



DEPARTMENT OF THE TREASURY

31 CFR Part 33

RIN 1505-AC78

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 155, 156

[CMS-9906-F]

RIN 0938-AU60

Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332

Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and

Beyond

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Monetary Offices,

Department of the Treasury.

ACTION: Final rule.

SUMMARY: This final rule sets forth revised 2022 user fee rates for issuers offering qualified health plans (QHPs) through federally-facilitated Exchanges and State-based Exchanges on the Federal platform; repeals separate billing requirements related to the collection of separate payments for the portion of QHP premiums attributable to coverage for certain abortion services; expands the annual open enrollment period and Navigator duties; implements a new monthly special enrollment period for qualified individuals or enrollees, or the dependents of a qualified individual or enrollee, who are eligible for advance payments of the premium tax credit (APTC) and whose household income does not exceed 150 percent of the Federal poverty level, available during periods of time during which APTC benefits are available such that certain applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022 under the section 9661 of the American Rescue Plan Act of 2021; repeals the recent establishment of a

Direct Enrollment option for Exchanges; and modifies regulations and policies related to section 1332 waivers.

DATES: This final rule is effective on [Insert date 60 days after the date of publication in the Federal Register.]

FOR FURTHER INFORMATION CONTACT: Adrienne Patterson, (410) 786-0686, Jacquelyn Rudich, (301) 492-5211, or Nora Simmons, (410) 786-1981, for general information.

Gian Johnson, (301) 492-4323, or Meredyth Woody, (301) 492-4404, for matters related to Navigator program standards.

Robert Yates, (301) 492-5151, for matters related to the Exchange Direct Enrollment option for federally-facilitated Exchanges, State-based Exchanges on the Federal platform, and State Exchanges.

Carly Rhyne, (301) 492-4188, or Aziz Sandhu, (301) 492-4437, for matters related to the annual open enrollment period.

Carolyn Kraemer, (301) 492-4197, for matters related to special enrollment periods for Exchange enrollment under parts 147 and 155.

Nikolas Berkobien, (301) 492-4400, for matters related to standardized options.

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

Rebecca Bucchieri, (301) 492-4341, for matters related to provision of essential health benefits and separate billing and segregation of funds for abortion services.

Erika Melman, (301) 492-4348, Deborah Hunter, (410) 786-0625, or Emily Martin, (301) 492-4400, for matters related to network adequacy.

Lina Rashid, (202) 260-6098, Michelle Koltov, (301) 492-4225, or Kimberly Koch, (202) 622-0854, for matters related to section 1332 waivers.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

- II. Background
 - A. Legislative and Regulatory Overview
 - B. Stakeholder Consultation and Input
 - C. Structure of the Final Rule
- III. Provisions of the Updating Payment Parameters and Improving Health Insurance Markets for 2022 and Beyond Final Rule and Responses to Public Comments
 - A. Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets
 - B. Part 155 – Exchange Establishment Standards and Other Related Standards under the Affordable Care Act
 - C. Part 156 – Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges
- IV. Provisions of the Final Rule for Section 1332 Waivers and Responses to Public Comments
 - A. 31 CFR Part 33 and 45 CFR Part 155 – Section 1332 Waivers
- V. Collection of Information Requirements
 - A. ICRs Regarding Navigator Program Standards (§ 155.210)
 - B. ICRs Regarding Segregation of Funds for Abortion Services (§ 156.280)
 - C. ICRs Regarding Section 1332 Waivers (31 CFR Part 33 and 45 CFR Part 155)
- VI. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Overall Impact
 - C. Impact Estimates of the Payment Notice Provisions and Accounting Table
 - D. Regulatory Alternatives Considered
 - E. Regulatory Flexibility Act
 - F. Unfunded Mandates

G. Federalism

H. Congressional Review Act

I. Executive Summary

American Health Benefit Exchanges, or “Exchanges,” are entities established under the Patient Protection and Affordable Care Act (ACA)¹ through which qualified individuals and qualified employers can purchase comprehensive health insurance coverage through QHPs. Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. This rule finalizes policies designed to promote greater access to comprehensive health insurance coverage through the Exchanges, consistent with applicable law and with the administration’s policy priorities detailed in recent Presidential executive orders.

On January 28, 2021, President Biden issued Executive Order 14009, “Executive Order on Strengthening Medicaid and the Affordable Care Act” (EO 14009), which stated the Administration’s policy to protect and strengthen the ACA and to make high-quality health care accessible and affordable for every American.² This Executive Order instructed the Secretary of Health and Human Services (hereinafter referred to as “the Secretary” or the “Secretary of HHS”), along with the Secretaries of the Departments of Labor and the Treasury, to review all existing regulations, guidance documents, and other agency actions to determine whether they are consistent with the aforementioned policy, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with it.

On January 20, 2021, President Biden issued Executive Order 13985, “On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”

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

² 86 FR 7793 (Feb. 2, 2021).

(EO 13985),³ directing that as a policy matter, the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. EO 13985 also directs HHS to assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups.

Those who have insurance frequently face barriers to using it because of affordability concerns related to premiums, deductibles, copayments, and coinsurance, as well as challenges related to health literacy and the ability for the insured to find and access in-network providers. These barriers to using insurance are particularly problematic for those with chronic conditions and individuals with social risk factors (such as poverty, minority race and/or ethnicity, social isolation, and limited community resources),⁴ which also includes members of underserved communities, people of color, and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Today, of the 30 million uninsured, half are people of color.⁵ The COVID-19 public health emergency (PHE) has highlighted the negative effects of these circumstances as COVID-19 has unequally affected many racial and ethnic minority groups, putting them more at risk of getting sick and dying from COVID-19.⁶

As part of its review of regulations and policies under the Executive Orders described in the preceding paragraphs, HHS analyzed whether certain policies and requirements addressed in this final rule are consistent with policy goals outlined in the Executive Orders, including whether they might create or perpetuate systemic barriers to obtaining health insurance coverage. The results of HHS's analyses led to the policies and rules finalized in this rule.

³ 86 FR 7009 (Jan. 25, 2021).

⁴ See "Social Risk Factors and Medicare's Value-Based Purchasing Programs," HHS Office of the Secretary of Planning and Evaluation, available at <https://aspe.hhs.gov/social-risk-factors-and-medicare-value-based-purchasing-programs>.

⁵ "Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, January–June 2020," National Center for Health Statistics, February 2021, available at <https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur202102-508.pdf> <https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur202102-508.pdf>.

⁶ See Centers for Disease Control and Prevention, "Health Equity Considerations and Racial and Ethnic Minority Groups," updated April 19, 2021, available at <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html#print>, <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html#print>.

In previous rulemakings, HHS established provisions and parameters to implement many ACA requirements and programs. In this final rule, HHS amends and repeals some of these provisions and parameters, with a focus on making high-quality health care accessible and affordable for consumers. These changes provide consumers greater access to coverage through, for example, greater education and outreach, improved affordability for consumers, reduced administrative burden for issuers and consumers, and improved program integrity. As discussed more fully later in the preamble, each of these measures strengthen the ACA or otherwise promote the policy goals outlined in the Executive Orders described earlier in this preamble.⁷

HHS amends § 147.104(b)(2) to specify that issuers are not required to provide a special enrollment period in the individual market with respect to coverage offered outside of an Exchange to qualifying individuals who would be eligible for the proposed special enrollment period triggering event at § 155.420(d)(16) described below.

HHS also amends § 155.210(e)(9) to reinstitute previous requirements that Navigators in federally-facilitated Exchanges (FFE) be required to provide consumers with information and assistance on certain post-enrollment topics, such as the Exchange eligibility appeals process, the Exchange-related components of the PTC reconciliation process, and the basic concepts and rights of health coverage and how to use it.

HHS also finalizes the removal of § 155.221(j) and repeal of the Exchange Direct Enrollment option which established a process for State Exchanges, State-based Exchanges on the Federal platform (SBE-FPs), and FFEs to work directly with private sector entities (including QHP issuers, web-brokers, and agents and brokers) to operate enrollment websites through which consumers can apply for coverage, receive an eligibility determination from the Exchange, and purchase an individual market QHP offered through the Exchange with APTC and cost-sharing reductions (CSRs), if otherwise eligible.

⁷ Although many of the policies in this rule support the goals outlined in recent Executive Orders, as described later in the preamble discussions related to individual provisions, each of the provisions is supported by statutory authority independent of the Executive Orders.

For the 2022 coverage year and beyond, HHS amends § 155.410(e) to lengthen the annual open enrollment period for coverage through all individual market Exchanges to November 1 through January 15, as compared to the current annual open enrollment period of November 1 through December 15, and HHS codifies flexibility for State Exchanges that operate their own eligibility and enrollment platform to set annual open enrollment period end dates no earlier than December 15.

HHS adds a new paragraph at § 155.420(d)(16) to establish a monthly special enrollment period for qualified individuals or enrollees, or the dependents of a qualified individual or enrollee, who are eligible for APTC and whose household income does not exceed 150 percent of the Federal poverty line (FPL), in order to provide low-income individuals who generally will have access to a premium-free silver plan with a 94 percent actuarial value (AV) with more opportunities to enroll in coverage. This monthly special enrollment period will be available during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the American Rescue Plan Act of 2021 (Pub. L. 117-2) (ARP). HHS also clarifies, for purposes of the special enrollment periods provided at § 155.420(d), that a qualified individual who meets the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is not considered APTC eligible. This approach will ensure that § 155.420 reflects appropriate special enrollment period eligibility for qualifying individuals who qualify for a maximum APTC amount of zero dollars and for those who become eligible for APTC amounts greater than zero.

In addition, to reflect updated analysis of enrollment and the cost of expanded services offered through the Federal platform, HHS is finalizing the 2022 user fee rate at 2.75 percent of total monthly premiums charged by the issuer for each policy under plans offered through an FFE, and 2.25 percent of the total monthly premiums charged by the issuer for each policy under plans offered through an SBE-FP (rather than 2.25 and 1.75 percent of the total monthly

premiums charged by the issuer for each policy under plans offered through an FFE or SBE-FP, respectively, as finalized in the HHS Notice of Benefit and Payment Parameters for 2022 (hereinafter referred to as “part 1 of the 2022 Payment Notice final rule”).⁸ These finalized 2022 user fee rates are still less than the 2021 user fees currently being collected – 3.0 and 2.5 percent of the total monthly premiums charged by the issuer for each policy under plans offered through an FFE or SBE-FP, respectively.

HHS is also finalizing a technical amendment to requirements at § 156.115(a)(3) pertaining to the provision of the essential health benefits (EHB), to include a cross-reference to the Public Health Service (PHS) Act to make clear that health plans subject to EHB requirements must comply with all of the requirements under Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), including any amendments to MHPAEA.

HHS is repealing the separate billing regulation at § 156.280(e)(2), which requires individual market QHP issuers that offer coverage of abortion services for which Federal funds are prohibited⁹ to separately bill for this portion of the policy holder’s premium and to instruct the policy holder to pay for the separate bill in a separate transaction. Specifically, HHS will revert to, finalize, and codify the policy finalized in the 2016 Payment Notice¹⁰ such that QHP issuers offering coverage of abortion services for which Federal funds are prohibited again have flexibility in selecting a method to comply with the separate payment requirement in section 1303 of the ACA. As finalized, individual market QHP issuers covering abortion services for which Federal funds are prohibited would still be expected to comply with all statutory requirements in section 1303 of the ACA and all applicable regulatory requirements codified at § 156.280.

This rulemaking also finalizes modifications to the section 1332 Waivers for State Innovation (referred to throughout this rule as section 1332 waivers) implementing regulations,

⁸ 86 FR 6138.

⁹ These abortion services refer to abortion coverage that is subject to the Hyde Amendment’s funding limitations which prohibit the use of Federal funds for such coverage.

¹⁰ 80 FR 10750 (Feb. 27, 2015).

including changes to many of the policies and interpretations of the statutory guardrails recently codified in regulation. The policies and interpretations finalized in this rule supersede and rescind those outlined in the October 2018 “State Relief and Empowerment Waivers” guidance¹¹ (hereinafter referred to as the “2018 Guidance”) and repeal the previous codification of the interpretations of the statutory guardrails in part 1 of the 2022 Payment Notice final rule.¹² HHS and the Department of the Treasury (collectively, the Departments) are also finalizing flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers under certain future emergent situations. The Departments are also finalizing the processes and procedures for amendments and extensions for approved waiver plans.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the PHS Act to establish various reforms to the group and individual health insurance markets. These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans¹³ 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.¹⁴

Section 1301(a)(1)(B) of the ACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the ACA, including coverage of the services described in section

¹¹ 83 FR 53575.

¹² 86 FR 6138.

¹³ The term “group health plan” is used in title XXVII of the PHS Act and is distinct from the term “health plan” as used in other provisions of title I of the ACA. The term “health plan” does not include self-insured group health plans.

¹⁴ Before enactment of the ACA, HIPAA amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

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

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

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

Section 1303 of the ACA, as implemented in 45 CFR 156.280, specifies standards for issuers of QHPs through the Exchanges that cover abortion services for which Federal funding is prohibited. The statute and regulation establish that, unless otherwise prohibited by state law, a QHP issuer may elect to cover such abortion services. If an issuer elects to cover such services under a QHP sold through an individual market Exchange, the issuer must take certain steps to

ensure that no PTC or CSR funds are used to pay for abortion services for which public funding is prohibited.

As specified in section 1303(b)(2) of the ACA, one such step is that individual market Exchange issuers must determine the amount of, and collect, from each enrollee, a separate payment for an amount equal to the AV of the coverage for abortions for which public funding is prohibited, which must be no less than \$1 per enrollee, per month. QHP issuers must also segregate funds collected through this payment for abortion services for which Federal funds are prohibited into a separate allocation account used to pay for such abortion services.

Sections 1311(b) and 1321(b) of the ACA provide that each state has the opportunity to establish an individual market Exchange that facilitates the purchase of insurance coverage by qualified individuals through QHPs and meets other standards specified in the ACA. Section 1321(c)(1) of the ACA directs the Secretary to establish and operate such Exchange within states that do not elect to establish an Exchange or, as determined by the Secretary on or before January 1, 2013, will not have an Exchange operable by January 1, 2014.

Section 1311(c)(1) of the ACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs, including network adequacy standards at section 1311(c)(1)(B) of the ACA. Section 1311(d) of the ACA describes the minimum functions of an Exchange. 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)(1) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the state. Section 1311(c)(6) of the ACA establishes authority for the Secretary to require Exchanges to provide enrollment periods, including special enrollment periods, including the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act, per section 1311(c)(6)(D) of the ACA.

Sections 1311(d)(4)(K) and 1311(i) of the ACA require each Exchange to establish a Navigator program under which it awards grants to entities to carry out certain Navigator duties.

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

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

Sections 1313 and 1321 of the 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 1321 of the ACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a)(1) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA for, among other things, the establishment and operation of Exchanges. 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 establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1321(d) of the ACA provides that nothing in title I of the ACA must be construed to preempt any state law that does not prevent the application of title I of the ACA. Section

1311(k) of the ACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 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 section 1332 waivers.

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, 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 or disclosure of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs.

Section 5000A of the Internal Revenue Code (“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 (Pub. L. 115-97, December 22, 2017) the individual shared responsibility payment has been reduced to \$0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under 45 CFR 155.305(h) or 156.155.

1. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), HHS published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the “first Program Integrity Rule” published in the August 30, 2013 **Federal Register** (78 FR 54069) and the “second Program Integrity Rule” published in the October 30, 2013 **Federal Register** (78 FR 65045). In the December 27, 2019 **Federal Register** (84 FR 71674), HHS published a final rule that revised standards relating to oversight of Exchanges established by states and periodic data matching frequency. It also added new requirements for certain issuers related to the separate billing and collection of the separate payment for the premium portion attributable to coverage for certain abortion services. In the May 8, 2020 **Federal Register** (85 FR 27550), HHS published the Medicare and Medicaid Programs, Basic Health Programs and Exchanges interim final rule with public comment (“May 2020 IFC”) and postponed the implementation deadline for those separate billing and collection

requirements by 60 days. In light of court rulings in the ongoing litigation in Federal courts in Maryland, Washington, and California challenging the separate billing regulation,¹⁵ the separate billing policy is not currently in effect.

2. Market Rules

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

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

In the 2022 Payment Notice final rule in the May 5, 2021 **Federal Register** (86 FR 24140) (hereinafter referred to as the “part 2 of the 2022 Payment Notice final rule”), HHS made additional amendments to the guaranteed availability regulation regarding special enrollment periods and finalized new special enrollment periods related to untimely notice of triggering

¹⁵ Washington v. Azar, 461 F. Supp. 3d 1016 (E.D. Wash. 2020); Planned Parenthood of Maryland, Inc. v. Azar, No. CV CCB-20-00361 (D. Md. July 10, 2020); California v. U.S. Dep’t of Health & Hum. Servs., 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020).

events, cessation of employer contributions or government subsidies to COBRA continuation coverage, and loss of APTC eligibility.

3. Exchanges

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

In the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541), HHS set forth standards related to Exchange user fees. HHS 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 in the February 27, 2015 **Federal Register** (80 FR 10750), HHS finalized changes related to network adequacy and provider directories.

In the 2017 Payment Notice in the March 8, 2016 **Federal Register** (81 FR 12203), HHS finalized six standardized plan options to simplify the plan selection process for consumers on the Exchanges and codified SBE-FPs along with relevant requirements, including the associated user fee. In the 2017 Payment Notice, HHS also finalized policies relating to network adequacy for QHPs on the FFEs. In the May 11, 2016 **Federal Register** (81 FR 29146), HHS published an

interim final rule with amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). HHS finalized these amendments in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058). The 2018 Payment Notice also modified the standardized options finalized in the 2017 Payment Notice and included three new sets of standardized options.

In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), HHS amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), HHS modified parameters around certain special enrollment periods and discontinued the designation of standardized options. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period. In the May 14, 2020 **Federal Register** (85 FR 29204), the 2021 Payment Notice final rule made certain changes to plan category limitations and special enrollment period coverage effective date rules, allowed individuals provided a non-calendar year qualified small employer health reimbursement arrangement (QSEHRA) to qualify for an existing special enrollment period, and discussed plans for future rulemaking for employer-sponsored coverage (ESC) verification and non-enforcement discretion for Exchanges that do not conduct random sampling to verify whether an employer offers ESC until plan year 2021.

In part 1 of the 2022 Payment Notice final rule, published in the January 19, 2021 **Federal Register** (86 FR 6138), HHS finalized a new Exchange Direct Enrollment (DE) option. In part 2 of the 2022 Payment Notice final rule in the May 5, 2021 **Federal Register** (86 FR 24140) HHS finalized new special enrollment periods related to untimely notice of triggering events, cessation of employer contributions or government subsidies to COBRA continuation coverage, loss of APTC eligibility, and clarified the regulation imposing network adequacy standards with regard to QHPs that do not use provider networks.

4. Essential Health Benefits

On December 16, 2011, HHS released a bulletin¹⁶ that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). HHS established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), HHS added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond.

5. Section 1332 Waivers

In the March 14, 2011 **Federal Register** (76 FR 13553), 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 (hereinafter referred to as the “2012 Final Rule”). In the October 24, 2018 **Federal Register** (83 FR 53575), the Departments issued the 2018 Guidance, which superseded the previous guidance¹⁷ published in the December 16, 2015 **Federal Register** (80 FR 78131) (hereinafter referred to as the “2015 Guidance”), and provided additional information about the requirements that states must meet for waiver proposals, the Secretaries’ application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. In the November 6, 2020 **Federal Register** (85 FR 71142), the Departments issued an interim final rule (hereinafter referred to as the “November 2020 IFC”), which revises regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for waivers under section 1332 during the COVID-19

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

¹⁷ <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

PHE. 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 (hereinafter referred to as the “2022 Payment Notice proposed rule”) to codify certain policies and interpretations of the 2018 Guidance. In the January 19, 2021 **Federal Register** (86 FR 6138), the Departments published part 1 of the 2022 Payment Notice final rule which codified many of the policies and interpretations outlined in the 2018 Guidance into section 1332 regulations.

B. Stakeholder Consultation and Input

HHS consulted with stakeholders on policies related to the operation of Exchanges relevant to the policies in this final rule. HHS held a number of listening sessions with consumers, providers, employers, health plans, advocacy groups and the actuarial community to gather public input. HHS has solicited input from state representatives on numerous topics, particularly the direct enrollment option for FFEs, SBE-FPs and State Exchanges.

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

C. Structure of Final Rule

The regulations outlined in this final rule were proposed in the “Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond Proposed Rule” published in the July 1, 2021 **Federal Register** (86 FR 35156 through 35216) and will be codified in 45 CFR parts 147, 155, and 156. In addition, the regulations outlined in this final rule governing waivers under section 1332 of the ACA at 45 CFR part 155 subpart N will also be codified in 31 CFR part 33.

The changes to part 147 specify that issuers are not required to provide a special enrollment period in the individual market with respect to coverage offered outside of an Exchange to consumers who would be eligible for the special enrollment period at § 155.420(d)(16).

The changes to part 155 repeal the establishment of the Exchange DE option, which established a process for State Exchanges, SBE-FPs, and FFEs to elect to transition to use direct enrollment technology and non-Exchange websites developed by approved web brokers, issuers and other direct enrollment partners to enroll qualified individuals in QHPs offered through the Exchange. HHS is finalizing an extension of the annual individual market open enrollment period to end on January 15 of the applicable year, rather than December 15 of the previous year beginning with the open enrollment period for the 2022 coverage year, and HHS is codifying flexibility for State Exchanges that operate their own eligibility and enrollment platform to set individual market annual open enrollment period end dates no earlier than December 15 and to adopt accelerated effective dates. HHS is also finalizing the reinstitution of previous requirements that Navigators in FFEs provide consumers with information and assistance on certain post-enrollment topics, such as the Exchange eligibility appeals process, the Exchange-related components of the PTC reconciliation process, and the basic concepts and rights of health coverage and how to use it. HHS is further finalizing the provision of a monthly special enrollment period for qualified individuals or enrollees, or the dependents of a qualified individual or enrollee, who are eligible for APTC and whose household income does not exceed 150 percent of the FPL for periods of time during which enhanced APTC benefits are also available, such that certain applicable taxpayers' applicable percentage is set at zero, as provided by the section 9661 of the ARP or any subsequent statute or rule. HHS is finalizing a clarification that, for purposes of the special enrollment periods provided at § 155.420(d), a qualified individual, enrollee, or his or her dependent who is eligible for APTC because they

meet the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is not considered APTC eligible for purposes of these special enrollment periods.

The changes to part 156 update the user fee rates for the 2022 benefit year for all issuers participating on the Exchanges using the Federal platform. HHS is also finalizing the repeal of the separate billing requirement, which required individual market QHP issuers that offer coverage for abortion services for which Federal funding is prohibited to separately bill policy holders for the portion of the premium attributable to coverage of such abortion services and instruct the policy holder to pay for this portion of their premium in a separate transaction. Finally, HHS is finalizing an update to cross reference to mental health parity standards in the provision of EHB regulations.

The changes in 31 CFR part 33 and 45 CFR part 155 related to section 1332 waivers rescind the previous incorporation into regulation of certain policies and interpretations announced in the 2018 Guidance and are adopting new policies and interpretations for the statutory guardrails. The Departments are finalizing modifications to the section 1332 implementing regulations, and the proposals related to section 1332 waivers, which include adoption of processes and procedures for amendments and extensions for approved waiver plans. Additionally, the Departments are finalizing the extension of certain flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers during future emergent situations.

III. Provisions of the Updating Payment Parameters and Improving Health Insurance Markets for 2022 and Beyond the Final Rule and Analysis and Responses to Public Comments

In the July 1, 2021 **Federal Register** (86 FR 35156) HHS published the “Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond” proposed rule.¹⁸ HHS received a total of 390

¹⁸ 86 FR 35156.

comments, including 168 comments that were substantially similar to one form letter. Comments were received from state entities, such as departments of insurance and State Exchanges, health insurance issuers, providers and provider groups, consumer groups, industry groups, national interest groups, and other stakeholders. The comments ranged from general support for the proposed rule, to specific support of or opposition to the proposed provisions, to specific questions regarding proposed changes. HHS also received a number of comments and suggestions that were outside the scope of the proposed rule. These out-of-scope comments are not addressed in this final rule.

In this final rule, HHS provides a summary of proposed provisions, a summary of the public comments received that directly related to those proposals, its responses to these comments and a description of the provisions HHS is finalizing.

HHS first addresses comments regarding the publication of the proposed rule and the comment period.

Comment: Some commenters were concerned about the length of the comment period, stating that a longer comment period is necessary to allow stakeholders to review the proposed rule and provide thoughtful comments. Some commenters expressed concern that HHS should not calculate the comment period from the posting of the public inspection version, and that HHS would not have time to adequately review and consider all the comments before issuing a final rule.

Response: HHS disagrees that the comment period was not long enough to allow stakeholders to provide meaningful comments. HHS found commenters' submissions to be thoughtful and reflective of a detailed review and analysis of the proposed rule. HHS notes that in the interest of providing valuable information for issuers to set their rates for the 2022 plan year as soon as possible, HHS started the 30-day comment period with the posting of the rule for public inspection.

HHS further recognizes the importance of Federal agencies reviewing and considering all the relevant comments before issuing a final rule. The comment period for the proposed rule closed on July 28, 2021. HHS has had ample time to review and fully consider comments relevant to the rules and policies addressed in this final rule.

Comment: HHS received several comments of general support for the rule and for the proposed provisions which expand access to affordable health coverage. Some commenters expressed support for EOs 13985 and 14009. Other commenters expressed concern regarding the timing of the rule and the repeal of policies finalized in part 1 of the 2022 Payment Notice final rule.¹⁹ A few commenters stated that this rule is being published too late in the 2021 plan year for policy implementation and rate-setting for the 2022 plan year.

Response: HHS recognizes that this rulemaking has occurred later than usual in the plan year. However, HHS believes that the policies finalized in this rule align with the goals included in EOs 13985 and 14009.²⁰

While several of the policies in this final rule do not directly impact rate-setting, this final rule is being released prior to the September 21, 2021 deadline for signing final QHP agreements to participate in FFEs and SBE-FPs during the 2022 plan year. The purpose of the policies in this final rule is to strengthen the health insurance markets comprising plans that are subject to the ACA market reforms, and HHS encourages issuers to continue their participation in the Exchanges for 2022. HHS also believes that there is sufficient time to implement the applicable policies in advance of the start of the 2022 plan year.

Comment: One commenter requested that HHS assess and address systemic barriers to access for American Indian and Alaskan Native populations and establish guidance to address the social determinants of health that affect these communities and other communities of color.

¹⁹ 86 FR 24140.

²⁰ See 86 FR 7009 (Jan. 25, 2021) and 86 FR 7793 (Feb. 2, 2021).

Response: While this comment is outside of the scope of this rule, HHS appreciates this feedback. HHS notes that it is actively seeking ways to engage with stakeholders in an effort to advance health equity and address the social determinants of health that disparately impact communities of color in line with EO 13985 as described previously.

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

1. Guaranteed availability of coverage (§ 147.104)

a. Special Enrollment Periods (§ 147.104(b)(2))

As further discussed in the preamble section regarding the monthly special enrollment period for APTC-eligible qualified individuals with an expected household income no greater than 150 percent of the FPL (§ 155.420(d)(16)), HHS is finalizing the proposed special enrollment period with amendments, so that it is available only during periods of time during which APTC benefits are available such that the applicable taxpayers' applicable tax percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP. HHS is otherwise finalizing this new special enrollment period as proposed, including adding a new paragraph at § 147.104(b)(2)(i)(G) to specify that issuers are not required to provide this special enrollment period in the individual market with respect to coverage offered outside of an Exchange. HHS proposed to add this paragraph because eligibility for the special enrollment period is based on eligibility for APTC, as discussed in the § 155.420(d)(16) preamble section, and APTC cannot be applied to coverage that is not a QHP offered through an Exchange.²¹ HHS requested comment on this proposal. HHS did not receive many comments on this aspect of the proposed special enrollment period. However, comments that HHS did receive supported the proposal to not require issuers to provide the proposed special enrollment period for consumers to enroll in coverage off-Exchange. HHS appreciates this support and is finalizing the proposed

²¹ See IRC 36B(b)(2)(A), (c)(2)(A)(i).

special enrollment period to specify that issuers are not required to provide it in the individual market with respect to coverage offered outside of an Exchange.

