fee to account for any direct or indirect costs of making CSI income data accessed through VCI Hub service available to State Exchanges and State Medicaid and CHIP agencies.³⁵⁰ In accordance with the modified policy being finalized in this rulemaking, we updated our proposed cost estimates between the proposed and final rules. We now estimate that the costs to HHS to build the structure and set up operations for the purposes of distinguishing costs of accessing CSI data through the VCI Hub service between the State Exchange and State Medicaid and CHIP agencies will be \$2,557,077 in 2024. We also estimate that the cost to States associated with the administrative fee to account for any direct or indirect costs to HHS of making CSI income data accessed through the VCI Hub service available to Exchanges and State Medicaid and CHIP agencies will be \$867,539 in 2024, and \$1.7 million annually beginning in 2025.

Because the price per transaction for CSI data is proprietary information, we are unable to provide those numbers in this rulemaking, or the precise utilization rates for State Exchanges and State Medicaid and CHIP agencies as this would be a direct conflict with the contract that HHS holds with the CSI contractor. However, based on HHS' own analysis, in fiscal year (FY) 2022, State Exchange utilization of the VCI Hub service led to costs of approximately \$26 million dollars. Similarly, in FY 2022, State Medicaid and CHIP agency utilization of the VCI Hub service resulted in costs of approximately \$77 million dollars. We also estimate that by having State Medicaid and CHIP agencies pay for 25 percent of their transaction costs, the Federal Government can save between \$32 to \$55 million per year. By having State Exchanges pay for 100 percent of their transaction costs, we estimate savings to the Federal Government could be between \$39 and \$67 million per year; this cost estimate includes an assumption of one to two States transitioning to State Exchanges in future years. Assuming one to two new States transition to a State Exchange in the next 4 years, we applied a 5 percent increase to estimate the additional pings from these additional States. We

³⁵⁰ See Circular No. A-25 Revised. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>. See also Circular No. A-97. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-097.pdf>.

estimate that taken together, this finalized policy will result in a transfer of between \$72 to \$122 million per year of costs from the Federal Government to States beginning in 2024.

We are aware that six State Exchanges currently only have one connection for both their State Exchange and State Medicaid and CHIP agency, which may pose a challenge when determining which VCI Hub transactions are attributable to the State Exchange, and which are attributed to the State Medicaid and CHIP agency. We anticipate that one to three State Exchanges may elect to build a separate connection in order to accurately account for which VCI Hub transactions originate from their State Exchange and their State Medicaid and CHIP agency and we estimate about \$1 to 3 million in one-time costs in 2024 to build the IT infrastructure for a second Hub connection, totaling about \$3 to 6 million in one-time costs for the one to three States that choose to make any changes with how they currently access the VCI Hub service. States that do not elect to build a separate connection would instead need to develop a cost allocation methodology to track VCI Hub transaction volume from their State Exchange and State Medicaid and CHIP agency and communicate this to HHS so that HHS can invoice accurately and appropriately.

We sought comment on these estimates.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed with the following modification that rather than requiring States to pay in advance for their use of the VCI Hub Service, HHS will invoice States on a monthly basis for their actual utilization of the CSI income data accessed through the VCI Hub Service, as well as an administrative fee to account for any direct or indirect costs of making CSI income data accessed through the VCI Hub service available to Exchanges and State Medicaid and CHIP agencies, in accordance with the Intergovernmental Cooperation Act and interpretive OMB Circulars A-97 and A-25.³⁵¹

19. Eligibility Redetermination During a Benefit Year (45 CFR 155.330(d))

We are finalizing revisions to § 155.330(d) to require Exchanges to conduct periodic checks for deceased enrollees twice yearly and subsequently

end deceased enrollees' QHP coverage beginning with the 2025 calendar year. Additionally, we are finalizing amendments to § 155.330(d)(3) to grant the Secretary the authority to temporarily suspend the PDM requirement during certain situations or circumstances that lead to the limited availability data needed to conduct PDM or of documentation needed for an enrollee to notify the Exchange that the result of PDM is inaccurate, as described in § 155.330(e)(2)(i)(C).

Currently, § 155.330(d)(3) defines "periodically" only for PDM activities that identify enrollment in Medicare, Medicaid, CHIP, and BHP, meaning that Exchanges must conduct Medicare PDM, Medicaid or CHIP PDM, and BHP PDM twice a year. The current regulation does not specify the frequency by which PDM activities to identify deceased enrollees must occur. The 2019 Program Integrity Rule did not require Exchanges to perform PDM for death at least twice in a calendar year so that Exchanges could prioritize the implementation of the new requirement to conduct PDM for Medicare, Medicaid, CHIP and, if applicable, BHP eligibility or enrollment at least twice yearly. Periodic checks for deceased enrollees are a critical aspect to ensuring Exchange program integrity.

We are finalizing revisions to § 155.330(d) to require Exchanges to conduct periodic checks for deceased enrollees twice yearly and subsequently end deceased enrollees' QHP coverage beginning with the 2025 calendar year. This policy will not only align with current policy and operations on the Exchanges on the Federal platform but will also prevent overpayment of QHP premiums and accurately capture household QHP eligibility based on household size.

Based on internal data, we anticipate that it will cost the Federal Government approximately \$58,923 to conduct an additional check for deceased enrollees per year. In 2023, we conducted two rounds of Death PDM where the average number of expired households was 7,151; the average APTC amount per household was \$549 per month; and, at the time of the expiration activities, there was an average of 6.5 months left in the plan year. We calculate the APTC savings to be approximately \$25 million. Prior to implementing Death PDM in 2019, we looked at the number of consumers that were removed from coverage by the surviving family without the aid of Death PDM and close to 50 percent of the deceased consumers were removed from coverage. Thus, we estimate the net amount of APTC saved

is estimated will be approximately \$12.5 million per year beginning in 2025.

State Exchanges that are not already conducting Death PDM with the finalized required frequency, or deemed in compliance with PDM requirements, will be required to engage in IT system development activity to communicate with these programs and act on enrollment data either in a new way, or in the same way more frequently if this proposal is finalized. Thus, there may be additional associated administrative cost for these State Exchanges to implement the PDM requirement. As discussed in the information collection requirements section of this final rule, for a State Exchange not already conducting Death PDM at least twice a year, we estimate that it will cost approximately \$3,932 per State Exchange (a total of \$43,252 for all 11 State Exchanges currently not meeting the finalized requirement) to implement this finalized provision through their system. We assume that this cost will be incurred primarily in 2025 by State Exchanges. These costs will be incurred by the State Exchanges as they are required to be financially self-sustaining and do not receive Federal funding for their establishment or operations.

We sought comments in response to the burden estimates for this policy.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing as proposed.

20. Incorporation of Catastrophic Coverage Into the Auto Re-Enrollment Hierarchy (45 CFR 155.335(j))

We are finalizing the policy to incorporate catastrophic coverage as defined in section 1302(e) of the ACA into the auto re-enrollment hierarchy at § 155.335(j) as proposed, except that we are amending the language at § 155.335(j)(1)(v) and (j)(2)(iv) to incorporate the phrase, "to the extent permitted by applicable State law." As further discussed in preamble for this policy, this language is to reflect that, as with existing re-enrollment hierarchy rules, Exchanges must take into account applicable State law when implementing auto re-enrollment. We are also finalizing the addition of § 155.335(j)(5) to establish that an Exchange may not newly auto re-enroll an enrollee into catastrophic coverage who is currently enrolled in coverage of a metal level as defined in section 1302(d) of the ACA. Because this policy is being finalized, we will also update the FFE Enrollment Manual to incorporate catastrophic coverage into the re-enrollment hierarchy for alternate enrollments.

³⁵¹ See Circular No. A-25 Revised, <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>. See also Circular No. A-97, <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-097.pdf>.

We sought comment on the proposal's impacts, including whether it would result in an increase in costs and burden for issuers and Exchanges. In the proposed rule, we stated that burden for Exchanges on the Federal platform and issuers participating in those Exchanges would be mitigated because we already encourage issuers to submit crosswalk options for catastrophic enrollees, including those who will lose eligibility for catastrophic coverage. We also sought comment on our belief that this change would make it more likely that catastrophic coverage enrollees would be auto re-enrolled.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates as proposed. We summarize and respond to public comments received regarding the policy to incorporate catastrophic coverage into the auto re-enrollment hierarchy below.

Comment: Some commenters stated that some State Exchanges already incorporate catastrophic coverage enrollees into their re-enrollment processes, and some comments that cited State Exchanges that do not do so. Other commenters stated that the policy could increase burden on State Exchanges and issuers that do not currently auto re-enroll catastrophic coverage enrollees.

Response: For a more detailed of these comments and our responses, see the preamble for § 155.335(j).

Comment: A few commenters suggested that the proposed policy could impact the individual market risk pool. One commenter stated that the policy would have a net positive effect on the individual market risk pool, which would benefit market stability and affordability overall, because it would increase enrollment in comprehensive coverage among individuals who age out of catastrophic coverage. A few commenters stated that the policy could help stabilize the individual market by improving continuity of coverage. One commenter voiced concern about automatically re-enrolling those losing catastrophic coverage eligibility into a bronze or higher coverage level QHP because this would transfer risk from the catastrophic risk pool into the non-catastrophic individual market risk pool for the HHS risk adjustment program, and because enrollees changing from catastrophic to a higher level of coverage would likely see premium increases. However, the commenter noted that in some cases this increase could be offset by APTC for eligible individuals and by lower out-of-pocket

costs and expressed general support for actions to prevent enrollees from becoming uninsured.

Response: We agree that promoting continuity of coverage can help stabilize the individual market risk pool. However, we do not believe that the policy will have a significant impact on the individual market risk pool given the small number of catastrophic coverage enrollees. For example, during the 2022 open enrollment period for Exchanges on the Federal platform, total health plan selections through *HealthCare.gov* for catastrophic coverage were less than one percent of total health plan selections, which was 42,087 out of over 10.2 million, or about 0.41 percent. During the 2023 open enrollment period, this total decreased to 28,903 out of over 12.2 million, just 0.24 percent.³⁵²

21. Premium Payment Deadline Extensions (45 CFR 155.400(e)(2))

We anticipate that the finalized amendment to § 155.400(e)(2) to codify that flexibility for issuers experiencing billing or enrollment problems due to high volume or technical errors is not limited to extensions of the binder payment will benefit issuers. Because HHS has already provided enforcement discretion in the past to account for such situations, we do not anticipate that there will be any additional costs for HHS associated with this finalized policy, nor do we anticipate any costs to interested parties.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

22. Initial and Annual Open Enrollment Periods (45 CFR 155.410)

We are finalizing amendments to § 155.410(e)(4) to revise parameters around the adoption of an alternative open enrollment period by a State Exchange not utilizing the Federal platform. We are finalizing that for benefit years beginning on or after January 1, 2025, State Exchanges must adopt an open enrollment period that begins on November 1 of the calendar year preceding the benefit year and ends January 15 of the applicable benefit year or later. We are also adding paragraph (e)(4)(iii) to grandfather the open enrollment period of any State Exchange that held an open enrollment period that began before November 1, 2023,

and ended before January 15, 2024, for the 2024 benefit year so that it can continue to begin open enrollment before November 1 in consecutive future benefit years, so long as that State Exchange's open enrollment period continues uninterrupted for at least 11 weeks. If the State Exchange later changes the dates of its open enrollment period after the effective date of this rule, it must for that, and subsequent benefit years, hold an open enrollment period that is compliant with the requirements of (e)(4)(i) and (ii). We have previously observed that when open enrollment ends in December, certain consumers may be subjected to unexpected plan cost increases that they may not be notified about until January. For consumers in the vast majority of Exchanges, this policy will be beneficial for reducing such unexpected plan cost increases since most Exchanges will end on or after January 15. This policy will also ensure ample time for Navigators, certified application counselors, agents, and brokers to fully assist all interested consumers during open enrollment while also improving access to health coverage by giving consumers ample time to react to updated plan cost information and seek enrollment assistance, including consumers in underserved communities who face additional barriers to accessing health coverage. Finally, by reducing consumer confusion, increasing consumer access to assisters, and giving consumers more time to consider up-to-date plan cost information, this policy could increase QHP enrollment, benefiting all interested parties, including consumers, Exchanges, issuers, and assisters.

All 19 State Exchanges except one already meet these finalized parameters, beginning their annual open enrollment periods on November 1 and concluding on or after January 15 of the benefit year, pursuant to current § 155.410(e)(4)(ii). Since most State Exchanges already are aligned with the parameters described in the policy, we anticipate that this new amendment would have a *de minimis* impact and not impose significant additional burden overall.

We sought comment on this burden estimate and assumptions. We were particularly interested in comments regarding whether this proposal would impose a significant burden on outlying State Exchanges and interested parties (for instance, Navigators, assisters, issuers).

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

³⁵² 2022 and 2023 OEP State, Metal Level, and Enrollment Status Public Use Files: see Table 6: Enrollment Status by Metal Level.

23. Special Enrollment Periods—
Effective Dates of Coverage (45 CFR
155.420(b))

We are finalizing amendments to § 155.420(b)(1) and (b)(3)(i) to align the effective dates of coverage after selecting a plan during certain special enrollment periods across all Exchanges, including State Exchanges, so that during a special enrollment period that follows the regular effective dates of coverage listed at § 155.420(b)(1), qualifying individuals or enrollees who select and enroll in a QHP receive coverage beginning the first day of the month after the consumer selects a QHP.

In the 2021 Payment Notice final rule (85 FR 29251), where this policy was finalized for Exchanges on the Federal platform, we noted that ensuring that consumers who select a plan during a special enrollment period using the regular effective dates at § 155.420(b)(1) receive coverage on the first day of the following month, rather than on the first day of the second month following plan selection, would result in several benefits, such as reducing consumer confusion and minimizing coverage gaps while also enhancing operational efficiency. In addition, we noted that the standardization of effective coverage dates for special enrollment periods provided using the regular effective dates at § 155.420(b)(1) would result in standardization for issuers due to more plans beginning in the same month, Exchanges, and consumers; the reduction of system errors and related casework, including reduced confusion among relevant consumer support staff; and simplified Exchange billing practices due to the expedited effective dates. We believe that, similarly, State Exchanges and the issuers and consumers in their States will also experience these benefits under the policy to align the effective coverage dates across all Exchanges for special enrollment periods that use the regular effective dates of coverage at § 155.420(b)(1) (unless an earlier coverage effective date were selected pursuant to § 155.420(b)(3), which would reduce potential burdens associated with this policy).

Additionally, we expect that issuers will not incur substantial new costs as a result of applying this policy across Exchanges since they routinely effectuate coverage on the first of the month following plan selection or earlier when permitted or required under applicable regulation. We expect that consumers in States which do not currently apply this policy will also benefit from a faster effectuation of coverage, as this will result in fewer

coverage gaps for consumers transitioning between or newly enrolling in a health insurance plan.

We sought comment on these assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates as proposed. We summarize and respond to public comments received regarding the policy to align effective dates of coverage during certain special enrollment periods across all Exchanges.

Comment: One commenter expressed concern that this policy would lead to increased adverse selection by consumers and would lead to increased costs to insurers.

Response: The commenter did not provide evidence or examples of why adverse selection would increase, nor have we received information from issuers that operate in State Exchanges that follow similar effective dates of coverage that adverse selection increased. In addition, we believe the benefit of reducing coverage gaps in consumers outweighs this potential harm. As a result, we are finalizing this policy as proposed.

24. Special Enrollment Periods—
Monthly Special Enrollment Period for
APTC-Eligible Qualified Individuals
With a Projected Annual Household
Income at or Below 150 Percent of the
Federal Poverty Level (45 CFR
155.420(d)(16))

We are finalizing amendments to § 155.420(d)(16) to revise the parameters around the availability of a special enrollment period (SEP) for APTC-eligible qualified individuals with a projected annual household income at or below 150 percent of the Federal Poverty Level (FPL), hereinafter referred to as the “150 percent FPL SEP.” Specifically, we are finalizing to remove the limitation that this SEP is only available to a consumer whose applicable percentage, which is used to determine the amount of the consumer’s premium not covered by APTC, is zero percent, a circumstance provided for under section 9661 of the ARP and later under the IRA.

The impact of this policy will be zero if enhanced subsidies under the IRA are continued beyond 2025. It is difficult to estimate, with confidence, the impacts of this policy on premiums, APTC payments, and enrollment if the enhanced subsidies are not continued, and we note that those impacts are likely to be quite different by State. However, under various scenarios, we estimated that if this policy were to be

finalized, national premiums in the individual market could increase by an average of 3 to 4 percent for plan year 2026 when the enhanced PTC provisions of the IRA are due to expire. We would expect that any average national impact would have a high variance between States that have expanded Medicaid coverage compared to States that have not, because States that have not expanded Medicaid coverage are likely to have more consumers with projected annual household income below 150 percent FPL applying for coverage through the Exchange. Unknown factors making these parameters difficult to estimate include the utilization of this SEP by healthy and unhealthy enrollees, the impact to the average duration of coverage for enrollees, and additional policy changes between now and 2025. At an aggregate level, APTC outlays could increase nationally up to \$2 billion to \$3 billion beginning in 2026. The direction and magnitude of enrollment changes in the individual market is also highly uncertain.

We sought comment on these estimates, including on the premium impacts at the State level, but did not receive responses.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

25. Termination of Exchange Enrollment
or Coverage (45 CFR 155.430)

We anticipate that the policy to permit enrollees in Exchanges on the Federal platform to retroactively terminate coverage back to the date in which they retroactively enroll in Medicare Part A or B (including enrollment in Parts A or B through a Medicare Advantage plan), but no earlier than (a) the day before the first day of coverage under Medicare Parts A or B or a Medicare Advantage plan, and (b) the day that is 6 months before retroactive termination of QHP coverage is requested, will benefit enrollees by allowing them to avoid an overlap in coverage and paying premiums for coverage they do not need. We anticipate that there may be some minor costs for the FFE associated with implementing this policy, which is at the option of HHS, such as processing the additional requests for retroactive terminations of coverage allowed by this policy. However, we do not have adequate data to estimate the number of requests for retroactive termination HHS is likely to receive, and so we cannot provide an estimate for these costs, nor for the amount of APTC that is likely to be returned to the government as a

result of this policy. In addition, we anticipate that there would be a minor financial impact to issuers associated with processing the additional retroactive termination requests allowed by this policy, including reversing claims and refunding premium paid by the enrollee, but we likewise do not have adequate data to estimate these costs.

Finally, we also anticipate that there may be a financial impact to State Exchanges associated with implementing this policy, which is optional for State Exchanges. However, we do not have access to the data necessary to estimate the costs to State Exchanges associated with implementing this policy, nor do we have access to the data necessary to determine how long it will take State Exchanges to implement it.

We sought comment on these impacts and assumptions, as well as any additional data sources we could use to estimate the costs associated with this proposal.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

26. Establishment of Exchange Network Adequacy Standards (45 CFR 155.1050)

Under § 155.1050(a)(2)(i)(A), we are finalizing that for plans years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must establish and impose quantitative time and distance network adequacy standards for QHPs that are at least as stringent as standards for QHPs participating on the FFEs under § 156.230(a)(2)(i)(A). For these purposes, “as stringent as” means time and distance standards that use a specialty list that includes at least the same specialties as our provider specialty lists and time and distance parameters that are at least as short as our parameters. States will be permitted to implement network adequacy standards that are more stringent than those performed by the FFEs under § 156.230. In other words, States could use a specialty list that is broader than our specialty lists, but it must include all the provider specialties included in our lists. Similarly, the time and distance parameters could also be narrower than our parameters, meaning they could require shorter time and/or distances, but they cannot be less demanding than our time and distance parameters. Consistent with the standards for the FFEs, and to strengthen QHP enrollees’ timely access to a variety of providers to meet their health care needs, the State Exchanges and SBE-FPs’ time and distance

standards will be calculated at the county level and vary by county designation. State Exchanges and SBE-FPs will be required to use a county type designation method that is based upon the population size and density parameters of individual counties. Under this policy, the time and distance standards State Exchanges and SBE-FPs will establish and impose will apply to our provider specialty lists. To count towards meeting the time and distance standards, individual and facility providers in these lists will have to be appropriately licensed, accredited, or certified to provide services in their State, as applicable, and will need to have in-person services available.

Second, we are finalizing that, for plans years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must conduct quantitative network adequacy reviews prior to certifying any plan as a QHP, consistent with the reviews conducted by the FFEs under § 156.230. Specifically, we are finalizing at § 155.1050(a)(2)(i)(B) that, for plans years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must conduct quantitative network adequacy reviews to evaluate a plan’s compliance with network adequacy standards under § 156.230(a)(1)(ii), (a)(1)(iii), and (a)(2)(i)(A) prior to certifying any plan as a QHP, while providing QHP certification applicants the flexibilities described under § 156.230(a)(2)(ii) and (a)(3) and (4). Under these flexibilities, the issuer will include its justification as part of its QHP application and describe 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 will be required to provide information as requested by the State Exchange or SBE-FP to support the justification. State Exchanges and SBE-FPs will be required to review the issuer’s justification to determine whether making such health plan available through the Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates as specified under § 156.230(a)(3). In making this determination, the factors State Exchanges and SBE-FPs could consider include whether the justification is reasonable based on circumstances such as the local availability of providers and variables reflected in local patterns of care. If the State Exchange or SBE-FP determines that making such health plan available

through its Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates, it could then certify the plan as a QHP. Under this policy, State Exchanges and SBE-FPs will be prohibited from accepting an issuer’s attestation as the only means for plan compliance with network adequacy standards.

We are aware that some States Exchanges employ robust, quantitative network adequacy standards that differ from those used by the FFEs, but still ensure that QHPs provide consumers with reasonable, timely access to practitioners and facilities to manage their health care needs, consistent with the ultimate aim of these policies. Therefore, we are finalizing § 155.1050(a)(2)(ii) to provide that, for plans years beginning on or after January 1, 2026, HHS may grant an exception to the requirements described under § 155.1050(a)(2)(i) to a State Exchange or SBE-FP that demonstrates with evidence-based data, in a form and manner specified by HHS, that (1) the Exchange applies and enforces alternate quantitative network adequacy standards that are reasonably calculated to ensure a level of access to providers that is as great as that ensured by the Federal network adequacy standards established for QHPs under § 156.230(a)(1)(iii), (a)(2)(i)(A), and (a)(4); and (2) the Exchange evaluates whether plans comply with applicable network adequacy standards prior to certifying any plan as a QHP. In this final rule, for this exceptions process, we are clarifying that, for (1) above, issuers on the State Exchanges and SBE-FPs do not need to comply with the appointment wait time standards under § 156.230(a)(2)(i)(B).

Lastly, we are finalizing § 155.1050(a)(2)(i)(C) to provide that, for plans years beginning on or after January 1, 2026, State Exchanges and SBE-FPs must require that all issuers seeking certification of a plan as a QHP submit information to the Exchange reporting whether or not network providers offer telehealth services. This data will be for informational purposes; it will be intended to help inform the future development of telehealth standards and will not be displayed to consumers. We note that this policy is not intended to suggest that telehealth services will be counted in place of in-person service access for the purpose of meeting network adequacy standards for PY 2025. While we acknowledge the growing importance of telehealth, we want to ensure that telehealth services do not reduce the availability of in-person care. For this purpose, telehealth encompasses professional consultations,

office visits, and office psychiatry services delivered through technology-based methods, including virtual check-ins, remote evaluation of pre-recorded patient data, and inter-professional internet consultations. Currently, for issuers in FFEs to comply with telehealth reporting standards, issuers must indicate whether each provider offers telehealth with the options “Yes,” “No,” or “Requested information from the provider, awaiting their response.” We are finalizing the policy that State Exchanges and SBE-FPs also impose this same standard.

As discussed in the information collection requirements section of this final rule, we estimate that the total annual burden associated with State Exchanges and SBE-FPs establishing and imposing the finalized network adequacy standards, conducting the network adequacy reviews as finalized, collecting telehealth information from issuers seeking QHP certification, and submitting any exception to be up to 19,800 hours and to have a total cost of \$1,365,012 per year. This estimate includes State Exchanges and SBE-FPs developing the finalized standards, reviewing any issuer justification, and submitting any exception requests to HHS. We further estimate that the total annual burden associated with both medical QHP and SADP issuers in State Exchanges and SBE-FPs gathering and submitting the time and distance and telehealth data, including any justification, to the respective State Exchanges or SBE-FPs beginning in 2025 would be approximately \$114,992.

As discussed in the information collection requirements section of this final rule, the requirement that State Exchanges and SBE-FPs collect telehealth data may increase related administrative costs for State Exchange and SBE-FP issuers that do not already possess these data, though many issuers already collect and submit this information for network adequacy submissions in other markets. While we anticipate that increased burden related to telehealth data collection will be minimal for many State Exchange and SBE-FP issuers, the increased burden could ultimately lead to an increase in premiums for consumers. As noted previously, we believe that obtaining telehealth information and using it to inform future network adequacy standards is in the best interests of both QHP enrollees and QHP issuers. As such, we anticipate that the additional burden will be outweighed by the expected benefits.

We sought comment on the potential costs and benefits associated with this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates as proposed. We summarize and respond to public comments received regarding the establishment of Exchange network adequacy standards policy below.

Comment: A few commenters expressed opposition to the collection of information about which providers offer telehealth services indicating that the proposed rule underestimated the burden of this proposal and that the information would not capture the availability of telehealth services.

Response: We believe that the telehealth reporting standards, pursuant to which issuers in State Exchanges and SBE-FPs must indicate whether each network provider offers telehealth services with the options “Yes,” “No,” or “Requested information from the provider, awaiting their response,” would not require extensive administrative time to gather. Approximately half of the parent companies of issuers on the State Exchanges and over two thirds of the parent companies of issuers on SBE-FPs offer Medicare Advantage plans, and Medicare Advantage offers a telehealth credit for network adequacy. Therefore, many more issuers on State Exchanges and SBE-FPs likely already have access to this information. We also believe that 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 directories. For these reasons, we estimate that any additional burden resulting from the requirement that QHP issuers report whether each network provider is furnishing telehealth services would be minimal.

We stated in the proposed rule (88 FR 82591, 82638 through 82639) that this data would be for informational purposes, would be intended to help inform the future development of telehealth standards, and would not be displayed to consumers. We believe that the above-described telehealth reporting standards support these objectives by providing State Exchanges and SBE-FPs with a general picture regarding the availability of telehealth services in their State. Additionally, at this time, since this data will not be displayed to consumers, it is not necessary for State Exchanges and SBE-FPs to collect more granular telehealth data from their issuers.

27. FFE and SBE-FP User Fee Rates for the 2025 Benefit Year (45 CFR 156.50)

We are finalizing an FFE user fee rate of 1.5 percent of monthly premiums for the 2025 benefit year, which is a decrease from the 2.2 percent FFE user fee rate finalized in the 2024 Payment Notice (88 FR 25845 through 25847). We are also finalizing an SBE-FP user fee rate of 1.2 percent for the 2025 benefit year, which is a decrease from the 1.8 percent SBE-FP user fee rate finalized in the 2024 Payment Notice. Based on our estimated costs, enrollment (including anticipated transitions of States from the FFE and SBE-FP models to either the SBE-FP or State Exchange model, increased Open Enrollment numbers and anticipated Medicaid redeterminations), premiums for the 2025 benefit year, and user fee rates, we are estimating that FFE and SBE-FP user fee transfers from issuers to the Federal Government will be \$340 million lower compared to those estimated for the prior benefit year. We also anticipate that the lower user fee rates may exert downward pressure on premiums.

We sought comment on the impact estimates and assumptions in the proposed rule (88 FR 82639).

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these lower estimates.

28. State Selection of EHB-Benchmark Plans for Plan Years Beginning On or After January 1, 2026 (45 CFR 156.111)

For plan years beginning on or after January 1, 2026, we are finalizing revisions to the standards for State selection of EHB-benchmark plans at § 156.111 to consolidate the options for States to change EHB-benchmark plans at § 156.111(a); revisions to the regulatory standard for States to comply with scope of benefit requirements at § 156.111(b)(2); and revisions to § 156.111(e)(3) to require States to submit a formulary drug list as part of their application to change EHB-benchmark plans only if the State is seeking to change its prescription drug EHB.

We understand that certain aspects of the current process to change EHB-benchmark plans under § 156.111 may impose unanticipated difficulty for and burden on States, and we have received feedback that this difficulty can have a chilling effect on States' ability to make more frequent or more substantial changes to their EHB-benchmark plans. We believe that, to the extent States take advantage of the finalized changes to the EHB-benchmark plan standard, States

will experience an overall decrease in burden to develop new EHB-benchmark plans compared to if they were to do so under the existing requirements at § 156.111. We anticipate that these policies will reduce the burden on States to perform additional actuarial analyses to comply with the typicality and generosity standards at § 156.111(b)(2)(i) and (ii), respectively. Instead of performing an indeterminate number of actuarial analyses to find a typical employer plan with an actuarial equivalent scope of benefits, a State may only need to perform two such actuarial analyses to identify the State's least generous typical employer plan and the State's most generous typical employer plan. Further, States will no longer need to perform an actuarial analysis to demonstrate compliance with the generosity standard at § 156.111, which we are removing as a requirement in this final rule. As a result, we estimate an overall decrease in burden to States utilizing this finalized provision to change their EHB-benchmark plan.