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

1. Standardized Options (§ 155.20)

On March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus v. Cochran*, No. 18-2364, 2021 WL 825973 (D. Md. Mar. 4, 2021). The court reviewed nine separate policies HHS had promulgated in the 2019 Payment Notice final rule. The court vacated four of these policies. One of the policies vacated was the 2019 Payment Notice’s cessation of the practice of designating some plans in the FFEs as “standardized options.”²² Additionally, in July 2021, President Biden’s Executive Order 14036 on Promoting Competition in the American Economy directed HHS to standardize plan options in order to facilitate the plan selection process for consumers on the Exchanges.²³

HHS intends to implement the court’s decision as soon as possible, as explained in part 2 of the 2022 Payment Notice final rule.²⁴ HHS will not be able to fully implement those aspects of the court’s decision regarding standardized options in time for issuers to design plans and for CMS to be prepared to certify such plans as QHPs for the 2022 plan year. With the rule removing standardized options vacated, HHS will also need to design and propose new standardized options that otherwise meet current market reform requirements.²⁵ HHS will need to design, propose, and finalize such plans in time for issuers to design their own standardized options in accord with HHS’s parameters and to submit those plans for approval by applicable regulatory authorities and for certification as QHPs. This is not feasible for the upcoming QHP certification cycle for the 2022 plan year. The plan certification process for that year has already begun as of April 22, 2021. CMS’s planning for the QHP certification cycle for the 2022 plan

²² See 83 FR 16974-16975.

²³ See 86 FR 36987 (Jul. 9, 2021).

²⁴ See 86 FR 24140, 24264-24265.

²⁵ See 45 CFR 155.220(c)(3)(i)(H).

year has taken into account the existing policies that the court vacated, and it is too late now to revisit those factors if the process is to go forward in time for plans to be certified in time for the annual open enrollment period later this year.

Specifically, in the last iteration of standardized options HHS finalized in the 2018 Payment Notice, HHS created three sets of standardized options based on FFE and SBE-FP enrollment data and state cost-sharing laws. The basis on which HHS created these three sets of options, as well as a number of other factors in the individual market (for example, states with FFEs or SBE-FPs transitioning to State Exchanges), have changed considerably since the last iteration of standardized options in 2018. Further, HHS does not have sufficient time to conduct a full analysis of the changes that have occurred in the last several years necessary to timely design and propose standardized options suitable for the current environment. Additionally, in prior years, HHS proposed and finalized standardized option plan designs prior to the start of the QHP certification cycle for the following plan year such that issuers had sufficient time to assess these standardized options and could thus determine if they wanted to offer them and take the steps necessary to do so. Issuers will not have a sufficient amount of time to meaningfully assess any standardized options HHS would propose and decide whether or not to offer them if such proposals were made effective before the 2023 plan year.

For these reasons, HHS intends to resume the designation of standardized options and to propose specific plan designs in more complete detail in the 2023 Payment Notice. HHS sought the views of stakeholders regarding issues related to the proposal of new standardized options, including the views of states with FFEs or SBE-FPs regarding how unique state cost-sharing laws could affect standardized option plan designs.

The following is a summary of the comments received and HHS's responses related to standardized options.

Comment: Some commenters recommended not requiring issuers to offer standardized options. Some commenters also recommended permitting issuers to voluntarily offer

standardized options in states with State Exchanges, including SBE-FPs, even if issuers in the FFEs were required to offer them. Some commenters also noted opposition to limiting the number of non-standardized plans issuers could offer. Some commenters also recommended not preferentially or differentially displaying standardized options on HealthCare.gov.

These commenters explained that issuers are already required to cover the EHB at specified metal tiers of coverage, which provides consumers a sufficient degree of standardization. These commenters also explained that requiring issuers to offer standardized options could result in an influx of options that fail to provide additional value to consumers and make it more difficult to compare plan options. These commenters also explained that limiting the number of non-standardized plans issuers could offer would inhibit innovative plan designs that meet diverse coverage needs. These commenters also explained that the preferential or differential display of standardized options would appear to favor some plans over others, inadvertently steer consumers towards standardized plans, and discourage consumers from exploring all available options. These commenters recommended that CMS identify issuers with a disproportionately high volume of plan options in a given geographic region and work with these issuers to ensure there are actual meaningful differences among the plans.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Some commenters recommended that CMS should employ a minimally disruptive approach in designing standardized options and not design plans to be radically different from those currently offered. These commenters explained that such plans would be more complicated for issuers to develop and could be challenging for consumers to interpret. These commenters recommended that CMS offer standardized options that are based on the most popular plans currently offered on the Exchanges, a similar approach to that taken in past iterations. Several of these commenters also recommended that CMS not be overly prescriptive

in standardizing every aspect of cost sharing, but instead focus on setting annual deductible and out-of-pocket limits.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Some commenters explained that plan standardization could stifle competition. These commenters explained that if cost sharing is standardized, the only difference between plans will be networks. These commenters also explained that if standardization strengthens the importance of networks while deemphasizing other aspects of coverage, issuers may not stay in markets where network costs exceed their competitors'. These commenters further explained that with every additional aspect of coverage that is standardized, issuers will have to consider their ability to compete as potential areas to innovate and differentiate are limited.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Commenters also expressed support for requiring issuers to offer standardized options, limiting the number of non-standardized plans that issuers could offer, and preferentially or differentially displaying standardized options.

Commenters explained the importance of simplifying the complex process of purchasing insurance and the important role that standardized options could play in that simplification. Commenters explained that there is significant variation in the cost sharing structures of non-standardized plans, much of which cannot be identified without a detailed analysis of benefit designs. Commenters explained that many individuals do not have the time, resources, or health literacy necessary for this level of analysis. Commenters explained that enrollees typically choose plans based on more readily available comparison points, like premiums, rather than factors that would be illuminated by a more detailed examination of plan designs, like expected out-of-pocket costs. Commenters explained that selecting a plan solely based on its premium

without taking into consideration other attributes of its design, such as its cost sharing structure, deductible, or expected out-of-pocket costs, can result in unexpected costs and financial harm for consumers.

Commenters explained that barriers to conducting a detailed analysis of plan designs are particularly pronounced for those whose resources are already severely constrained, including those with limited English proficiency, those with inadequate internet access, and those with complex health needs. Commenters explained that facilitating consumer understanding and streamlining decision-making would benefit these populations as well as populations with disproportionately high rates of chronic diseases.

Commenters also explained that standardized plans could help individuals more easily identify plans that have potentially discriminatory benefit designs, such as plans that have coinsurance subject to the deductible as the cost sharing type for specialty tier prescription drugs. These commenters explained that discriminatory benefit designs target individuals with particular disabilities or health conditions by leaving them with substantial out-of-pocket costs. Commenters explained that conditions that are typically targeted, including HIV, diabetes, cancer, and mental health conditions, disproportionately affect individuals of color. Commenters explained that discriminatory benefit designs continue to violate the ACA's protections for people with preexisting conditions and its prohibition on discrimination based on race, sex, and disability.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Commenters also recommended taking a more prescriptive approach beyond requiring issuers to offer standardized plans, limiting the number of non-standardized plans, and preferentially or differentially displaying standardized plans. These commenters recommended requiring issuers to offer standardized options exclusively, pointing to Covered California's approach, which has required issuers to offer standardized plans exclusively since 2014. These

commenters explained that in Covered California's approach, to the extent issuers want to offer non-standardized products, they need to demonstrate that such designs are also patient-centered. These commenters explained that issuers in California have not seen the value in offering non-standardized options to date, suggesting that California's approach to standardized options has satisfied the needs of issuers and enrollees alike.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Commenters also made recommendations regarding specific aspects of standardized plan designs. Some commenters expressed concern about the cost-sharing structure in the first set of standardized plans in the 2018 Payment Notice in particular, which had coinsurance subject to the deductible as the form of cost sharing for occupational, physical, and speech therapies. Many commenters also noted a strong preference for copayments over coinsurance as the form of cost sharing for as many benefit categories as possible. These commenters explained that consumers prefer copayments to coinsurance because copayments are more transparent and make it easier to predict out-of-pocket costs. Commenters also explained that in the context of prescription drugs, the use of coinsurance results in patients paying cost sharing amounts based on a medicine's list price, rather than a medicine's net price, which accounts for manufacturer discounts and rebates paid to pharmacy benefit managers (PBMs) and issuers. Some commenters recommended that standardized plans include a nominal cost-sharing cap in the form of copayments for all tiers of prescription drug coverage to limit the amount that consumers spend on prescriptions every month, as several states have already done.

Commenters also recommended having low deductibles, explaining that deductibles act as a barrier to access. One commenter pointed to Washington's standardized plans, which have a deductible that is on average \$1,000 less than non-standard offerings and provide more pre-deductible services. Commenters also recommended exempting a range of benefits from the deductible, including primary care visits, specialist visits, outpatient visits, mental health

services, habilitative and rehabilitative services, pediatric preventative services, preventative care, chronic condition management, and prescription drug coverage. One commenter explained that any standardized plan that is also a high deductible health plan (HDHP) should provide pre-deductible coverage for preventive care the Internal Revenue Service (IRS) has determined is permitted to be provided without a deductible pursuant to section 223(c)(2)(C) of the Code.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: One commenter recommended delaying the implementation of standardized options requirements until plan year 2024 to allow issuers sufficient time to prepare for this change.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

2. Navigator Program Standards (§ 155.210)

HHS proposed to amend § 155.210(e)(9) to reinstitute the requirement that Navigators in the FFEs provide information and assistance with regard to certain post-enrollment topics.

Sections 1311(d)(4)(K) and 1311(i) of the ACA require each Exchange to establish a Navigator program under which it awards grants to entities to conduct public education activities to raise awareness of the availability of QHPs; distribute fair and impartial information concerning enrollment in QHPs, and the availability of PTCs and CSRs; facilitate enrollment in QHPs; provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate state agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. The statute also requires the Secretary, in collaboration with states, to develop standards to ensure that information made available by

Navigators is fair, accurate, and impartial. HHS has implemented the statutorily required Navigator duties through regulations at §§ 155.210 (for all Exchanges) and 155.215 (for Navigators in FFEs).

Further, section 1311(i)(4) of the ACA requires the Secretary to establish standards for Navigators to ensure that Navigators are qualified, and licensed, if appropriate, to engage in the Navigator activities described in the statute and to avoid conflicts of interest. This provision has been implemented at §§ 155.210(b) (generally for all Exchanges) and 155.215(b) (for Navigators in FFEs).

HHS has also established under § 155.205(d) and (e) that each Exchange must have a consumer assistance function, including the Navigator program, and must conduct outreach and education activities to educate consumers about the Exchange and insurance affordability programs to encourage participation.

HHS proposed to amend § 155.210(e)(9) to reinstitute the requirement that Navigators in the FFEs provide information and assistance with regard to certain post-enrollment topics rather than merely being authorized to do so.

Following a reduction in overall funding available to the FFE Navigator program in 2020, HHS provided more flexibility to FFE Navigators by making the provision of certain types of assistance, including post-enrollment assistance, permissible, but not required, for FFE Navigators under Navigator grants awarded in 2019 or any later year.²⁶ On August 27, 2021, HHS awarded \$80 million in grant funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year.²⁷ With this substantially increased funding for the FFE Navigator program for the 2022 plan year, HHS noted that HHS believes there will be sufficient Navigator grant

²⁶ 84 FR 17511-17514 (April 25, 2019). These post-enrollment topics included: Understanding the process of filing Exchange eligibility appeals; understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange; understanding the availability of exemptions from the requirement to maintain MEC and from the individual shared responsibility payment that are claimed through the tax filing process and how to claim them; the Exchange-related components of the PTC reconciliation process; understanding basic concepts and rights related to health coverage and how to use it; and referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice on certain Exchange-related topics.

²⁷ <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open>.

funding available to support the post-enrollment duties HHS proposed to once again require of FFE Navigators. HHS also noted that HHS believes this proposal aligns with EO 14009 on Strengthening Medicaid and the ACA because it will improve consumers' access to health coverage information, not only when selecting a plan, but also throughout the year as they use their coverage.²⁸ In addition, the proposal was designed to ensure that consumers would have access to skilled assistance beyond applying for and enrolling in health insurance coverage through the Exchange, including, for example, assistance with the process of filing Exchange eligibility appeals, understanding basic information about PTC reconciliation, and understanding basic concepts and rights related to health coverage and how to use it, such as locating providers and accessing care.

Section 1311(i)(3)(D) of the ACA and 45 CFR 155.210(e)(4) already expressly require Navigators to provide post-enrollment assistance by referring consumers with complaints, questions, or grievances about their coverage to appropriate state agencies. This suggests that Congress anticipated that consumers would need assistance beyond the application and enrollment process, and that Navigators would maintain relationships with consumers and be a source of such post-enrollment assistance.

Consistent with the requirements under section 1311(i)(3)(B) and (C) of the ACA that Navigators distribute fair and impartial information concerning enrollment in QHPs and facilitate enrollment in QHPs, and pursuant to the Secretary's authority under section 1321(a)(1)(A) of the ACA, HHS proposed to reinstitute as a requirement at § 155.210(e)(9)(i) that Navigators in the FFEs must help consumers with understanding the process of filing appeals of Exchange eligibility determinations. HHS noted that HHS was once again not proposing to establish a duty for Navigators to represent a consumer in an appeal, sign an appeal request, or file an appeal on the consumer's behalf. HHS noted that HHS believes that helping consumers understand Exchange appeal rights when they have received an adverse eligibility determination when

²⁸ 86 FR 7793 (Feb. 2, 2021).

applying for health insurance coverage, and assisting them with the process of completing and submitting appeal forms, would help to facilitate enrollment through the FFEs and would help consumers obtain fair and impartial information about enrollment through the FFEs. HHS discussed that HHS would interpret the proposal to include helping consumers file appeals of eligibility determinations made by an Exchange related to enrollment in a QHP, special enrollment periods, and any insurance affordability program, including eligibility determinations for Exchange financial assistance, Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program.

Currently, pursuant to § 155.210(e)(9)(ii), Navigators in the FFEs are permitted to provide information and assistance to consumers with regard to understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange, understanding the availability of exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment that are claimed through the Federal income tax filing process and how to claim them, and understanding the availability of the IRS resources on this topic. HHS proposed to amend § 155.210(e)(9)(ii) slightly to reinstitute as a requirement that Navigators in the FFEs must help consumers understand and apply for exemptions from the requirement to maintain minimum essential coverage granted by the Exchange. Although consumers who do not maintain minimum essential coverage no longer need to receive an exemption from the individual shared responsibility payment to avoid having to make such a payment, Navigators can still assist consumers age 30 or above with filing an exemption to qualify to enroll in catastrophic coverage under § 155.305(h). HHS noted that HHS believes that the proposal was consistent with Navigators' duty under section 1311(i)(3)(B) and (C) of the ACA to distribute fair and impartial information concerning enrollment in QHPs, since impartial information concerning the availability of exemptions for consumers age 30 or above to enroll in catastrophic coverage would help consumers make informed decisions about whether or not to enroll in such coverage. This

assistance with Exchange-granted exemptions from the requirement to maintain minimum essential coverage would include informing consumers about the availability of the exemption; helping consumers fill out and submit Exchange-granted exemption applications and obtain any necessary forms prior to or after applying for the exemption; explaining what the exemption certificate number is and how to use it; and helping consumers understand and use the Exchange tool to find catastrophic plans in their area.

In addition, HHS proposed to reinstitute as a requirement at § 155.210(e)(9)(iii) that Navigators must help consumers with the Exchange-related components of the PTC reconciliation process and with understanding the availability of IRS resources on this process. As explained in the proposed rule, this would include ensuring consumers have access to their Forms 1095–A and receive general, high-level information about the purpose of this form that is consistent with published IRS guidance on the topic. The proposal stemmed from the requirement under section 1311(i)(3)(B) of the ACA that Navigators distribute fair and impartial information concerning the availability of the PTC under section 36B of the Code.

Consumers who receive premium assistance through APTC may need help with a variety of issues related to the requirement to reconcile the APTC with the PTC allowed for the year of coverage. As explained in the proposed rule, FFE Navigators would be required to help consumers obtain IRS Form 1095–A, Health Insurance Marketplace Statement, and Form 8962, Premium Tax Credit (PTC), and the instructions for Form 8962, and to provide general information, consistent with applicable IRS guidance, about the significance of the forms. HHS noted that, as proposed, Navigators would also be required to help consumers understand (1) how to report errors on the Form 1095–A; (2) how to find silver plan premiums using the Exchange tool; and (3) the difference between APTC and PTC and the potential implications for enrollment and reenrollment of not filing a tax return and reconciling the APTC paid on consumers' behalf with their PTC for the year.

HHS noted that, as proposed, Navigators would still not be permitted to provide tax assistance or advice, or interpret tax rules and forms within their capacity as FFE Navigators. However, their expertise related to the consumer-facing aspects of the Exchange, including eligibility and enrollment rules and procedures, would uniquely qualify them to help consumers understand and obtain information from the Exchange that is necessary to understand the PTC reconciliation process. Because the proposal included a requirement that Navigators provide consumers with information and assistance understanding the availability of IRS resources, HHS noted that Navigators would be expected to familiarize themselves with the availability of materials on [irs.gov](https://www.irs.gov), including the Form 8962 instructions, IRS Publication 974, Premium Tax Credit, and relevant FAQs, and to refer consumers with questions about tax law to those resources or to other resources, such as free tax return preparation assistance from the Volunteer Income Tax Assistance or Tax Counseling for the Elderly programs.

To help ensure consumers have seamless access to Exchange-related tax information beyond the basic information that Navigators can provide, HHS proposed to reinstitute as a requirement at § 155.210(e)(9)(v) that FFE Navigators must refer consumers to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, and PTC reconciliations.²⁹

In the proposed rule, HHS discussed that it interprets the Navigator duties to facilitate enrollment in QHPs in section 1311(i)(3)(C) of the ACA, to distribute fair and impartial information concerning enrollment in QHPs under section 1311(i)(3)(B) of the ACA, and to conduct public education activities to raise awareness about the availability of QHPs in section 1311(i)(3)(A) of the ACA to include helping consumers understand the kinds of decisions they

²⁹ HHS notes that HHS did not propose to reinstitute at § 155.210(e)(9)(v) the requirement that Navigators must provide referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about exemptions from the requirement to maintain MEC and from the individual shared responsibility payment in light of the fact that the individual shared responsibility payment was reduced to zero for months beginning after December 31, 2018 under the Tax Cuts and Jobs Act (Pub. L. 115-97, December 22, 2017).

will need to make in selecting coverage, and how to use their coverage after they are enrolled.

HHS has previously stated that one of the overall purposes of consumer assistance programs is to help consumers become fully informed and health literate.³⁰

To improve consumers' health literacy related to coverage generally, and to ensure that individual consumers are able to use their coverage meaningfully, HHS proposed to reinstitute at § 155.210(e)(9)(iv) the requirement that Navigators in the FFEs must help consumers understand basic concepts and rights related to health coverage and how to use it. HHS also proposed to expand its interpretation of this requirement and the activities that fall within the requirement's scope. As explained in the proposed rule, these activities could be supported through the use of existing resources such as the CMS "From Coverage to Care" initiative, which HHS encourages Navigators to review, and which are now available in multiple languages.³¹ HHS noted that, as proposed, the provision would improve consumers' access to health coverage information, not just when selecting a plan, but also when using their coverage.

HHS noted that HHS believes expanding its interpretation of the requirement that Navigators help consumers understand basic concepts and rights related to health coverage and how to use it and the activities that fall within the scope of this requirement is vital to improving health equity and helping to address social determinants of health, particularly among underserved and vulnerable populations.³² Navigators are already required under § 155.210(e)(8) to provide targeted assistance to underserved or vulnerable populations. Underserved and vulnerable populations often experience lower levels of health literacy, which can be a barrier to enrolling in and accessing care.³³ Social determinants of health can also create significant disparities in whether and how an individual is able to afford and access health coverage and health care services, including primary and preventive care. As trusted partners and members of

³⁰ See 79 FR 30276.

³¹ See <https://marketplace.cms.gov/c2c>.

³² 86 FR 7009 (Jan. 25, 2021).

³³ Access to Health Services: Healthy People 2020. Office of Disease Prevention and Health Promotion, Department of Health & Human Services. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/access-to-health>.

local communities, HHS noted that Navigators are uniquely positioned to establish and build trust with individuals and families as they transition from enrolling in health coverage to using and maintaining their coverage throughout the year.

Additionally, HHS noted that Navigators in FFEs are already required under § 155.215(c)(1) to develop and maintain general knowledge about the racial, ethnic, and cultural groups in their service area, including each group’s health literacy and other needs, and under § 155.215(c)(2) to collect and maintain updated information to help understand the composition of the communities in the service area. Because the health literacy needs of consumers will vary depending on their circumstances, HHS noted that HHS is not requiring Navigators to help consumers with specific health literacy topics. Instead, HHS proposed to expand its interpretation of the Navigator duties to be reinstituted as requirements at § 155.210(e)(9)(iv) to include, for example, helping consumers understand (1) key terms used in health coverage materials, such as “deductible” and “coinsurance,” and how they relate to the consumer’s health plan; (2) the cost and care differences between a visit to the emergency department and a visit to a primary care provider under the coverage options available to the consumer; (3) how to evaluate their health care options and make cost-conscious decisions, including through the use of information required to be disclosed by their health plan as a result of the Transparency in Coverage Final Rules;³⁴ (4) how to identify in-network providers to make and prepare for an appointment with a provider—including utilizing tools and resources available through the No Surprises Act³⁵ to make informed decisions about their care; (5) how the consumer’s coverage addresses steps that often are taken after an appointment with a provider, such as making a follow-up appointment and filling a prescription; and (6) the right to coverage of certain preventive health services without cost sharing under QHPs—including information and resources related to accessing viral testing and vaccination options supported by Exchange

³⁴ 85 FR 72158.

³⁵ Title I of Division BB of the Consolidated Appropriations Act, 2021, Pub. L. 116-260 (Dec. 27, 2020).

coverage. HHS noted that, if this proposal were finalized, CMS intends to make training materials and other educational resources available to Navigators regarding the proposed expanded interpretation of this requirement.

HHS noted that, as proposed, FFE Navigators would continue to be permitted to perform the Navigator duties specified in § 155.210(e)(9) until this provision, if finalized, became effective. HHS explained that if the proposal was finalized, FFE Navigators would be required to perform the Navigator duties specified in § 155.210(e)(9) beginning with Navigator grants awarded after the effective date of this rule, including non-competing continuation awards. For example, if the proposal was finalized prior to Navigator grant funding being awarded in fiscal year (FY) 2022, FY 2021 Navigator grantees would be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance. To the extent FFE Navigators awarded grant funding in FY 2021 are not already performing these duties under their year one project plans when the provision, if finalized, becomes effective, HHS noted that they can revise their project plans to incorporate performance of the duties specified in § 155.210(e)(9) as part of their non-competing continuation application for their FY 2022 funding. HHS also noted that if the provision was finalized as proposed, HHS would codify in § 155.210(e)(9) the applicability date to make clear when the Navigator duties specified in § 155.210(e)(9) would once again be required.

HHS discussed in the proposed rule that HHS interprets the requirement to facilitate enrollment in a QHP under section 1311(i)(3)(C) of the ACA, and the requirement at § 155.210(e)(2) to provide information that assists consumers with submitting the eligibility application, to include assistance with updating an application for coverage through an Exchange, including reporting changes in circumstances and assisting with submitting information for eligibility redeterminations. Additionally, HHS noted that Navigators are already permitted, but not required, to help with a variety of other post-enrollment issues. For example,

HHS noted that HHS interpreted the requirements in § 155.210(e)(1) and (2) that Navigators conduct public education activities to raise awareness about the Exchange and provide fair and impartial information about the application and plan selection process to mean that Navigators may educate consumers about their rights with respect to coverage available through an Exchange, such as nondiscrimination protections, prohibitions on preexisting condition exclusions, and preventive services available without cost-sharing. HHS also noted that HHS interpreted these requirements, together with the requirement in section 1311(i)(3)(B) of the ACA that Navigators distribute fair and impartial information concerning enrollment in QHPs, and the availability of Exchange financial assistance, to mean that Navigators may assist consumers with questions about paying premiums for coverage or insurance affordability programs enrolled in through an Exchange. Finally, HHS noted that HHS interpreted the requirement in section 1311(i)(3)(D) of the ACA and § 155.210(e)(4) to provide referrals for certain post-enrollment issues to mean that Navigators may help consumers obtain assistance with coverage claims denials.

Certified application counselors (CACs) do not receive grants from the FFEs, and thus may have more limited resources than Navigators. As a result, while HHS did not propose to require CACs to further expand their required duties, HHS noted that HHS encouraged CACs to help with activities consistent with their existing regulatory duties and recognized that many of these CACs may already be participating in these post-enrollment activities.

The following is a summary of the comments received and HHS's responses related to Navigator program standards at §155.210.

Comment: The vast majority of comments HHS received in relation to this proposal expressed enthusiastic support. Many commenters stated that they believe it is important that high-quality consumer assistance to help people find, keep, and use health coverage be free and widely available. Several commenters emphasized that this was particularly important for individuals with limited English proficiency (LEP) or those who lack basic health insurance

literacy to reduce health disparities in rural and underserved communities, including the Black, Indigenous, and other People of Color (BIPOC) community. Additionally, several commenters supported and noted the importance of increased funding for the Navigator program.

Response: HHS appreciates the comments in support of this proposal and is finalizing the proposal to amend § 155.210(e)(9) to reinstitute the requirement that Navigators in the FFEs provide information and assistance with regard to certain post-enrollment topics as proposed. HHS also appreciates commenters' support of increased funding for the Navigator program, which has funded 60 Navigator grantees in 30 FFE states for plan year 2022.

Comment: A few commenters said they believe the proposed Navigator duties duplicate services provided by issuers or agents and brokers. A few commenters suggested that Navigators be required to be licensed, carry errors and omissions insurance, and be under the oversight of state regulators.

Response: HHS believes it is important for consumers to have access to a variety of assistance options. HHS especially believes it is important that consumers have access to Navigators who, unlike agents and brokers, are required under § 155.210(e)(2) to provide information and services in a fair, accurate, and impartial manner, and to abide by the conflict of interest provision at § 155.210(d)(4) prohibiting Navigators from receiving any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP. Although they are not required by CMS to carry errors and omissions insurance, Navigators are required to complete HHS-approved training, achieve a passing score on all approved certification examinations, and be certified or recertified on at least an annual basis before carrying out any consumer assistance functions under § 155.210. Additionally, Navigators in all states are required under § 155.210(c)(1)(iii) to meet any licensing, certification, or other standards prescribed by the state or Exchange, if applicable, so long as the standards do not prevent the application of the provisions of title I of the ACA.

Comment: A few commenters expressed concern that CMS did not propose to restore the requirements to have at least two in-person Navigator organizations in each state and to ensure that at least one of those organizations was a community and consumer-focused nonprofit group.

Response: HHS recognizes that trusted community non-profits and in-person presence are desirable qualities for Navigator organizations, and that these can be particularly valuable in serving vulnerable populations such as minorities, individuals with LEP, and individuals with disabilities. However, the existing Navigator grant process already gives considerable weight to the capacity of the Navigator organization to serve vulnerable populations, including those who may need communications assistance, lack broadband access, or have specialized needs. Therefore, HHS believes that reinstating these requirements would not be beneficial to Exchanges, as they currently have the flexibility to award funding to the number and type of entities that will be most effective for the specific Exchange, thus optimizing use of the funding amounts available to direct investments to effective and efficient Navigators, which may include selecting a single, high performing grantee in an Exchange.

Additionally, reinstating the requirement that one Navigator grantee in each Exchange must be a community and consumer-focused nonprofit group may unnecessarily limit an Exchange's ability to award grants to the strongest applicants, particularly in an Exchange that opts to have only one Navigator grantee, and where the strongest applicant is not a community and consumer-focused nonprofit group. Reinstating this requirement would effectively exclude any other type of statutorily eligible entities from becoming Navigators in an Exchange that opts to have only one Navigator grantee and would limit an Exchange's ability to target to the highest scoring and performing entities, regardless of organization type.

Comment: A few commenters suggested HHS reinstate the requirement that Navigators receiving grants maintain a physical presence in the Exchange service area.

Response: HHS agrees with commenters who emphasized the importance of providing more flexibility to each Exchange to structure its Navigator program to best serve the

Exchange's service area. HHS believes that entities with a physical presence and strong relationships in their FFE service areas tend to deliver the most effective outreach and enrollment results. Navigator grant applicants that demonstrate the ability to maintain these relationships and establish new relationships through a physical presence in their proposed service area(s) may receive a higher score on their application than those who do not. The majority of HHS's 2021 Navigator grantees will be maintaining a physical presence in the state they are serving, and there will be at least one physically present Navigator organization in every FFE state. Additionally, nothing in this final rule prevents an Exchange from selecting grantees that are physically present and available to provide a spectrum of in-person, local outreach, education, and assistance, including directing these services towards vulnerable and underserved populations, if the Exchange elects to weight its selection process in that way and its selection process is consistent with section 1311(i)(2)(A) of the ACA and § 155.210(c)(1)(ii).

After consideration of the comments received, HHS is finalizing the proposals as proposed. FFE Navigators will continue to be permitted to perform the Navigator duties specified in § 155.210(e)(9) until Navigator grants are awarded in 2022. FFE Navigators will be required to perform the Navigator duties specified in § 155.210(e)(9) beginning with Navigator grants awarded in 2022, including non-competing continuation awards. Thus, prior to Navigator grant funding being awarded in FY 2022, FY 2021 Navigator grantees will be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance.

3. Exchange Direct Enrollment Option (§ 155.221(j))

In part 1 of the 2022 Payment Notice final rule, HHS codified § 155.221(j), which established a process for states to elect a new Exchange Direct Enrollment option (Exchange DE option). Under the Exchange DE option, State Exchanges, SBE-FPs, and FFE states may work directly with private sector entities (including QHP issuers, web-brokers, and agents and brokers) to transition to private-sector enrollment pathways through which consumers can apply for

coverage, receive an eligibility determination from the Exchange, and purchase an individual market QHP offered through the Exchange with APTC and CSRs, if otherwise eligible. These private-sector pathways could be offered in addition to or instead of a centralized eligibility and enrollment website operated by an Exchange. Subject to meeting HHS approval requirements under § 155.221(j)(1) and (2), the Exchange DE option may be implemented in states with a State Exchange beginning in plan year 2022 and in SBE-FP or FFE states beginning in plan year 2023. HHS also finalized a 2023 user fee rate of 1.5 percent of the total monthly premiums charged by issuers for each policy in FFE and SBE-FP states that elect the Exchange DE option. Since the publication of part 1 of the 2022 Payment Notice final rule, there have been significant changes to policy and operational priorities, as well as the enactment of new Federal laws. Given these changes, as well as a general lack of interest expressed by states in the option, and potential for the Exchange DE option to be misaligned with administration priorities, HHS proposed to remove § 155.221(j) and repeal the Exchange DE option.

On January 20, 2021, President Biden issued the EO 13985,³⁶ directing that as a policy matter the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. On January 28, 2021, President Biden issued EO 14009.³⁷ Section 3 of EO 14009 directs HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether they are inconsistent with policy priorities described in Section 1 of EO 14009, to include protecting and strengthening the ACA by assisting people who are potentially eligible for coverage, and eliminating unnecessary difficulties to obtaining health insurance. Specifically, this agency review must evaluate whether existing policies or

³⁶ 86 FR 7009 (Jan. 25, 2021).

³⁷ 86 FR 7793 (Feb. 2, 2021).

regulations, “...undermine the Health Insurance Marketplace^{®38} or the individual, small group, or large group markets for health insurance...” or “...present unnecessary barriers to individuals and families attempting to access Medicaid or ACA coverage...”³⁹

Section 2 of EO 14009 also requires that the Secretary of HHS consider whether to implement an Exchange special enrollment period for exceptional circumstances pursuant to § 155.420(d)(9) and other existing authorities, for uninsured and underinsured individuals to obtain coverage in light of the special circumstances caused by the COVID-19 pandemic. After EO 14009 was issued, HHS used its discretion to make such a special enrollment period available to uninsured and underinsured consumers through HealthCare.gov from February 15, 2021, through May 15, 2021. To support outreach, education and enrollment efforts for this special enrollment period, HHS has provided \$2.3 million in additional funding to current Navigator grantees in the FFEs.⁴⁰

All State Exchanges followed suit and implemented corresponding special enrollment periods on similar timelines. HHS later made a decision to extend the ability of consumers to access the special enrollment period through HealthCare.gov through August 15, 2021, and many State Exchanges extended their special enrollment periods, as well. As of August 10, 2021, 2.5 million consumers have enrolled in coverage through HealthCare.gov and the State Exchanges, which represents a substantial increase from previous years when special enrollment periods were available primarily for normal qualifying life events.⁴¹

In addition, Congress recently passed the ARP,⁴² which was signed into law on March 11, 2021. The ARP establishes new ACA programs, including a new grant program for Exchange modernization, which appropriates \$20,000,000 in Federal funding, which is available until

³⁸ Health Insurance Marketplace[®] is a registered service mark of the U.S. Department of Health & Human Services.

³⁹ 86 FR 7793 (Feb. 2, 2021).

⁴⁰ <https://www.cms.gov/newsroom/press-releases/cms-announces-additional-navigator-funding-support-marketplace-special-enrollment-period>.

⁴¹ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

⁴² Pub. L. 117-2.

September 30, 2022, to State Exchanges to implement Exchange system, program, or technology updates to ensure compliance with applicable Federal requirements. It also modifies eligibility criteria for existing ACA programs. For example, the provisions in the ARP include a temporary change (for taxable years 2021 and 2022) that allows consumers with household income above 400 percent of the FPL to be applicable taxpayers potentially eligible for PTC, an update to applicable percentage tables to increase the amount of PTC for qualified individuals in all income brackets, and a modification of eligibility for PTC for consumers receiving, or approved to receive, unemployment compensation in 2021. Beginning on April 1, HHS operationalized these new requirements through HealthCare.gov, and is providing technical assistance to State Exchanges that are operationalizing these requirements at the state level. The approximately 2.5 million consumers that have enrolled in coverage through HealthCare.gov and the State Exchanges during the COVID-19 special enrollment period have reduced their monthly premiums by \$40 per person per month due to the ARP's premium credits, with more than one-third of consumers finding coverage for \$10 or less per month. In addition, out-of-pockets costs have fallen for new consumers that have enrolled since April, with the median plan deductible falling by nearly 90 percent from \$450 to \$50.⁴³

There are also new obligations established via other health care-related legislation for which HHS is responsible to implement in coordination with states and other Federal Departments. This includes the No Surprises Act,⁴⁴ which was enacted on December 27, 2020, and establishes an extensive array of Federal and state requirements and programs to protect consumers against surprise medical bills.

Given its obligation to review all existing policies and regulations in line with EO 14009, EO 13985, and recent actions by Congress, including the health care-related provisions of the ARP and other new Federal legislation, for which HHS is now responsible or centrally involved

⁴³ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

⁴⁴ Title I of Division BB of the Consolidated Appropriations Act, 2021, Pub. L. 116-260 (Dec. 27, 2020).

in implementing, HHS determined that all available resources should be directed to ensuring HHS is able to efficiently and effectively meet those obligations. Permitting the establishment of the Exchange DE option would detract from those efforts. Furthermore, meeting the new requirements of the health care provisions of the ARP would add complexity to Exchange operations that could reduce the prospects for successful implementation of the Exchange DE option, even if temporarily. For instance, states and DE entities would need to coordinate and implement new procedures to ensure that consumers receive eligibility determinations and are enrolled in coverage in line with the modified PTC eligibility criteria under the ARP, and then take steps and expend resources to end these new procedures since this temporary modification no longer applies after taxable year 2022. As part of this process, HHS would need to ensure the adoption of appropriate procedures, proper approvals, and ongoing oversight. To foreclose the possibility that Federal funding and resources will be diverted from efforts to provide direct benefits to consumers made available under recent legislation to optional programs, HHS proposed to repeal the Exchange DE option. As explained in the proposed rule, this would help ensure that available resources are allocated consistent with administration health care priorities and dedicated to implementation of newly-enacted Federal laws that provide greater financial assistance and protections to consumers.

HHS further explained that repealing the Exchange DE option should generally have a minimal impact on states and other interested parties. States with State Exchanges already could engage with DE entities preceding the addition of § 155.221(j). In addition, the FFEs have already implemented the DE program (including classic direct enrollment and enhanced direct enrollment, or EDE), which provides broad availability of non-Exchange websites to assist consumers applying for, or enrolling in QHPs through an FFE or SBE-FP with APTC and CSRs, when otherwise eligible.⁴⁵ Additionally, HHS noted that nothing in the previous regulatory framework prohibited State Exchanges from engaging DE entities similar to the FFEs in order to

⁴⁵ The FFE DE pathways are also available in SBE-FP states. See 45 CFR 155.220(l) and 155.221(i).

supplement Exchange operations in their states should they so choose. HHS also noted that although HHS understands that several State Exchanges have engaged with DE entities to discuss possibilities for collaboration, State Exchanges and other stakeholders nearly universally cautioned against the Exchange DE option in public comments submitted in response to the initial proposal to establish the Exchange DE option. HHS further noted that, to date, no state had expressed interest in implementing the Exchange DE option.

Finally, in reviewing § 155.221(j) in line with EO 13985 and EO 14009, and after further consideration of public comments received when the Exchange DE option was proposed, HHS explained in the proposed rule that HHS determined that the Exchange DE option is inconsistent with policies described in EO 13985 and sections 1 and 3 of EO 14009. Consistent with many public comments received when the Exchange DE option was proposed, HHS noted that HHS believed that shifting away from HealthCare.gov or State Exchange websites as the primary pathway to enroll in and receive information about coverage would harm consumers by unnecessarily fracturing enrollment processes among the Exchange and possibly multiple DE entities operating in a state. HHS noted that such a shift would be particularly harmful now when over 2.5 million consumers have relied upon and successfully navigated HealthCare.gov and State Exchange websites during the COVID-19 special enrollment period to enroll in Exchange coverage. HHS also agreed with many commenters who noted that a fractured process could foster consumer confusion about how to get covered and what coverage options are available, since consumers could be directed to DE entities that only offer assistance with a limited selection of products and some of those products may not provide, for example, MEC for consumers.⁴⁶ Many commenters raised concerns that this consumer confusion or limited product selection through DE entities could also potentially disrupt coordination of coverage with other insurance affordability programs, including Medicaid and CHIP, which is inconsistent with

⁴⁶ Multiple commenters cited the following report as support for their comments related to DE entities offering limited plan selection and potential disruptions to coordination of coverage with other insurance affordability programs:
<https://www.cbpp.org/research/health/direct-enrollment-in-marketplace-coverage-lacks-protections-for-consumers-exposes>.

HHS’s “no wrong door” policy.⁴⁷ In addition, these consequences could act as an unnecessary barrier to consumers seeking Medicaid or ACA coverage rather than facilitating enrollment in comprehensive coverage, and could have additional downstream impacts including an increased uninsured or underinsured population, or more consumers enrolling in less comprehensive coverage options. These downstream impacts could lead to health inequities by disparately impacting certain vulnerable groups that tend to have a greater need for comprehensive coverage or rely more heavily on Medicaid and CHIP. These concerns and the accompanying risks to the health and well-being of underserved groups and consumers in general are heightened as the COVID-19 PHE continues.

After finding the Exchange DE option inconsistent with recent Executive Orders, to ensure that resources are not diverted from fulfilling requirements under the new health care legislation and other initiatives like the COVID-19 special enrollment period, and because no state had yet expressed interest in implementing the Exchange DE option, HHS proposed to remove § 155.221(j) and repeal the Exchange DE option. As explained in the preamble section regarding user fee rates for the 2022 benefit year (§ 156.50), HHS also proposed to repeal the accompanying user fee rate for FFE-DE and SBE-FP-DE states for 2023.

The following is a summary of the comments received and HHS’s responses to the proposed repeal of the Exchange DE option (§155.221(j)).

Comment: The overwhelming majority of commenters supported the proposal to repeal the Exchange DE option. These commenters both endorsed the rationale behind this proposal, and reiterated concerns about the potential negative ramifications of the Exchange DE option that were expressed in comments when the Exchange DE option was originally proposed in the 2022 Payment Notice. These include a lack of empirical research to quantify potential impacts or demonstrate the value that would be added by implementation of this option; the potential for

⁴⁷ This policy is intended to ensure that consumers can complete a single eligibility application to receive determinations of eligibility across multiple health insurance affordability programs, including for QHPs, APTC, CSRs, as well as Medicaid and CHIP. See, for example, sections 1311(d)(4)(F) and 1413 of the ACA.

consumer confusion due to fragmentation among multiple DE entities; the potential for DE entities with misaligned incentives to steer consumers toward less comprehensive coverage options or fail to inform consumers that they are eligible for Medicaid or CHIP; an increase in funding and resources that would be needed to provide effective oversight; and other downstream impacts, including the potential for an increase in uninsured and underinsured populations, particularly within the QHP, Medicaid, and CHIP populations.

Several commenters also raised health equity concerns, asserting that the Exchange DE option could have a disproportionate impact on certain underserved or historically-marginalized groups, and others that face barriers navigating the health care system to get coverage. Supporting commenters commented on behalf of those with pre-existing conditions, the LGBTQ+ population, women and children, those with substance use disorders, young adults, and others. One commenter noted that the Exchange DE option would disproportionately impact historically-marginalized populations by making Medicaid less accessible, asserting that DE entities do not necessarily provide Medicaid eligibility information to consumers. Another commenter noted that making Medicaid less accessible would be particularly harmful to women of color and those in the LGBTQ+ community who, due to discrimination and depressed wages, are disproportionately eligible for Medicaid and CHIP. Several commenters expressed concern that the Exchange DE option would disproportionately impact people with substance use disorders and mental health conditions given the increased prevalence of those conditions during the PHE. Commenters expressed concern that those with limited health literacy also could be particularly harmed by the Exchange DE option, citing consumers in underserved communities, young people, people who do not speak English as a first language, and others. These commenters stated that such consumers are particularly susceptible to being harmed by insufficient information, coverage, and hidden costs. One commenter also noted that women generally have more health care needs and are more vulnerable to high health costs, which means enrolling in substandard coverage could result in care being delayed or denied, medical debt, and

overall worse health outcomes. Commenters also noted that the potential increase in the number of consumers enrolled in substandard coverage as a result of the Exchange DE option would be particularly harmful for consumers with pre-existing conditions, since through such substandard coverage they could experience a denial of coverage due to their pre-existing conditions. Most of these commenters underscored that health equity concerns are heightened by the ongoing PHE.

Supporting commenters strongly encouraged the repeal to be finalized as proposed to remedy these concerns and protect consumers, particularly underserved and historically-marginalized consumers.

Response: HHS appreciates the support of this proposal and generally agrees with commenters' concerns, particularly those regarding the potential negative impacts to underserved and historically-marginalized consumers during the PHE. The new enrollment and coverage opportunities available to consumers, including the special enrollment period to enroll in Exchange coverage through HealthCare.gov or their State Exchange website during the COVID-19 PHE, and the increased financial assistance under the ARP, have proven to be successful at increasing enrollment in comprehensive coverage options, such as ACA coverage offered through Exchanges.⁴⁸ HHS believes it is critical to build on this success by maximizing opportunities for consumers to get comprehensive ACA coverage through the Exchanges and to enroll in insurance affordability programs (for example, Medicaid and CHIP), when eligible. Moreover, HHS believes that this will best serve underserved and historically-marginalized groups, as well as support health equity. For example, as raised in comments that are summarized earlier in this preamble, consumers in these groups tend to have a greater need for more comprehensive coverage (for example, those with pre-existing conditions) or to require robust consumer support and ample opportunity to successfully navigate the health care system (for example, those with limited health literacy). HHS believes that focusing resources on the

⁴⁸ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

Exchanges and the new health care programs they are leading is the best approach to support these, and other consumer needs, for underserved and historically-marginalized groups, and for consumers in general.

HHS also notes that repealing the Exchange DE option will not foreclose states' option to leverage the existing FFE DE pathways,⁴⁹ nor the ability of State Exchanges to implement DE pathways similar to the FFEs, should they find that it is appropriate given their specific market dynamics, priorities, and needs. However, on balance, HHS believes there is much greater risk that the Exchange DE option could serve as a barrier to consumers getting comprehensive coverage rather than facilitate such enrollment. The repeal of the Exchange DE option also permits HHS to direct available resources to implementation of the new Federal requirements (for example, the No Surprises Act consumers protections and the ARP increased subsidies), rather than diverting resources to implement an optional program. Finally, as detailed earlier in this preamble, it aligns with the policy goals and directives in the recent Executive Orders to advance health equity for all, protect and strengthen the ACA, and eliminate unnecessary difficulties to obtaining health insurance. After consideration of comments, HHS is finalizing the repeal of the Exchange DE option and accompanying user fees, as proposed.

Comment: Commenters requested clarification regarding the scope of the proposed repeal and whether HHS's intent is to eliminate the existing FFE DE pathways or just to eliminate the Exchange DE option.

Response: HHS clarifies that the existing FFE DE pathways, including both classic DE and EDE, will not be impacted by the repeal of the Exchange DE option. Those pathways will continue to be available to consumers shopping for Exchange coverage in FFE and SBE-FP states. In addition, states with State Exchanges also still have the option to leverage DE should they choose to do so based on their specific market dynamics, priorities, and needs. The proposed repeal, which HHS is finalizing in this rule, is specific to removing the Exchange DE

⁴⁹ The FFE DE pathways are also available in SBE-FP states. See 45 CFR 155.220(l) and 155.221(i).

option codified at § 155.221(j) and the accompanying FFE-DE and SBE-FP-DE user fees. The other Federal requirements applicable to the FFE DE pathways, as outlined in §§ 155.220, 155.221, and 156.1230, remain intact.

Comment: Several opposing commenters asserted it is premature to repeal the Exchange DE option on the grounds of lacking state interest, given the limited time since the proposal was finalized. They stated that reliance on this ground was questionable in light of the many other health care priorities that have occupied states such as implementing and operationalizing the health care provisions of recent legislation, including the ARP. Some opposing commenters recommended that the rollout of the Exchange DE option merely be delayed, rather than repealed, to give states additional time to explore its feasibility. Several commenters also expressed general support for the Exchange DE option, noting that it meets all applicable ACA statutory and regulatory requirements. One commenter suggested that the lowered user fee for the Exchange DE option for FFE and SBE-FP states could be attractive to states and weigh favorably in the balance for those states who may be interested in pursuing the Exchange DE option, if given more time to consider it. This commenter noted that another attractive feature to states is the potential cost savings on consumer support functions resulting from potentially having more enrollment channels available to consumers. Other commenters in opposition of the proposed repeal stated that there would be no cost to the Federal Government beyond oversight costs in states that elected to implement the Exchange DE option.

Response: HHS acknowledges that the Exchange DE option was only recently finalized and it is plausible that but for competing health care priorities perhaps some states would express interest in the Exchange DE option. However, HHS clarifies that the lack of interest from states was just one factor that lead to the proposed repeal of the Exchange DE option. As detailed earlier in this preamble and in the proposed rule, HHS was also concerned that permitting the establishment of the Exchange DE option would detract from efforts to implement new Federal requirements, including consumer protections against surprise medical billing, for which HHS is

now responsible and centrally involved in implementing. HHS was also concerned about the additional complexity to Exchange operations resulting from newly passed legislation that could impact the successful implementation of the Exchange DE option, which could negatively impact consumers ability to enroll in comprehensive coverage. Finally, the proposal was made following HHS's evaluation of the Exchange DE option as directed by EOs 13985 and 14009, which determined the option was inconsistent with the policies outlined in those Executive Orders to advance health equity for all, protect and strengthen the ACA, and eliminate unnecessary difficulties to obtaining health insurance.

HHS appreciates that there are potentially attractive features of the Exchange DE option both for states and the Federal Government, particularly from a financial perspective. This was one of the considerations that led to the proposed establishment of the Exchange DE option. However, HHS does not believe that a reduced user fee or potential savings on consumer support costs outweighs the potential harm to consumers, or other considerations, outlined earlier in this preamble and in the proposed rule, that HHS considered as part of its recent evaluation of the Exchange DE option. Delaying the rollout of the Exchange DE option and giving states more time to evaluate its feasibility would not assuage the multitude of concerns expressed by the public or those outlined earlier in this preamble and in the proposed rule, including the need to focus health care resources on the emergent needs of struggling vulnerable and historically-marginalized consumers and the need to focus available Department resources on implementing new Federal requirements, including the new consumer protections against surprise medical billing. In part 1 of the 2022 Payment Notice final rule, HHS outlined many potential direct and indirect costs of startup, approval, and oversight.⁵⁰ HHS therefore disagrees that the Federal Government would incur only oversight costs in states that elect to implement the Exchange DE option.

⁵⁰ See 86 FR 6169-6170.

Comment: All opposing commenters argued that state flexibility, particularly the flexibility to tailor enrollment portals, should not be curtailed, especially during a PHE. Relatedly, these commenters asserted that consumers universally benefit from an increase in choice. One of these commenters stated that DE entities would serve to supplement and extend the reach of Exchanges rather than replacing them.

Response: HHS agrees that proposals that encourage and promote state flexibility are important, as states are best suited to tailor programs to address local health care priorities and the needs of their residents. HHS also reiterates that the existing FFE DE pathways are not impacted by the repeal of the Exchange DE option. States using the HealthCare.gov platform and State Exchanges will still have the option to leverage DE as a supplement to the Exchange should they find that it would provide value for their consumers given their specific market dynamics, priorities, and needs. States that currently use HealthCare.gov also have flexibility to transition to a State Exchange model and adapt Exchange functions to their local markets and unique needs of their residents. HHS also believes that in this situation, on balance, the potential for expanded choice does not outweigh the potential consumer harms when there is a danger of fragmenting consumers' path to getting comprehensive coverage and directing consumers to less comprehensive coverage options that, in many cases, will not cover their health care costs. This places an outsized burden on consumers that, after further evaluation, HHS determined is unnecessary given their existing choice of multiple enrollment pathways offered by Exchanges, QHP issuers, web-brokers, agents and brokers, generally harmful for consumers, and unacceptable during a PHE.

HHS also highlights the recent enrollment increases driven by HealthCare.gov and State Exchange websites, which are outlined earlier in this preamble. In particular, HHS reiterates that as of August 10, 2021, approximately 2.5 million consumers have enrolled in coverage through HealthCare.gov and State Exchange websites during the COVID-19 special enrollment period, and have reduced their monthly premiums by \$40 per person per month due to the ARP's

premium credits, with more than one-third of consumers finding coverage for \$10 or less per month.⁵¹ In addition, out-of-pockets costs have fallen for new consumers that have enrolled since April, with the median plan deductible falling by nearly 90 percent from \$450 to \$50. This increased enrollment and cost savings to consumers, which has been driven by the current Exchange programs, further demonstrates their importance and effectiveness.

Comment: All opposing commenters asserted that DE entities and their platforms are better suited than Navigators and centralized, government-run Exchanges to innovate to meet consumer needs. Relatedly, they argue that the FFE DE pathways have in many ways surpassed the consumer support functionality of HealthCare.gov, and that this is largely driven by competition among DE entities to attract consumers. They also claim that the success of the FFE DE pathways is evidenced by the enrollment statistics from the successful plan year 2021 open enrollment period.⁵² One commenter argued that EOs 13985 and 14009 would actually be better served by maintaining the Exchange DE option since it would provide more consumer-centric access to coverage, including for vulnerable populations.

Response: While HHS does not agree with many of these characterizations, HHS reiterates again that the FFE DE pathways will not be impacted by the repeal of § 155.221(j). Those pathways and their success may continue unimpeded since HHS is only repealing the Exchange DE option. DE may indeed be the right choice for some states and certain consumers, and HHS does not intend to diminish its success or inhibit innovation in this area. However, HHS maintains that the policy goals outlined in EOs 13985 and 14009 are best served by repealing the Exchange DE option. More specifically, the dangers that this optional program that would remove the centralized Exchange website could fragment consumers' path to getting comprehensive coverage, direct consumers to less comprehensive coverage options that, in many

⁵¹ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

⁵² Several commenters cited in particular that CMS data show that the FFE DE pathways more than doubled enrollments during the plan year 2021 open enrollment period, increasing from 521,000 to 1,130,000. They also noted that the FFE DE pathways have attracted a higher proportion of new consumers and increased the number of consumers who made active plan selections.

cases, will not cover their health care costs, and disproportionately impact certain underserved and historically marginalized groups are inconsistent with advancing health equity, protecting and strengthening the ACA, and eliminating unnecessary barriers to obtaining health insurance. These dangers are heightened during a PHE. HHS believes that access to comprehensive coverage options, including Exchange plans, and advancing health equity among consumers will be best served by enhancing access to coverage through proven enrollment channels like the Exchanges or the FFEs' DE pathways, and eliminating optional programs that have the potential to cause significant consumer confusion and harm at a time when consumer protection and enrollment in comprehensive coverage is of paramount importance. Notwithstanding the claim that centralized, government-run Exchanges are not as well equipped to innovate to meet consumer needs as DE entities and platforms, HHS highlights that Exchanges do innovate, and are central participants in innovative programs. For instance, the State Exchanges and HealthCare.gov have administered innovative new health care programs in 2021 detailed previously⁵³ that have resulted in 2.5 million consumers successfully enrolling through the Exchanges with significant premium assistance. In addition, the FFEs have been central participants in innovating through the Federal DE pathways.⁵⁴ These pathways are designed to foster innovation of new consumer-based tools and functionality by approved DE partners.⁵⁵ HHS believes that these and other examples of Exchange innovation and collaboration with the private sector help dispel concerns about the ability of centralized, government-run Exchanges to meet consumer needs.

Comment: Opposing commenters argued that concerns about consumers being steered toward non-comprehensive coverage options like short-term limited duration insurance or

⁵³ These include the efforts to administer the health care provisions of the ARP and the related COVID-19 special enrollment period.

⁵⁴ One of the critical consumer-centric innovations of the Federal EDE pathway is to enable consumers to access eligibility and enrollment information directly through a DE entity's website by means of various application program interfaces rather than having to re-direct to HealthCare.gov.

⁵⁵ For instance, DE entities may offer plan comparison tools with functionality targeted specifically to serve the needs of their consumer base.

association health plans are exaggerated since there are existing FFE DE requirements and limitations that would mitigate such concerns. They also highlighted that § 155.221(j) requires that a State Exchange electing to implement the Exchange DE option must have at least one DE entity that meets all requirements of the FFE DE program, including displaying all available QHPs. These commenters also suggested that concerns about potential disruptions to coordination of coverage with insurance affordability programs like Medicaid and CHIP are exaggerated because the DE entities participating in the FFE DE pathways use the same single, streamlined application and eligibility notices as HealthCare.gov to assist the Exchange with rendering an eligibility determination for all insurance affordability programs in compliance with the “no wrong door” policy.

Response: HHS appreciates that there are Federal DE requirements and operational practices in place designed to protect consumers, including certain requirements to protect against steering QHP consumers to less comprehensive coverage options.⁵⁶ The Exchange DE option also included certain safeguards, including the requirement that at least one DE entity must meet all of the requirements to participate in the FFE DE program. However, HHS maintains that the previously identified dangers that this optional program could harm consumers by fragmenting the path to comprehensive coverage, directing consumers to less comprehensive coverage options, and disproportionately impacting certain underserved and historically marginalized groups are inconsistent with advancing health equity, protecting and strengthening the ACA, and eliminating unnecessary barriers to obtaining health insurance. These dangers are real,⁵⁷ they are heightened during a PHE, and after further evaluation, HHS determined they place an unnecessary and unacceptable outsized burden on consumers. HHS believes that access to comprehensive coverage options, including Exchange plans, and advancing health equity among consumers will be best served by enhancing access to coverage through proven

⁵⁶ See, for example, 45 CFR 155.220(c)(3)(i)(A) – (L), 155.220(j), 155.221(b)(1)–(3) and 156.1230(a) and (b).

⁵⁷ See, e.g., <https://www.cbpp.org/research/health/direct-enrollment-in-marketplace-coverage-lacks-protections-for-consumers-exposes>.

enrollment channels, which includes maintaining a centralized Exchange website for consumers to apply for an enroll in QHPs and insurance affordability programs. The increased enrollment through Exchange websites during the COVID-19 special enrollment period underscores the importance of maintaining these known enrollment pathways for consumers. Finalizing the repeal of the Exchange DE option also ensures HHS can focus resources and efforts on implementing new Federal requirements, including consumer protections against surprise medical billing, for which HHS is now responsible and centrally involved in implementing, rather than on implementing and overseeing an optional program, which has the potential to cause significant confusion and harm at a time when consumer protection is paramount. Finally, HHS reiterates that the repeal of the Exchange DE option does not impact or change the other Federal requirements applicable to the FFE DE pathways, which will continue to be available in FFE and SBE-FP states. States with State Exchanges can also still leverage DE as a supplement to the Exchange website should they find it would provide value for their consumers given their specific market dynamics, priorities, and needs.

After consideration of these comments, HHS is finalizing the repeal of the Exchange DE option and the FFE-DE and SBE-FP-DE user fees, as proposed.

4. Annual Open Enrollment Period Extension (§ 155.410(e))

HHS proposed to amend paragraph (e) of § 155.410, which provides the dates for the annual individual market Exchange open enrollment period in which qualified individuals and enrollees may apply for or change coverage in a QHP. The annual individual market Exchange open enrollment period is extended by cross-reference to non-grandfathered plans in the individual market, both inside and outside of an Exchange, under guaranteed availability regulations at § 147.104(b)(1)(ii). HHS specifically proposed to alter the annual open enrollment period for the 2022 coverage year and beyond so that it begins on November 1 and runs through January 15 of the applicable benefit year.

In previous rulemaking, HHS established that the annual open enrollment period for benefit years beginning on or after January 1, 2018 would begin on November 1 and extend through December 15. In doing so, HHS indicated a preference for a shorter 6-week annual open enrollment period, noting HHS's belief that it provides sufficient time for consumers to enroll in or change QHPs and that an end date of December 15 carries the benefit of ensuring consumers receive a full year of coverage and simplifies operational processes for issuers and the Exchanges.⁵⁸ Accordingly, the annual open enrollment period dates have been set to November 1 through December 15 for the 2018, 2019, 2020, and 2021 plan years. As discussed in the proposed rule, HHS has observed several benefits using the present annual open enrollment period dates. Prior enrollment data suggests that the majority of new consumers to the Exchange select plans prior to December 15 so as to have coverage beginning January 1.