We also estimate a potential increase in burden to States and issuers to develop new policies and implement new plan designs, to the extent these finalized changes would result in more frequent or more substantial changes to EHB-benchmark plans by States. It is our aim that these policies will allow States and issuers to offer more comprehensive and innovative benefit structures that benefit the consumer, including by addressing health equity concerns.

However, we realize that this policy will have varied impact on consumers depending on how a State chooses to implement these changes. To the extent these finalized changes result in more frequent or more substantial changes to EHB-benchmark plans by States, consumers enrolled in individual and small group market plans will be impacted by changes to EHB in that their benefits may change, and in some cases, premiums could increase or decrease depending upon State implementation of the policies. CMS has approved changes in nine EHB-benchmark plans since 2018. Every approved EHB-benchmark plan application was estimated an increase in premiums of less than one percent.³⁵³ While we expect the amendments to § 156.111 finalized in this rule will result in consistent or marginally higher increases in premiums for plans in States that change EHB-benchmark

plans to add benefits, we still expect any such increase in premiums to be around one percent.

Additionally, a State's EHB-benchmark plan selection may impact the amount of APTC and CSRs for enrollees in a State. For these consumers, subsidies will increase or decrease when compared to their State's current EHB-benchmark plan. PTC is available only for that portion of a plan's premium attributed to EHB, so to the extent that a State's EHB-benchmark plan leads to lower premiums for the second lowest cost silver plan, APTC will be reduced, but not the percent of income a consumer with APTC is expected to contribute to their premium. This effect will represent a transfer from consumers who receive APTC to the Federal Government. Individual and small group market enrollees who do not receive APTC would experience lower premiums for less comprehensive coverage that could result in more affordable coverage options but possibly higher out-of-pocket costs for the consumer. To the extent that a State's EHB-benchmark plan leads to higher premiums for the second lowest cost silver plan, we expect the opposite outcome to occur. Given the nine previously approved State EHB-benchmark plan changes, we expect the amendments to § 156.111 finalized in this rule will result in around a one percent increase in premium costs for the second lowest cost silver plan in State(s) that seek to update their EHB-benchmark plans with corresponding impacts on PTC.

It is not possible to provide more specific estimations for the potential cost impacts of these policy changes due to the number of unascertainable variables in projecting future State EHB-benchmark plan selections and how those selections could influence changes in the premiums of plans to cover those EHB, and therefore, cost to the Federal Government in the form of APTC. These variables include but are not limited to: the number of States that choose to pursue EHB-benchmark plan updates, the scope of benefits among the set of typical employer comparison plans in each of those States, the number and types of benefits each State looks to add to or subtract from their EHB-benchmark plan, and the variable cost and utilization of those benefits, especially as they may change over time.

Consumers who have specific health needs may also be impacted by the finalized changes. In the individual and small group markets, depending on the selection made by the State in which the consumer lives, consumers with more

comprehensive plans may gain coverage for certain services. In other States, again depending on State choices, consumers may no longer have coverage for some services, though we note that no State has sought to remove benefits from their EHB-benchmark plan to date under § 156.111.

Although we cannot anticipate in advance exactly how States might adjust their EHB-benchmark plan applications as a result of these amendments, and as States are not required to make any changes to their EHB-benchmark plans, we also believe the reduced burden might produce premium savings in the long-term, as States will have greater incentive to update their EHB-benchmark plans more frequently and more substantively. We believe that States with more regular and more substantive EHB-benchmark plan changes would better respond to public health priorities and may adjust benefits in ways that could more cost-effectively contribute to greater overall population health, which would improve the health of the State's risk pool over time, reducing cost to insurers, therefore potentially enabling issuers to reduce plan premiums, increasing affordability of health insurance for consumers in the individual and small group markets in the State.

We stress that States would not be required to make any changes under this policy; as already implemented at § 156.115(d)(1), if a State does not make an EHB-benchmark plan 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.

As discussed in the ICR for this policy, we anticipate a total annual cost estimate associated with this policy of approximately \$18,036, in addition to the potential effects on premium costs and therefore PTC discussed elsewhere.

We sought comments on the impact of these proposals on the EHB-benchmark plan selection process and whether other impacts should be considered.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates as proposed. We summarize and respond to public comments received regarding the proposed updates to the process for State Selection of EHB-benchmark plans below.

³⁵³ The actuarial analyses for all EHB-benchmark plan changes are available at <https://www.cms.gov/marketplace/resources/data/essential-health-benefits>.

Comment: A few commenters supported the estimates, noting that the proposals clarifying and improving the process for States to determine and update EHB will reduce the time and costs to States seeking to update their EHB-benchmark plan. One commenter suggested that a less burdensome approach to the typicality and generosity standards under the EHB-benchmark plan process will enable States to focus more of their energy on assessing the package of benefits that would be most valuable to include as EHB. Another commenter similarly suggested that the reduced administrative burden on State actuaries will provide resources that can be utilized to perform the network adequacy oversight requirements also included in this rule.

Response: We agree with these commenters that the estimated reduced administrative burden on States resulting from this policy will afford States flexibility to allocate their resources towards other important policy aims, including those pertaining to EHB and network adequacy.

Comment: A few commenters expressed concern regarding the potential APTC impacts of the proposed revisions to § 156.111. Specifically, these commenters expressed two concerns: (1) that, generally, making the EHB-benchmark plan update process simpler and less burdensome could lead to increased EHB-benchmark plan changes and potentially expansions of coverage, which could be costly, and (2) that removing the generosity standard at § 156.111(b)(2)(ii) would enable States to increase the generosity of their EHB-benchmark plans ad infinitum, which would lead to equally increasing APTC expenditures.

Response: We agree with commenters on the first point, that a simpler and less burdensome EHB-benchmark plan update process may incentivize more frequent EHB-benchmark plan updates. However, we believe that this is a positive impact of the proposed provisions, which for the reasons discussed elsewhere in this rule, has the potential to both improve consumer health and reduce Federal outlays in the form of PTC in the long run. The nine States that have sought to update their EHB-benchmark plans under § 156.111 thus far have done so by affecting only modest, thoughtful increases in plan generosity, even when they could have increased generosity more substantially. As such, we are not concerned that a marginally more straightforward and less costly EHB-benchmark plan update approach will elicit very different reactions from States than those we

have already observed, in which generosity increases, and therefore potentially PTC cost increases, have been modest. Further, while we may expect that that the majority of applications we will receive from States to change EHB-benchmark plans with these new flexibilities will seek to add or improve the existing scope of benefits, we also do not discount or preclude the possibility that a State may change its EHB-benchmark plan by reducing the scope of benefits by removing benefits that may no longer be clinically effective or high-value for its population.

Moreover, we disagree with commenters on the second point—that the removal of the generosity standard creates an environment in which States can add significantly more generous benefits to their EHB-benchmark plans with impunity. Rather, as discussed elsewhere, while we are finalizing the removal of the generosity standard at § 156.111(b)(2)(ii), the typicality standard at § 156.111(b)(2)(i) will still require that State EHB selections be constrained to a particular scope of benefits by demonstrating their EHB-benchmark plan is as or less generous than the most generous plan among a set of typical employer comparison plans. We believe this requirement will sufficiently balance States' desired flexibility to design a benefit package that best fits the needs of their consumers, while also ensuring that coverage does not become unaffordable, nor unreasonably increase Federal outlays in the form of PTCs.

29. Provision of EHB (45 CFR 156.115)

We are finalizing the removal of the regulatory prohibition at § 156.115(d) on issuers from including routine non-pediatric dental services as an EHB. We are also finalizing that the changes at § 156.115(d) will be effective beginning with PY 2027.

Removing the prohibition on issuers from including routine non-pediatric dental services as an EHB will remove regulatory and coverage barriers to expanding access to non-pediatric dental benefits. This will allow States greater flexibility to add benefits to improve non-pediatric oral health and overall health outcomes, which are disproportionately low among marginalized communities such as people of color and people with low incomes. Therefore, this policy will promote health equity by addressing non-pediatric oral health disparities and improving the health outcomes of vulnerable populations.

Pursuant to section 2707(b) of the ACA, a group health plan must ensure

that any annual cost sharing imposed under the plan does not exceed the limitations provided for under section 1302(c)(1) of the ACA. To the extent that a group health plan selects an EHB-benchmark plan that includes routine non-pediatric dental coverage as an EHB, such plan will need to ensure that any cost sharing for those services is limited in accordance with section 1302(c)(1) of the ACA.

We do not anticipate any immediate costs to the Federal Government, States, issuers, or enrollees because of this policy. This policy will simply remove the prohibition on issuers from including routine non-pediatric dental services as an EHB; it will not automatically make any routine non-pediatric dental services an EHB. This policy will only have a premium impact to the extent that States choose to include routine non-pediatric dental services in their EHB-benchmark plans. It may also increase costs for issuers to expand their networks to cover these new required services, although issuers could contract with a dental vendor to administer the routine non-pediatric dental EHB if such a benefit is adopted by a State as an EHB. It should also be noted that the size of non-pediatric dental networks varies by State. Therefore, some States would be affected by the need to build a new network of dental providers (or contract with dental vendors) more than others. It is up to each State to consider the potential costs and network burden and determine whether to add routine non-pediatric dental services as an EHB.

We sought comment on the impact of this proposal to remove the regulatory prohibition on issuers from including routine non-pediatric dental services as an EHB and whether other impacts should be considered.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates as proposed. We summarize and respond to public comments received regarding the routine non-pediatric dental EHB policy below.

Comment: One commenter noted that removing the restriction on adult dental care would allow States to include it in their benchmark plans if they choose to do so and expressed concern that this could raise affordability issues for members as well as operational concerns. They recommended that HHS coordinate with health plan actuaries and others to conduct a thorough and realistic analysis of potential cost impact to individual and small group members before finalizing the proposal.

Response: We thank the commenter for their feedback. Please refer to III.E.3 of this final rule for a detailed response to potential cost and operational concerns for this policy. We emphasize that States adding routine non-pediatric dental benefits as EHB are still required to comply with the scope of benefits requirements at § 156.111(b)(2) and must design their EHB-benchmark plans with that limitation in mind.

Accordingly, any increases in premium and PTC resulting from a State adding routine non-pediatric dental benefits as EHB is limited by those scope of benefit requirements. CMS has approved changes in nine EHB-benchmark plans since 2018. Every approved EHB-benchmark plan application has estimated an increase in premiums of less than one percent.³⁵⁴ With the revisions to § 156.111 and § 156.115 in this rule, we still expect any such increase in premiums to be around one percent, even for States that add routine non-pediatric dental benefits as EHB.

Given that States are the primary enforcers of EHB and this policy is optional for States to adopt, we emphasize that the decision to add routine non-pediatric dental benefits as an EHB is entirely up to each individual State. Each State considering adding this benefit should weigh the advantages against the disadvantages before implementing this policy. Therefore, we recommend that States interested in adding routine non-pediatric dental benefits as an EHB coordinate with health plan actuaries and other relevant stakeholders to conduct a thorough analysis of the potential cost impact before implementing this policy, should the State see a benefit to conducting such an analysis. We also anticipate that the benefit design, cost, and operational impacts will vary heavily by each State.

30. Prescription Drug Benefits (45 CFR 156.122)

At § 156.122(a)(3)(i), we are finalizing updates to P&T membership standards by adding new § 156.122(a)(3)(i)(E), which will require the P&T committee to include a patient representative as part of its membership for plan years beginning on or after January 1, 2026. While there is no Federal requirement to provide compensation to P&T committee members, those plans or issuers that choose to compensate their P&T committee members for their service to the committee may incur a

nominal fee when adding an additional member to the committee. Further, we estimate a potential increase in burden to States and issuers to develop criteria used to select a consumer representative for the P&T committee, to create or revise standard operating procedures for the committee, as well as for any additional training that may be required of the selectee because of the new membership standard. We believe that the impact of this burden will be most notable during the initial plan year that this policy goes into effect and should be minimal in future years. We solicited comments on the impact of this proposal to the P&T committee membership standards and whether other impacts should be considered. We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

We also are finalizing amendments to § 156.122 to codify the requirement for coverage of prescription drug benefits. Specifically, we are finalizing amendments to § 156.122 by adding a new § 156.122(f) to further clarify that, to the extent that a health plan covers prescription drugs in excess of the benchmark, these drugs will be considered EHB and are subject to requirements including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits. This policy will apply unless the coverage of the drug is mandated by State action and is in addition to EHB pursuant to § 155.170, in which case the drug will not be considered EHB. Given that this revision merely codifies our existing policy regarding the coverage of prescription drugs as EHB, we do not anticipate any additional burden on States or issuers.

We sought comment on these impact estimates and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the burden estimates as proposed. We summarize and respond to public comments received below.

Comment: One commenter asked that HHS clarify whether the proposed amendment at § 156.122 to add paragraph (f), which states that drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB, is not applicable to the large group market and self-insured plans and, if not, requested an updated cost estimate to reflect the projected impact that this change would have on self-insured plan sponsors and beneficiaries.

Response: As described earlier, the proposed rule addressed the application of this policy with respect to individual

and small group market plans. We are finalizing this proposal as proposed. Accordingly, this final rule does not address the application of this policy to large group market health plans, grandfathered group health plans, and self-insured group health plans.

31. Standardized Plan Options (45 CFR 156.201)

We are finalizing updates to the standardized plan options for PY 2025 with minor changes to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level. We believe that maintaining a high degree of continuity in the approach to standardized plan options year over year minimizes the risk of disruption for interested parties, including issuers, agents, brokers, States, and enrollees. We believe that making major departures from the approach to standardized plan options set forth in the 2023 and 2024 Payment Notices could result in changes that may cause undue burden for interested parties. For example, if the standardized plan options we create vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost sharing for services they rely upon differs substantially from the previous year. Ultimately, we believe consistency in standardized plan options is important to allow both issuers and enrollees to become accustomed to these plan designs.

Thus, like the approach taken in the 2023 and 2024 Payment Notices, we are finalizing a standardized plan options that will continue to resemble the most popular QHP offerings that millions of consumers are already enrolled in. As such, these finalized standardized plan options are based on updated PY 2023 cost sharing and enrollment data to ensure that these plans continue to reflect the most popular offerings in the Exchanges.

By finalizing a policy to maintain an approach to standardized plan options like that taken in the 2023 and 2024 Payment Notices, issuers will continue to be able to utilize many existing benefit packages, networks, and formularies, including those paired with standardized plan options for PY 2024. Also, issuers will continue to not be required to extend plan offerings beyond their existing service areas.