HHS also observed that consumer casework volumes related to coverage start dates and inadvertent dual enrollment decreased in the years after the December 15 end date was adopted, suggesting that the consumer experience was improved by having a singular deadline of December 15 to enroll in coverage for the upcoming plan year. HHS noted that an extension to January 15 may cause some previously observed consumer confusion to resurface surrounding the need to enroll by December 15 for a full year of coverage versus the final deadline of January 15 to enroll for a plan that would begin on February 1. This confusion could cause some consumers to miss out on coverage for the month of January altogether. A January 15 end date may also require enrollment assisters allocate budget resources over a longer period of time.

However, after observing the effects of a 6-week annual open enrollment period over these years, HHS has also observed negative impacts to consumers that may justify an extension of the annual open enrollment period end date to January 15. In particular, HHS has observed that consumers who receive financial assistance, who do not actively update their applications during the annual open enrollment period, and who are automatically re-enrolled into a plan are

⁵⁸ See 82 FR 18346 at 18381.

subject to unexpected plan cost increases if they live in areas where the second lowest-cost silver plan has dropped in price. These consumers will experience a reduction in their allocation of APTC based on the second lowest-cost silver plan price, but are often unaware of their increased plan liabilities until they receive a bill from the issuer in early January after the annual open enrollment period has concluded. Extending the annual open enrollment period end date to January 15 would allow these consumers the opportunity to change plans after receiving updated plan cost information from their issuer and to select a new plan that is more affordable to them. HHS also noted in the proposed rule that HHS has also observed concerns from Navigators, CACs, and agents and brokers that the current annual open enrollment period does not leave enough time for them to fully assist all interested Exchange applicants with their plan choices. Extending the annual open enrollment period end date to January 15 would allow more time for consumers to seek assistance from one of these entities. Together, the impacts of providing consumers with more time to react to updated plan cost information and more time to seek enrollment assistance may improve access to health coverage. The additional time for enrollment assistance provided by this proposal may be particularly beneficial to consumers in underserved communities who may face time or language barriers in accessing health coverage by extending the period in which these consumers can seek in-person assistance to enroll.

HHS sought comment on whether a January 15 end date would provide a balanced approach to providing consumers with additional time to make informed plan choices and increasing access to health coverage, while mitigating risks of adverse selection, consumer confusion, and issuer and Exchange operational burden. HHS invited comments from stakeholders that would experience specific benefits or adverse effects from a January 15 end date, and encourage comments on potential impacts to resources, consumer assistance budgets, overall enrollment numbers, premiums, and market stability. HHS sought comment on whether this extension would incentivize consumers who need coverage to begin on January 1 to still make a choice and enroll by December 15, while also preserving sufficient time in the remainder

of the plan year for issuers and Exchanges to perform other obligations such as QHP certification.

HHS further invited comments on alternative approaches to extending the annual open enrollment period to address coverage gaps or enrollment challenges facing consumers and stakeholders. HHS also invited comments to address whether HHS should explore the possibility of a new special enrollment period, such as for current enrollees who are automatically re-enrolled and experienced a significant cost increase, to address concerns for specific consumer challenges as an alternative to extending the annual open enrollment period. HHS also noted that HHS is considering whether approaches such as enhanced noticing or special, targeted outreach would address the needs of consumers who are automatically re-enrolled in areas where the second lowest-cost silver plan drops in value, thereby reducing APTC amounts. HHS sought comment on how HHS may improve communications and consumer engagement around potential cost changes for consumers who do not actively re-enroll in coverage. HHS also noted that HHS is considering if improved education and outreach during the coverage year to raise awareness of existing special enrollment period opportunities, such as those for loss of coverage or becoming newly eligible or ineligible for financial assistance, may serve consumers who do not enroll or change plans during the annual open enrollment period. HHS sought comment on whether adoption of these or other outreach approaches would be a viable alternate approach to finalizing its proposal to extend the annual open enrollment period end date to January 15.

HHS noted that HHS anticipated that if an annual open enrollment period end date of January 15 were finalized, this change would apply to all Exchanges, including State Exchanges for the 2022 coverage year and beyond. HHS noted that in preceding plan years, a majority of State Exchanges operating their own eligibility and enrollment platform have used special enrollment period authority to offer additional enrollment time beyond the end date of December 15 in the Exchanges on the Federal platform. HHS invited additional comments on State

Exchange flexibility, as well as operational challenges relating to State Exchange implementation of the proposed change for 2022 and beyond.

HHS is finalizing this policy for the FFEs and SBE-FPs, and HHS codifies flexibility for State Exchanges that operate their own eligibility and enrollment platform to set individual market annual open enrollment period end dates no earlier than December 15 and to offer accelerated effective date rules. HHS is clarifying that the annual open enrollment period end dates chosen by State Exchanges operating their own eligibility and enrollment platform will apply to all non-grandfathered plans in the individual market, both inside and outside of an Exchange, under guaranteed availability regulations at § 147.104(b)(1)(ii). The following is a summary of the comments received and HHS's responses to its proposals related to the annual open enrollment period extension (§155.410(e)).

Comment: The majority of commenters supported HHS's proposal. Commenters agreed that lengthening the annual open enrollment period would provide valuable time to consumers to seek in-person assistance and make informed plan choices. Many commenters agreed that this time would be particularly helpful to those who are auto-reenrolled into coverage, but receive a lower subsidy than the prior year because the cost of their benchmark plan has dropped. Commenters also noted additional groups that would benefit from this extension: consumers whose coverage is terminated towards the end of the calendar year and who do not become aware of its termination until after January 1, consumers whose Medicaid eligibility is ending as the result of the potential expiration of the continuous enrollment provisions in section 6008(b)(3) of the Families First Coronavirus Response Act (Pub. L. 116-127), and consumers whose share of premiums may increase in plan year 2022 due to the expiration of extra subsidies provided for under the ARP. A January 15 end date would provide these consumers extra time and a streamlined process to understand their eligibility and plan cost changes and enroll in new coverage.

Several commenters highlighted the complex medical needs of consumers with chronic and serious medical conditions, noting that a longer annual open enrollment period would give these consumers more time to review and compare plan options, provider networks, and prescription drug offerings. Organizations and individuals providing application and enrollment assistance commented that there is often not enough time to provide individual or in-person help to all consumers who request it at the end of the current 6-week annual open enrollment period. Other commenters agreed with HHS's proposal that a longer annual open enrollment period would allow underserved populations more time to seek in person assistance and reduce barriers to enrollment, and that the proposal would allow agents and brokers, Navigators, and other consumer assisters more time to help and serve consumers shopping for plans. Finally, many commenters noted that the months of November and December are some of the busiest for consumers, and that holidays and end of the year activities cause significant time and financial constraints that are barriers to enrollment. Commenters argued that many consumers would benefit from additional time in January to complete plan shopping and enrollment activities.

Response: HHS agrees with these comments and is finalizing the policy to extend the annual open enrollment period to January 15 of the applicable benefit year, as proposed, and HHS codifies flexibility for State Exchanges that operate their own eligibility and enrollment platform to set individual market annual open enrollment period end dates no earlier than December 15 and to use accelerated effective date rules.

Comment: Many commenters noted that the majority of State Exchanges have already extended their annual open enrollment periods beyond the current December 15 deadline used by Exchanges on the Federal platform, and that State Exchanges have achieved enrollment gains in the month of January without introducing adverse selection into the market. Some State Exchange commenters noted that a longer annual open enrollment period allowed new consumers to enroll and resulted in a healthier risk pool mix. Another commenter noted that while most consumers continued to choose plans in December in order to have coverage

effectuate January 1, the additional time in January offered flexibility for consumers who needed more time to weigh coverage options and enroll.

Many state commenters noted that State Exchanges that offered extended periods for the annual open enrollment period beyond the end date used by the Exchanges on the Federal platform in some cases offered more accelerated effective date rules during the annual open enrollment period such that plan selections made by the last day of the month are effective the first day of the following month. These commenters asked that this flexibility be maintained and that January 15 be the minimum end date for the annual open enrollment period in the State Exchanges. Other commenters noted that not all State Exchanges have chosen to extend their annual open enrollment periods into January and requested that State Exchanges maintain an ability to end the annual open enrollment period earlier than January 15. These commenters noted that State Exchanges may face operational burdens in adjusting their systems to accommodate the January 15 end date and that State Exchanges should maintain autonomy to set annual open enrollment period dates that best serve their populations.

Response: HHS appreciates the comments highlighting evidence from State Exchange experiences with longer effective annual open enrollment periods, and are finalizing the policy to extend the annual open enrollment period to January 15. HHS agrees with commenters that State Exchanges are best suited to address the needs of their markets and are therefore codifying flexibilities for State Exchanges that operate their own eligibility and enrollment platform to set annual open enrollment period end dates no earlier than December 15. HHS also is codifying that these State Exchanges may extend their annual open enrollment periods beyond the end date of January 15 that will be used by the Exchanges on the Federal platform and may adopt more flexible accelerated effective date rules.

Comment: Many commenters encouraged HHS to extend the annual open enrollment period even further, specifically to January 31. Commenters also asked that HHS use accelerated effective dates to make coverage available February 1 for plan selections received by January 31.

Other commenters asked us to consider beginning the annual open enrollment period earlier in the year, for example on October 15, while still maintaining an end date of December 15 or December 31, as an alternative way to extend the total length of the annual open enrollment period. Still other commenters asked HHS to explore an October 15 start date in addition to the proposed extension, noting that the date would align with the beginning of Medicare's annual open enrollment period and that this alignment would facilitate additional consumer outreach and enrollments. Another commenter suggested providing an annual open enrollment period of January 1 through March 31 to avoid the holiday season and end of the calendar year altogether.

Response: HHS recognizes that a January 31 end date would provide additional time for consumers to enroll, and that some State Exchanges have adopted this date. However, HHS believes the proposed date of January 15 sufficiently balances its priorities of allowing consumers additional time to enroll after the end of the calendar year, while still promoting full coverage year enrollment and minimizing administrative burdens on Exchanges and issuers associated with longer annual open enrollment periods. Given the high volume of transactions processed by the Federal platform, HHS's operational experience suggests that adopting accelerated effective dates for the annual open enrollment period could cause delays in enrollments and claims processing and would require further study. Accordingly, HHS is not considering requiring changes to effective date rules at this time, but as noted earlier, is codifying flexibility for State Exchanges operating their own eligibility and enrollment platforms to adopt accelerated effective dates.

While beginning the annual open enrollment period in October instead of November 1 would effectively lengthen the total annual open enrollment period timeframe, it would not address the needs of consumers who receive updated plan cost information or who experience program eligibility changes after January 1 and would also create administrative burdens on Exchanges and issuers to complete QHP plan certification and other pre-enrollment readiness activities. Similarly, HHS believes a change to begin the annual open enrollment period on

January 1 and end in March would require a shift of the plan year calendar and create significant administrative burden on Exchanges, issuers, and state regulators, and HHS is not considering such a change at this time.

Comment: Other commenters opposed the proposal to extend the annual open enrollment period to January 15. Commenters stated that this change would introduce adverse selection into the market, as more consumers would delay enrollment and may enroll in January only after needing care. Others noted that the change would increase administrative burdens and marketing and operational costs on issuers. Commenters noted that consumers have become accustomed to a 6-week annual open enrollment period and some commenters assisting consumers with enrollment activities noted that in their experience consumers did not need more time. Other commenters argued that the change would actually decrease total enrollment figures, as measured by total coverage months, as more consumers delay enrollment and neglect coverage for the month of January.

Response: HHS acknowledges commenters' concerns regarding consumer confusion and coverage gaps, and recognizes that HHS will need to engage in consumer outreach activities to ensure consumers are aware of the new deadlines and the implications of signing up by December 15 for a January 1 effective date. However, HHS notes that the experience from State Exchanges operating their own eligibility and enrollment platforms suggests that extending the annual open enrollment period into January does result in increased consumer enrollments and does not introduce adverse selection into market. State Exchange commenters noted that the majority of consumers still enrolled in time to effectuate coverage for January 1, but that the Exchanges were able to achieve additional enrollments in January from consumers who simply missed the deadline or needed more time and help enrolling. The experience from these State Exchange commenters is also consistent with other comments received in support of this proposal which noted that underserved consumers, consumers with complex health needs, and consumers with unexpected plan cost or eligibility changes at the end of the year do not have

enough time to shop and get in-person assistance under the current annual open enrollment period timeframe.

Comment: HHS received comments in support of its suggestion to offer a special enrollment period for current enrollees who are automatically re-enrolled and experienced a significant cost increase as an alternative to extending the annual open enrollment period, and a request that HHS delay offering this special enrollment period until 2023. Other commenters opposed the idea of a targeted special enrollment period and noted that special enrollment periods create complexity and costs for issuers and are difficult and burdensome for consumers to navigate. Commenters stated that an extended annual open enrollment period offers a much more streamlined approach to achieving the policy goal of allowing consumers to change plans in response to updated cost information as compared to a special enrollment period. Commenters also supported HHS's suggestions to improve consumer outreach and education activities to address enrollment barriers, but did not agree this outreach is an adequate substitute for extending the annual open enrollment period.

Response: While HHS is not aware of increased issuer costs or consumer burden in the State Exchanges that have used special enrollment periods to effectively lengthen the annual open enrollment period, HHS acknowledges that the targeted special enrollment period as discussed in this rule would be limited to certain consumers meeting specified criteria and, as such, could require additional administrative steps for issuers, consumers, and Exchanges. HHS agrees that an extended annual open enrollment period offers a more streamlined approach for consumers, and also serves the added benefit of allowing other consumers, such as those with complex health needs, those in underserved communities, and those who receive a lower subsidy than the prior year that they are not aware of until receiving their January bill more time to determine their best coverage option.

Comment: Other commenters suggested HHS could do more to improve renewal notices to address the challenges faced by consumers who were automatically re-enrolled but then

experienced a significant cost increase as an alternative to extending the annual open enrollment period. Commenters suggested HHS consider aligning operational timelines and allowing issuers to provide more timely and accurate premium tax credit and plan cost information to consumers. Commenters suggested HHS could improve its communications around the automatic re-enrollment process to better avoid consumers receiving surprising plan cost information after the benefit year has begun. Another commenter asked HHS to consider a policy for providing retroactive terminations to consumers who were automatically re-enrolled into coverage that they no longer want, and that such a policy could reduce spending on APTC paid for these months of inadvertent coverage.

Response: HHS agrees that more improvements can be made in this area, and welcomes the suggestions by commenters to improve renewal notice processes to provide more accurate plan cost information to consumers earlier in the annual open enrollment period. However, after review of the range of public comments received, HHS does not believe improvements to the renewal noticing and automatic re-enrollment process alone is a sufficient alternative to providing additional enrollment time. HHS notes that current HHS policy does allow for consumers to request retroactive terminations under certain circumstance after their coverage has been automatically renewed, and that an extended annual open enrollment period deadline of January 15 will also allow consumers more time to become aware of their enrollment options after automatic reenrollment has occurred.

5. Monthly Special Enrollment Period for APTC-Eligible Qualified Individuals with a Household Income No Greater than 150 Percent of the Federal Poverty Level whose Applicable Taxpayer has an Applicable Percentage of Zero (§ 155.420(d)(16))

In order to make affordable coverage available to more consumers, HHS proposed to codify a monthly special enrollment period for qualified individuals or enrollees, or the dependents of a qualified individual or enrollee, who are eligible for APTC, and whose

household income is expected to be no greater than 150 percent of the FPL.⁵⁹ As discussed in the proposed rule, HHS proposed making this special enrollment period available to individuals based on household income level because enhanced financial assistance provided by the ARP for tax years 2021 and 2022 is such that many individuals with a household income no greater than 150 percent of the FPL have access to a silver plan with a zero dollar monthly premium after the application of APTC.⁶⁰ Specifically, section 9661 of the ARP amended section 36B(b)(3)(A) of the Code 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 for tax years 2021 and 2022.⁶¹ The applicable percentages are used in combination with factors including annual household income and the cost of the benchmark plan to determine the PTC amount for which a taxpayer can qualify to help pay for a QHP on an Exchange for themselves and their dependents.⁶² These decreased percentages generally result in increased PTC for PTC-eligible taxpayers, and for those with household incomes no greater than 150 percent of the FPL, the new applicable percentage is zero. As a result of these changes, many low-income consumers with a household income no greater than 150 percent of the FPL whose QHP coverage can be fully paid for with APTC have one or more options to enroll in a silver-level plan without needing to pay a premium after the application of APTC. All of these consumers, if eligible to enroll through an Exchange and to receive APTC, will qualify for CSRs to enroll in a silver plan with an AV of 94 percent.⁶³

⁵⁹ As noted in the proposed rule, a qualifying individual is generally not eligible for a PTC if their household income is below 100 percent of the FPL, but there are a small number of consumers with a household income below 100 percent of the FPL who may qualify for APTC. Specifically, section 36B(c)(1)(B) of the Code provides that a taxpayer with a household income which is not greater than 100 percent of the FPL, and who is a lawfully present immigrant and ineligible for Medicaid due to their immigration status, may qualify for a PTC. Consumers for whom this is the case would be able to qualify for the proposed special enrollment period, as well. Additionally, HHS notes that because individuals would qualify for this special enrollment period based on their household income level, household members who apply for coverage with financial assistance together generally will all qualify for the special enrollment period. However, it is also possible that one household member could trigger the special enrollment period based on a change in their eligibility for APTC – for example, a household member who loses access to an offer of coverage through an employer that is considered affordable based on 26 CFR 1.36B-2(c)(3)(v).

⁶⁰ 86 FR 35169.

⁶¹ Pub L. 117-2.

⁶² See 26 CFR 1.36B-3(g) for more information on the applicable percentage and its relationship to the PTC.

⁶³ See §§ 155.305(g)(2) and 156.420(a).

HHS proposed that this special enrollment period be available at the option of the Exchange, in order to allow State Exchanges to decide whether to implement it based on their specific market dynamics, needs, and priorities. Additionally, HHS proposed that Exchanges on the Federal platform will implement this special enrollment period by providing qualified individuals who are eligible with a pathway to access it through the HealthCare.gov application. HHS proposed that implementation in Exchanges on the Federal platform be consistent with current special enrollment period policy and operations, in particular such that there is no limitation on how often individuals who are eligible for this special enrollment period can obtain or utilize it.⁶⁴ Consistency in this area will mitigate consumer and other stakeholder confusion and simplify Exchange operations. To provide Exchanges with flexibility to prioritize ensuring that qualifying individuals are able to obtain coverage through this special enrollment period quickly following plan selection, or to implement this special enrollment period in keeping with their current operations, HHS proposed to add a new paragraph at § 155.420(b)(2)(vii) to provide that the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the month following plan selection, at the option of the Exchange.

HHS also proposed to add a new paragraph at § 155.420(a)(4)(ii)(D) to provide that an Exchange must permit eligible enrollees and their dependents to change to a silver-level plan, and to amend paragraph § 155.420(a)(4)(iii), which provides other plan category limitations for other special enrollment periods, to provide that these other plan category limitations do not apply to enrollees or dependents who qualify for the proposed special enrollment period.⁶⁵ Finally, HHS proposed to add a new paragraph at § 147.104(b)(2)(i)(G) to specify that issuers

⁶⁴ For example, those who qualify for the special enrollment period per § 155.420(d)(8) for qualifying individuals who gain or maintain status as an Indian, as defined by section 4 of the Indian Health Care Improvement Act, may change their plan selection multiple times each month, noting that only the last plan selection before the applicable cutoff date for coverage each month will take effect for the month in question.

⁶⁵ This provision would not prevent enrollees who qualify for the new special enrollment period from changing to a plan of any category through a special enrollment period that provides this flexibility, including the special enrollment periods at § 155.420(d)(4), (8), (9), (10), (12), and (14).

are not required to provide this special enrollment period in the individual market with respect to coverage offered outside of an Exchange, because eligibility for the special enrollment period is based on eligibility for APTC, and APTC cannot be applied to coverage that is not a QHP offered through an Exchange.⁶⁶

In consideration of public comments that HHS received, HHS is finalizing this monthly special enrollment period for APTC eligible consumers with a projected annual household income no greater than 150 percent of the FPL with coverage effective dates and other eligibility parameters as proposed, but is finalizing it so that the special enrollment period is only available during periods of time during which PTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero. HHS is also finalizing a revision to the language of proposed paragraph § 155.420(a)(4)(ii)(D) to reflect that an enrollee who is adding a qualified individual or dependent through this special enrollment period may add the newly-enrolling household member to their current QHP; or, change to a silver-level QHP and add the newly-enrolling household member to this silver-level QHP; or, change to a silver-level QHP and enroll the newly-enrolling qualified individual or dependent in a separate QHP. In consideration of concerns raised by commenters as further discussed below, HHS believes that this modification is appropriate to provide clarity on options and limitations for enrollees whose household members newly enroll through this special enrollment period. In particular, this change makes clear that while newly-enrolling qualified individuals and dependents are not subject to plan category limitations, enrollees with a newly-enrolling dependent or other household member may not use the new monthly special enrollment period to change to a plan of a different metal level other than a silver-level QHP to enroll together with their newly-enrolling household member, but can stay in the same plan or change to a silver plan to enroll together with the newly-enrolling household member. This limitation will help to mitigate adverse selection. Also, the revision HHS is finalizing makes clear that the limitation that applies to this new special

⁶⁶ See IRC 36B(b)(2)(A), (c)(2)(A)(i).

enrollment period functions similarly to other plan category limitations, such as those at § 155.420(a)(4)(iii)(B) and (C) for enrollees who are adding one or more newly-enrolling dependents or household members to their Exchange coverage.

In addition to finalizing the previously stated modifications, HHS is also finalizing conforming updates to regulatory text at § 155.420(a)(4)(ii)(C). HHS proposed to add new paragraph (a)(4)(ii)(D) which provided that where an enrollee “or” his or her dependents qualify for a special enrollment period under § 155.420(d)(16) and is not enrolled in a silver-level QHP, the Exchange must allow the enrollee and their dependents to change to a silver-level QHP if they elect to change their QHP enrollment. HHS also proposed to align existing regulatory text at § 155.420(a)(4)(ii)(C) with this new paragraph, and with the related special enrollment period triggering event at § 155.420(d)(6)(i) and (ii), by updating a sentence reading “if an enrollee *and* his or her dependents” to “if an enrollee *or* his or her dependents.” These edits align with corresponding special enrollment period triggering events at § 155.420(d) to which plan category limitations at (a)(4) refer.

As discussed in previous rulemaking, certain provisions under § 155.420(d) defining special enrollment period triggering events refer both to a qualified individual and the qualified individual’s dependents, and use “or” (rather than “and”) to be clear that when a qualified individual or enrollee, *or* his or her dependent, experiences the special enrollment period triggering event, all members of a household generally may enroll in or change plans together in response to the event experienced by one member of the household, subject to the limitations in § 155.420(a)(4).⁶⁷ Therefore, HHS is finalizing as proposed this change to § 155.420(a)(4)(ii)(C).

Although HHS proposed revisions to § 155.420(a)(4)(ii)(C) to align with the text of triggering event provisions under § 155.420(d), HHS neglected to propose similar but necessary

⁶⁷ See 78 FR 42262. Also, the 2017 Market Stabilization Rule used the phrase “if an enrollee *or* his or her dependent” when describing the rule that would be finalized at what is now paragraph § 155.420(a)(4)(ii)(A), See 82 FR 18359.

changes to the text of § 155.420(a)(4)(ii)(A) and (B). HHS intends to propose these changes in future rulemaking. Because this is a technical change, HHS does not anticipate that it will impact Exchanges' operations or messaging. However, if the change does affect an Exchange's operations, CMS will not consider the Exchange to be out of compliance with the rule due to interpreting the plan category limitations rules as aligning with the related special enrollment period qualifying events at § 155.420(d).

This new monthly special enrollment period will be available at the option of the Exchange, as proposed, in order to allow State Exchanges to decide whether to implement it based on their specific market dynamics, needs, and priorities. HHS is also finalizing that Exchanges on the Federal platform will implement this special enrollment period by providing qualified individuals who are eligible with a pathway to access it through the HealthCare.gov application.

The APTC benefit changes under the ARP make affordable coverage available to more uninsured people. However, as discussed in the proposed rule, if past trends continue, HHS believes that some consumers who qualify for these benefits under the ARP may continue to forgo enrollment in premium-free coverage due to a lack of awareness of the opportunity to enroll or a misconception about what the coverage would cost, and that low-income consumers who have lacked coverage for more than a year may be especially difficult to reach.⁶⁸ Therefore, while HHS will undertake extensive outreach and engagement efforts to promote enrollment during the open enrollment period for 2022 coverage and to help ensure consumer awareness of existing special enrollment periods for which they may qualify, given the established challenges with promoting awareness of access to coverage among low-income consumers, HHS believes additional enrollment opportunities for low-income consumers are appropriate and in the best interest of low-income consumers. Additionally, as noted in the proposed rule, the monthly

⁶⁸ Key Facts about the Uninsured Population: Kaiser Family Foundation; Nov 06, 2020, <https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/>.

special enrollment period policy would align with EO 14009, which requires Federal agencies to identify and appropriately address policies that create barriers to accessing ACA coverage, including access through mid-year enrollment.

In addition to providing certain low-income individuals with additional opportunities to newly enroll in free or low-cost coverage that is available to them, HHS believes this special enrollment period may help consumers who lose Medicaid coverage to regain health care coverage. While, as discussed in the proposed rule, these consumers can already qualify for a special enrollment period due to their loss of Medicaid coverage per § 155.420(d)(1), and may also have access to other flexibilities, whether members of this group of consumers are able to benefit from existing enrollment periods and flexibilities may vary, and may require Exchanges to assess eligibility on a case-by-case basis. This may also require consumers who generally have low household income and who therefore may face other barriers to accessing health care coverage, such as low health insurance literacy levels and lack of Internet access, to be aware of the potential for an extended enrollment timeframe and to request it from their Exchange. As also discussed in the proposed rule, after the COVID-19 PHE comes to an end, HHS expects to see a higher than usual volume of low-income individuals transitioning from Medicaid coverage to the Exchanges for at least several months as states begin to catch up on a backlog of redeterminations and terminations for Medicaid beneficiaries after having generally suspended Medicaid disenrollments since March 2020 to comply with the continuous enrollment provisions in section 6008(b)(3) of the Families First Coronavirus Response Act.⁶⁹ Therefore, while this special enrollment period would not be limited to qualified individuals who have lost Medicaid coverage, HHS noted that providing access to a monthly enrollment opportunity could help some consumers who lose Medicaid coverage to regain health insurance coverage, especially those who do not initially realize that loss of Medicaid is a special enrollment period triggering event.

⁶⁹ Pub. L. 116-127. These provisions enabled states to receive the temporary Federal Medical Assistance Percentage increase under that section.

This special enrollment period could help mitigate the risk of long-term coverage disruptions due to the potentially high volume of Medicaid terminations following the end of the COVID-19 PHE, by giving qualifying individuals who lose Medicaid and who may miss or misunderstand notifications about their coverage loss more time to enroll in Exchange coverage.⁷⁰

As proposed, Exchanges that elect to provide this special enrollment period would have the option to require consumers to submit documentation to confirm their eligibility in accordance with their pre- or post-enrollment verification programs. However as discussed in the proposed rule, CMS will determine eligibility for this special enrollment period in Exchanges on the Federal platform based on consumers' attested household income. Once an Exchange on the Federal platform grants this special enrollment period to a consumer based on their attested household income, the Exchange will then verify applicants' projected annual household income consistent with 45 CFR 155.320(c).⁷¹ Specifically, CMS will continue to require consumers whose projected annual household income cannot be verified using a trusted electronic data source to submit documentation to confirm their annual income (currently approved under OMB control number 0938-1207/Expiration date February 29, 2024). CMS will not require submission of household income documentation prior to enrollment, and will not pend the enrollment as part of a pre-enrollment verification process, in part because CMS's experience administering the verification processes for Exchanges on the Federal platform in accordance with § 155.320(c) shows that submitting documentation quickly to verify income can be especially onerous for those at the lowest income levels who may not have ready access to a computer or smartphone, the internet, a copier or scanner, or funds for postage.

In addition to outreach and education efforts, HHS noted that HHS believed that applying plan category limitations to this special enrollment period would help to mitigate adverse selection because it would limit the ability of enrollees to change to a higher metal level plan

⁷⁰ See 86 FR 35170 for discussion of this issue in the proposed rule.

⁷¹ Section 1411(c)(3) of the ACA.

based on a new health care need and then change back to a silver plan once the health issue is resolved. However, HHS acknowledged that enrollees may still choose to enroll in a silver-level plan that is more expensive than their zero dollar option, and, while HHS believes that enrollees will likely be deterred from changing plans mid-year because such a change will generally mean they lose progress they have made toward meeting their deductible and other accumulators, HHS acknowledged that through a monthly special enrollment period, enrollees could change plans mid-year based on differences in provider networks or prescription drug formularies. HHS sought comment on this proposal and on whether, alternatively, plan category limitations should not be applied. For example, HHS sought comment on whether to instead exempt the proposed special enrollment period at § 155.420(d)(16) from plan category limitations in order to alleviate the implementation burden on Exchanges, or due to a lack of concern that eligible enrollees would use the proposed special enrollment period to change to a plan category other than silver.