Furthermore, as discussed earlier in the preamble, we will continue to differentially display standardized plan options on *HealthCare.gov* per § 155.205(b)(1). Since we will continue to assume responsibility for differentially displaying standardized

³⁵⁴ The actuarial analyses for all EHB-benchmark plan changes are available at: <https://www.cms.gov/marketplace/resources/data/essential-health-benefits>.

plan options on *HealthCare.gov*, FFE and SBE–FP issuers will continue to not be subject to this burden.

In addition, as noted in the preamble, we will continue enforcement of the standardized plan option display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. We believe that continuing the enforcement of these differential display requirements will not impose a significant burden on these entities or require major modification of their non-Exchange websites, especially since the bulk of this burden was previously imposed in the 2018 Payment Notice,³⁵⁵ which finalized the standardized plan option differential display requirements, or during the PY 2023 open enrollment period, when enforcement of these requirements resumed.

Finally, since we will continue to allow approved web-brokers and QHP issuers to submit requests to deviate from the manner in which standardized plan options are differentially displayed on *HealthCare.gov*, the burden on these entities will continue to be minimal. We intend to continue providing access to information on standardized plan options to web-brokers through the Health Insurance Marketplace Public Use Files (PUFs) and QHP Landscape file to further minimize burden by ensuring that affected entities have timely access to accurate and helpful information on standardized plan option requirements, including those related to the differential display of these plans.

We sought comment on these impact estimates and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

32. Non-Standardized Plan Option Limits (45 CFR 156.202)

In this final rule, we are finalizing permitting issuers to offer non-standardized plan options in excess of the limit of two per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent years, if issuers demonstrate that these additional non-standardized plans beyond the limit at § 156.202(b) have specific design features that would

substantially benefit consumers with chronic and high-cost conditions and meet other requirements finalized in this rule.

Specifically, at § 156.202(d), for PY 2025 and subsequent years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, and service area, subject to the criteria discussed below.

We finalized several specifications for issuers seeking to utilize this exceptions process at § 156.202(d)(1) through (6). Specifically, at paragraph (d)(1), the 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions will be evaluated at the level of total out-of-pocket costs for the treatment of the chronic and high-cost condition for a population of enrollees with the relevant chronic and high-cost condition. At paragraph (d)(2), the reduction in cost sharing must not be limited to a part of the year, or an otherwise limited scope of benefits. At paragraph (d)(3), the reduction in cost sharing for these benefits cannot be conditioned on a consumer having a particular diagnosis.

At paragraph (d)(4), the required reduction in cost sharing only applies to the standard variant of the plan for which an issuer seeks an exception, and not to the income-based cost-sharing reduction plan variations required by § 156.420(a), nor to the zero and limited cost sharing plan variations required by § 156.420(b). At paragraph (e)(5), issuers are limited to one exception per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, for each chronic and high-cost condition. At paragraph (d)(6), the chronic and high-cost conditions that may qualify an issuer for this exception will be determined by HHS. Refer to § 156.202 of the preamble to this rule for a more detailed discussion regarding these requirements.

We do not anticipate that the exceptions process finalized in this rule will substantially impact the average weighted number of non-standardized

plan options available to each consumer, the average weighted number of standardized plan options available to each consumer, the average weighted number of total plan options available to each consumer, the number of plan-county discontinuations, or the number of affected enrollees since we do not anticipate a substantial number of issuers will utilize this exceptions process to offer the aforementioned additional non-standardized plan options that will substantially benefit consumers with chronic and high-cost conditions. This is because we expect that most issuers will believe that the burden of creating and certifying additional plans intended to benefit a comparatively small population of consumers outweighs the benefit of doing so.

Although we do not anticipate that a substantial number of issuers will utilize this exceptions process, we acknowledge that issuers that choose to do so will be impacted. Specifically, if issuers choose to utilize this exceptions process, they will be required to design additional non-standardized plan options and proceed through QHP certification for these plans, which will necessarily entail additional burden.

Additionally, at § 156.202(e), an issuer that seeks to utilize this exceptions process is required to submit a written justification in a form and manner and at a time prescribed by HHS. At paragraph (e)(1), the written justification must identify the specific chronic and high-cost condition that its additional non-standardized plan option offers substantially reduced cost sharing for, in accordance with the definition of "cost sharing" at § 156.20.

At paragraph (e)(2), the written justification must identify which benefits in the Plans and Benefits Template are discounted to provide reduced treatment-specific cost sharing for individuals with the specified chronic and high-cost condition. These discounts must be relative to the treatment-specific cost sharing for the same corresponding benefits in the issuer's other non-standardized plan offerings in the same product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area. For the purposes of this standard, treatment specific cost sharing consists of the costs for obtaining services that pertain to the treatment of a particular chronic and high-cost disease—but not the costs for obtaining services that do not pertain to the treatment of the relevant condition. The issuer must identify all services for which the benefits substantially reduce cost sharing in the Plans and Benefits

³⁵⁵ These differential display requirements were first effective and enforced beginning with PY 2018. See 81 FR 94117 through 94118, 94148.

Template. These benefits must encompass a complete list of relevant services pertaining to the treatment of the relevant condition.

At paragraph (e)(3), the written justification must explain how the reduced cost sharing for these services pertains to clinically indicated guidelines and a representative treatment scenario for treatment of the specified chronic and high-cost condition (and include any relevant studies, guidelines, or supplementary documents to support the application, as applicable). For the purposes of this standard, a representative treatment scenario is an annual course of treatment for a chronic and high-cost condition.

At paragraph (e)(4), the written justification must include a corresponding actuarial memorandum that explains the underlying actuarial assumptions made in the design of the plan the issuer is requesting to except. In this memorandum, an issuer must demonstrate how the benefits that are discounted to provide reduced treatment-specific cost sharing of at least 25 percent identified at § 156.202(e)(2) for the treatment of the condition identified at § 156.202(e)(1) under the excepted plan compare to the identified in-limit offering in the same product network type, metal level, inclusion of dental and/or vision coverage, and service area. This demonstration must specifically be in reference to the specific population that would be seeking treatment for the relevant condition and not the general population. This memorandum also must include an actuarial opinion confirming that this analysis was prepared in accordance with the appropriate Actuarial Standards of Practice and the profession's Code of Professional Conduct.

We estimate the burden of this will be approximately \$95,182 for an estimated 50 issuers annually, and we discuss this burden in further detail in the ICRs Regarding Non-Standardized Plan Option Limits (§ 156.202) section of the Collection of Information Requirements section of this final rule.

We also acknowledge that this exceptions process could impact consumers in a range of ways. Specifically, because we are finalizing the exceptions process, and if issuers choose to utilize this exceptions process to offer additional non-standardized plan options, consumers with qualifying chronic and high-cost conditions would benefit from reduced cost sharing for benefits that pertain to the treatment of these conditions. Reduced cost sharing for these benefits would reduce barriers

to access to benefits important to consumers with chronic and high-cost conditions, which could play an important role in combatting health disparities and advancing health equity since disadvantaged populations³⁵⁶ are disproportionately affected by many of these conditions.³⁵⁷ In addition to enhancing health outcomes, this exceptions process could also reduce the risk of financial harm to individuals with chronic and high-cost conditions by reducing their cost sharing obligations for treatment for those conditions.

We do not have sufficient data to further estimate the costs associated with these finalized changes. As such, we sought comment from interested parties regarding cost estimates associated with this proposal and data sources that may be used to determine those estimates.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

33. CO-OP Loan Terms (45 CFR 156.520)

In this rule, we are finalizing revisions to § 156.520(f) to provide a clear mechanism by which an existing CO-OP may request termination of its loan agreement with CMS to enable it to pursue new, innovative business plans that are otherwise not compatible with CO-OP requirements, but which CMS believes will be in the best interest of affected consumers. Of the 23 CO-OP loan agreements CMS successfully executed with qualified borrowers in 2012, only 3 remain in operation as active insurance companies offering QHPs. The others have been placed in receivership by State regulators, or otherwise gone out of business due to the borrower's inability to establish a viable CO-OP that is financially stable and on course to ultimately repay the loans. As discussed in section III.E.8 of this preamble, CO-OPs operate under governance and product limitations that can present significant obstacles to new business opportunities. To provide a means to overcome these limitations, under the finalized revisions to § 156.520(f), we will be able to approve a request by a CO-OP to terminate its loan agreement with us for the purpose

³⁵⁶ Disadvantaged populations are groups of persons that experience a higher risk of poverty, social exclusion, discrimination, and violence than the general population, including, but not limited to, ethnic minorities, migrants, people with disabilities, isolated elderly people, and children.

³⁵⁷ Waters, H., & Graf, M. (2018). The Cost of Chronic Disease in the U.S. Milken Institute. https://milkeninstitute.org/sites/default/files/reports-pdf/ChronicDiseases-HighRes-FINAL_2.pdf

of permitting the CO-OP to pursue innovative business plans that are not otherwise consistent with CO-OP requirements, if all outstanding CO-OP loans issued to the loan recipient are repaid in full prior to termination of the loan agreement, and we believe that granting the request would benefit consumers by meaningfully enhancing consumer access to quality, affordable, member-focused, non-profit health care options in affected markets. Examples of such proposals that may be deemed innovative and in the interests of consumers would be plans that appear well-calculated to lead directly to marketing non-profit, member-focused health plans in new regions of a State, to offer health plans on a Statewide basis for the first time, to expand operations into new States, or enhance consumer access to new non-profit products that are not qualified health plans, in particular when such plans are likely to favorably impact traditionally underserved communities. These examples are illustrative, however, not exclusive.

This finalized regulatory policy also contemplates plans that involve non-profit enterprises, and that reflect a strong consumer focus. A strong consumer focus will generally consist of an enterprise that focuses informational or financial resources, or plans to focus informational or financial resources, on member-oriented programs such as health education, consumer education, or forms of direct or indirect health-related financial assistance. We recognize that significant coordination with State regulators will be essential to implementing any plans to act on the finalized regulatory changes.

Given that only three CO-OPs remain in business operating with small portfolios across five States, we do not believe there will be a significant economic impact because of this policy for at least several years, if ever.

We sought comment on these impact estimates and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

34. Conforming Amendment to Netting Regulation To Include Federal IDR Administrative Fees (45 CFR 156.1215)

We are finalizing amendments to § 156.1215(b) and (c) to align with the policies and regulations proposed in the Federal Independent Dispute Resolution Operations proposed rule (88 FR 75744). These finalized amendments will provide that administrative fees for utilizing the No Surprises Act Federal IDR process for health insurance issuers

that participate in financial programs under the ACA would be subject to netting as part of HHS' integrated monthly payment and collections cycle.

To implement this policy, we are finalizing amendments to § 156.1215(b) to allow HHS to net payments owed to issuers and their affiliates operating under the same TIN against amounts due to the Federal Government from the issuers and their affiliates operating under the same TIN for APTC, advance payments of and reconciliation of CSRs, payment of FFE user fees, payment of SBE-FP user fees, HHS risk adjustment, reinsurance, and risk corridors payments and charges, and administrative fees from these issuers and their affiliates for utilizing the Federal IDR process in accordance with § 149.510(d)(2). We are also finalizing amendments to § 156.1215(c) to provide that any amount owed to the Federal Government by an issuer and its affiliates for unpaid administrative fees due to the Federal Government from these issuers and their affiliates for utilizing the Federal IDR process after netting under § 156.1215(b) will be the basis for calculating a debt owed to the Federal Government. We will not begin netting the Federal IDR administrative fees until disputing parties are required to pay Federal IDR administrative fees directly to HHS, if the proposal in Federal Independent Dispute Resolution Operations proposed rules (88 FR 75744) is finalized. We do not believe that the finalized amendments will impose substantial additional costs to HHS beyond the costs previously estimated in the Federal Independent Dispute Resolution Process proposed rule (88 FR 75814 through 75815). Furthermore, this policy will only apply to those issuers and their affiliates operating under the same TIN that participate in the financial programs under the ACA. Since the provisions of the Federal IDR process apply more broadly to include issuers and their affiliates that do not participate in the financial programs under the ACA currently specified in the list of programs for which netting is permitted (86 FR 55982),³⁵⁸ we believe that only a small proportion of issuers that utilize the Federal IDR process will be subject to netting under this policy.

Therefore, we anticipate that this policy will streamline our payments and collections processes and limit the administrative burden for operating our programs.

We sought comment on these impact estimates and assumptions.

We did not receive any comments in response to the burden estimates for this policy. We are finalizing these estimates as proposed.

35. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's final rule (286) will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the final rule. For these reasons, we believe that the number of past commenters will be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$100.80 per hour, including overhead and fringe benefits.³⁵⁹ Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 7.25 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is \$730.80 (7.25 hours × \$100.80 per hour). Therefore, we estimate that the total cost of reviewing this regulation is approximately \$209,009 (\$730.80 per reviewer × 286 reviewers).

D. Regulatory Alternatives Considered

For the HHS-operated risk adjustment program (§ 153.320), we are finalizing recalibrating the CSR adjustment factors for AI/AN zero cost sharing and limited cost sharing CSR plan variant enrollees for the 2025 benefit year, and retaining the AI/AN CSR adjustment factors for

future benefit years unless changed through notice-and-comment rulemaking. We are also finalizing maintaining the current CSR adjustment factors for silver plan variant enrollees (70 percent, 73 percent, 87 percent, and 94 percent AV plan variants)³⁶⁰ for the 2025 benefit year and beyond, unless changed through notice-and-comment rulemaking. As an alternative, we considered not proposing any changes to the CSR adjustment factors used in the State payment transfer formula. However, after continuing to conduct analyses on more recently available enrollee-level EDGE data, we found the underprediction of plan liability in the State payment transfer formula for AI/AN zero-cost sharing and limited cost sharing CSR plan variant enrollees continued. We also considered recalibrating all the silver CSR adjustment factors. However, we are not finalizing any changes to those factors at this time, because we continue to find that the current silver CSR adjustment factors (70 percent, 73 percent, 87 percent, and 94 percent plan variants) are reasonably accurately predicted given the offsets, described above in VI.4, that continue to occur for these enrollees.

As an alternative to amendments to § 155.315(e), we considered using an electronic data source other than PUPS to verify applicant incarceration status. However, we estimate that sourcing an alternative national incarceration verification data source would be a significant expense to HHS, costing the agency approximately \$35 million annually. Additionally, these other data sources are currently not sufficiently comprehensive to meet the needs of the Exchanges using the Federal eligibility and enrollment platform and therefore may not provide Exchanges with accurate results on a consistent basis. Thus, the alternative data source must be current, accurate, and minimize burden and costs to administration.

About the changes to § 155.320(c), we considered taking no action to add new language in paragraph(c)(1)(iii) that State Exchanges and State Medicaid and CHIP agencies must pay in advance for their use of the VCI Hub service to verify income. However, we determined that this finalized reinterpretation and policy change is appropriate given our better understanding of how the VCI Hub service is used by State Exchanges and State Medicaid and CHIP agencies to verify eligibility for QHP coverage or

³⁵⁸ Explaining that the No Surprises Act applies to group health plans and health insurance issuers offering group or individual health insurance coverage in the Code, ERISA, and the PHS Act.

³⁵⁹ https://www.bls.gov/oes/current/oes_nat.htm.

³⁶⁰ See 83 FR 16930 at 16953; 84 FR 17478 through 17479; 85 FR 29190; 86 FR 24181; 87 FR 27235 through 27236; and 88 FR 25772 through 25774.

other insurance affordability programs. We also considered requiring State Medicaid and CHIP agencies and State Exchanges to obtain their own contracts to administer their CSI data usage; however, we had concerns that these services cannot be procured reasonably and expeditiously, which would undermine the system we have implemented under section 1413 of the ACA. We also believe that there may be benefits to the State Medicaid and CHIP agencies and State Exchanges that prefer to use the CSI data accessible through the VCI Hub service in their States. Therefore, we are finalizing retaining optional access to the VCI Hub service on behalf of State Medicaid and CHIP agencies and State Exchanges that prefer to continue to use this service and are willing to pay for their CSI data usage with a modification to the original proposal that would have required that States pay in advance. Under this finalized policy, State Medicaid and CHIP agencies and State Exchanges can choose to discontinue their use of the CSI data accessible through the VCI Hub service. We are also finalizing that HHS will invoice States on a monthly basis for their actual utilization of CSI data provided by the VCI Hub service after that utilization occurs.

About amending 155.330(d)(2), we considered maintaining the status quo for continuing the PDM requirements under § 155.330(d)(1)(i) and (d)(ii) but note that it may be difficult or infeasible to operationalize existing processes and operations during certain emergency situations. Allowing consumers to go uninsured during a national emergency, such as a public health emergency like the COVID-19 public health emergency, will not improve the national health and well-being of all consumers. We found it to be least burdensome for Exchanges to implement as a successful pause of PDM operations occurred during the 2020 pandemic.

We considered only updating sub-regulatory guidance to incorporate catastrophic coverage into the auto re-enrollment hierarchy, for example, through the annual draft and final Letters to Issuers. However, we believe that instead incorporating catastrophic coverage into the auto re-enrollment hierarchy in regulation at § 155.335(j) creates stronger authority for Exchanges to auto re-enroll catastrophic enrollees and provides better transparency for our auto re-enrollment operations in the Exchanges on the Federal platform. Many public comments agreed that this policy would achieve these effects.

We considered taking no action regarding amendments to § 155.400(e)(2) to codify that the flexibility for issuers

experiencing billing or enrollment problems due to high volume or technical errors is not limited to extensions of the binder payment. However, we believe it is important to clarify for interested parties that HHS may provide enforcement discretion for other premium payment requirements.

We considered taking no action related to amendments to § 155.420(d)(16), to revise the parameters around the availability of a SEP that grants APTC-eligible qualified individuals with a projected household income at or below 150 percent of the FPL. However, HHS believes that many consumers will benefit from having additional opportunities to enroll in low-cost Exchange coverage, and that those who will be eligible for this special enrollment period and who do not enroll during the annual open enrollment period are likely to have been unaware of their option to enroll in a plan with no monthly premium through the Exchange, after application of APTC.

We considered taking no action regarding modifications to § 155.430(b)(1)(iv) to permit enrollees in Exchanges on the Federal Platform to retroactively terminate coverage back to the date in which they retroactively enroll in Medicare Parts A and B (including enrollment in Parts A and B through a Medicare Advantage plan), but no earlier than (a) the day before the first day of coverage under Medicare Parts A or B, and (b) the day that is 6 months before retroactive termination of QHP coverage is requested. However, we believe it is important to allow enrollees to retroactively terminate coverage when they were unable to do so prospectively due to retroactive enrollment in Medicare coverage. We considered whether to also permit Exchange enrollees to retroactively terminate coverage back to the date in which they enrolled in Medicaid, CHIP, or BHP coverage retroactively, but we determined that this would not be appropriate due to the increased risk that claims reversed by QHP issuers would not be covered by providers under these programs.

For standardized plan options (§ 156.201), we considered a range of proposals, such as modifying the methodology used to create the standardized plan options for PY 2025. Specifically, we considered lowering the deductibles in these plan designs and offsetting this increase in plan generosity by increasing cost sharing amounts for several benefit categories. We also considered simultaneously maintaining the current cost-sharing structures and decreasing the

deductibles for these plan designs, which would increase the AVs of these plans to the ceiling of each AV *de minimis* range. Ultimately, we decided to finalize maintaining the AVs of these plans near the floor of each *de minimis* range by largely maintaining the cost sharing structures and deductible values from the standardized plan options from PY 2024, as well as by increasing the maximum out-of-pocket limits and, to a lesser degree, the deductible values for these plan designs. We believe this finalized approach strikes the greatest balance in providing enhanced pre-deductible coverage while ensuring competitive premiums for these standardized plan options.

For non-standardized plan option limits (§ 156.202), we considered a range of proposals. Specifically, for PY 2025 and subsequent years, we considered maintaining the PY 2024 limit of four non-standardized plan options per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area. We also considered not proposing an exceptions process that would allow issuers to offer non-standardized plan options exceeding the limit of two that we previously finalized for PY 2025 and subsequent years. We also considered basing this exceptions process on a range of other factors, including the degree of plan proliferation in a given service area (as determined by the number of plan offerings per consumer or issuer), whether a plan has a sufficiently differentiated network, and whether a plan has a sufficiently differentiated formulary. We also considered permitting issuers to request to offer an indefinite number of additional non-standardized plan options per product network type, metal level, and service area, as opposed to one exception per chronic and high-cost condition (as in the finalized policy). We also considered permitting exceptions only for an exclusive list of chronic and high-cost conditions, as opposed to any condition that is chronic and high-cost in nature (as described in the finalized policy).

However, we ultimately decided to finalize an exceptions process that will allow an issuer to offer additional non-standardized plan options for each product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent

lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, and service area, in accordance with § 156.202(d) through (e). This policy is discussed in greater detail in section III.E.7 of the preamble to this rule.

We are finalizing this approach primarily because we believe that allowing exceptions to the non-standardized plan option limit of two could play an important role in enhancing the quality of life for those affected by these conditions, combatting health disparities, advancing health equity, and reducing health care expenditures. We further believe that introducing this exceptions process will balance the dual aims of reducing the risk of plan choice overload while simultaneously ensuring that issuers can continue to offer truly innovative plan designs that may benefit consumers with chronic and high-cost conditions.

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that small businesses, nonprofit organizations, and small governmental jurisdictions are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year). We do not anticipate that providers will be directly impacted by the provisions in this final rule. Individuals and States are not included in the definition of a small entity. The provisions in this final rule will affect issuers, agents, brokers, web-brokers, and DE entities.

For purposes of the RFA, we believe that health insurance issuers³⁶¹ and DE entities³⁶² will 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 \$47 million or less will be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard will be \$44.5 million or less.³⁶³ We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2021 MLR reporting year, approximately 87 out of 483 issuers of health insurance coverage nationwide had total premium revenue of \$47 million or less.³⁶⁴ This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 77 percent of these small issuers belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding \$47 million. Therefore, although it is likely that fewer than 87 issuers are considered small entities, for the purposes of this analysis, we assume 87 small issuers and/or DE entities would be impacted by this final rule.

We further believe that agents, brokers, and web-brokers³⁶⁵ will be classified under NAICS code 524210 (Insurance Agencies and Brokerages). According to SBA size standards, entities with average annual receipts of \$15 million or less will be considered small entities for these NAICS codes. Therefore, based on SBA data and for purposes of this analysis, we assume 122,547 agents, brokers, and web-brokers are small entities. However, the policies impacting agents, brokers, and web-brokers finalized in this rule will only impact such entities in States with State Exchanges that host web-broker programs. Currently, no States with State Exchanges host web-broker programs, but we estimate 5 States could opt to host a web-broker program for their State Exchange in the future. We further estimate that 20 web-brokers could operate in those States in the

future and sought comment on this estimate.

The finalized policies that will result in an increased burden to small entities are described below.

We proposed to require issuers of risk adjustment covered plans to complete, implement, and provide to HHS written documentation of any corrective action plans when required by HHS if a high-cost risk pool audit results in the inclusion of certain observations in the final audit report. The annual burden per issuer associated with this policy is \$627. For more details, please refer to the Regulatory Impact Analysis section associated with this policy in this final rule.

We proposed to apply to agents, brokers, and web-brokers operating in State Exchanges that operate their own eligibility and enrollment platform, and consequently in State Exchanges, in both the Individual Market Exchanges and SHOPs, certain existing HHS standards regarding web-brokers assisting consumers with enrolling in QHPs and applying for APTC/CSRs. The one-time burden per agent, broker, or web-broker associated with this policy is \$43,019. For more details, please refer to the information collection requirements section associated with this policy in this final rule.

We proposed to require that DE entities implement and prominently display website changes in a manner that is consistent with display changes made by HHS to *HealthCare.gov* by meeting standards communicated and defined by HHS within a time period set by HHS, unless HHS approves a deviation from those standards. The annual burden associated with this policy is \$2,608 (\$2,401 to comply with the requirements and \$207 to make a request to deviate from the requirements). For more details, please refer to the information collection requirements section associated with this policy in this final rule.

We proposed to apply to DE entities operating in State Exchanges that operate their own eligibility and enrollment platform, and consequently State Exchanges that utilize DE entities, certain existing HHS standards regarding DE entities assisting consumers with enrolling in QHPs and applying for APTC/CSRs, in both the Individual Market Exchanges and SHOPs. The one-time burden per DE entity associated with this policy is \$100,715.60. For more details, please refer to the information collection requirements section associated with this policy in this final rule.

We also proposed to require State Exchange and SBE-FP issuers to gather

³⁶³ <https://www.sba.gov/document/support-table-size-standards>.

³⁶⁴ <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

³⁶⁵ This includes web-brokers that act as DE entities in accordance with the definition under § 155.20 to assist consumers with direct enrollment in qualified health plans offered through the Exchange in a manner considered to be through the Exchange as authorized by § 155.220(c)(3), § 155.221, or § 156.1230.

³⁶¹ This includes health insurance issuers that act as DE entities pursuant to the definition in § 155.20.

³⁶² DE entities are entities that an Exchange permits to assist consumers with direct enrollment in qualified health plans offered through the Exchange in a manner considered to be through the Exchange as authorized by § 155.220(c)(3), § 155.221, or § 156.1230.

and submit network adequacy data, including time and distance data and telehealth data. The annual burden per issuer associated with this policy is \$689. For more details, please refer to the information collection requirements section associated with this policy in this final rule.

Finally, we finalized § 156.202(d) through (e) to permit each issuer to offer additional non-standardized plan options for each product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the

cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, and service area. The annual burden per issuer associated with this policy is \$1,904. For more details, please refer to the information collection requirements section associated with this policy in this final rule.

Thus, the per-entity estimated annual cost for small issuers and/or DE entities is \$5,828, and the total estimated annual cost for small issuers and/or DE entities is \$507,036. The per-entity estimated one-time cost for small issuers and/or DE entities is \$100,716, and the total estimated one-time cost for small issuers and/or DE entities is \$8,762,257. The per-entity estimated one-time cost for small agents, brokers, and web-brokers is \$43,019, and the total estimated one-

time cost for small agents, brokers, and web-brokers is \$860,380. There is no estimated annual cost for small agents, brokers, and web-brokers. See Tables 18, 19, 20, and 21.

TABLE 18—DETAILED ANNUAL COSTS FOR SMALL ENTITIES

| Description of cost | Annual cost per small issuer and/or DE entity |
|--|---|
| Risk adjustment audit | \$627 |
| Applying <i>HealthCare.gov</i> display changes | 2,608 |
| Network adequacy | 689 |
| Non-standardized plan option limit exceptions | 1,904 |
| Total | \$5,828 |

TABLE 19—AGGREGATE ANNUAL COSTS FOR SMALL ENTITIES

| Affected entity | Affected small entities | Annual cost per entity | Aggregate annual cost for small entities |
|----------------------------------|-------------------------|------------------------|--|
| Issuers and/or DE entities | 87 | \$5,828 | \$507,036 |

TABLE 20—ONE-TIME COSTS FOR SMALL ENTITIES

| Description of cost | One-time cost per small issuer/DE entity | One-time cost per small agent, broker, or web-broker |
|---|--|--|
| Applying HHS standards to State Exchange entities | \$100,716 | \$43,019 |
| Total | 100,716 | 43,019 |

TABLE 21—AGGREGATE ONE-TIME COSTS FOR SMALL ENTITIES

| Affected entity | Affected small entities | One-time cost per entity | Aggregate one-time cost for small entities |
|--|-------------------------|--------------------------|--|
| Issuers and/or DE entities | 87 | \$100,716 | \$8,762,257 |
| Agents, brokers, and web-brokers | 20 | 43,019 | 860,380 |

The annual cost per small issuer and/or DE entity of \$5,828 is approximately 0.32 percent of the average annual receipts per small issuer. We anticipate that small issuers could pass on these increased costs to consumers in the form of higher premiums, resulting in an increase in receipts commensurate with the increase in costs. However, because the proportion of cost to receipts is so small, we anticipate this would have a *de minimis* impact on premiums, if any impact at all. We sought comment on this assumption.

We sought comment on this analysis and seek information on the number of small issuers, agents, brokers, web-brokers, or DE entities that may be affected by the provisions in these final rules.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule, given that the annual per-entity cost of \$5,828 per small issuer represents

approximately 0.32 percent of the average annual receipts for a small issuer,³⁶⁶ and there is no annual per-entity cost per small agent, broker, or web-broker. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory

³⁶⁶ United States Census Bureau (March 2020). 2017 *SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size*. <https://www.census.gov/data/tables/2020/econ/susb/2020-susb-annual.html>.

impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For the purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that this rule will not affect small rural hospitals. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately \$183 million. Although we have not been able to quantify all costs, we expect that the combined impact on State, local, or Tribal governments and the private sector does not meet the UMRA definition of unfunded mandate.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In compliance with the requirement of E.O. 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, we have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the NAIC, and consulting with State insurance officials on an individual basis.

While developing this rule, we attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of E.O. 13132.

Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States

are not required to establish an Exchange or risk adjustment program. For States that elected previously to operate an Exchange, those States had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

This rule may have 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 (including merged) markets. For example, we are finalizing the addition of requirements by which a State seeking to transition to a State Exchange provides the public with a notice and copy of its State Exchange Blueprint application. We are further finalizing the requirement that a State, within 3 months of submitting its State Exchange Blueprint to HHS for approval, conduct at least one public hearing whereby interested parties can learn about the State's intent to transition, as well as a State's progress toward transitioning, and conduct regular hearings every 3 months until the transition is complete. However, the Federalism implications of this policy may be mitigated because States have the option to establish their own Exchange, and we do not anticipate any additional burden on States because of this policy.