HHS also sought comment on the degree to which the risk of adverse selection increases due to the fact that not all qualifying individuals who have a household income no greater than 150 percent of the FPL and whose applicable percentage is therefore set at zero will have access to a silver plan with a zero-dollar premium, and therefore might be more inclined to enroll in coverage due to a health care need and end coverage once this need has been met rather than pay even a relatively small premium.

HHS estimated that this 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, when the enhanced APTC provisions of the ARP are in effect (currently, plan year 2022). HHS described this impact in more detail in the regulatory impact analysis (RIA) section in the proposed rule.⁷² HHS also discussed some of the reasons adverse selection can be mitigated, but not altogether eliminated.

⁷² See the proposed rule at 86 FR 35206 through 35207 for more detail on this discussion.

HHS sought comment from health insurance issuers and other stakeholders on its position that adverse selection related to this special enrollment period will be mitigated by the availability of free or very low-cost coverage with a 94 percent AV and the application of plan category limitations to this new special enrollment period, or whether the adverse selection risk created by this new special enrollment period cannot be sufficiently mitigated such that its creation may result in significant rate increases. HHS also solicited comment regarding whether health insurance issuers and other stakeholders have concerns that the policy could cause any adverse selection among higher-income individuals with variable hours and income. HHS sought comment on whether the requirement that Exchanges verify applicants' projected annual household income post-enrollment, consistent with 45 CFR 155.320(c), is sufficient, or if there are other measures HHS should put in place to further protect program integrity. HHS also solicited comment on estimated implementation burdens for Exchanges that elect to provide this additional enrollment opportunity, including whether implementation of this special enrollment period will be possible in time for consumers to benefit from it during the 2022 plan year. HHS requested comment on whether issuers will have sufficient time to adjust rate filings to account for any increased risk and whether state regulators will have sufficient time to review those filings after a final rule is issued.

HHS further requested comment on whether this proposed special enrollment period should be available indefinitely (as proposed), or whether it should be time-limited. For example, HHS sought comment on whether HHS should finalize the proposed special enrollment period to be available only for coverage during years when enhanced APTC benefits are also available, as provided by the section 9661 of the ARP or any subsequent statute. Finally, HHS requested comment on strategies for providing outreach and education for consumers who may be eligible for this special enrollment period, in particular to help qualifying individuals understand and take advantage of the free or very low-cost coverage that is available to them. Within this group, HHS requested comments on strategies for educating consumers who qualify to enroll in a 94 percent

AV silver plan about the benefits of enrolling in such a plan even if they are required to pay a small premium, as opposed to electing a premium-free bronze plan with a lower AV.

The following is a summary of the comments received and HHS's responses regarding the proposals related to the monthly special enrollment period for APTC-eligible qualified individuals with a household income no greater than 150 percent of the FPL and whose applicable percentage therefore is zero (§ 155.420(d)(16)).

Comment: Many commenters supported the proposal to provide a monthly special enrollment period to APTC-eligible individuals with projected annual household income no higher than 150 percent of the FPL, and a number of them agreed with and expanded upon HHS's position that it would positively impact health equity. For example, several commenters agreed that lower-income individuals often face greater barriers to enrollment, such as a lack of an internet connection or other computer equipment, limited available time due to working multiple jobs, and LEP. Commenters also noted that this group of consumers is disproportionately made up of people of color. Several commenters noted that they expected this special enrollment period to be especially helpful to individuals in their area whose income is under 100 percent of the FPL, but who do not qualify for Medicaid because of their immigration status, and who therefore may qualify for APTC. They noted that this group can be difficult to reach through outreach and education, and therefore may benefit significantly from additional opportunities to enroll throughout the year. Several commenters voiced support for outreach and education to promote awareness of this special enrollment period as well as other special enrollment period qualifying events. Some added that currently-available enrollment opportunities are underutilized due to their complexity and due to the challenges associated with learning about and enrolling in coverage. Some commenters encouraged CMS to focus outreach and education efforts on vulnerable communities, individuals with LEP, immigrants, and the LGBTQ+ community. A few commenters specified potential outreach strategies, such as engaging schools and community health workers.

Response: As discussed in the proposed rule, HHS agrees that providing a monthly enrollment opportunity for certain low-income consumers will increase the likelihood that more of these consumers are able to access coverage in spite of barriers that this group, which disproportionately includes people of color, often face. A May 2021 report by the Kaiser Family Foundation estimates that there are approximately 10.9 million uninsured people who are both eligible for coverage through the Exchange and eligible for subsidies under the ACA and ARP.⁷³ The report found that compared to the general non-elderly population in the U.S., this population is more likely to be Hispanic, people with a high school diploma or less, and young adults ages 19 to 34. Additionally, it found that uninsured people eligible for subsidies are more likely to live in rural areas and lack internet access than the general non-elderly population in the U.S. The report also noted that the estimated 6 million uninsured people who may be eligible for a zero-dollar premium plan through the Exchange after application of APTC are more likely to be non-English speakers at home. Providing a monthly enrollment opportunity will give this population of uninsured people more opportunities to access coverage and provide more time for targeted outreach to consumers who may be harder to reach and enroll, such as those who are non-English speakers at home. HHS agrees with commenters' support for robust outreach and education efforts targeted in particular to ensuring awareness and understanding of this special enrollment period and other enrollment opportunities, and will continue to work with stakeholders to develop and optimize targeted messaging.

Comment: Some commenters who supported the proposed special enrollment period were skeptical that it would pose a significant adverse selection risk, citing as mitigating factors the high rate of subsidization for qualifying individuals and the likelihood that younger, healthier individuals would enroll. Many of these commenters also cited comparable state experiences as evidence of the low likelihood of adverse selection and high likelihood of a positive impact on

⁷³ Kaiser Family Foundation. A closer look at the uninsured marketplace eligible population following the American Rescue Plan Act. May 2021. <https://www.kff.org/private-insurance/issue-brief/a-closer-look-at-the-uninsured-marketplace-eligible-population-following-the-american-rescue-plan-act/>.

reducing uninsured rates should CMS finalize the proposed special enrollment period. Some commenters said that State Exchange data on risk factors associated with enrollees who accessed coverage through a special enrollment period, including the special enrollment period that State Exchanges provided during the 2020 or 2021 plan years due to the COVID-19 pandemic, indicated that these enrollees did not pose significant additional risk. One of these commenters asked that CMS analyze data on special enrollment period enrollees in states that use the HealthCare.gov platform, and suggested that such analysis would yield a similar result.

For example, multiple commenters cited the Massachusetts State Exchange's enrollment opportunity for individuals with a household income no higher than 300 percent of the FPL, and the ability of consumers up to 200 percent of the FPL to enroll in the Basic Health Program year-round in Minnesota and New York. Specifically, one commenter noted that in Massachusetts, consumers with household incomes up to 300 percent of the FPL may qualify for coverage with low or no monthly premiums, low copays, and no deductibles through the state's Health Connector's ConnectorCare program, and that these individuals, once determined eligible for ConnectorCare, qualify for a 60-day special enrollment period to enroll in coverage at any point during the plan year. The commenter added that in spite of this flexible enrollment opportunity, the state has not experienced individual market adverse selection within the program, and enrollment in the program has remained stable over time. In fact, the commenter noted that the average risk score for insurers participating in ConnectorCare is lower than the risk score for insurers in their individual market outside of ConnectorCare. Finally, the commenter noted a low rate of changes in plans among current enrollees during the mid-2021 enrollment period that the state established due to the COVID-19 pandemic, adding that this experience suggests less risk of adverse selection due to current enrollees changing plans in response to an emerging medical need.⁷⁴

⁷⁴ Specifically, the commenter stated that 0.23 percent of Health Connector members changed plans from June to July 2021.

Another commenter cited reports that indicated issuers had not found evidence of adverse selection due to the ability of individuals with a household income up to 200 percent of the FPL to enroll year-round in a Basic Health Program in New York or Minnesota.⁷⁵ This commenter also cited a report that suggested, based on data from states that offered a mid-year special enrollment period in 2020 due to the COVID-19 pandemic, that these enrollment periods resulted in individuals enrolling who were younger and healthier than those who enrolled during the annual open enrollment period.⁷⁶ Another commenter provided data from DC Health Link, the Washington, DC State Exchange, that indicated that a higher percentage of younger enrollees accessed coverage through the mid-2020 special enrollment period than through the annual open enrollment period.

However, some commenters did not support finalizing this special enrollment period, primarily due to concerns that it posed significant adverse selection risks. Several of these commenters said that in the proposed rule, CMS significantly underestimated the increase in rates due to adverse selection that would result from the proposed special enrollment period. Commenters also raised the concern that qualifying individuals would learn about their enrollment opportunity due to experiencing a health event, and a few also worried that consumers would decline to renew coverage once a medical need had ended, or lose coverage because of the need to pay even a relatively small premium. Commenters also voiced concerns specifically about adverse selection the proposed special enrollment period could create for plans with broad provider networks due to the potential for qualifying enrollees to change plans mid-year to access a specific provider or prescription drug. Some of these commenters were concerned that health care providers would encourage current enrollees to change plans based on an emerging health care need, in order to access coverage for items or services furnished by a

⁷⁵ See Improving the Affordability of Coverage through the Basic Health Program in Minnesota and New York, Kaiser Family Foundation, Dec. 8, 2016, available at <https://www.kff.org/report-section/improving-the-affordability-of-coverage-through-the-basic-health-program-in-minnesota-and-new-york-issue-brief/>.

⁷⁶ See Many States with COVID-19 Special Enrollment Periods See Increase in Younger Enrollees, The Commonwealth Fund, Jan. 28, 2021, available at <https://www.commonwealthfund.org/blog/2021/many-states-covid-19-special-enrollment-periods-see-increase-younger-enrollees>.

provider that does not participate in the consumer's current plan's network. Several commenters added that due to these adverse selection risks, the proposed special enrollment period would result in narrower networks and fewer choices for consumers.

Other concerns included the likelihood that adverse selection would drive up rates and that these rate increases would disproportionately impact unsubsidized consumers. Additionally, several commenters agreed that, as noted in the proposed rule, adverse selection and related increases in individual health insurance premiums would vary significantly by state based on specific market conditions such as Medicaid expansion status. Several commenters, including some that supported the proposal, asked that CMS monitor the individual market for impacts of adverse selection, and one commenter asked us to engage in additional rulemaking if evidence of significant adverse selection is found. A few commenters were also concerned that the applicable risk adjustment methodology would not adequately compensate issuers for individuals who enroll through the special enrollment period and, as a result, have partial-year or short enrollment terms.

Response: HHS agrees that, in many cases, special enrollment periods may encourage consumers who are younger and healthier than average to enroll. Additionally, HHS acknowledges that some Exchanges that have expanded enrollment opportunities for consumers with a projected annual household income below a certain threshold have not experienced significant negative impacts from adverse selection. However, HHS appreciates concerns that the risk of adverse selection may vary significantly based on market conditions specific to different Exchanges, and HHS's goal is also to achieve a balanced approach that takes into account these varying conditions as much as possible. Therefore, HHS is finalizing this special enrollment period as proposed but limiting it to be available only during periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero.

HHS believes that the time-limited nature of this special enrollment period, and providing Exchanges with flexibility in terms of whether to implement it, will help to mitigate concerns

about adverse selection, especially when combined with robust outreach and education efforts to maximize the number of qualifying individuals who gain coverage through the special enrollment period based on an understanding of its availability as opposed to due to an emerging health care need.

HHS also appreciates concerns about the impact of rate increases on unsubsidized enrollees and will work with stakeholders to monitor the markets to track potential adverse selection impacts of the special enrollment period. Currently, however, HHS is of the view that the enhanced benefits available under the ARP mitigate adverse selection risk such that premiums for subsidized and unsubsidized consumers will rise no more than 0.5 to 2 percent as a result of this special enrollment period. In assessing the impact on unsubsidized consumers, HHS also considered that under section 9661 of the ARP, consumers may qualify for premium tax credits at any point at which they would be required to contribute more than 8.5 percent of their annual household income to their benchmark health insurance plan. However, HHS will work with stakeholders to monitor and evaluate the impacts of this policy on individuals who do not qualify for PTC (or who qualify for a maximum amount of zero dollars of PTC), including consideration of possible approaches to address them as may be necessary.

Finally, HHS notes that the HHS-operated risk adjustment methodology added enrollment duration factors to the adult risk adjustment models starting with the 2017 benefit year.⁷⁷ These enrollment duration factors are used in the calculation of adult enrollee risk scores under the state payment transfer formula to account for additional risk associated with enrollees with partial-year enrollment.⁷⁸ They do so through a set of 11 enrollment duration binary indicatory variables that signify that an enrollee had exactly one to 11 months of enrollment in a

⁷⁷ See 81 FR at 94071 - 94074. Since the 2017 benefit year, HHS has operated the risk adjustment program in all 50 states and the District of Columbia. Massachusetts ran its own risk adjustment program for benefit years 2014-2016. See, e.g., page 5 of the March 2016 Risk Adjustment Methodology White Paper (March 24, 2016), available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

⁷⁸ For more information on the enrollment duration factors, see 85 FR at 7103, 7104.

given plan.⁷⁹ The value of these indicators decreases monotonically from one to 11 months, reflecting the increased annualized costs associated with fewer months of enrollment. Adult enrollees who enrolled during this special enrollment period will receive the applicable risk adjustment enrollment duration factor in the risk score calculation. While HHS continues to evaluate the current enrollment duration factors, HHS generally disagrees with comments asserting the risk adjustment methodology does not adequately address partial year enrollees.⁸⁰

Comment: Some commenters voiced the concern that providing this open-ended enrollment opportunity would undermine the goal of continuous coverage, decreasing issuers' ability to connect with beneficiaries and making it less likely that certain qualifying consumers would take advantage of preventive care. A few added the concern that consumers changing plans mid-year might not realize their deductibles and other accumulators would reset, and unexpectedly would end up paying more out-of-pocket than if they had remained enrolled in the same plan. Some commenters were concerned about individuals attesting to a lower-than-accurate annual household income in order to gain coverage, and one commenter added the concern that these consumers would unexpectedly have to pay back APTC at tax time for which they were not eligible based on actual annual household income. Some commenters suggested that qualifying enrollees might decide to change plans in spite of the knowledge that their accumulators would reset, with one commenter noting that the relatively low deductible and other cost-sharing requirements for a plan with a 94 percent AV were not a sufficient incentive for enrollees to preserve progress they had made towards meeting maximum cost-sharing requirements. Finally, a few commenters said that HHS does not have statutory authority to establish the proposed special enrollment period, because section 1311(c)(6) of the ACA refers

⁷⁹ See, e.g., *Enrollment Duration Factors* in Table 2: Final Adult Risk Adjustment Factors for 2017 Benefit Year, 81 FR at 94088; and *Enrollment Duration Factors* in Table 1: Final Adult Risk Adjustment Factors for 2022 Benefit Year, available at <https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf>.

⁸⁰ HHS proposed but did not finalize updates to the enrollment duration factors in the 2022 Payment Notice. See 86 FR at 24151 – 24162. Also see 85 FR at 78581 – 78586.

to specific qualifying events and HHS has limited authority to establish special enrollment periods that are not included in this list.

Response: HHS disagrees that this special enrollment period opportunity will discourage eligible consumers from maintaining continuous coverage once they have learned about and been able to access the free or low-cost coverage available to them. In HHS's view and based on State Exchanges' experiences, it is more likely that consumers who newly gain access to free or low-cost coverage through this special enrollment period will maintain such coverage because of its affordability and comprehensiveness. HHS appreciates concerns that consumers who are enrolled in Exchange coverage may not be aware that changing plans mid-year will cause their deductible and other accumulators to reset, and HHS will continue working to develop and enhance messaging to make consumers and other stakeholders, such as enrollment assisters, understand that this is the case. HHS disagrees that qualifying enrollees with a 94 percent AV silver plan will not have an incentive to preserve progress they make during the year toward meeting their deductible and other cost-sharing requirements, because for enrollees who qualify for income-based CSRs, the deductible and cost-sharing requirements under the plan variation is based on household income, and such amounts therefore likely do not represent insignificant amounts relative to that household income.

HHS notes that consumers who apply for Exchange coverage on HealthCare.gov are required to attest multiple times, at the beginning and end of the application process, that the information they have provided is correct.⁸¹ As part of the implementation of this special enrollment period, HHS will also continue to emphasize to applicants and current enrollees the importance of attesting to an accurate and up-to-date estimate of their annual household income. Additionally, when applicants attest to a household income amount that CMS cannot verify using a trusted data source, HHS generates an income "inconsistency" explaining that this is the case

⁸¹ For example, before signing and submitting their application, all consumers see the statement, "I'm signing this application under penalty of perjury, which means I've provided true answers to all of the questions to the best of my knowledge. I know I may be subject to penalties under Federal law if I intentionally provide false information."

and requiring the consumer to submit additional information. This process involves extensive outreach and education, which helps ensure that consumers understand the importance of attesting to an accurate household income amount, including how their attested household income informs the APTC that they receive. Further, once the special enrollment period has been implemented, HHS will monitor uptake and the occurrence of income inconsistencies among qualifying individuals, and work with stakeholders as appropriate to address instances of potential abuse. Finally, 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.⁸²

Comment: Several commenters raised the concern that HHS underestimated rate increases due to the proposed special enrollment period, and that issuers had not incorporated this risk into their rates for the 2022 plan year. However, no commenters recommended giving issuers an additional opportunity to adjust rates – one did not believe such an opportunity was needed, and the others did not believe that there was enough time for issuers to submit and regulators to review updated rates before the 2022 plan year. One commenter requested that HHS delay making the proposed special enrollment period available until the 2023 plan year in order to provide issuers with adequate time to incorporate related risk into their rates. Some commenters who did not support the special enrollment period suggested that, if it were to be finalized, it should be limited to the first few months of the year. These commenters noted that the tax season could be leveraged to promote the special enrollment period, and that this limitation was reasonable because consumers should be able to accurately predict their annual income once they have completed the Federal income tax filing process.

⁸² See, for example, 77 FR 18310, 18312 (Mar. 27, 2012), and 78 FR 42160, 42162 (July 15, 2013).

Response: Because of the benefit to consumers who are eligible for free or very low-cost coverage provided by enhanced APTC through the ARP from having additional opportunities to enroll in Exchange coverage while this enhanced assistance is in place, HHS is finalizing the special enrollment period to be available for the 2022 plan year. However, HHS is limiting it to be available only during periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero. Further, HHS appreciates concerns that issuers and other stakeholders benefit from having as much time as possible to adjust rates and other planning processes based on upcoming developments. However, in some instances, particularly in the context of a PHE such as the COVID-19 pandemic, HHS believes that rapid responses are warranted and necessary to help ensure as many individuals as possible can access basic necessities such as health insurance coverage and care. Further, HHS believes it is appropriate to provide this special enrollment period for the full duration of time that enhanced APTC benefits are available in order to maximize opportunities for qualifying individuals to enroll. Finally, while the Federal income tax filing process may be helpful for some consumers as a way to estimate their annual household income, HHS notes that this is not necessarily the case, because the Federal income tax filing process is based on prior year household income, and applicants for future or current year Exchange coverage with financial assistance must estimate their household income for the upcoming or current coverage year, and annual household income can fluctuate significantly from one year to another.

Comment: Several commenters that opposed the special enrollment period due to concerns about adverse selection and resulting rate increases said that, if finalized, they strongly supported applying plan category limitations as proposed. Some of these commenters also recommended that qualifying individuals be limited even further; for example, to a specific plan or plans such as the second lowest-cost or lowest-cost silver plan available to them, or to a plan with an AV of 94 percent. Some commenters expressed stronger concerns about adverse selection due to enrollees changing plans based on provider network rather than based on metal

level. Some commenters asked that only currently uninsured consumers be permitted to use the special enrollment period, or that consumers only be permitted to access the special enrollment period once per year, or if they had not yet received any APTC for the year, in order to help mitigate adverse selection.

Response: As discussed in the proposed rule, HHS believes that applying plan category limitations to this special enrollment period will help to mitigate adverse selection, because it will limit the ability of enrollees to change to a higher metal level plan based on a new health care need and then change back to a silver plan once the health issue is resolved. Further, HHS notes that all consumers who qualify for this special enrollment period and choose to enroll in a silver-level plan will gain coverage with a 94 percent AV based on their projected annual household income level. HHS does not believe that it is necessary to limit enrollees to one or several specific silver-level plan(s), because HHS believes that enrollees who are interested in changing plans during the year will generally be deterred as such a change will often mean they lose progress they have made toward meeting their deductible and other accumulators. Additionally, requiring this type of restriction, limiting use of the special enrollment period to once per year per consumer, or limiting the special enrollment period to consumers who had not yet received APTC during the applicable plan year, would impose additional complexity on Exchanges to the point that implementation would not be possible in time for the 2022 plan year. However, in consideration of these concerns, HHS is clarifying at § 155.420(a)(4)(ii)(D) that an enrollee who is adding a qualified individual or dependent may add the newly-enrolling household member to their current QHP; or, change to a silver-level QHP and add their newly-enrolling household member to this silver-level QHP; or, change to a silver-level QHP and enroll the newly-enrolling qualified individual or dependent in a separate QHP. HHS believes that this language is appropriate to provide clarity on options and limitations for enrollees whose household members newly enroll through this special enrollment period. In particular, this language clarifies that, while newly-enrolling qualified individuals and

dependents are not subject to plan category limitations, current enrollees with a newly-enrolling dependent or other household member may not use this new special enrollment period to change to a plan of any metal level along with their newly-enrolling household member.

Comment: One commenter misunderstood the proposal to newly permit enrollees to change from one metal level to another, and raised concerns about how such changes could affect enrollment in standalone dental plans. Another commenter asked for clarification that individuals will still qualify for the other special enrollment periods only when they experience a special enrollment period qualifying event that makes them eligible.

Response: HHS clarifies that this proposal, and the resulting final rule, do not newly permit Exchange enrollees to change to a plan of a different metal level or make policy changes to plan category limitations for existing special enrollment periods. Rather, the new rule establishes a plan category limitation to address a newly-created special enrollment period triggering event and makes a small technical clarification to the preceding paragraph, as further discussed earlier in this preamble. Further, HHS has discussed and extensively investigated concerns about accidental standalone dental plan disenrollment due to a change in medical QHP and has not found this to be a problem in practice for HealthCare.gov enrollees, who are always offered the opportunity to select or re-select their standalone dental plan after completing medical QHP selection. Finally, HHS clarifies that the new monthly special enrollment period does not change or expand eligibility requirements for other special enrollment period qualifying events at § 155.420(d).

Comment: A few commenters asked that HHS require pre-enrollment verification of income for consumers to qualify for this special enrollment period. However, several commenters supported the proposal not to require such verification, and one commenter encouraged HHS to monitor even post-enrollment income verification to ensure that it did not present a significant barrier to low-income consumers seeking to enroll in coverage.

Response: As discussed in the proposed rule, HHS believes that the post-enrollment income verification process already in place consistent with § 155.320(c) is sufficient to ensure program integrity, because consumers who do not verify their attested household income through the post-enrollment verification process will have their APTC adjusted accordingly. Further, HHS agrees with commenters' concerns that imposing a pre-enrollment income verification process would prevent eligible consumers from accessing coverage through the special enrollment period, especially those who represent marginalized communities that face barriers to accessing documentation quickly and those who are younger and healthier, and therefore, have less incentive to devote time to a complex enrollment process.

Comment: Some commenters that did not have adverse selection concerns asked HHS not to finalize the proposed special enrollment period to be limited to the period of time during which enhanced APTC is available per ARP or other statutory authority. These commenters' position was that even without the ARP's enhanced APTC, consumers with household income below a certain FPL are heavily subsidized enough to mitigate adverse selection. However, commenters with concerns about adverse selection, including some who otherwise supported offering the special enrollment period as proposed, requested that, if finalized, CMS limit its availability to periods when APTC is available at the level provided for under the ARP.

Response: To an extent, HHS agrees with certain commenters that some markets could see limited effects of adverse selection if the proposed special enrollment period were available permanently, depending on individual market conditions. However, as discussed in the proposed rule, HHS believes that that access to 94 percent AV coverage premium-free or at very low-cost after application of APTC will help to mitigate risk of adverse selection, because qualifying individuals will not have an incentive not to enroll or to end coverage when health care services are no longer needed. HHS also agrees with commenters' concerns that even a relatively small premium could introduce additional risk of adverse selection. Therefore, HHS is finalizing this special enrollment period to be available only during periods of time during which APTC

benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP.

Comment: Several issuers provided recommendations for alternatives to the proposed special enrollment period that would assist consumers with transitioning between Medicaid and Exchange coverage – for example, a few commenters suggested providing an extended loss of coverage special enrollment period window to those who lose Medicaid coverage due to the end of the COVID-19 PHE. Other suggestions included establishing policy similar to a Medicaid waiver in New York under section 1115 of the Social Security Act that allows issuers who are Medicaid Managed Care Organizations (MCOs) to assist consumers with re-enrollment, and suggested that HHS permit MCOs to auto-enroll consumers eligible to transition into a corresponding QHP, or generally facilitate enhanced communication between issuers and enrollees to allow issuers to provide more support for transitions. One commenter suggested that instead of providing this special enrollment period, HHS automatically enroll all qualifying individuals into coverage with the option to opt out. One commenter supported the proposed special enrollment period but also offered suggestions for improving consumers' transition from Medicaid to Exchange coverage. Another commenter who supported the proposed special enrollment period requested that, in addition, HHS also provide guidance in rulemaking on an “Automatic Retention” program that would automatically enroll individuals who miss premium payments into a plan available without premiums after application of the APTC until they lose eligibility or cancel their plan.

Response: As discussed in the proposed rule, HHS believes that providing a special enrollment period for all APTC-eligible individuals with a household income up to 150 percent of the FPL, and whose applicable percentage is therefore set at zero, will be an important tool to help these consumers access coverage. However, HHS also appreciates the interest in developing additional strategies for improving the transition from Medicaid to Exchange coverage and

encouraging newly enrolling individuals and current enrollees to maintain continuous coverage, and HHS will continue to work with stakeholders in the future to do so.

Further, HHS notes that there are other existing special enrollment periods that may support Medicaid beneficiaries' transition to Exchange coverage at the end of the COVID-19 PHE. For example, if state Medicaid programs or Medicaid MCOs experience delays in delivering notices informing beneficiaries that their Medicaid eligibility is terminating, Exchanges currently have flexibility and authority to provide additional relief for consumers who lose Medicaid coverage. As discussed in the proposed rule,⁸³ Exchanges could provide consumers who do not timely learn of their opportunity to enroll in Exchange coverage with additional time to enroll in health coverage based on the regulation at § 155.420(c)(5), recently finalized in part 2 of the 2022 Payment Notice final rule. Additionally, § 155.420(d)(9) provides a special enrollment period to consumers who demonstrate to the Exchange, in accordance with guidelines issued by HHS, the individual meets exceptional circumstances as the Exchange may provide. In the FFE and FF-SHOP Enrollment Manual, which provides operational policy and guidance on key topics related to eligibility and enrollment for FFEs and SBE-FPs, HHS explains that an individual may qualify for a special enrollment period through authority at § 155.420(d)(9) if their enrollment or non-enrollment in a QHP (or that of their dependent) is the result of an exceptional circumstance, as determined by the Secretary.⁸⁴ In 2018, HHS issued guidance to provide that an individual or their dependents who are affected by an emergency or major disaster that is recognized with a formal declaration from the Federal Emergency Management Agency (FEMA) and that prevents the qualified individual or their dependents from enrolling during the annual open enrollment period or during the enrollment window for a special enrollment period for which they qualified will be eligible for an Exceptional Circumstances special enrollment period under § 155.420(d)(9). If needed, HHS will similarly

⁸³ See 86 FR 35170.

⁸⁴ See FFEs and FF-SHOP Enrollment Manual: Section 6, Exhibit 14, https://www.regtap.info/uploads/library/ENR_FFEFFSHOPENrollmentManual2020_5CR_090220.pdf.

provide a special enrollment period to former Medicaid beneficiaries who are prevented from enrolling in Exchange coverage by challenges they experience as a result of the end of the PHE, and HHS notes that State Exchanges can also take similar action. Further, HHS will continue to engage with all Exchanges and other stakeholders to provide additional support for consumer transitions between Medicaid and Exchange coverage following the end of the PHE.⁸⁵ HHS believes the special enrollment period finalized in this rule, along with existing special enrollment authorities granted to Exchanges discussed here, are sufficient to ensure that consumers who lose Medicaid coverage due to the end of the PHE are able to transition to Exchange coverage.

Comment: Multiple commenters that supported the proposal were optimistic about Exchanges' ability to implement it in time for the 2022 plan year based on availability of comparable special enrollment periods in some Exchanges, such as Massachusetts'. Other commenters were generally supportive of the special enrollment period, but strongly supported that it be finalized, as proposed, at the option of the Exchange, and varied in their assessments of level of effort to implement it. One estimated that the special enrollment period could be implemented for the 2022 plan year, but that state regulators would first need to be consulted about potential impact on individual market rates to determine whether they should. One commenter did not think that Exchanges could implement the special enrollment period in time for the 2022 plan year, and another was unsure about whether they could do so.