We believe that the finalized revisions to § 155.220(h) do not have Federalism implications as the CMS Administrator's review of agent, broker, and web-broker requests for reconsideration of administrative decisions is not based on State law, nor does it prevent a State from taking other legal actions under State law against an entity whose Exchange agreement(s) are terminated for cause by HHS.

The finalized revisions to §§ 155.220 and 155.221 applying certain web-broker and DE entity standards to State Exchanges that operate their own eligibility and enrollment platform may have Federalism implications, but they are substantially mitigated by allowing State Exchanges to leverage the oversight framework established by HHS for Exchanges that utilize the Federal Platform to evaluate web-broker and DE entity operational readiness to participate in an Exchange. We expect

State Exchanges will be able to leverage audits conducted for the FFEs and SBE-FPs, as well as disclaimer language developed by HHS, while State operational costs would include any State-specific requirements or language to be added at the States' discretion. We believe that providing State Exchanges the opportunity to leverage the FFEs' oversight framework will likely reduce costs to State Exchanges as compared to the costs associated with State Exchanges establishing an independent framework for oversight and web-broker or DE entity approval independent of the FFEs.

The finalized revisions to § 155.315(e) may have Federalism implications due to our policy to use existing requirements and flexibilities under § 155.315(e) permitting all Exchanges to accept consumer attestation of incarceration status without further electronic verification. However, Exchanges that wish to continue electronically verifying an individual's incarceration status will be permitted to do so, if HHS determines their data source is current, accurate, and minimizes administrative costs and burdens.

In addition, this final rule may have Federalism implications due to the finalized revisions pertaining to State selection of EHB-benchmark plans. The existing requirements pertaining to State selection of EHB-benchmark plans at § 156.111 already imposed Federalism implications on States that choose to change or revise their EHB-benchmark plans. As discussed elsewhere in this final rule, we understand that certain aspects of the current process to change or revise EHB-benchmark plans may impose unanticipated difficulty on and create confusion for States. Accordingly, the finalized revisions to § 156.111 are intended to reduce State burden and confusion to change or revise EHB-benchmark plans. As a result, the finalized revisions to § 156.111 may reduce the existing Federalism implications.

Our finalized amendments to § 155.320 adding new paragraph (c)(1)(iii) may have Federalism implications for States given that State Exchanges and State Medicaid agencies will pay fees for use of the VCI Hub service. However, the Federalism implications may be mitigated because use of the VCI Hub service is optional such that State Exchanges and State Medicaid agencies continue to have flexibility under § 155.315(h) and § 155.320(c)(3)(iv) to use other data sources, like State wage data, when income is not verified using IRS tax data or SSA Title II data.

Our finalized amendments to § 155.420(d)(16) may have Federalism implications; however, by maintaining the 150 percent FPL SEP to be available at the option of the Exchange, these implications may be mitigated because we allow State Exchanges to decide whether to implement it based on their specific market dynamics, needs, and priorities.

Comment: One commenter disagreed with the assessment in the Federalism section of this rule that there would be no additional burden on States, stating that the network adequacy provisions would place additional burdens on some States because some State departments of insurance conduct network adequacy assessments on behalf of the SBE. They asserted that, if the proposal is finalized, some State departments of insurance would need to contract for additional network adequacy assessments, or possibly increase personnel at significant cost to the State. Furthermore, the commenter disagreed with the conclusion in the Regulatory Flexibility Act section of this rule that the rule would not have a significant impact on the operations of a substantial number of small rural hospitals. The commenter stated that if exchange plans become unavailable in rural counties to the same extent that Medicare Advantage plans are unavailable, then some States' rural hospitals will be threatened with significant revenue losses.

Response: We note that the Federalism and Regulatory Flexibility Act sections of this final rule have been revised with an updated assessment of the implications of this final rule for Federalism, and the impact on small entities. The concerns that commenters raised regarding Federalism and the Regulatory Flexibility Act are addressed in those updated sections.

H. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C 801 *et seq.*) OIRA has determined that this rule does meet the criteria set forth in 5 U.S.C. 804(2). Accordingly, this rule has been submitted to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on March 27, 2024.

List of Subjects

31 CFR Part 33

Health care, Health insurance, and Reporting and recordkeeping requirements.

42 CFR Part 600

Administrative practice and procedure, Health care, health insurance, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

Department of the Treasury

For the reasons set forth in the preamble, the Department of the Treasury amends 31 CFR subtitle A, part 33, as set forth below:

PART 33—WAIVERS FOR STATE INNOVATION

■ 1. The authority citation for part 33 continues to read as follows:

Authority: Sec. 1332, Pub. L. 111–148, 124 Stat. 119.

■ 2. Section 33.112 is amended by adding paragraph (c)(3) to read as follows:

§ 33.112 State public notice requirements.

* * * * *

(c) * * *

(3) Such public hearings shall be conducted in an in-person, virtual (that is, one that uses telephonic, digital, and/or web-based platforms), or hybrid (that is, one that provides for both in-person and virtual attendance) format.

* * * * *

■ 3. Section 33.120 is amended by revising paragraph (c) introductory text to read as follows:

§ 33.120 Monitoring and compliance.

* * * * *

(c) *Post award.* Within at least 6 months after the implementation date of a section 1332 waiver and annually thereafter, a State must hold a public forum to solicit comments on the progress of a section 1332 waiver. The State must hold the public forum at which members of the public have an opportunity to provide comments and must provide a summary of the forum to the Secretary as part of the quarterly report specified in § 33.124(a) that is associated with the quarter in which the forum was held, as well as in the annual report specified in § 33.124(b) that is associated with the year in which the forum was held. The public forum shall be conducted in an in-person, virtual (that is, one that uses telephonic, digital, and/or web-based platforms), or hybrid (that is, one that provides for both in-person and virtual attendance) format.

* * * * *

Department of Health and Human Services

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 42 CFR chapter IV, subchapter I, and 45 CFR subtitle A, subchapter B, as set forth below.

42 CFR Chapter IV, Subchapter I

PART 600—ADMINISTRATION, ELIGIBILITY, ESSENTIAL HEALTH BENEFITS, PERFORMANCE STANDARDS, SERVICE DELIVERY REQUIREMENTS, PREMIUM AND COST SHARING, ALLOTMENTS, AND RECONCILIATION

■ 4. The authority citation for part 600 continues to read as follows:

Authority: Section 1331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1029).

■ 5. Section 600.320 is amended by revising paragraph (c) to read as follows:

§ 600.320 Determination of eligibility for and enrollment in a standard health plan.

* * * * *

(c) *Effective date of eligibility.* The State must establish a uniform method of determining the effective date of eligibility for enrollment in a standard health plan which—

(1) Follows the Exchange effective date standards at 45 CFR 155.420(b)(1);

(2) Follows the Medicaid effective date standards at § 435.915 of this chapter exclusive of § 435.915(a); or

(3) Follows an effective date of eligibility of the first day of the month following the month in which BHP eligibility is determined; or

(4) Follows an effective date of eligibility standard established by the State and subject to HHS approval to ensure that the effective date is:

(i) No later than the first day of the second month following the date that an individual has been determined BHP-eligible; and

(ii) No more restrictive than paragraphs (c)(1) through (3) of this section.

* * * * *

45 CFR Subtitle A, Subchapter B

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND HHS RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 6. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 7. The heading for part 153 is revised to read as set forth above.

■ 8. Section 153.620 is amended by revising the section heading and paragraph (c)(4) introductory text to read as follows:

§ 153.620 Compliance with HHS risk adjustment standards.

* * * * *

(c) * * *

(4) *Final audit findings.* If an audit results in the inclusion of a finding or observation in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following, if required by HHS:

* * * * *

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.

■ 10. Section 155.105 is amended—

■ a. In paragraph (b)(2) by removing “and” after the semicolon;

■ b. In paragraph (b)(3) by removing the period at the end and adding in its place “; and”; and

■ c. Adding paragraph (b)(4).

The addition reads as follows:

§ 155.105 Approval of a State Exchange.

* * * * *

(b) * * *

(4) The Exchange first operates a State Exchange on the Federal platform under § 155.106(c), meeting all requirements established under § 155.200(f), for at least one plan year, including its first open enrollment period.

* * * * *

■ 11. Section 155.106 is amended by revising paragraph (a)(2) to read as follows:

§ 155.106 Election to operate an Exchange after 2014.

(a) * * *

(2) Submit an Exchange Blueprint application for HHS approval at least 15 months prior to the date on which the Exchange proposes to begin open enrollment as a State Exchange. HHS requires that a State submitting a Blueprint Application to operate a State Exchange provide, upon request, supplemental information to HHS detailing the State’s implementation of its State Exchange functionality, including information on the ability to implement and comply with Federal requirements for operating an Exchange.

(i) *Public notice.* Upon submission of an Exchange Blueprint application to operate a State Exchange, the State shall issue a public notice of its Exchange Blueprint application submission through its website and include a copy of the Exchange Blueprint application, a description of the Plan Year for which the State seeks to transition to a State Exchange, language indicating that the State is seeking approval from HHS to transition to a State Exchange, and information about when and where the State will conduct public engagements regarding the State’s Exchange Blueprint application, as described in paragraph (a)(2)(ii) of this section.

(ii) *Public engagements.* After a State issues its public notice as described in

paragraph (a)(2)(i) of this section and until HHS approves, or conditionally approves, the State’s Exchange Blueprint application, a State must conduct at least one public engagement (such as a townhall meeting or public hearing) either in-person or virtually, regarding the State’s Exchange Blueprint application progress, in a timeline and manner considered effective by the State and with HHS’ concurrence. A State shall provide public notice of the public engagement. Such public engagement shall also provide interested parties the opportunity to learn about the State’s progress in transitioning to a State Exchange and offer input on that transition. Following the initial public engagement described in this paragraph and until HHS approves or conditionally approves the State Exchange Blueprint application, a State shall conduct periodic public engagements, either in-person or virtually, in a timeframe and manner considered effective by the State.

* * * * *

■ 12. Section 155.170 is amended by revising paragraph (a)(2) to read as follows:

§ 155.170 Additional required benefits.

(a) * * *

(2) A benefit required by State action taking place on or before December 31, 2011, a benefit required by State action for purposes of compliance with Federal requirements, or a benefit covered in the State’s EHB-benchmark plan is considered an EHB. A benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with Federal requirements, that is not a benefit covered in the State’s EHB-benchmark plan is considered in addition to the essential health benefits.

* * * * *

■ 13. Section 155.205 is amended by revising paragraphs (a) and (b)(4) and (5) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center.* If the Exchange is not an Exchange described in paragraph (a)(1) or (2) of this section, the Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance and meets the requirements outlined in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section and at § 155.405(c)(2)(ii). At a minimum, the Exchange call center must provide consumers with access to a live call center representative during an Exchange’s published hours of operation and a live call center

representative who must be able to assist consumers with filing their Exchange application, including providing consumers with information on their eligibility for advance premium tax credits and cost-sharing reductions, facilitating a consumer's comparison of QHPs, and helping consumers complete their Exchange applications for submission to the Exchange. If the Exchange is an Exchange described in paragraph (a)(1) or (2) of this section, the Exchange must provide at a minimum a toll-free telephone hotline that includes the capability to provide information to consumers about eligibility and enrollment processes, and to appropriately direct consumers to the applicable Exchange website and other applicable resources.

* * * * *

(b) * * *

(4) Allows for an individual to submit a single streamlined eligibility application to the Exchange in accordance with § 155.405 and for the Exchange to make all determinations of eligibility for enrollment in a QHP and insurance affordability programs, in accordance with subpart D of this part, through the operation of a centralized eligibility and enrollment platform on the Exchange's website; or, if the Exchange is a State-based Exchange on the Federal platform, through the Federal eligibility and enrollment platform.

(5) Allows a qualified individual to select a QHP and allows the Exchange to maintain records of all QHP enrollments, in accordance with subpart E of this part, through the operation of a centralized eligibility and enrollment platform on the Exchange's website; or, if the Exchange is a State-based Exchange on the Federal platform, through the Federal eligibility and enrollment platform.

* * * * *

■ 14. Section 155.220 is amended by adding paragraph (c)(4)(iii), revising paragraphs (h)(2) and (3), and adding paragraph (n) to 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) * * *

(4) * * *

(iii) Web-brokers operating in State Exchanges that do not use the Federal platform that permit other agents and brokers, through a contract or other arrangement, to use their internet website to help an applicant or enrollee complete a QHP selection or complete the Exchange eligibility application

must comply with the standards in paragraphs (c)(4)(i)(A), (B), (D) and (F) of this section, except that all references to "Federally-facilitated Exchange" or "HHS" in paragraphs (c)(4)(i)(A), (B), (D), and (F) will be understood to mean "the applicable State Exchange."

* * * * *

(h) * * *

(2) *Timeframe for request.* The agent, broker, or web-broker must submit a request for reconsideration to the CMS Administrator within 30 calendar days of the written notice from HHS.

(3) *Notice of reconsideration decision.* The CMS Administrator will provide the agent, broker, or web-broker with a written notice of the reconsideration decision within 60 calendar days of the date the CMS Administrator receives the request for reconsideration. This decision will constitute HHS' final determination.

* * * * *

(n) *Application to State Exchanges that do not use the Federal platform.* A web-broker that assists or enrolls qualified individuals, qualified employers or qualified employees in coverage in a manner that constitutes enrollment through the State Exchange, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through the State Exchange, must comply with the Federally-facilitated Exchange standards in paragraphs (c)(3)(i)(A), (G), (I), and (j)(2)(i) of this section, including any additional State-specific standards under paragraph (n)(1) of this section, and the State Exchange's operational readiness standards under paragraph (n)(2) of this section. For the purposes of paragraph (j)(2)(i) of this section, references to "HHS" and "the federally facilitated Exchanges" will be understood to mean "the applicable State Exchange, applied for web-brokers", and the reference to "HealthCare.gov" will be understood to mean "the State Exchange website, applied for web-brokers."

(1) State Exchanges may add State-specific information to the standardized disclaimers and information under paragraphs (c)(3)(i)(A), (G), and (I) of this section that does not conflict with the HHS-provided language.

(2) State Exchanges must establish the form and manner for their web-brokers to demonstrate operational readiness and compliance with applicable requirements in order for the web-broker's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion

of the following items to the State Exchange, in the form and manner specified by the Exchange:

(i) Operational data including licensure information, points of contact and third-party relationships;

(ii) Enrollment testing, prior to approval or renewal;

(iii) website reviews performed by the State Exchange;

(iv) Security and privacy documentation, including:

(A) Penetration testing results;

(B) Security and privacy assessment reports;

(C) Vulnerability scan results;

(D) Plans of action and milestones; and

(E) System security and privacy plans.