Finally, several commenters said that the special enrollment period could be implemented in time for the 2022 plan year, but without plan category limitations, and suggested that these limitations be optional for Exchanges due to significant additional level of effort for implementation, and because of the likely very small affected population. One state regulator

⁸⁵ For example, in 2018, HHS issued guidance to provide that an individual or their dependents who are affected by an emergency or major disaster that is recognized with a formal declaration from FEMA and that emergency or major disaster prevents the qualified individual or their dependents from enrolling during the annual open enrollment period or during the enrollment window for a special enrollment period for which they qualified will be eligible for an exceptional circumstances special enrollment period under § 155.420(d)(9). See <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/8-9-natural-disaster-SEP.pdf>.

requested that plan category limitations not be applied because some qualifying individuals would be better served by enrolling in a very low-cost bronze plan, and that they should be permitted to determine with an agent or broker which metal level was best for them.

Response: HHS agrees with commenters that State Exchanges should have the option of whether to implement this special enrollment period, and therefore have finalized, as proposed, that it be at the option of the Exchange. While HHS understands concerns about complexity of implementation, in consideration of strong support from other commenters for guardrails to help mitigate adverse selection, HHS agrees that the proposed plan category limitations, as clarified in this final rule, will be helpful in mitigating potential adverse selection, even in Exchanges in which the population of consumers potentially eligible for this special enrollment period is small.

Comment: Based on a belief that adverse selection would be limited and that the uninsured rates would decrease due to the proposed special enrollment period, several commenters asked that HHS increase the household income threshold for qualifying individuals to 200 or 250 percent of the FPL. These commenters' rationale was that individuals with household income below this threshold are also highly subsidized to an extent that would mitigate adverse selection risk. Several commenters also noted that this income range would include more consumers who make minimum wage, and who regularly transition between Medicaid and Exchange coverage.

Response: HHS shares the goal of reducing barriers to coverage for as many individuals as possible. However, as discussed in the proposed rule, HHS believes that access to premium-free or very low-cost coverage with a 94 percent AV after application of APTC and CSRs will be an important factor to help mitigate risk of adverse selection, because qualifying individuals will not have an incentive not to enroll or to end coverage when health care services are no longer needed. While many individuals with projected annual household income greater than 150 percent of the FPL also benefit from APTC that covers a significant portion of their monthly premium, given a number of commenters' concerns about adverse selection risk, HHS believes it

is appropriate to make the special enrollment period available only to individuals whose applicable taxpayer has an applicable premium percentage set at zero. Limiting the special enrollment period in this way also ensures that eligible individuals will have access to a silver plan with a 94 percent AV, which may reinforce qualifying individuals' interest in maintaining coverage when health care services are no longer needed, even for those who must pay a small premium, because of the ability to access care without significant cost sharing.

Further, as also addressed in the proposed rule, adverse selection risk presented by the proposal stems, in part, from qualifying individuals who live in states where premiums for Exchange coverage cannot be fully paid for with APTC, such that these individuals will not have access to a silver plan with a zero-dollar premium, because these individuals may have more incentive to end their coverage when they no longer believe that they need it, or to inadvertently allow their coverage to lapse due to missing multiple premium payments. Therefore, HHS is finalizing the special enrollment period for APTC-eligible individuals with a household income up to 150 percent of the FPL, but limiting it to be available only during periods of time during which APTC benefits are available, such that the applicable taxpayers' applicable percentage is set at zero.

6. Clarification of Special Enrollment Periods for Enrollees who are Newly Eligible or Newly Ineligible for Advance Payments of the Premium Tax Credit (§ 155.420(f))

HHS proposed new language to clarify that, for purposes of the special enrollment period rules at § 155.420(d), references to ineligibility for APTC refer to being ineligible for such payments or being technically eligible for such payments but qualifying for a maximum of zero dollars per month of such payments. That is, a qualified individual, enrollee, or his or her dependent who is technically eligible for APTC because they meet the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is also considered ineligible for APTC for purposes of these special enrollment periods, even if they experience a change in circumstance from an APTC ineligible status in accordance with § 155.305(f), such as having

other MEC. As discussed in the proposed rule, currently, the special enrollment periods to which this clarification is applicable are the triggering events at § 155.420(d)(6), but HHS proposed that the clarification apply to all of § 155.420 to ensure consistency, for example, between special enrollment period triggering events at § 155.420(d) and related coverage effective date and enrollment window rules at § 155.420(b) and (c), respectively. After consideration of public comments, as further discussed below, HHS is finalizing § 155.420(f) as proposed.

As discussed in the proposed rule, IRS rules at 26 CFR 1.36B-3 govern the APTC amount an individual may receive once they are found eligible for APTC under § 155.420(d)(6). Pursuant to these IRS rules, an Exchange enrollee's monthly APTC amount is the excess of the adjusted monthly premium for the applicable benchmark plan⁸⁶ over 1/12 of the product of the taxpayer's household income and the applicable percentage for the taxable year. Under this formula, if the applicable percentage of 1/12 of a taxpayer's estimated annual household income is higher than the adjusted monthly premium of the relevant benchmark plan, a taxpayer will be eligible generally for APTC under § 155.305(f)(1), but will qualify for a maximum APTC amount of zero dollars under 26 CFR 1.36B-3. Currently, neither § 155.305(f)(1) or 26 CFR 1.36B-3 recognize or explain that an individual generally could be APTC-eligible, but not qualify to receive any amount in APTC greater than zero. The current text of § 155.420 similarly does not address this issue, such that there could exist some ambiguity about what it means to be APTC-eligible or ineligible for purposes of the special enrollment periods under § 155.420.

HHS proposed to add text to § 155.420 to clarify that an individual who qualifies for a maximum APTC amount of zero dollars is considered ineligible for APTC for purposes of the § 155.420 special enrollment periods. Specifically, any determination that an individual cannot receive an APTC amount greater than zero dollars is equivalent to being found APTC-ineligible for purposes of special enrollment period eligibility under § 155.420(d). HHS noted that HHS

⁸⁶ Per IRS rules at 26 CFR 1.36B-3(f), the term "benchmark plan" is generally used to refer to the second lowest-cost silver plan, as described in section 1302(d)(1)(B) of the ACA (42 U.S.C. 18022(d)(1)(B)), offered to the taxpayer's coverage family through the Exchange for the rating area where the taxpayer resides.

believed this interpretation comports with the perspective of an applicant for Exchange coverage who will take their available financial assistance amount into account when selecting a QHP for the upcoming coverage year and who may wish to change their QHP partway through a coverage year because of a change in their financial assistance. Because HHS believes that the current regulation permits this interpretation, but could instead be interpreted to require strict adherence to the listed requirements for APTC eligibility at § 155.305(f) (which does not address situations where a consumer meets these requirements but qualifies for a zero-dollar APTC amount), HHS proposed regulation text to ensure consistent and correct interpretation of what it means to be determined ineligible for APTC. This reading of APTC ineligibility is also consistent with HHS's discussion of the policy in previous rulemaking. For example, in the 2020 Payment Notice final rule,⁸⁷ HHS added a new paragraph at § 155.420(d)(6)(v) allowing Exchanges to provide a special enrollment period for qualified individuals who experience a decrease in household income and receive a new determination of eligibility for APTC by an Exchange, and who had MEC for one or more days during the 60 days preceding the financial change.

HHS stated that HHS believes that this clarification will be especially helpful in light of the removal of the upper APTC eligibility limit on household income at 400 percent of the FPL for taxable years 2021 and 2022 under the ARP.⁸⁸ This is because, with this change, any applicants with household incomes over 400 percent of the FPL may be eligible for APTC, so more consumers likely will qualify for APTC technically, but for an APTC amount of zero dollars. This clarification ensures that special enrollment period regulations clearly reflect that enrollees for whom this is the case may qualify for a special enrollment period based on a decrease in their household income, or any other change that makes them newly eligible for an APTC amount of greater than zero dollars.

⁸⁷ 84 FR 17526.

⁸⁸ Pub. L. 117-2.

HHS explained that HHS believes that this clarification should also apply to the special enrollment periods provided in § 155.420(d)(6)(iii) through (v), which include special enrollment periods for individuals who become newly eligible for APTC. However, HHS sought comment on whether the clarification that a qualified individual, enrollee, or his or her dependent is considered APTC-ineligible if they meet the requirements at § 155.305(f), but qualify for a maximum APTC amount of zero dollars, should be applied as proposed to all of the special enrollment period qualifying events at § 155.420(d)(6), or whether it should be limited to only apply to some of them. For example, HHS sought comment on whether HHS should only apply this clarification to the special enrollment periods at § 155.420(d)(6)(i) and (ii) and (iv) and (v), to permit individuals whose ESC is no longer considered affordable or no longer meets the minimum value standard to qualify for a special enrollment period to enroll in Exchange coverage through § 155.420(d)(6)(iii) regardless of whether they qualify for an APTC amount of greater than zero dollars.

HHS also sought comment on the proposal, including from State Exchanges, regarding whether this definition of APTC eligibility reflects their current implementation of the special enrollment period qualifying events per § 155.420(d)(6), and if not, whether there are policy concerns about this clarification, or the burden of making related changes to Exchange operations. HHS also sought comment on whether HHS should provide Exchanges with flexibility in terms of when they are required to ensure that their operations reflect this definition, and whether Exchanges should be permitted to adopt a more inclusive definition, for example, to consider an individual to be newly eligible or ineligible for APTC for purposes of the special enrollment periods at § 155.420(d)(6) based on a change from a zero-dollar maximum APTC amount to APTC ineligibility for another reason per regulations at § 155.305(f).

The following is a summary of the comments received and HHS's responses regarding these proposals related to the clarification of the special enrollment period for enrollees who are

newly eligible or newly ineligible for advance payments of the premium tax credit (§ 155.420(f)).

Comment: Multiple commenters supported this clarification, and one commenter confirmed that it reflected their State Exchange's implementation of the applicable special enrollment periods. Several commenters, including another State Exchange, agreed that this clarification is helpful for mitigating issuer and consumer confusion. However, one commenter raised the concern that the clarification would result in fewer consumers qualifying for a special enrollment period due to confusion about how to report life changes related to special enrollment period access and eligibility. The commenter added that some consumers who are not receiving PTCs may wish to change plans based on having reported a change to their household income. This commenter also raised the concern that it would require their State Exchange to make significant system and messaging adjustments to change how they implement applicable special enrollment periods.

Response: HHS appreciates comments that this clarification is helpful, and HHS is finalizing it as proposed. In response to the concern that it will cause fewer consumers to qualify for special enrollment periods, HHS notes that in addition to providing general clarity, HHS's primary purpose for this update is be clear that enrollees may qualify for a special enrollment period at § 155.420(d)(6)(i) or (ii) based on a change from being eligible for a maximum APTC of zero dollars per month to an amount greater than zero dollars per month, or who become newly eligible for a maximum of zero dollars per month after previously having qualified for an amount of more than zero dollars. While this may require some Exchanges to make system changes, HHS is finalizing the clarification as proposed to ensure that enrollees in this situation may qualify for a special enrollment period based on a meaningful change in eligibility for APTC as opposed to a change that is not meaningful.

Additionally, HHS appreciates the comment that some consumers who experience a change in household income mid-year may wish to change to a different QHP based on this

clarification. However, current rules do not include special enrollment periods based only on a change in household income, and qualifying events at § 155.420(d)(6) are not based on changes in household income, but rather on changes in eligibility for APTC, to account for whether, based on their household income, a qualifying individual can receive assistance with their monthly QHP premium payments. HHS disagrees that this clarification will result in fewer special enrollment periods for consumers who qualify based on experiencing an established special enrollment period triggering event, because special enrollment period rules at § 155.420(d) do not currently include an enrollment opportunity based solely on a change in household income. However, HHS commits to continue working with State Exchanges on an ongoing basis to mitigate confusion related to eligibility rules to promote greater access to coverage. HHS also commits to collaborating to promote continuity of coverage for all Exchange enrollees, including by helping enrollees to understand the importance of reporting changes to their household income so that they receive an up-to-date APTC amount even if their change does not make them eligible for a special enrollment period.

Comment: One commenter generally supported the proposal, but requested that HHS finalize it to exempt the special enrollment period at § 155.20(d)(6)(iii) so that employees or dependents who are enrolled in an employer-sponsored plan and determined newly APTC-eligible based in part on a finding that they are no longer eligible for qualifying coverage in an eligible employer-sponsored plan in accordance with 26 CFR 1.36B-2(c)(3) may qualify for a special enrollment period even if they qualify for a maximum payment of zero dollars per month. This commenter explained that individuals in this situation could benefit from an opportunity to change to coverage that meets the minimum value standards that apply to Exchange coverage, even if they are required to pay full price for Exchange coverage.

Response: HHS appreciates this comment and agrees that an individual whose ESC is no longer considered affordable or no longer provides minimum value may wish to access

individual market coverage through an Exchange, even if they will not qualify for APTC to help reduce their premiums.

HHS does not agree that additional special enrollment period authority is necessary at this time, because there are existing pathways to enrollment in individual market coverage through an Exchange for many individuals who meet the conditions of the triggering event at § 155.420(d)(6)(iii), except that they do not qualify for APTC. Further, based on HHS's experience, changes to ESC that would have these effects are rarely made mid-plan year. Therefore, employees and dependents who experience this type of change and whose ESC renews on a calendar year basis can enroll in individual market coverage through an Exchange during the annual open enrollment period, and those whose ESC renews on a non-calendar year basis can qualify for a special enrollment period per § 155.420(d)(1)(ii), based on the last day of the plan year of their ESC. In what HHS expects will be rare instances that an individual's ESC ceases to meet the minimum value or affordability standards in the middle of a plan year under circumstances that would not qualify the individual for a special enrollment period under § 155.420(d)(1)(ii), an Exchange could exercise its authority to find that this change is an exceptional circumstance that qualifies the individual for a special enrollment period under § 155.420(d)(9).

Due to the existing special enrollment period authorities available to Exchanges, HHS is of the view that additional special enrollment period authority is not necessary at this time. HHS will monitor these circumstances and, if necessary, consider proposing such authority in future rulemaking.

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

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

In the December 4, 2020 **Federal Register** (85 FR 78572), HHS published the proposed 2022 Payment Notice that proposed to reduce fiscal and regulatory burdens across different

program areas and to provide stakeholders with greater flexibility that included a proposed 2022 user fee rate. In the January 19, 2021 **Federal Register** (86 FR 6138), HHS published part 1 of the 2022 Payment Notice final rule that addressed a subset of the policies proposed in the proposed rule. That final rule, among other things, finalized the 2022 user fee rates for issuers offering QHPs through the FFEs at 2.25 percent of total monthly premiums, and the user fee rate for issuers offering QHPs through SBE-FPs at 1.75 percent of total monthly premiums.

On January 28, 2021, President Biden issued EO 14009,⁸⁹ directing HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether such agency actions are inconsistent with this Administration's policy to protect and strengthen the ACA and to make high-quality health care accessible and affordable for every American. As part of this review, HHS examined policies and requirements under the proposed 2022 Payment Notice and part 1 of the 2022 Payment Notice final rule to analyze whether the policies under these rulemakings might undermine the Health Benefits Exchanges or the health insurance markets, and whether they may present unnecessary barriers to individuals and families attempting to access health coverage. HHS also considered whether to suspend, revise, or rescind any such actions through appropriate administrative action.

In compliance with EO 14009 and as a result of HHS's review of the proposed 2022 Payment Notice and part 1 of the 2022 Payment Notice final rule, HHS discussed in the proposed rule that HHS has reanalyzed the additional costs of expanded services, such as consumer outreach and education in the FFEs and SBE-FPs, and Navigators in the FFEs in 2022. As explained in part 2 of the 2022 Payment Notice final rule,⁹⁰ HHS indicated the intention to propose to increase the user fee rates for the 2022 benefit year in future rulemaking. Therefore,

⁸⁹ 86 FR 7793 (Feb. 2, 2021).

⁹⁰ 86 FR 24140, 24288.

in the proposed rule, HHS proposed new QHP issuer user fee rates for the 2022 plan year: a new FFE user fee rate of 2.75 percent of total monthly premiums, and a new SBE-FP user fee rate of 2.25 percent of monthly premiums. The proposed rates are based on internal projections of Federal costs for providing special benefits to FFE and SBE-FP issuers during the 2022 benefit year, taking into account estimated changes in parameters, specifically the increased funding to the FFE Navigator program and consumer outreach and education. As discussed in the proposed rule, HHS is of the view that pursuit of the proposal was necessary for consistency with EO 14009 and this Administration's goal of protecting and strengthening the ACA and making high-quality health care accessible and affordable for every American. HHS noted that HHS believed that expanded outreach and education will lead to broader risk pools, lower premiums, fewer uninsured consumers, and expanded use of Exchange services.

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), HHS specifies that a participating issuer offering a plan through an FFE or SBE-FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE-FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE-FP. In addition, OMB Circular No. A-25 establishes Federal policy regarding the assessment of user fee charges under other statutes, and applies to the extent permitted by law. Furthermore, OMB Circular No. A-25 specifically provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public.

Activities performed by the Federal Government that do not provide issuers participating in an FFE with a special benefit, or that are performed by the Federal Government for all QHPs,

including those offered through State Exchanges, are not covered by this user fee. As in benefit years 2014 through 2021, issuers seeking to participate in an FFE in the 2022 benefit year will receive two special benefits not available to the general public: (1) the certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP.

a. FFE User Fee Rate

For the 2022 benefit year, issuers participating in an FFE will receive the benefits of the following Federal activities:

Under Consumer Information and Outreach:

- Provision of consumer assistance tools;
- Consumer outreach and education; and
- Management of a Navigator program.

Under Health Plan Bid Review, Management, and Oversight:

- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification); and
- Regulation of agents and brokers.

Under Eligibility and Enrollment:

- Eligibility determinations; and
- Enrollment processes.

Activities through which FFE issuers receive a special benefit also include use of the Health Insurance and Oversight System (HIOS), which is partially funded by FFE and SBE-FP user fees, and the Multidimensional Insurance Data Analytics System (MIDAS) platform, which is fully funded by FFE and SBE-FP user fees. In light of EO 14009,⁹¹ published on January 28, 2021, the administration has a priority to increase accessibility and affordability of health care for every American. Consistent with increasing accessibility for every American an expanded

⁹¹ 86 FR 7793 (Feb. 2, 2021).

budget for consumer support activities and Navigators was developed, and HHS conducted additional analytic review which revealed that the user fee rates established in part 1 of the 2022 Payment Notice final rule⁹² need to be increased to sustain essential Exchange-related activities. Based on this new analysis of the increased contract costs and projected premiums and enrollment (including changes in FFE enrollment resulting from anticipated establishment of State Exchanges or SBE-FPs in certain states in which FFEs currently are operating) for the 2022 plan year, HHS proposed to establish the FFE user fee for all participating FFE issuers at 2.75 percent of total monthly premiums.

b. SBE-FP User Fee Rate

As previously discussed, OMB Circular No. A-25 establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

SBE-FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and Federal programs. Accordingly, in § 156.50(c)(2), HHS specifies that an issuer offering a plan through an SBE-FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE-FP, unless the SBE-FP and HHS agree on an alternative mechanism to collect the funds from the SBE-FP or state.

The benefits provided to issuers in SBE-FPs by the Federal Government include use of the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, as defined at section 1413(e) of the ACA, and QHP enrollment functions under

⁹² 86 FR 6138 at 6152.

§ 155.400. The user fee rate for SBE-FPs is calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE-FPs, as issuers in SBE-FPs receive those special benefits and will be able to access the increased consumer support and education.

Similar to the FFEs, activities through which SBE-FP issuers receive a special benefit also include use of HIOS, which is partially funded by FFE and SBE-FP user fees, and the MIDAS platform, which is fully funded by FFE and SBE-FP user fees. In light of EO 14009,⁹³ the administration has a priority to increase accessibility and affordability of health care for every American. Consistent with increasing accessibility for every American, an expanded budget for consumer support activities and Navigators was developed, and HHS conducted additional analytic review which revealed that the user fee rates established in part 1 of the 2022 Payment Notice final rule⁹⁴ need to be increased to sustain essential Exchange-related activities. Based on this new analysis of the increased contract costs and projected premiums and enrollment (including changes in FFE enrollment resulting from anticipated establishment of State Exchanges or SBE-FPs in certain states in which FFEs currently are operating) for the 2022 plan year, HHS proposed to establish the SBE-FP user fee for all participating SBE-FP issuers at 2.25 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE-FP for benefit year 2022.

HHS sought comment on the FFE and SBE-FP user fee rates for 2022. The following is a summary of the comments received and the responses to HHS' proposals related to the FFE and SBE-FP user fee rates for 2022.

Comment: Most commenters supported the proposal to increase the 2022 user fee rates for the FFEs and SBE-FPs. These commenters supported funding increases for consumer

⁹³ 86 FR 7793 (Feb. 2, 2021).

⁹⁴ 86 FR 6138 at 6152.

outreach and education and Navigators, and for building up the Exchange infrastructure. Other commenters were concerned about changes to user fees happening this late into the 2022 rate - setting process. One commenter suggested that the increased user fee collections be aimed at only consumer outreach and education and not toward funding Navigators.

Response: HHS is finalizing the higher 2022 user fee rates for the FFEs and SBE-FPs as proposed. These higher user fee rates will allow for an expanded budget for consumer support activities and Navigators and will ensure that HHS can sustain essential Exchange-related activities.

HHS is finalizing the proposal to increase the user fee rates to fund both consumer outreach and education and Navigators. Pursuant to EO 14009, HHS is aiming to increase accessibility and affordability of health care for every American. On August 27, 2021, CMS awarded \$80 million in grant funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year.⁹⁵ Extending funding for Navigators through 2022 is consistent with increasing accessibility for every American.

HHS also appreciates commenters' concerns about rate-setting. To help stakeholders anticipate a possible increase to the FFE and SBE-FP user fee rates for 2022, HHS announced in part two of the 2022 Payment Notice final rule⁹⁶ that HHS intended to propose increased new user fee rates for 2022 and provided the projected user fee rates that HHS was considering. Therefore, HHS believes that stakeholders may have been anticipating the proposed changes to the 2022 user fee rates and reasonably could have taken steps to accommodate the possible change.

Comment: Some commenters recommended that HHS further increase the user fee rates to 3.5 percent or 3.0 percent of total monthly premiums. Other commenters were concerned about the proposed higher user fee rates. Some of these commenters were concerned that

⁹⁵ <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open>.

⁹⁶ 86 FR 24141.

increasing user fee rates is unnecessary as increased enrollment should provide adequate revenue to fund Exchange activities. Other commenters expressed concern that the costs of increased user fee rates would be passed on to consumers in the form of higher premiums. One commenter was concerned that increasing user fee rates could result in reduced commission paid to agents and brokers and limit enrollment growth through those channels. Another commenter suggested that, rather than increasing user fee rates, HHS should use excess collections from prior years to cover the costs of the expanded Navigator and consumer information and outreach activities. One commenter observed that the higher user fee rates will be covered by higher APTC payments, which results in transferring funds from one program to another program.

Response: HHS believes that these newly finalized 2022 user fee rates will provide adequate funding for the full functioning of the Federal platform, and HHS does not need to further increase these rates at this time. HHS acknowledges that the user fee rates in this final rule are higher than those previously finalized for 2022 in part 1 of the 2022 Payment Notice final rule, which could increase premiums for consumers, but in accordance with EO 12866, HHS believes that the benefits of this regulatory action justify the costs. The FFE and SBE-FP user fee rates for the 2022 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE-FPs and were developed based on an evaluation of expected enrollment and premiums for the 2022 benefit year. HHS also notes that the 2022 user fee rates are still lower than the 2021 user fee rates.

Regardless, HHS will continue to examine cost estimates for the special benefits provided to issuers offering QHPs on the FFEs and SBE-FPs for future benefit years. This will include annually evaluating outreach and education efforts to consider what the appropriate level of funding should be.

HHS also notes that it is consistent with the ACA and implementing regulations for user fees to be included in premiums (as determined by the issuer) and for these premiums to be partially covered by APTC payments for eligible enrollees.

Comment: Some commenters requested that HHS provide greater budget transparency and more data reporting on how and where user fees are spent.

Response: HHS believes that the information provided in the proposed rule in support of the proposed user fee rate was sufficient to allow commenters to meaningfully assess and comment on the appropriateness of the user fee rate proposals. The FFE and SBE-FP user fee rates for the 2022 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE-FPs, and are based on an evaluation of expected enrollment and premiums for the 2022 benefit year. Annually, HHS and CMS also publish detailed information on Federal Exchange Activities and budget request estimates, including expected Exchange user fee-eligible costs.⁹⁷ To calculate these expected costs, HHS makes reasonable assumptions about the expected market for the upcoming benefit year, and reconsiders these assumptions and re-estimate these costs on an annual basis with the most recent data available. For example, for the 2022 benefit year, HHS considered whether they needed to make changes to the cost, premium, and enrollment assumptions based on data from the 2020 benefit year and made updates to their projections as appropriate. User fee-eligible costs are generally estimated in advance of the benefit year and are based upon cost targets for specific contracting activities that are not yet finalized, and therefore contain proprietary information related to contracting activities that should not be disclosed. HHS will continue to outline user fee-eligible functional areas in the annual HHS notice of benefit and payment parameters, and will evaluate contract activities related to operation of Federal platform user fee-eligible functions.

Comment: HHS received comments that HHS should switch to a per member per month (PMPM) capitated user fee, rather than a premium based user fee, and a comment requesting that HHS conduct and publish a study on a PMPM user fee.

⁹⁷ The FY 2022 CMS Budget Request is available at <https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf> and the FY 2022 HHS Budget Request is available at <https://www.hhs.gov/sites/default/files/fy-2022-budget-in-brief.pdf>.

Response: HHS did not propose to switch to a PMPM capitated user fee and therefore is not finalizing a PMPM capitated user fee. The FFE and SBE-FP user fee rates will continue to be assessed as a percent of the monthly premium charged by participating issuers. Setting the user fee as a percent of premium avoids disproportionately increasing premiums in lower-cost areas and for lower-premium plans, since, holding all other factors constant, issuers of plans with lower premiums will experience lower user fees, and issuers of plans with higher premiums will experience a proportional increase in user fees. Although a PMPM user fee rate would yield lower user fees for higher-premium plans, it would likely cause issuers of lower-premium plans to increase premiums, thus decreasing the affordability of the most affordable plans.

Comment: One commenter suggested that more user fee money be aimed at enrolling immigrants by, for example, offering the option to receive educational material in different languages.

Response: A portion of user fee funds is used for the management of the FFE Navigator program, as well as consumer outreach and education for the FFEs and SBE-FPs. In previous Payment Notices, commenters have acknowledged the important role that Navigators play in assisting individuals with LEP. On August 27, 2021, CMS awarded \$80 million in grant funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year.⁹⁸ This is the largest funding allocation HHS has made available for Navigator grants to date. As part of this grant funding, HHS has encouraged current and past Navigators to apply, especially those that focus on education, outreach, and enrollment efforts to underserved and diverse communities, including those with LEP. HHS also notes that under § 155.205(c)(2)(i)(A), HHS currently provides accessibility services in at least 150 languages at no cost to applicants and enrollees. These translation services are provided telephonically and for written communications at no cost to the consumer.

⁹⁸ <https://www.cms.gov/newsroom/press-releases/cms-announces-80-million-funding-opportunity-available-navigators-states-federally-facilitated-0> <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open>.

After considering the public comments, HHS is finalizing the proposed rates of 2.75 percent for the FFE user fee rate and 2.25 percent for the SBE-FP user fee rate for the 2022 benefit year.

c. 2023 Exchange DE Option User Fee Rate

In the January 19, 2021 **Federal Register** (86 FR 6138), HHS published part 1 of the 2022 Payment Notice final rule that codified § 155.221(j), which established a process for states to elect a new Exchange DE option. When finalizing this new Exchange option, HHS also finalized a 2023 user fee rate of 1.5 percent of the total monthly premiums charged by issuers for each policy in FFE and SBE-FP states that elect the Exchange DE option. As explained earlier in this preamble, HHS proposed to repeal the Exchange DE option; accordingly, HHS also proposed to repeal the user fee rate associated with § 155.221(j) for the FFE-DE and SBE-FP-DEs for 2023. HHS sought comment on this proposal.

HHS did not receive public comments specific to the proposal to repeal the user fee rates for FFE-DEs and SBE-FP-DEs for 2023. HHS summarizes the comments received on the accompanying proposal to repeal the Exchange DE option under part 155 earlier in this preamble. After consideration of those comments, HHS is finalizing the proposal to repeal the Exchange DE option and the accompanying 2023 user fee rates for FFE-DEs and SBE-FP-DEs, as proposed.

2. Provision of EHB (§ 156.115)

HHS proposed a technical amendment to § 156.115. Section 156.115(a)(3) provides that, to satisfy the requirement to provide EHB, a health plan must provide mental health and substance use disorder services, including behavioral health treatment services required under § 156.110(a)(5), in a manner that complies with the parity standards set forth in § 146.136, implementing the requirements under MHPAEA. Instead of referencing the regulation implementing MHPAEA, HHS proposed to reference section 2726 of the PHS Act and its

implementing regulations. HHS proposed this change to make clear that health plans must comply with all the requirements under MHPAEA, including any amendments to MHPAEA, such as those made by the Consolidated Appropriations Act, 2021,⁹⁹ in order to satisfy the EHB requirements.

The following is a summary of the comments received and responses to the HHS proposals related to EHB provision (§ 156.115).

Comment: HHS received several comments in support of the proposed amendment. The commenters expressed that the amendment would affirm HHS' commitment to the goal of ensuring access to mental health and substance use disorder coverage for individuals, and also will strengthen national and local efforts to enforce MHPAEA requirements.

Response: HHS appreciates the support of the commenters and are finalizing this policy as proposed.

3. Network Adequacy (§ 156.230)

As discussed in more detail in the preamble to § 155.20, on March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus v. Cochran*, 2021 WL 825973 (D. Md. Mar. 4, 2021). One of the policies the court vacated was the 2019 Payment Notice's elimination of the Federal Government's reviews of the network adequacy of QHPs offered through the FFEs in certain circumstances by incorporating the results of the states' reviews.¹⁰⁰

As explained in part 2 of the 2022 Payment Notice final rule,¹⁰¹ HHS intends to implement the court's decision through rulemaking as soon as possible. However, HHS also will not be able to fully implement the aspects of the court's decision regarding network adequacy in time for issuers to design plans and for CMS to be prepared to certify such plans as QHPs for the

⁹⁹ See section 203 of Title II of Division BB of the Consolidated Appropriations Act, 2021, Pub. L. 116-260 (Dec. 27, 2020).

¹⁰⁰ This policy was first announced in the 2018 Letter to Issuers in the federally-facilitated Marketplaces, December 16, 2016, available at <https://wayback.archive-it.org/2744/20200125161008/https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-federally-facilitated-Marketplaces-and-February-17-Addendum.pdf>. See also 83 FR 17024-17026.

¹⁰¹ 86 FR 24140.

2022 plan year. HHS noted in the proposed rule that HHS instead intends to address these issues in time for plan design and certification for plan year 2023. Specifically, with the rule vacated, HHS would need to set up a new network adequacy review process, and issuers would need sufficient time before the applicable plan year to assess that their networks meet the new regulatory standard, submit network information, and have the information reviewed by applicable regulatory authorities to have their plans certified as QHPs. Issuers might also have to contract with other providers in order to meet the standard. This was not feasible for the QHP certification cycle for the 2022 plan year, which began on April 22, 2021. HHS plans to propose specific steps to address Federal network adequacy reviews in future rulemaking. HHS requested comments and input regarding how the Federal Government should approach network adequacy reviews.

The following is a summary of the comments received and the responses to HHS' solicitation for comments related to network adequacy (§ 156.230).

Comment: Many commenters highlighted the importance of ensuring adequate network access for all consumers seeking coverage through QHPs offered through the FFEs. Commenters encouraged HHS to specifically review networks for: full accessibility to consumers with disabilities, language access, cultural competency, capacity to deliver anti-bias care, specialist and sub-specialist access, end-of-life care services, diverse providers reflecting backgrounds of enrollees, and extended hours of operation. Commenters also suggested networks' capacity to deliver LGBTQ+-affirming care should be assessed as part of network adequacy review processes. Other commenters specified that broad and equitable access to sexual and reproductive health services, contraceptive services, and HIV care should be evaluated.

Response: HHS agrees that adequacy metrics supporting equitable access for all consumers should be a high priority. For future rulemaking, HHS is carefully considering standards that promote health equity (for example, provider directory requirements to include

information about the race/ethnicity, language(s) spoken, accessibility, and office hours of in-network providers).

Comment: Many commenters offered network adequacy enforcement strategies for HHS to consider, stating HHS should implement direct testing of provider availability as an enforcement method, per the 2014 HHS Office of Inspector General Report.¹⁰² Others encouraged HHS to examine out-of-network claims submission rates and claims denials rates (adjusted for enrollment numbers) to monitor and enforce network adequacy. Additional enforcement and monitoring strategies cited by commenters included: submission and review of access plans for new networks, submission and review of parity compliance reports on network standards, use of consumer surveys and complaint data, and use of geographic mapping tools and secret shopper surveys to identify adequacy gaps.

Response: HHS will take these comments under advisement when detailing the specific criteria and processes for meeting network adequacy standards.

Comment: Some comments cautioned against creating a quantitative Federal standard that is overly prescriptive for issuers, citing differences across states. A Federal standard may not allow for the needed tailored flexibilities and innovations in adequacy assessment that respond to the unique workforces, geographies, populations, and markets of each state. Additionally, several comments called for maximum consistency of approach across states. One commenter encouraged HHS to utilize the network adequacy standards developed by the National Committee for Quality Assurance (NCQA) for medical and behavioral health services. Conversely, one commenter noted accreditation organizations are not the appropriate arbiter of network adequacy.

Response: HHS aims to establish Federal oversight standards that complement state standards while meeting Federal obligations, including for QHPs on FFEs. HHS will continue to

¹⁰² <https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>.

coordinate closely with state authorities to address compliance issues, eliminate duplicative requirements or reviews, and reduce stakeholder burden.

Comment: Several comments supported the application of telehealth for fulfilling network adequacy standards. Some commenters cautioned against the use of telehealth or virtual-only providers to fulfill quantitative standards for adequacy in lieu of in-person care.

Response: Telehealth is of special interest to HHS given its recent expansion during the COVID-19 pandemic. HHS intends to detail the specific criteria and processes for meeting network adequacy standards. Standards that account for the availability of telehealth services are under consideration.

Comment: Some commenters asserted that Federal network adequacy reviews should prevent discrimination against and examine the availability of a diverse set of provider types, including nurse practitioners, certified registered nurse anesthetists, and other mid-level practitioners. Commenters called for including all applicable provider types such as skilled nursing facilities, durable medical equipment suppliers, and prosthetists and orthotists. Specifically, some commenters noted the importance of ensuring access, via quantitative standards, to behavioral health and substance use disorder providers and services at all care levels, including intermediate care.

Response: HHS intends to evaluate QHP issuer networks for access to providers enrollees most generally use and/or that have historically been the subject of network adequacy concerns raised by patients and other stakeholders (for example, behavioral health providers).

Comment: Commenters suggested use of a range of general and specific network adequacy metrics and standards, including time and distance, provider-to-enrollee ratio minimums, availability of providers accepting new patients, timely notification of provider terminations, provision of out-of-network services, provider directory data elements, and appointment wait times. Commenters also suggested that when assessing network adequacy,

HHS should consider enrollees' health care needs (for example, by using the Community Need Index) and transportation and topographical complexities that influence geographic accessibility.

Response: HHS intends to ensure that network adequacy standards ensure enrollee access to care, are applicable and meaningful across diverse state settings, are achievable, and do not place an undue burden on issuers to collect and validate the necessary data.

HHS will take the comments into consideration while formulating forthcoming rulemaking. HHS will also consider these comments in specifying QHP certification requirements related to network adequacy. Pursuant to 45 CFR 156.230(a)(2), an issuer of a QHP that has a provider network must maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible to enrollees without unreasonable delay.

For the certification cycle for plan years beginning in 2023, HHS is considering the adoption of time and distance standards to assess whether QHP issuer networks fulfill this regulatory requirement. HHS is considering evaluating QHP issuer networks for compliance with this standard based on the numbers and types of providers that enrollees most generally use and/or that have historically been the subject of network adequacy concerns raised by patients and other stakeholders (for example, behavioral health providers); providers' geographic location; and other factors to be determined by HHS. HHS would calculate time and distance standards at the county level. Issuers that are unable to meet the specified standards would be able to submit a justification to account for variances, and the FFEs would review the justification to determine whether the variance(s) is/are reasonable based on a specific set of circumstances, such as the local availability of providers and variables reflected in local patterns of care. HHS would also include a requirement for issuers to make the information necessary to evaluate their QHP issuer networks under these standards available in a machine-readable file and format specified by HHS.

HHS anticipates:

- Using standards that are informed by those used in Medicare Advantage;
- Implementing methodologies that account for local geographical and topographical features that influence real-world access to providers such as the physical environment (for example, bodies of water, unpassable mountainous areas) and varied travel modes (for example, car, public transportation); and
- Expanding the use of the Java Script Object Notation (JSON) files QHP issuers currently make available as part of meeting provider directory requirements.

In light of the expanded use of, and reimbursement for, telehealth services during the COVID-19 PHE, time and distance standard methodologies that account for the availability of telehealth services are also under consideration.

For future rulemaking, HHS is carefully considering other network adequacy standards, including appointment wait times and standards that promote health equity (for example, provider directory requirements to include information about the race/ethnicity, language(s) spoken, accessibility, and office hours of in-network providers).

4. Segregation of funds for abortion services (§ 156.280)

HHS proposed to repeal the separate billing regulation at § 156.280(e)(2)(ii) that required individual market QHP issuers to send a separate bill for that portion of a policy holder's premium that is attributable to coverage for abortion services for which Federal funds are prohibited and to instruct such policy holders to pay for the separate bill in a separate transaction. Specifically, HHS proposed to revert to and codify in amended regulatory text at § 156.280(e)(2)(ii) the prior policy announced in the preamble of the 2016 Payment Notice under which QHP issuers offering coverage of abortion services for which Federal funds are prohibited have flexibility in selecting a method to comply with the separate payment requirement in section 1303 of the ACA. As proposed, HHS noted that individual market QHP issuers covering such abortion services would still be expected to comply with all statutory requirements in section 1303 of the ACA and all applicable regulatory requirements codified at § 156.280. HHS

is finalizing removal of the separate billing regulation and codification of the prior policy at § 156.280(e)(2)(ii) as proposed.

Section 1303 of the ACA outlines requirements that issuers of individual market QHPs covering abortion services for which Federal funds are prohibited must follow to ensure compliance with these funding limitations, which are based on the law in effect as of the date that is 6 months before the beginning of the plan year involved. Since 1976, Congress has included language, commonly known as the Hyde Amendment, in the Labor, Health and Human Services, Education and Related Agencies appropriations legislation that sets out funding restrictions for abortions.¹⁰³ The Hyde Amendment, as currently in effect, permits Federal funds subject to its funding limitations to be used for abortion services only in the limited cases of rape, incest, or if a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed. Abortion coverage beyond those limited circumstances is subject to the Hyde Amendment's funding limitations which prohibit the use of Federal funds for such coverage.

Section 1303(b)(2) prohibits QHPs from using any amount attributable to PTC (including APTC) or CSRs (including advance payments of those funds to an issuer, if any) for coverage of abortion services for which Federal funds are prohibited. Under sections 1303(b)(2)(B) and (b)(2)(D) of the ACA, as implemented in § 156.280(e)(2)(i) and (e)(4), QHP issuers must collect a separate payment from each enrollee without regard to the enrollee's age, sex, or family status, for an amount equal to the greater of the AV of coverage of abortion services for which public funding is prohibited, or \$1 per enrollee per month. Section 1303(b)(2)(D) of the ACA establishes certain requirements with respect to a QHP issuer's estimation of the AV of abortion services for which Federal funds are prohibited including that a QHP issuer may not estimate

¹⁰³ The Hyde Amendment is not permanent Federal law, but applies only to the extent reenacted by Congress from time to time in appropriations legislation.

such cost at less than \$1 per enrollee, per month. Section 1303(b)(2)(C) of the ACA, as implemented at § 156.280(e)(3), requires that QHP issuers segregate funds for coverage of such abortion services collected from enrollees into a separate allocation account used to pay for such abortion services. Thus, if a QHP issuer disburses funds for an abortion for which Federal funds are prohibited on behalf of an enrollee, it must draw those funds from the segregated allocation account.

Notably, section 1303 of the ACA does not specify the method a QHP issuer must use to comply with the separate payment requirement under section 1303(b)(2)(B)(i) of the ACA. In the 2016 Payment Notice, HHS provided guidance with respect to acceptable methods that an issuer of individual market QHPs could use to comply with the separate payment requirement.¹⁰⁴ HHS stated that QHP issuers could satisfy the separate payment requirement in one of several ways, including by sending the enrollee a single monthly invoice or bill that separately itemized the premium amount for coverage of abortion services for which Federal funds are prohibited; sending the enrollee a separate monthly bill for these services; or sending the enrollee a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. HHS also stated that an enrollee could make the payment for coverage of such abortion services and the separate payment for coverage of all other services in a single transaction.¹⁰⁵ On October 6, 2017, HHS released a bulletin that discussed the statutory requirements for separate payment, as well as this previous guidance on the separate payment requirement.¹⁰⁶

The 2019 Program Integrity Rule¹⁰⁷ prohibited the compliance options that the 2016 Payment Notice previously provided to QHP issuers with regard to the separate payment requirement. Specifically, the 2019 Program Integrity Rule finalized a policy requiring issuers of

¹⁰⁴ 80 FR 10750 (February 27, 2015).

¹⁰⁵ 80 FR 10750, 10840 (February 27, 2015).

¹⁰⁶ CMS Bulletin Addressing Enforcement of Section 1303 of the Patient Protection and Affordable Care Act (October 6, 2017), available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Section-1303-Bulletin-10-6-2017-FINAL-508.pdf>.

¹⁰⁷ 84 FR 71674 (December 27, 2019).

individual market QHPs offering coverage of abortion services for which Federal funds are prohibited to send an entirely separate monthly bill to policy holders just for the portion of the premium attributable to coverage of such abortion services. QHP issuers were required to either send separate paper bills (which could be sent in the same envelope or mailing), or send separate bills electronically (which were required to be in separate emails or electronic communications). The separate billing regulation also required QHP issuers to instruct the policy holder to pay for the portion of their premium attributable to coverage of abortion services for which Federal funds are prohibited through a separate transaction from any payment made for the portion of their premium not attributable to this coverage. It also required QHP issuers to make reasonable efforts to collect the payments separately. QHP issuers were to begin complying with these billing requirements on or before the QHP issuer's first billing cycle following June 27, 2020. Although HHS recognized that the previous methods of itemizing or providing advance notice about the amounts noted as permissible in the preamble of the 2016 Payment Notice arguably identified two 'separate' amounts for two separate purposes, HHS also reasoned that the separate billing policy would better align the regulatory requirements for QHP issuer billing of enrollee premiums with the intent of the separate payment requirement in section 1303 of the ACA.¹⁰⁸

HHS announced in the 2019 Program Integrity Rule that it would exercise enforcement discretion to mitigate risk of inadvertent coverage terminations that might result from enrollee confusion in connection with receiving two separate bills for one insurance contract. HHS explained that it would not take enforcement action against a QHP issuer that implemented a policy under which the issuer would not place an enrollee into a grace period and would not terminate QHP coverage based solely on the policy holder's failure to pay the separate bill. The 2019 Program Integrity Rule provided that HHS was adopting this enforcement posture effective June 27, 2020.

¹⁰⁸ 84 FR 71674, 71693.

In response to the proposal to adopt the separate billing requirement finalized in the 2019 Program Integrity Rule, HHS also received comments expressing concern that lack of transparency into whether QHPs provided coverage of abortion services for which Federal funds are prohibited presented the risk that consumers could unknowingly purchase such coverage. To address this risk, HHS announced that as of the effective date of the final rule, February 25, 2020, it would not take enforcement action against QHP issuers that allowed enrollees to opt out of coverage of such abortion services by not paying the separate bill for such services (the opt-out non-enforcement policy). The opt-out non-enforcement policy effectively gave issuers the flexibility to modify the benefits of a plan during a plan year based on an enrollee's desire to opt out of a plan's coverage of such abortion services.

In light of the immediate need for QHP issuers to divert resources to respond to the COVID-19 PHE, HHS published an interim final rule with comment in May 2020 for Medicare and Medicaid Programs, Basic Health Programs and Exchanges ("May 2020 IFC").¹⁰⁹ Finalized at § 156.280(e)(2)(ii), the rule delayed by 60 days the date when individual market QHP issuers would be required to begin separately billing policy holders such that QHP issuers were expected to comply with the separate billing regulation beginning on or before the QHP issuer's first billing cycle following August 26, 2020. The May 2020 IFC noted that a 60-day delay was justified in light of the ongoing litigation in Federal courts in Maryland, Washington, and California challenging the separate billing regulation. The May 2020 IFC also noted that the extended compliance deadline would only apply to the non-enforcement policy under which issuers would have flexibility to refrain from triggering grace periods or coverage terminations where a policy holder failed to pay the separate monthly bill, delaying when this enforcement posture would become available by 60 days (to August 26, 2020).

¹⁰⁹ 85 FR 27550.

A district court in Washington¹¹⁰ invalidated the 2019 Program Integrity Rule’s separate billing regulation in the state of Washington in April 2020, and district courts in Maryland¹¹¹ and California¹¹² vacated the 2019 Program Integrity Rule’s separate billing regulation in July 2020, in advance of the postponed compliance deadline of August 26, 2020. On April 9, 2020, the United States District Court for the Eastern District of Washington issued an opinion declaring the separate billing regulation invalid in the State of Washington.¹¹³ The district court specifically found that the separate billing regulation was in conflict with Washington’s “Single-Invoice Statute,”¹¹⁴ which requires health insurance issuers in the state to bill enrollees using a single invoice. The district court held that the separate billing regulation did not preempt Washington’s Single-Invoice Statute.

On July 10, 2020, the United States District Court for the District of Maryland found the separate billing regulation to be contrary to section 1554 of the ACA and arbitrary and capricious under the Administrative Procedure Act, thus declaring it invalid and unenforceable nationwide.¹¹⁵ The district court found the separate billing regulation to be in conflict with section 1554 of the ACA, which, among other key provisions, prohibits the Secretary from promulgating regulations that create any unreasonable barriers to obtaining appropriate medical care or impede timely access to health care services. The district court concluded that the policy imposed an unreasonable barrier because it would make it harder for enrollees to pay for insurance because they must keep track of two separate bills, which is likely to cause confusion and might lead to some enrollees losing health insurance. The district court also held the separate billing regulation to be arbitrary and capricious, finding that HHS failed to provide a reasoned explanation for abandoning the policy that existed prior to the adoption of the current separate billing regulation in the 2019 Program Integrity Rule. The district court also held that the

¹¹⁰ Washington v. Azar, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

¹¹¹ Planned Parenthood of Maryland, Inc. v. Azar, No. CV CCB-20-00361 (D. Md. July 10, 2020); 5 U.S.C. § 706.

¹¹² California v. U.S. Dep’t of Health & Hum. Servs., 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020).

¹¹³ Washington v. Azar, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

¹¹⁴ Wash. Rev. Code § 48.43.074.

¹¹⁵ Planned Parenthood of Maryland, Inc. v. Azar, No. CV CCB-20-00361 (D. Md. July 10, 2020); 5 U.S.C. § 706.

implementation deadline was arbitrary and capricious because HHS failed to consider and adequately address specific, contrary evidence from regulated stakeholders that the implementation deadline for compliance with the separate billing regulation was unreasonable and would not provide QHP issuers with sufficient time to comply.

On July 20, 2020, the United States District Court for the Northern District of California issued an opinion¹¹⁶ holding that the separate billing regulation was arbitrary and capricious, setting it aside nationwide. The district court held that the required mid-year implementation date for issuers to comply with the separate billing regulation would cause substantial transactional costs to states, issuers, and enrollees without any corresponding benefit. The court further found that the 2019 Program Integrity Rule lacked a reasoned explanation for deviating from the prior acceptable methods available to QHP issuers for compliance with the separate payment requirement and for departing from industry billing practice.

HHS initially appealed all three decisions, but those appeals have been placed on hold following the recent change in administration. As explained in the proposed rule, in light of these developments, and upon further consideration of the court decisions invalidating the policy, HHS reassessed the value of the separate billing regulation and no longer believe it is justified in light of the high burden it would impose on issuers, states, Exchanges, and consumers, as well as the high likelihood of consumer confusion and unintended losses of coverage. Nor does HHS believe section 1303 of the ACA restricts issuers offering coverage of abortion services for which Federal funds are prohibited to collect the required separate payment through a separate bill and instruct consumers to pay for such a bill in a separate transaction. Rather, section 1303 of the ACA outlines requirements that issuers of individual market QHPs covering abortion services for which Federal funds are prohibited must follow to ensure that no public funding is utilized for coverage of such abortion services, including requiring issuers to collect separate payments for this portion of the premium, to segregate the funds, and to deposit such funds into separate

¹¹⁶ California v. U.S. Dep't of Health & Hum. Servs., 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020).

allocation accounts. As the 2019 Program Integrity Rule acknowledged, section 1303 of the ACA does not specify the method a QHP issuer must use to comply with the separate payment requirement.¹¹⁷

After considering comments received on this proposal, HHS is finalizing amendments to § 156.280(e)(2)(ii) to revert to and codify the policy previously adopted in the 2016 Payment Notice such that QHP issuers offering coverage of abortion services for which Federal funds are prohibited have flexibility in selecting a reasonable method to comply with the section 1303 separate payment requirement. As finalized, acceptable methods for satisfying the separate payment requirement are outlined at § 156.280(e)(2)(ii) and include sending the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of such abortion services; sending the policy holder a separate monthly bill for these services; or sending the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. Since HHS is finalizing these policies, the non-enforcement policies adopted in the 2019 Program Integrity rule and the May 2020 IFC are discontinued.

HHS is also finalizing as proposed the technical change to the section heading of § 156.280 to more accurately reflect its contents. As finalized, it will instead read, “Segregation of funds for abortion services.”

Comment: The majority of commenters supported the proposed changes to repeal the separate billing regulation and codify the prior policy at § 156.280(e)(2)(ii). A minority of commenters objected to the proposal.

Commenters supporting repeal of the separate billing regulation asserted that eliminating the separate billing requirements would streamline issuer billing practices, alleviate consumer and issuer burden, lessen the confusion for consumers pertaining to billing for their health needs, and prevent termination of coverage that would have otherwise resulted from substantial

¹¹⁷ 84 FR 71674, 71683.

consumer confusion over a second bill for such a miniscule amount. These commenters highlighted how the separate billing regulation would have caused considerable and unnecessary confusion and frustration for consumers that may have jeopardized their health insurance coverage if not for court intervention invalidating the policy prior to implementation. Commenters supporting repeal also noted that the separate billing framework contradicted well established industry practices for sending one bill for the entire premium for a set period. These commenters highlighted that HHS never offered examples of where the new approach of separate billing is used for other types of insurance billing successfully and without harm to consumers, and that HHS broadly failed to support the change to separate billing with evidence that the approach was reasonable. Commenters stated that such an unreasonable requirement is arbitrary and capricious and therefore unlawful, and noted that the separate billing regulation was so egregious of an interpretation of section 1303 of the ACA that multiple Federal courts invalidated the policy in 2020.

Commenters supported repeal from both a policy and legal perspective, noting that repeal of the separate regulation aligns with the vacatur of the policy by multiple Federal district courts in 2020. Commenters specifically raised that the Maryland District Court vacated the separate billing regulation in part because it would have created unreasonable barriers to obtaining appropriate medical care and impeded timely access to health care services, as it would have made it harder for enrollees to pay for insurance by making consumers keep track of two separate bills—in conflict with section 1554 of the ACA. Commenters also noted that court decisions invalidating the separate billing regulation focused on the harm that the requirements would have caused to enrollees if it went into effect. For example, commenters emphasized that the United States District Court for the Northern District of California issued an opinion holding that the separate billing regulation was arbitrary and capricious and focused on the substantial costs of the policy to states, issuers, and enrollees without any corresponding benefit.

Commenters also raised that the separate billing regulation was incompatible with some state laws, including Washington law. Commenters asserted that the United States District Court for the Eastern District of Washington found that the separate billing regulation was invalid in Washington State because of Washington's "single invoice statute," which the court found was not preempted by the separate billing regulation.

Commenters also expressed support for codifying the policy put in place under the 2016 Payment Notice for issuer compliance with section 1303's separate payment requirement, asserting that separately billing was unnecessary to achieve the congressional objective to section 1303 of segregating funds into separate allocation accounts and ensuring no Federal funds are used for coverage of abortion services for which Federal funding is prohibited. Specifically, commenters noted that for the five years preceding the separate billing regulation, individual market QHP issuers covering abortion services for which Federal funding is prohibited had executed HHS-approved methods for complying with section 1303 as permitted under the 2016 Payment Notice and, in doing so, achieved the congressional intent of segregating funds as the statute requires, without the variety of negative consequences from the separate billing regulation. Supporting commenters explained that reverting to the pre-2019 policy properly prioritizes a more efficient policy that will alleviate any burden the separate billing regulation would have imposed on consumers and issuers. Commenters commended HHS for proposing to allow issuers and states to choose the best compliance option for the separate payment requirement in section 1303 that will minimize carrier and consumer burden in the context of the local, state-specific landscape.

Some commenters expressing strong support for repeal of the separate billing policy and codification of the prior policy also asserted that, because the separate billing regulation has been vacated and because issuers never implemented the requirements, HHS does not technically need to finalize the proposed rule in order to grant issuers, consumers, and other stakeholders the requisite relief. These commenters emphasized that, by virtue of the Federal district courts'

vacatur, the policy finalized in the preamble of the 2016 payment notice is already currently in effect, which was itself a policy adopted after notice-and-comment rulemaking.

Other commenters supported the repeal of the separate billing regulation and codification of the pre-2019 policy, but requested that HHS prohibit issuers from sending separate bills entirely. These commenters asserted that compliance with section 1303 falls on the issuers, not the consumers, and that the negative consequences of the issuer billing and the consumer paying for coverage through separate transactions—increasing consumer confusion without any real benefit and the risk of coverage termination—are significant. Commenters noted that section 1303 requires that any notice regarding payments “shall provide information only with respect to the total amount of the combined payments for services” covered by the plan and that this restriction suggests that bills regarding abortion should only bill “the total amount of the combined payments.” These commenters therefore urged HHS to eliminate the option for QHP issuers to send a separate monthly bill for abortion services for which Federal funding is prohibited because it is prohibited by the statute, consistent with the purpose of section 1303, and supported by the record and common industry practice. Other commenters urged HHS to emphasize the third option for compliance, sending the consumer a notice at or shortly after time of enrollment, over the others as it is the least burdensome to consumers and would reduce potential confusion. If the option to send separate bills is maintained, some commenters encouraged HHS to consider adopting consumer protections to guard against the potential for policy holders to lose their health insurance coverage because they fail to pay the *de minimis* amount of the separate premium bill for abortion services for which Federal funds are prohibited, if issuers still choose to send separate bills.

Commenters opposing the proposal objected to abortion coverage altogether and asked that HHS retain the separate billing regulation and continue to require separate checks, separate envelopes, and separate transactions for all QHPs that provide coverage for abortion services for which Federal funding is prohibited. Many commenters objecting to the proposal also asked that

HHS allow issuers to permit consumers to opt out of such coverage by refusing to pay the portion of their premium attributable to coverage for abortions for which Federal funding is prohibited. Objecting commenters also challenged the assertion that the separate billing regulation would cause undue consumer confusion, pointing to how some policy holders receive multiple bills anyway from their insurance issuers or providers, such as consumers who have Medicare as well as a supplemental Medigap policy.

Objecting commenters generally argued that section 1303 of the ACA expressly requires separate billing as the only appropriate method for collection of the separate payment required under section 1303, that the burden estimated for implementation of the separate billing regulation is necessary to achieve compliance with the statute, and that repeal of the separate billing regulation will deprive consumers of needed transparency into coverage for which they may object on conscience or other grounds. Commenters asserted that all of the revised options for compliance with section 1303 proposed at § 156.280(e)(2)(ii) other than separate billing are inadequate to satisfy the section 1303 requirement as they would conceal the portion of the premium attributable to certain abortion services and would permit issuers to collect monthly premiums in a single, rather than separate, payment. Commenters also questioned HHS's reasoning for continuing to allow issuers to bill separately as one of the available compliance options when such a billing method leads to so many unjustified burdens, consumer confusion, barriers to care, and inequities.

Most commenters supported the proposal to change the section heading of § 156.280 to "Segregation of funds for abortion services." Commenters asserted that this technical change would better align with the intention of section 1303 of the ACA which expressly requires issuers to segregate funds and accounts for certain abortion coverage but does not pass on that burden to consumers. Commenters that objected to the proposal to repeal the separate billing regulation also objected to renaming the section heading, arguing that the technical change is

inappropriate and a further attempt to establish regulations that deviate from the law, for the same reasons that such commenters object to the proposal overall.

Response: HHS agrees with commenters that repealing the separate billing regulation is consistent with the Federal district court decisions invalidating the separate billing regulation and the requirements of section 1303 of the ACA. HHS also agrees that codifying the pre-2019 policy reinstates a policy that supports meaningful issuer compliance with section 1303 by ensuring appropriate segregation of funds as required by statute, without imposing the operational and administrative burdens of the separate billing regulation and without causing additional consumer confusion and unintended losses of coverage.

Although HHS acknowledges that some commenters continue to support the separate billing regulation, HHS emphasizes that multiple Federal district courts have already invalidated the separate billing regulation, preventing HHS from requiring its implementation.