(v) Agreements between the web-broker and the State Exchange.

■ 15. Section 155.221 is amended by revising paragraphs (a) introductory text and adding paragraphs (a)(1)(i) and (ii), (b)(6), and (j) to read as follows:

§ 155.221 Standards for direct enrollment entities and for third-parties to perform audits of direct enrollment entities.

(a) *Direct enrollment entities.* All Exchanges may permit the following entities to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner that is considered to be through the Exchange, to the extent permitted by applicable State law:

(1) * * *

(i) For purposes of applying the requirements of § 156.1230(b) of this subchapter to State Exchanges, all references to "Federally-facilitated Exchange" and "HHS", and "HealthCare.gov" will be understood to mean "the applicable State Exchange", "the applicable State Exchange", and "the applicable State Exchange website", respectively.

(ii) [Reserved]

* * * * *

(b) * * *

(6) Implement and prominently display website changes in a manner that is consistent with display changes made to the Federally-facilitated Exchange website by meeting standards communicated and defined by HHS within a time period set by HHS, unless HHS approves a deviation from those standards. Direct enrollment entities may request a deviation by submitting a proposed alternative *display and* accompanying rationale to HHS for review.

* * * * *

(j) *Application to State Exchanges that do not use the Federal platform.* A direct enrollment entity that enrolls

qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through the State Exchange, or assists consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through the State Exchange, must comply with the Federally-facilitated Exchange standards in paragraphs (b)(1) through (3) and (d) of this section, including the exceptions in paragraph (c) of this section, where applicable; any additional State-specific standards under paragraph (j)(1) of this section; the State Exchange's operational readiness standards under paragraph (j)(2) of this section; and the State Exchange's website display change standards under paragraph (j)(3) of this section. References to §§ 155.415(b), and 155.415(b)(1) in paragraph (d) of this section will be understood to also apply to State Exchanges.

(1) State Exchanges may add State-specific information to the standardized disclaimer under paragraph (b)(2) of this section that does not conflict with the HHS-provided language.

(2) State Exchanges must establish the form and manner for their direct enrollment entities to demonstrate operational readiness and compliance with applicable requirements in order for the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion of the following documentation to the State Exchange, in the form and manner specified by the Exchange:

(i) Business audit documentation including:

(A) Notices of intent to participate including auditor information;

(B) Documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and

(C) Business audit reports including testing results.

(ii) Security and privacy audit documentation including:

(A) Interconnection security agreements;

(B) Security and privacy controls assessment test plans;

(C) Security and privacy assessment reports;

(D) Plans of action and milestones;

(E) Privacy impact assessments;

(F) System security and privacy plans;

(G) Incident response plans; and

(H) Vulnerability scan results.

(3) State Exchanges must require their direct enrollment entities to implement and prominently display website changes in a manner that is consistent

with the display changes made by State Exchanges to the State Exchanges' websites, consistent with the process of defining and communicating standards and setting advance notice periods in paragraph (b)(6) of this section, except that all references in paragraph (b)(6) of this section to "Federally-Facilitated Exchange website" would be understood to mean "State Exchange website," references to "HHS" would be understood to mean "State Exchange," and the reference to "unless HHS approves a deviation from those standards" would be understood to mean "unless the State Exchange approves a deviation from those standards under the deviation request process it is required to establish should the State Exchange elect to permit deviation requests."

■ 16. Section 155.302 is amended by revising paragraph (a)(1) to read as follows:

§ 155.302 Options for conducting eligibility determinations.

(a) * * *

(1) Directly, through contracting arrangements in accordance with § 155.110(a) under which the Exchange carries out all eligibility determinations for QHP coverage and related insurance affordability programs; or, as a State-based Exchange on the Federal platform, through a Federal platform agreement under which HHS carries out eligibility determinations and other requirements contained within this subpart; or

* * * * *

■ 17. Section 155.305 is amended by adding paragraphs (f)(4)(i) and (ii) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(4) * * *

(i) If HHS notifies the Exchange as part of the process described in § 155.320(c)(3) that APTC payments were made on behalf of either the tax filer or spouse, if the tax filer is a married couple, for 1 year for which tax data would be utilized for verification of household income and family size in accordance with § 155.320(c)(1)(i), and the tax filer or the tax filer's spouse did not comply with the requirement to file an income tax return for that year as required by 26 U.S.C. 6011, 6012, and their implementing regulations and reconcile APTC for that period ("file and reconcile"), the Exchange must:

(A) Send a notification to the tax filer, consistent with the standards applicable to the protection of Federal Tax Information, that informs the tax filer that the Exchange has determined that

the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file and reconcile, and educate the tax filer of the need to file and reconcile or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive tax year; or

(B) Send a notification to either the tax filer or their enrollee, that informs the tax filer or enrollee that they may be at risk of being determined ineligible for APTC in the future. These notices must educate tax filers or their enrollees on the requirement to file and reconcile, while not directly stating that the IRS indicates the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file and reconcile.

(ii) [Reserved]

* * * * *

■ 18. Section 155.315 is amended by revising paragraph (e) to read as follows:

§ 155.315 Verification process related to eligibility for enrollment in a QHP through the Exchange.

* * * * *

(e) *Verification of incarceration status.* The Exchange must verify an applicant's attestation that the applicant meets the requirements of § 155.305(a)(2) by—

(1) Accepting an applicant's attestation that they are not currently incarcerated; or

(2) Verifying an applicant's attestation of incarceration status using any electronic data source that is available to the Exchange and which has been approved by HHS for this purpose. HHS will approve an electronic data source for incarceration verification if it provides data that are current and accurate, and if its use minimizes administrative costs and burdens.

(3) If an Exchange verifies an applicant's attestation of incarceration status using an approved data source under paragraph (e)(2) of this section, to the extent that an applicant's attestation is not reasonably compatible with information from the approved data source or other information provided by the applicant or in the records of the Exchange, the Exchange must follow the procedures specified in § 155.315(f).

* * * * *

■ 19. Section 155.320 is amended by adding paragraph (c)(1)(iii) to read as follows.

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(c) * * *

(1) * * *

(iii) *Payment to use income data through the Verify Current Income Hub*

service. Beginning July 1, 2024, State Exchanges that elect the option to access the Verify Current Income service through the Federal Data Services Hub (“the Hub”) to verify an individual’s income as described in paragraph (c)(3)(vi)(A) of this section, must reimburse HHS for the costs of their access to and use of the income data provided by the Verify Current Income Hub service. HHS will invoice States monthly for the amount the State must pay to HHS based on their actual utilization of CSI income data from the prior month and this invoiced amount will equal the product of the number of purchased transactions returned from the Verify Current Income Hub service and the price per transaction established under the contract maintained by HHS to provide the VCI Hub service, as well as an administrative fee to account for any direct or indirect costs of making CSI income data accessed through the VCI Hub service available to State Exchanges and State Medicaid and CHIP agencies.

* * * * *

■ 20. Section 155.330 is amended by revising paragraph (d)(3) to read as follows:

§ 155.330 Eligibility redetermination during a benefit year.

* * * * *

(d) * * *

(3) *Definition of periodically.* (i) Beginning with the 2021 calendar year, the Exchange must perform the periodic examination of data sources described in paragraphs (d)(1)(ii) of this section at least twice in a calendar year. State Exchanges that have implemented a fully integrated eligibility system with their respective State Medicaid programs, that have a single eligibility rules engine that uses MAGI to determine eligibility for advance payments of the premium tax credit, cost-sharing reductions, Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, will be deemed in compliance with the Medicaid/CHIP PDM requirements and, if applicable, BHP PDM requirements, in paragraphs (d)(1)(ii) and (d)(3) of this section.

(ii) Beginning with the 2025 calendar year, the Exchange must perform the periodic examination of data sources described in paragraph (d)(1)(i) of this section at least twice in a calendar year.

(iii) Notwithstanding the requirements of paragraphs (d)(3)(i) and (ii) of this section, the Secretary has authority to temporarily suspend the requirement that Exchanges conduct the PDM processes described at paragraph (d)(3)(i) or (ii) of this section during

certain situations or circumstances that leads to the limited availability of data needed to conduct PDM or of documentation needed for an enrollee to notify the Exchange that the result of PDM is inaccurate as described in paragraph (e)(2)(i)(C) of this section.

* * * * *

■ 21. Section 155.335 is amended by—

- a. Revising paragraphs (j)(1)(ii) through (iv);
- b. Adding paragraph (j)(1)(v);
- c. Revising paragraphs (j)(2)(i) through (iii); and
- d. Adding paragraphs (j)(2)(iv) and (j)(5).

The revisions and additions read as follows:

§ 155.335 Annual eligibility redetermination.

* * * * *

(j) * * *

(1) * * *

(ii) If the enrollee’s current QHP is not available through the Exchange, the Exchange will re-enroll the enrollee in a QHP within the same product at the same coverage level as described in sections 1302(d) or (e) of the ACA as the enrollee’s current QHP that has the most similar network compared to the enrollee’s current QHP;

(iii) If the enrollee’s current QHP is not available through the Exchange and the enrollee’s product no longer includes a QHP at the same coverage level as described in sections 1302(d) or (e) of the ACA as the enrollee’s current QHP and—

(A) The enrollee’s current QHP is a silver level plan, the Exchange will re-enroll the enrollee in a silver level QHP under a different product offered by the same QHP issuer that is most similar to the enrollee’s current product and that has the most similar network compared to the enrollee’s current QHP. If no such silver level QHP is available for enrollment through the Exchange, the Exchange will re-enroll the enrollee in a QHP under the same product that is coverage level higher or lower than the enrollee’s current QHP and that has the most similar network compared to the enrollee’s current QHP; or

(B) The enrollee’s current QHP is not a silver level plan, the Exchange will re-enroll the enrollee in a QHP under the same product that is one coverage level higher or lower than the enrollee’s current QHP and that has the most similar network compared to the enrollee’s current QHP;

(iv) If the enrollee’s current QHP is not available through the Exchange and the enrollee’s product no longer includes a QHP that is at the same coverage level as described in sections

1302(d) or (e) of the ACA as, or one coverage level higher or lower than, the enrollee’s current QHP, the Exchange will re-enroll the enrollee in any other QHP offered under the product in which the enrollee’s current QHP is offered in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee’s current QHP; or

(v) Notwithstanding the other provisions in this paragraph (j)(1), to the extent permitted by applicable State law, if the enrollee’s current QHP is a catastrophic plan as described in section 1302(e) of the ACA, and the enrollee will no longer meet the criteria for enrollment in a catastrophic plan as described in section 1302(e)(2) of the ACA:

(A) The Exchange will re-enroll the enrollee in a bronze metal level QHP within the same product as the enrollee’s current QHP that has the most similar network compared to the enrollee’s current QHP; or

(B) If no bronze plan is available through this product, the Exchange will re-enroll the enrollee in the QHP with the lowest coverage level offered under the product in which the enrollee’s current QHP is offered in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee’s current QHP.

(2) * * *

(i) The Exchange will re-enroll the enrollee in a QHP at the same coverage level as the enrollee’s current QHP in the product offered by the same issuer that is the most similar to the enrollee’s current product and that has the most similar network compared to the enrollee’s current QHP;

(ii) If the issuer does not offer another QHP at the same coverage level as the enrollee’s current QHP, the Exchange will re-enroll the enrollee in a QHP that is one coverage level higher or lower than the enrollee’s current QHP and that has the most similar network compared to the enrollee’s current QHP in the product offered by the same issuer through the Exchange that is the most similar to the enrollee’s current product;

(iii) If the issuer does not offer another QHP through the Exchange at the same coverage level as, or one metal level higher or lower than the enrollee’s current QHP, the Exchange will re-enroll the enrollee in any other QHP offered by the same issuer in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee’s current QHP in the product that is most similar to the enrollee’s current product; or

(iv) Notwithstanding the other provisions in this paragraph (j)(2), to the

extent permitted by applicable State law, if the enrollee's current QHP is a catastrophic plan as described in section 1302(e) of the ACA, and the enrollee will no longer meet the criteria for enrollment in a catastrophic plan as described in section 1302(e)(2) of the ACA:

(A) The Exchange will re-enroll the enrollee in a bronze metal level QHP offered by the same issuer in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee's current QHP in the product that is most similar to the enrollee's current product; or

(B) If no bronze plan is available through this product, the Exchange will re-enroll the enrollee in the QHP with the lowest coverage level offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee's current QHP.

* * * * *

(5) For purposes of this section, catastrophic coverage is not a coverage level that is considered higher or lower than metal level coverage when re-enrolling an enrollee to a plan that is a metal level higher or lower than their current plan, and an Exchange may not re-enroll an enrollee that has coverage under section 1302(d) into catastrophic coverage.

* * * * *

■ 22. Section 155.400 is amended by revising paragraph (e)(2) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(e) * * *

(2) *Premium payment deadline extension.* Exchanges may, and the Federally-facilitated Exchanges and State-based Exchanges on the Federal platform will, allow issuers experiencing billing or enrollment problems due to high volume or technical errors, or issuers directed to do so by applicable State or Federal authorities, to implement a reasonable extension of the binder payment and other premium payment deadlines.

* * * * *

■ 23. Section 155.410 is amended by revising paragraph (e)(4)(i) and (ii) and adding paragraph (e)(4)(iii) to read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) * * *

(4) * * *

(i) Subject to paragraphs (e)(4)(ii) and (iii) of this section, the annual open enrollment period begins on November 1 of the calendar year preceding the benefit year and extends through January 15 of the benefit year.

(ii) For State Exchanges, for the benefit years beginning on or after January 1, 2025, a later annual open enrollment period end date may be adopted, such that the open enrollment period begins on November 1 of the calendar year preceding the benefit year and ends after January 15 of the benefit year.

(iii) For any State Exchange with an annual open enrollment period that began before November 1, 2023, and ended before January 15, 2024, for the 2024 benefit year, that State Exchange may continue to begin open enrollment before November 1 for consecutive future benefit years, so long as the open enrollment period continues uninterrupted for at least 11 weeks. If such State Exchange changes the date(s) of their annual open enrollment period, it must comply with paragraphs (e)(4)(i) and (ii) for all future annual open enrollment periods.

* * * * *

■ 24. Section 155.420 is amended by revising paragraphs (b)(1), (b)(3)(i), and (d)(16) to read as follows:

§ 155.420 Special enrollment periods.

* * * * *

(b) * * *

(1) *Regular effective dates.* Except as specified in paragraphs (b)(2) and (3) of this section, for a QHP selection received by the Exchange from a qualified individual, the Exchange must ensure a coverage effective date of the first day of the month following the QHP selection; except that before January 1, 2025, for a QHP selection received by the Exchange from a qualified individual between the sixteenth and the last day of any month, the Exchange may ensure a coverage effective date of the first day of the second month following QHP selection.

* * * * *

(3) * * *

(i) For a QHP selection received by the Exchange under a special enrollment period for which the effective dates of coverage specified in paragraph (b)(1) or (b)(2)(i) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph.

* * * * *

(d) * * *

(16) At the option of the Exchange, a qualified individual or enrollee, or the dependent of a qualified individual or

enrollee, who is eligible for advance payments of the premium tax credit, and whose household income, as defined in 26 CFR 1.36B-1(e), is expected to be at or below 150 percent of the Federal poverty level, may enroll in a QHP or change from one QHP to another one time per month.

* * * * *

■ 25. Section 155.430 is amended by revising paragraph (b)(1)(iv) introductory text and adding paragraph (b)(1)(iv)(D) to read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(b) * * *

(1) * * *

(iv) The Exchange must permit an enrollee to retroactively terminate or cancel the enrollee's coverage or enrollment in a QHP in the following circumstances:

* * * * *

(D) In a Federally-facilitated Exchange or a State-based Exchange on the Federal platform, if HHS elects to permit such terminations, and in a State Exchange that elects to permit such terminations, the enrollee demonstrates to the Exchange that the enrollee enrolled in Medicare Part A or B coverage with a retroactive effective date, and requests retroactive termination of QHP coverage within 60 days of the enrollment. The effective date of the retroactive termination must be no earlier than the later of the day before the first day of coverage under Medicare Part A or B, and the day that is six months before the retroactive termination in QHP coverage is requested. A retroactive termination date as described in this paragraph is not available for enrollments in stand-alone dental plans.

* * * * *

■ 26. Section 155.1050 is amended by revising paragraph (a) to read as follows:

§ 155.1050 Establishment of Exchange network adequacy standards.

(a) Except with regard to multi-State plans:

(1) A federally facilitated Exchange must ensure that the provider network of each QHP meets the standards specified in § 156.230 of this subtitle.

(2) State Exchanges and State-based Exchanges on the Federal Platform must ensure that the provider network of each QHP meets applicable standards specified in § 156.230(a)(1)(ii), (a)(1)(iii), and (a)(4) of this subchapter.

(i) For plan years beginning on or after January 1, 2026, to comply with the requirement under paragraph (a)(2) of

this section, State Exchanges and State-based Exchanges on the Federal platform must:

(A) Establish and impose network adequacy time and distance standards for QHPs that are at least as stringent as standards for QHPs participating on the Federally-facilitated Exchanges under § 156.230(a)(2)(i)(A) of this subchapter;

(B) Conduct, prior to QHP certification, quantitative network adequacy reviews to evaluate compliance with requirements under § 156.230(a)(1)(ii), (a)(1)(iii), and (a)(2)(i)(A) of this subchapter, while providing QHP certification applicants the flexibilities described under § 156.230(a)(2)(ii) and (a)(3) and (4); and

(C) Require that all issuers seeking certification of a plan as a QHP submit information to the Exchange reporting whether or not network providers offer telehealth services.

(ii) For plan years beginning on or after January 1, 2026, HHS may grant an exception to the requirements described under paragraphs (a)(2)(i) of this section to a State Exchange or State-based Exchange on the Federal platform that demonstrates with evidence-based data, in a form and manner specified by HHS, that:

(A) the Exchange applies and enforces alternate quantitative network adequacy standards that are reasonably calculated to ensure a level of access to providers that is as great as that ensured by the Federal network adequacy standards established for QHPs under § 156.230(a)(1)(iii), (a)(2)(i)(A), and (a)(4) of this subchapter; and

(B) the Exchange evaluates whether plans comply with applicable network adequacy standards prior to certifying any plan as a QHP.

* * * * *

■ 27. Section 155.1312 is amended by adding paragraph (c)(3) to read as follows:

§ 155.1312 State public notice requirements.

* * * * *

(c) * * *

(3) Such public hearings shall be conducted in an in-person, virtual (that is, one that uses telephonic, digital, and/or web-based platforms), or hybrid (that is, one that provides for both in-person and virtual attendance) format.

* * * * *

■ 28. Section 155.1320 is amended by revising paragraph (c) introductory text to read as follows:

§ 155.1320 Monitoring and compliance.

* * * * *

(c) *Post award.* Within at least 6 months after the implementation date of

a section 1332 waiver and annually thereafter, a State must hold a public forum to solicit comments on the progress of a section 1332 waiver. The State must hold the public forum at which members of the public have an opportunity to provide comments and must provide a summary of the forum to the Secretary as part of the quarterly report specified in § 155.1324(a) that is associated with the quarter in which the forum was held, as well as in the annual report specified in § 155.1324(b) that is associated with the year in which the forum was held. The public forum shall be conducted in an in-person, virtual (that is, one that uses telephonic, digital, and/or web-based platforms), or hybrid (that is, one that provides for both in-person and virtual attendance) format.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 29. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 30. Section 156.111 is amended by revising paragraphs (a), (b)(2), and (e)(2) and (3) to read as follows:

§ 156.111 State selection of EHB-benchmark plans for plan years beginning on or after January 1, 2020.

(a)(1) Subject to paragraphs (b) through (e) of this section, for plan years beginning on or after January 1, 2020, through December 31, 2025, a State may change its EHB-benchmark plan by:

(i) Selecting the EHB-benchmark plan that another State used for the 2017 plan year under §§ 156.100 and 156.110;

(ii) Replacing one or more categories of EHBs established at § 156.110(a) in the State's EHB-benchmark plan used for the 2017 plan year with the same category or categories of EHB from the EHB-benchmark plan that another State used for the 2017 plan year under §§ 156.100 and 156.110; or

(iii) Otherwise selecting a set of benefits that would become the State's EHB-benchmark plan.

(2) Subject to paragraphs (b) through (e) of this section, for plan years beginning on or after January 1, 2026, a State may change its EHB-benchmark plan by selecting a set of benefits that would become the State's EHB-benchmark plan.

(b) * * *

(2) *Scope of benefits.* (i) For plan years beginning on or after January 1, 2020, through December 31, 2025:

(A) Provide a scope of benefits equal to the scope of benefits provided under a typical employer plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), defined as either:

(1) One of the selecting State's 10 base-benchmark plan options established at § 156.100, and available for the selecting State's selection for the 2017 plan year; or

(2) The largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the State, as product and plan are defined at § 144.103 of this subchapter, provided that:

(i) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(ii) The plan provides minimum value, as defined under § 156.145;

(iii) The benefits are not excepted benefits, as established under § 146.145(b), and § 148.220 of this subchapter; and

(iv) The benefits in the plan are from a plan year beginning after December 31, 2013.

(B) Not exceed the generosity of the most generous among a set of comparison plans, including:

(1) The State's EHB-benchmark plan used for the 2017 plan year, and

(2) Any of the State's base-benchmark plan options for the 2017 plan year described in § 156.100(a)(1), supplemented as necessary under § 156.110.

(ii) For plan years beginning on or after January 1, 2026, provide a scope of benefits that is equal to the scope of benefits of a typical employer plan in the State. The scope of benefits in a typical employer plan in a State is any scope of benefits that is as or more generous than the scope of benefits in the least generous plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), and as or less generous than the scope of benefits in the most generous plan in the State (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), among the following:

(A) One of the selecting State's 10 base-benchmark plan options established at § 156.100, and available for the selecting State's selection for the 2017 plan year; or

(B) The largest health insurance plan by enrollment within one of the five

largest large group health insurance products by enrollment in the State, as product and plan are defined at § 144.103 of this subchapter, provided that:

(1) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(2) The plan provides minimum value, as defined under § 156.145;

(3) The benefits are not excepted benefits, as established under § 146.145(b), and § 148.220 of this subchapter; and

(4) The benefits in the plan are from a plan year beginning after December 31, 2013.

* * * * *

(e) * * *

(2) An actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms that the State's EHB-benchmark plan complies with the applicable scope of benefits requirements at paragraph (b)(2) of this section.

(3) The State's EHB-benchmark plan document that reflects the benefits and limitations, including medical management requirements, a schedule of benefits and, if the State is changing the number of prescription drugs pursuant to § 156.122(a)(1)(ii), a formulary drug list in a format and manner specified by HHS; and

* * * * *

■ 31. Section 156.115 is amended by revising paragraph (d) to read as follows:

§ 156.115 Provision of EHB.

* * * * *

(d) For plan years beginning on or before January 1, 2026, an issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB. For plan years beginning on or after January 1, 2027, an issuer of a plan offering EHB may not include routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB.

■ 32. Section 156.122 is amended by adding paragraphs (a)(3)(i)(E) and (f) to read as follows:

§ 156.122 Prescription drug benefits.

(a) * * *

(3) * * *

(i) * * *

(E) For plan years beginning on or after January 1, 2026, include at minimum one patient representative who must:

(1) Represent the patient perspective as a member of the P&T committee.

(2) Have relevant experience or participation in patient or community-based organizations.

(3) Be able to demonstrate the ability to integrate data interpretations with practical patient considerations.

(4) Have no fiduciary obligation to a health facility or other health agency and have no material financial interest in the rendering of health services.

(5) Have a broad understanding of one or more conditions or diseases, associated treatment options, and research.

(6) Disclose financial interests on their conflict-of-interest statements. Disclosed financial interests must include all interests with any entity that would benefit from decisions regarding plan formularies as well as specific information about their financial interests, such as the nature of the relationship and the value of the financial interest.

* * * * *

(f) If a health plan covers prescription drugs in excess of the prescription drugs required to be covered under paragraph (a)(1) of this section, the additional prescription drugs are considered an essential health benefit and subject to requirements including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits, unless coverage of the drug is mandated by State action and is in addition to an essential health benefit pursuant to § 155.170, in which case the drug would not be considered an essential health benefit.

■ 33. Section 156.202 is amended by adding paragraphs (d) and (e) to read as follows:

§ 156.202 Non-standardized plan option limits.

* * * * *

(d) For plan year 2025 and subsequent years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the

cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, and service area.

(1) The 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions will be evaluated at the level of total out-of-pocket costs for the treatment of the chronic and high-cost condition for a population of enrollees with the relevant chronic and high-cost condition.

(2) The reduction in cost sharing must not be limited to a part of the year, or an otherwise limited scope of benefits.

(3) The reduction in cost sharing for these benefits cannot be conditioned on a consumer having a particular diagnosis.

(4) The required reduction in cost sharing only applies to the standard variant of the plan for which an issuer seeks an exception, and not to the income-based cost-sharing reduction plan variations required by § 156.420(a), nor to the zero and limited cost-sharing plan variations required by § 156.420(b).

(5) Issuers are limited to one exception per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, for each chronic and high-cost condition.

(6) Chronic and high-cost conditions that may qualify an issuer for this exception will be determined by HHS.

(e) An issuer that seeks to utilize this exceptions process is required to submit a written justification in a form and manner and at a time prescribed by HHS that:

(1) Identifies the specific chronic and high-cost condition that its additional non-standardized plan option offers substantially reduced cost sharing for, in accordance with the definition of "cost sharing" at § 156.20;

(2) Identifies which benefits in the Plans and Benefits Template are discounted to provide reduced treatment-specific cost sharing for individuals with the specified chronic and high-cost condition. These discounts must be relative to the treatment-specific cost sharing for the same corresponding benefits in the issuer's other non-standardized plan offerings in the same product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area. For the purposes of this standard, treatment specific cost sharing consists of the costs for obtaining services that pertain to the treatment of a particular chronic and high-cost condition—but not the costs for obtaining services that do not pertain to

the treatment of the relevant condition. The issuer must identify all services for which the benefits substantially reduce cost sharing in the Plans and Benefits Template. These benefits must encompass a complete list of relevant services pertaining to the treatment of the relevant condition;

(3) Explains how the reduced cost sharing for these services pertains to clinically indicated guidelines and a representative treatment scenario for treatment of the specified chronic and high-cost condition (and include any relevant studies, guidelines, or supplementary documents to support the application, as applicable). For the purposes of this standard, a representative treatment scenario is an annual course of treatment for a chronic and high-cost condition; and

(4) Includes a corresponding actuarial memorandum that explains the underlying actuarial assumptions made in the design of the plan the issuer is requesting to except. In this memorandum, an issuer must demonstrate how the benefits that are discounted to provide reduced treatment-specific cost sharing of at least 25 percent identified at § 156.202(e)(2) for the treatment of the condition identified at § 156.202(e)(1) under the excepted plan compare to the identified in-limit offering in the same product network type, metal level, inclusion of dental and/or vision coverage, and service area. This demonstration must specifically be in reference to the specific population that would be seeking treatment for the relevant condition and not the general population. This memorandum must also include an actuarial opinion confirming that this analysis was prepared in accordance with the

appropriate Actuarial Standards of Practice and the profession's Code of Professional Conduct.

■ 34. Section 156.520 is amended by revising paragraph (f) to read follows:

§ 156.520 Loan terms.

* * * * *

(f) *Conversions and voluntary terminations.* (1) The loan recipient shall not convert or sell to a for-profit or non-consumer operated entity at any time after receiving a loan under this subpart. The loan recipient shall not undertake any transaction that would result in the CO-OP implementing a governance structure that does not meet the standards in this subpart.

(2) CMS may, in its sole discretion, approve a request by a loan recipient to voluntarily terminate its loan agreement with CMS, and cease to constitute a QNHII, for the purpose of permitting a loan recipient to pursue innovative business plans that are not otherwise consistent with the requirements of this subpart, provided that all outstanding CO-OP loans issued to the loan recipient are repaid in full prior to termination of the loan agreement, and CMS believes granting the request would meaningfully enhance consumer access to quality, affordable, member-focused, non-profit health care options in affected markets.

■ 35. Section 156.1215 is amended by revising paragraphs (b) and (c) to read as follows:

§ 156.1215 Payment and collections processes.

* * * * *

(b) *Netting of payments and charges for later years.* As part of its payment and collections process, HHS may net payments owed to issuers and their

affiliates operating under the same tax identification number against amounts due to the Federal Government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of federally facilitated Exchange user fees, payment of State Exchanges utilizing the Federal platform user fees, HHS risk adjustment, reinsurance, and risk corridors payments and charges, and administrative fees for utilizing the Federal Independent Dispute Resolution process in accordance with § 149.510(d)(2) of this subchapter.

(c) *Determination of debt.* Any amount owed to the Federal Government by an issuer and its affiliates for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, Federally-facilitated Exchange user fees, including any fees for State-based Exchanges utilizing the Federal platform, HHS risk adjustment, reinsurance, risk corridors, and unpaid administrative fees for utilizing the Federal Independent Dispute Resolution process in accordance with § 149.510(d)(2), after HHS nets amounts owed by the Federal Government under these programs, is a determination of a debt.

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