HHS agrees with commenters' assertions that the invalidation of the separate billing regulation by the Federal district courts is binding on HHS and currently prohibits implementation of the separate billing policy.¹¹⁸ HHS also believes the potential harms to consumers, costs to issuers and states, consumer confusion, and potential loss of consumer coverage that would have occurred under the separate billing regulation warrant a formal repeal of the policy through notice and comment rulemaking not only to reflect these legal developments but also to rectify the interpretation and implementation of section 1303 of the ACA as a matter of Federal policy. HHS also believes it is important to codify the pre-2019 options for issuer compliance with section 1303 of the ACA, as such compliance options were noted only in the preamble to the 2016 Payment Notice. Taken together, HHS believes the Federal district court cases invalidating the separate billing regulation in combination with finalizing repeal of the regulation and codifying the pre-2019 options in this rule will provide

¹¹⁸ *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB-20-00361 (D. Md. July 10, 2020); 5 U.S.C. § 706; *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020); *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

additional clarity regarding compliance with section 1303 for stakeholders and remove contradictory policy interpretations at the Federal level.

Therefore, HHS is repealing the separate billing regulation and codifying the policy previously adopted in the 2016 Payment Notice such that QHP issuers offering coverage of abortion services for which Federal funds are prohibited again have flexibility in selecting a reasonable method to comply with the section 1303 separate payment requirement. As finalized at § 156.280(e)(2)(ii), acceptable methods for satisfying the separate payment requirement include sending the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of such abortion services; sending the policy holder a separate monthly bill for these services; or sending the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. As finalized, issuers will no longer be required to send separate paper bills or separate electronic communications for the portion of the policy holder's premium attributable to coverage of abortions services for which Federal funding is prohibited. Nor will an issuer electing to send separate bills, or utilizing any of the acceptable methods for collecting the separate payment, be required to instruct consumers to pay for the portion of their premium attributable to coverage of abortion services for which Federal funds are prohibited in a separate transaction, or to make efforts to collect these payments separately.

HHS again emphasizes that under this finalized revision to § 156.280(e)(2)(ii), individual market QHP issuers covering abortion services for which Federal funds are prohibited are still required to comply with section 1303 of the ACA and all applicable requirements codified at § 156.280. As discussed in the proposed rule, this includes collecting a separate payment from each policy holder per month for an amount equal to the greater of \$1 or the AV of coverage of abortion services for which Federal funds are prohibited, continuing to ensure that no Federal funding is used to pay for coverage of such abortion services, submitting a plan to the relevant state insurance regulator outlining how it will comply with the segregation of funds

requirements, and continuing to segregate funds for coverage of such abortion services collected from policy holders into a separate allocation account that is to be used to pay for such abortion services.

HHS understands commenter concerns regarding issuers that might choose to continue sending separate bills for the portion of the policy holder's premium attributable to abortion services for which Federal funding is prohibited. However, HHS continues to anticipate most issuers will decline to send two separate monthly bills and will instead choose to collect separate payments by one of the other proposed acceptable methods, as those alternatives minimize administrative complexity for issuers, align with industry billing practice, are less costly and administratively burdensome, and promote a more seamless consumer billing and payment experience. Although sending two bills would continue to be an option under the revisions HHS is finalizing, HHS emphasizes that any issuer electing to send two separate monthly bills should do so in a manner that minimizes consumer confusion, promotes continuity of coverage, and complies with section 1303 of the ACA. For example, if an issuer still chooses to send two separate monthly bills, issuers should include both bills in the same mailing, include the total premium due on both bills, explain on both bills that the total premium due is inclusive of the amount attributable to coverage of such abortion services for which Federal funding is prohibited, and explain that the consumer may pay for both bills in a single transaction. Issuers that do choose to send separate bills should also explain to the consumer that non-payment of any premium due, including for the portion of premium attributable to such abortion services, would continue to be subject to state and Federal rules regarding grace periods to mitigate risk of inadvertent loss of coverage from failure to pay a portion of the premium due. Although HHS encourages issuers to utilize the other available options for compliance, HHS also believes separately billing in the manner described (without direction to pay in two separate transactions and with adequate consumer protections in place) would comply with section 1303, which does

not specify a single method for compliance with the separate payment requirement, and would continue to alleviate the burden from the rigid requirements of the separate billing regulation.

Comment: Commenters who objected to repealing the separate billing regulation argued that the revised options for compliance with section 1303's separate payment requirement would not adequately address the concerns of consumers who object to coverage of abortions for which Federal funding is prohibited based on their conscience or religion. Such commenters maintain that abortion is immoral, has no place in health care, and that the separate billing regulation is the best way to affirm consumer conscience rights. These commenters asserted that the proposed revisions to § 156.280(e)(2)(ii) weaken statutory prohibitions on Federal funding for certain abortions that protect the conscience rights of taxpayers consistent with the Hyde Amendment. Such commenters asked that HHS allow consumers to opt out of coverage for abortions for which Federal funding is prohibited by not paying the portion of their premium attributable to such coverage, thereby avoiding the separate charge entirely.

Objecting commenters also stated that repealing the separate billing regulation removes transparency for consumers into which QHPs cover abortion services for which Federal funding prohibited and that the proposal to codify prior policy options for compliance with section 1303 would leave it up to QHP issuer discretion to determine how to comply with the statutory requirements of the ACA, when in fact the only method that complies with the statute existed under the separate billing regulation. Such commenters also asserted that the prior methods for compliance with section 1303 under the 2016 Payment Notice deprive consumers of needed transparency and allow many unwittingly to purchase plans that include abortion coverage that might be contrary to their religious and moral convictions. These commenters urged HHS to pursue greater transparency by being open to consumers about their coverage options and what they are paying for in their insurance.

Commenters supporting the proposal to repeal the separate billing regulation and codify the prior options for compliance noted that transparency on HealthCare.gov could be further

improved for consumers who value coverage of abortion services by including language during plan selection that indicates when a plan does not cover abortion services for which Federal funding is prohibited so that consumers are aware of this lack of coverage and can seek out a different plan with such coverage.

Commenters supporting repeal also supported discontinuing the opt-out non-enforcement policy. These commenters noted that HHS never sought public comment on that policy, which was especially harmful to consumers as the opt-out would have applied not only to the policy holder but also to anyone else on the policy, such as a spouse or an adult child, potentially causing consumers to lose coverage of abortion services. Commenters supporting discontinuation of the opt-out non-enforcement policy also asserted that allowing opt-outs in this manner runs afoul of the plain language of section 1303, which distinguishes between plans that offer abortion coverage for which Federal funding is prohibited to all enrollees on one hand, and plans that do not offer such coverage, on the other. Commenters asserted that section 1303 therefore leaves no room for the issuer of a single plan to offer such abortion coverage to some enrollees but not others, or to permit enrollees to opt-out of such coverage and effectively turn a single plan otherwise approved by the Exchange and offered to consumers into two separate plans. Commenters also noted that, in announcing the opt-out non-enforcement policy, HHS did not quantify the financial impact that was certain to result from it, as the issuers and plan participants who maintained abortion coverage would be left to shoulder the cost of that coverage without those who had opted out.

Response: Repealing the separate billing regulation and codifying the prior policy will allow issuers to bill using one of the prior acceptable methods that would eliminate all risk of inadvertent coverage terminations that could result from consumer confusion due to receiving two monthly bills (one for a miniscule amount, not less than \$1) in connection with one insurance policy.

As such, HHS affirms that repealing the separate billing regulation will also discontinue the non-enforcement policies adopted in the 2019 Program Integrity Rule and the May 2020 IFC, including the opt-out non-enforcement policy, which were in large part intended to mitigate potential coverage losses resulting from enrollee confusion that leads to enrollees' failures to pay the separate, small monthly bill covering abortion services for which Federal funds are prohibited.

HHS acknowledges that the 2019 Program Integrity Rule noted that the opt-out non-enforcement policy was also intended to address commenter concerns regarding insufficient transparency into whether QHPs include coverage of abortion services for which Federal funds are prohibited and the risk that consumers could unknowingly purchase QHPs that include such coverage, and potentially conflict with their conscience. In response to comments again raising these concerns, HHS reiterates that it has already taken steps to improve transparency regarding QHP offerings of abortion coverage by making it easier for consumers to select QHPs that they believe are best suited to their needs and preferences. For instance, information is available during plan selection on HealthCare.gov that can assist consumers in more readily identifying QHPs that offer coverage of such abortion services and provide consumers with the requisite information to make an informed choice about their plan selections regarding coverage of such services.¹¹⁹ Further, although section 1303 requires collection of a separate payment and segregation of funds for coverage of certain abortion services, it does not require issuers to alert consumers to this coverage for purposes of transparency of benefits. Like with coverage of other benefits, consumers seeking a QHP that covers abortion services should review plan details and plan documents for information during plan selection that affirms the plan's coverage of such services. Consumers are able to make plan selections based on their unique health needs and benefit coverage preferences prior to enrollment, and updates made to plan selection on

¹¹⁹ Frequently Asked Questions for Agents, Brokers, and Assistants Providing Consumers with Details on Plan Coverage of Certain Abortion Services (November 21, 2018), available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-on-Providing-Consumers-with-Details-on-Plan-Coverage-of-Certain-Abortion-Services.pdf>.

HealthCare.gov to list coverage of abortion services for which Federal funding is prohibited facilitates this selection process for individuals with conscience objections or other preferences regarding their coverage.

Although HHS acknowledges that there are some states where there may be no QHP available on the Exchange that omits coverage for such abortion services, HHS again emphasizes that such plan availability is subject to state law and issuer choice in plan design as permitted under section 1303 of the ACA. Specifically, section 1303(b)(1)(A)(ii) specifies that an issuer shall determine whether or not the plan provides coverage for abortion services for which Federal funds are prohibited for the applicable plan year, expressly providing that issuers are able to determine whether to offer coverage for such abortion services, subject to state law. Therefore, it is state law that dictates to what extent issuers may cover abortion services for which Federal funding is prohibited, the issuer's option whether to offer such services pursuant to state law, and the enrollee's option whether to enroll in such a plan.

HHS therefore continues to believe that allowing an opt-out policy would conflict with the flexibility in issuer plan design expressly provided under section 1303. HHS also believes the opt-out non-enforcement policy conflicts with § 147.106(e)(1), which generally provides that only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan or an individual, as applicable.

It also specifies that any such modification in the individual market must be consistent with state law and be effective uniformly for all individuals with that product. Finally, the United States District Court for the Northern District of California cited the opt-out non-enforcement policy in finding that the 2019 Program Integrity Rule lacked a reasoned explanation for deviating from the prior acceptable methods available to QHP issuers for compliance with the separate payment requirement.¹²⁰ The court explained that inclusion of the opt-out non-

¹²⁰ California v. U.S. Dep't of Health & Hum. Servs., 473 F. Supp. 3d 992, 1003 (N.D. Cal. July 20, 2020) (citing Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2125 (2016)).

enforcement policy, which was not subject to public comment, supported the court's conclusion that HHS changed its prior policy without affording any reasoned explanation for the change.

For these reasons, and given that the separate billing requirements finalized in the 2019 Program Integrity Rule have been invalidated, these non-enforcement policies are no longer necessary or feasible long-term and are therefore discontinued. Section 1303 of the ACA requires certain billing, accounting, and notice requirements of issuers in the individual market to ensure that issuers that do offer abortion services for which Federal funding is prohibited do so in a manner that ensures separation of funds consistent with statute. HHS believes the permissible methods finalized at § 156.280(e)(2)(ii) for issuer compliance with section 1303 of the ACA offer issuers several ways to comply with section 1303 of the ACA in a manner that works best for them and minimizes burden on consumers.

Comment: Commenters supporting the proposal to repeal the separate billing regulation and codify the prior policy explained that the separate billing regulation would have imposed new overly burdensome costs on issuers, states, State Exchanges, and FFEs, which would have been passed on to consumers in the form of higher premiums.

Supporting commenters stated that issuers subject to the separate billing requirements would have had to redesign their billing systems and imposed expensive IT changes on issuers and states, requiring creation of an operating billing system only for individual Exchanges and not for products sold in any other market. Commenters also agreed that the separate billing regulation would have required costly changes to other issuer operations such as invoice processing, collections, customer service support, and electronic data interchange (EDI) transactions with Exchanges. Commenters also agreed there would be added administrative costs of mailing separate bills in separate envelopes and collecting separate payments. Commenters also expressed concern that the highest costs from the separate billing regulation would have been concentrated in states that require abortion coverage. Some commenters noted that issuers have already incurred ongoing costs for printing and mailing, additional staffing, and

reprogramming billing systems and that the separate billing regulation already resulted in increased burden for issuers and consumers, widespread confusion by consumers and other stakeholders, and an increase in frustration and confusion around grace periods and terminations.

Supporting commenters also stated that the separate billing regulation would have been so burdensome on issuers and consumers that it would have impeded access to abortion coverage, which is a common and safe medical intervention, and a legally and constitutionally protected form of medical care in the United States. These commenters noted that some issuers would find the separate billing regulation so burdensome that they would either leave the Exchange or drop coverage for abortion care entirely. These commenters asserted that coverage for abortion care often means the difference between getting the health care that a consumer needs and being denied that care, and that individuals denied abortions are more likely to experience eclampsia, other serious medical complications, and death, remain in relationships where interpersonal violence is present, and suffer anxiety after being denied an abortion.

Commenters agreed that it would have had a disproportionate effect on consumer groups who already face barriers in navigating health insurance, particularly people of color, immigrants, individuals with LEP or low literacy and educational levels, and those living with visual disabilities and/or impairments. Commenters explained that restrictions to abortion coverage such as the separate billing regulation particularly harm BIPOC as well as LGBTQ+ individuals who disproportionately struggle with poverty and who are over-represented in the population of individuals receiving abortions. Commenters noted that 28 percent of individuals who receive abortions are Black and 25 percent are Latinx, while they represent only 13 percent and 18 percent of the U.S. population, respectively. These commenters also noted that the separate billing regulation would have exposed many of these individuals and families to untenable economic circumstances because, if issuers were to drop such abortion coverage, the costs would be transferred to consumers and such costs would likely disproportionately impact low-income women who already face barriers to accessing health care services. Commenters

also asserted that termination of coverage due to confusion over payment of the second bill would be especially problematic for consumers with critical medical needs such as cancer patients and survivors, as gaps in coverage may interrupt treatment schedules which could jeopardize outcomes in care.

Commenters also noted that repealing the separate billing regulation and interpreting section 1303 of the ACA in the least burdensome manner is consistent with both the Department's mission to "enhance the health and well-being of all Americans" and EO 14009, which directed HHS to review all existing regulations to determine whether they are inconsistent with the Administration's policy priority of "eliminating unnecessary difficulties to obtaining health insurance." Commenters also expressed support that the proposal is consistent with EO 13985, which directed HHS to assess whether, and to what extent, its programs and policies "perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups."¹²¹

Commenters objecting to repeal of the separate billing regulation and codification of the pre-2019 policy asserted that justifying repeal of the policy based partially on a reassessment of burden ignores the issuers, states, Exchanges, and consumers for which separate billing regulation had no impact. For example, such commenters explained that the separate billing regulation had no effect on issuers, states, Exchanges, and consumers in states that prohibit insurance coverage of abortion services for which Federal funding is prohibited or on issuers that do not include such coverage in their plans for other reasons.

Objecting commenters broadly criticized HHS's cost estimates for the burden associated with the separate billing regulation, arguing that HHS failed to consider important factors, explore sufficient data, and make necessary estimates. These commenters asserted that HHS based its cost estimates on the projections from the 2019 Program Integrity Rule which commenters claim lack sufficient justification. For example, commenters asserted that HHS did

¹²¹ 86 FR 7009 (Jan. 25, 2021).

not provide sufficient evidence that certain groups of people are more likely to be impacted by the separate billing regulation than others or that the burden will fall more heavily on marginalized communities. Such commenters added that, in any event, such arguments cannot justify violating the separate billing requirement that commenters argue is expressly required under section 1303.

Commenters also argued that HHS has not shown how repeal of the separate billing regulation and codification of the prior policy will add a financial benefit for either consumers or issuers that outweighs the harm caused to consumer transparency, conscience protections, and statutory compliance with section 1303. Such commenters asserted that the separate billing regulation would have rightly shifted the burden of complying with section 1303 away from individual consumers and onto issuers. Commenters also asserted that, without exploring further information, HHS cannot claim a full and complete savings of the estimated costs had the separate billing regulation been implemented.

Objecting commenters also alleged that, regardless of the extent of burden associated with the separate billing regulations on issuers, states, Exchanges, and consumers, any such burden is not unreasonable, but rather is necessary to ensure compliance with section 1303. Commenters objecting to repeal of the separate billing regulation also posited that HHS provided insufficient evidence to support the assertion that marginalized communities would be disproportionality burdened by the separate billing regulation had it been implemented.

Commenters also asserted that the cost estimates fail to address or take into account recent changes in the law made by the ARP. Commenters stated that millions of Americans are newly eligible for zero-dollar coverage under ARP but that, in states where all or most individual market plans cover abortion for which Federal funding is prohibited, consumers will not be able to purchase a zero-dollar premium plan because of section 1303's funding restrictions. Commenters therefore argued that individuals in such situations are already paying, in effect, a "separate bill" for that coverage and would not face additional burdens established by the

separate billing regulation. Commenters raising this objection asked HHS to explain how the Department will enforce section 1303's funding restrictions for otherwise zero-premium Exchange plans and to provide a state-by-state analysis of the effects of the proposed rule.

Response: HHS agrees with commenters that the burden on stakeholders and consumers to comply with the separate billing regulation would have been overly burdensome if the policy had ultimately been implemented. HHS also agrees that the increased burden associated with issuers complying with the separate billing regulation could have influenced whether a QHP issuer continues to offer coverage of abortion services for which Federal funding is prohibited in states that do not require it, an outcome which was also acknowledged in the 2019 Program Integrity Rule. HHS also agrees with commenters that, had the separate billing regulation been implemented, consumer confusion over receiving a separate bill for a relatively small amount of premium could have caused inadvertent loss of coverage and would have imposed significant burden on states and issuers to implement the new billing framework.

HHS generally disagrees with commenters contesting the estimated cost savings of repealing the separate billing regulation, particularly those claiming that the estimated cost savings are too high because they believe that the estimated burden in the 2019 Program Integrity rule was inflated. Some commenters noted that issuers have already incurred ongoing costs for printing and mailing, additional staffing, and reprogramming billing systems and that the separate billing regulation already resulted in increased burden for issuers and consumers, widespread confusion by consumers and other stakeholders, and an increase in frustration and confusion around grace periods and terminations. HHS acknowledges that some costs may have already been incurred by issuers and that the actual cost savings, especially for one-time IT related costs, may be lower than HHS estimates. Unfortunately, HHS does not have an estimate of costs already incurred by issuers and can only estimate savings going forward. HHS nonetheless continues to believe the timing of the courts' actions likely dissuaded issuers from assuming further costly administrative and operational burdens required to build the separate

billing policy into their billing and IT systems. As the courts' nationwide invalidation of the policy prevented HHS from requiring initial implementation of the separate billing regulation, the potential consumer confusion over payment obligations, which could have inadvertently led to non-payment of enrollee premium and subsequent termination of consumer coverage, was also avoided. Furthermore, HHS continues to believe that requiring separate billing is unnecessary and overly burdensome to achieve compliance with section 1303 of the ACA. Section 1303 does not specify a method for compliance with the separate payment requirement, and HHS believes the new issuer compliance options codified at § 156.280(e)(2)(ii) minimize stakeholder burden and protect against consumer confusion and potential loss of coverage.

HHS acknowledges that consumers who live in states where premiums for Exchange coverage cannot be fully paid for with APTC, such as states that require coverage of abortion services for which Federal funding is prohibited, will not have access to a silver plan with a zero-dollar premium, as further explained in the preamble to § 155.420(d)(16) of the proposed rule.¹²² However, HHS also notes that individual market QHP issuers covering abortion services for which Federal funds are prohibited offering coverage to consumers who qualify for zero-dollar premium plans are still required to comply with section 1303 of the ACA and all applicable requirements codified at § 156.280. HHS also notes that the ARP was enacted in 2021 and, therefore, the consumer cost and burden estimates in each respective rule regarding the separate billing regulation were based on the estimated number of all consumers enrolled in QHPs offering coverage for abortion and are reflective of the anticipated burden at that time.

HHS similarly disagrees with commenters questioning the validity of the cost estimates and cost-benefit analysis for repealing the separate billing regulation and codifying the prior acceptable methods for compliance with section 1303. In response to comments that objected to the omission of issuers that do not cover abortion services for which Federal funding is prohibited and states that ban such coverage, HHS notes that such an omission is appropriate as

¹²² 86 FR 35156.

such issuers and states would not be impacted by the requirements or the high costs and burden from the separate billing regulation. The 2019 Program Integrity Rule included a detailed account of the anticipated financial and operational burdens from the separate billing regulation, estimates which were based upon plan and premium data, actuarial estimates, public comments from issuers and states directly regulated by the separate billing policy, and consumer enrollment figures. Those burdens are discussed in further detail in sections III., “Collection of Information Requirements,” and IV., “Regulatory Impact Analysis,” of that rule and explain from where such estimates are derived. Those burdens included one-time cost estimates for issuers and State Exchanges performing premium billing and payment processing for operational changes such as implementation of the technical build to implement the necessary system changes to support separate billing and receipt of separate payments, which would require significant changes to current billing practice and pose increased challenges given the mid-plan year implementation timeline. The anticipated burden also included ongoing annual costs for sending a separate bill to impacted enrollees, associated record keeping, customer service, and compliance, as well as annual materials costs related to printing of and sending the separate bill. HHS also acknowledged that the separate billing regulation would impose burdens on State Exchange operations due to one-time technical changes such as updating online payment portals to accept separate payments and updating enrollment materials, as well as ongoing annual costs associated with increased customer service, outreach, and compliance.

The Program Integrity Rule also projected that FFEs would incur additional costs due to one-time technical changes and increased call volumes and additional customer services efforts. HHS also stated that QHP issuers were likely to consider these new costs when setting actuarially sound rates and that this would likely lead to higher premiums for enrollees. HHS also anticipated increased costs to consumers for the time required to read and understand the separate bills and to seek help from customer service if necessary, and additional time to read and send separate payments in subsequent months. In total, the projected burden to all issuers,

states, State Exchanges performing premium billing and payment processing, the FFEs, and consumers totaled \$546.1 million in 2020, \$232.1 million in 2021, \$230.7 million in 2022, and \$229.3 million annually in 2023 and onwards.

As stated in the proposed rule, HHS has since reassessed these burdens and agree with commenters that the consumer confusion and new logistical obstacles from the separate billing regulation would disproportionately burden communities that already face barriers to accessing care, such as individuals with LEP, individuals with disabilities, rural residents, those with inconsistent or no access to the Internet, those with low levels of health care system literacy, and individuals within other marginalized communities. The impact of these barriers to access for the aforementioned segments of consumers are routinely borne out in multiple studies and supported by readily available data and evidence.¹²³ For example, the National Council on Disability concludes that, “[p]eople with disabilities experience more problems accessing health care than other groups, and these difficulties increase for those with the most significant disabilities and who are in the poorest health.”¹²⁴ Existing inequalities in access to health care resulting from those barriers would be exacerbated by the addition of further and unnecessary requirements that result in consumers receiving a second separate bill for a relatively miniscule amount with an arbitrary requirement to pay both bills in separate transactions. As many commenters noted, failure to pay the separate bill entirely due to consumer confusion could also lead to a complete loss of coverage, further exacerbating existing health disparities and jeopardizing health outcomes.¹²⁵ The 2019 Program Integrity Rule also acknowledged that the high burden associated with the separate billing regulation might result in issuers withdrawing coverage of

¹²³ See Rural Health, Centers for Disease Control and Prevention, available at <https://www.cdc.gov/chronicdisease/resources/publications/factsheets/rural-health.htm>; Accenture, The Hidden Cost of Healthcare System Complexity (2018), available at https://www.accenture.com/_acnmedia/pdf-104/accenture-health-hidden-cost-of-healthcare-system-complexity.pdf; The Current State of Health Care for People with Disabilities, The National Council on Disability, available at <https://www.ncd.gov/publications/2009/Sept302009#Overview>. See Victor G. Villagra et al., *Health Insurance Literacy: Disparities by Race, Ethnicity, and Language Preference*, American Journal of Managed Care (Mar. 2019), available at <https://www.ajmc.com/view/health-insurance-literacy-disparities-by-race-ethnicity-and-language-preference>.

¹²⁴ See The Current State of Health Care for People with Disabilities, The National Council on Disability, available at <https://www.ncd.gov/publications/2009/Sept302009#Overview>.

¹²⁵ See Health Coverage by Race and Ethnicity, 2010-2019, Kaiser Family Foundation, available at <https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/>.

abortion services for which Federal funds are prohibited altogether to avoid the associated burden, requiring some enrollees to pay for these services out-of-pocket. Based on a 2014 study, the average costs to patients for first-trimester abortion care was \$461, and anywhere from \$860 to \$1,874 for second-trimester abortion care.¹²⁶ Transferring these costs to enrollees could disproportionately impact low-income women for whom these out-of-pocket costs could represent a significant financial burden. In addition, low-income women may already face barriers to accessing quality health care due to their socioeconomic status, gender, sexual orientation, nationality, or race.¹²⁷ HHS believes proposing repeal of the separate billing regulation would remove these burdensome requirements and obstacles, promoting health equity.

Comment: Commenters supporting the proposal to repeal the separate billing regulation and codify the prior policy from the 2016 Payment Notice expressed support for reverting to an interpretation of section 1303 that is consistent with Congressional intent. Such commenters emphasized that, although Congress decided to treat abortion differently when passing section 1303, it did so specifically to ensure that private insurance plans could continue to decide whether or not to cover abortion in a state that did not ban such coverage. These commenters also noted that during the ACA debates and negotiations, Congress rejected amendments aimed at more stringent restrictions or prohibitions of abortion coverage. Commenters also supported repeal of the separate billing regulation, noting it would have interfered with flexibility provided to states under section 1303 of the ACA by interfering with states' requirements to offer or allow abortion coverage in their plans, which section 1303 expressly permits.

Commenters also noted that section 1303(b)(2)(E)(i) of the ACA designates state insurance commissioners as the entities responsible for monitoring, overseeing, and enforcing the provisions in section 1303 related to the segregation of funds for QHPs that cover abortion services for which Federal funding is prohibited.

¹²⁶ See Roberts, Sarah C. M., Heather Gould, Katrina Kimport, Tracy A. Weitz, and Diana Greene Foster. "Out-of-Pocket Costs and Insurance Coverage for Abortion in the United States." *Women's Health Issues*, vol. 24, no. 2 (2014): e211-e218.

¹²⁷ See Disparities, *Healthy People 2020*, available at <https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>.

Commenters supporting repeal of the separate billing regulation agreed that section 1303 does not expressly require a specific method for collecting the separate payment for abortion services for which Federal funding is prohibited. Commenters also highlighted that section 1303(b)(3)(B) of the ACA specifies that issuer notifications shall provide information only with respect to the total amount of the combined payments for abortion services for which Federal funding is prohibited and other services covered by the plan. Commenters therefore stated that requiring separate billing for these services directly contradicts section 1303(b)(3)(B) as it would have required issuers to separately notify the consumer on a monthly basis of the portion of their premium attributable to coverage of abortion services for which Federal funds are prohibited.

Commenters also stated that codifying the pre-2019 options for compliance with the separate payment requirement comply with the section 1303(b)(2)(E) of the ACA, which states that health plans shall “comply with the segregation requirements in this subsection through the segregation of plan funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget, and guidance on accounting of the Government Accountability Office.” Specifically, commenters noted that generally accepted accounting requirements would permit one single bill outlining the separate charges for any covered abortion services for which Federal funding is prohibited. Commenters noted that requiring separate bills for each charge, as established in the 2019 Program Integrity Rule, goes too far, is against industry practice, and is not what section 1303 requires.

Commenters objecting to the proposal to repeal the separate billing regulation asserted that section 1303 is unambiguous in requiring a separate bill for coverage of abortion for which Federal funding is prohibited, and that any ambiguity is clarified by the legislative history of section 1303 of the ACA. Objecting commenters also stated that, prior to the separate billing regulation, HHS failed to enforce section 1303’s separate payment requirements sufficiently, citing a 2014 Government Accountability Office (GAO) report that found issuer inconsistencies

in compliance with section 1303 requirements¹²⁸ and a 2018 letter from Congress which cited the same GAO report.¹²⁹ Such commenters objected to repeal of the separate billing regulation, stating that requiring two separate bills would have addressed what commenters believed was insufficient enforcement of section 1303. Commenters argued that money that originates as a single payment and is later separated into separate allocation accounts is not separate within the meaning of section 1303 and that only with separation from intake to expenditure can health care providers meaningfully ensure that abortion services are not being funded from the same pool of resources as other health care services. These commenters asserted that the separate billing regulations align best with the text of the ACA and the intent of Congress in including section 1303 by providing the most common-sense route to encourage consumers to make separate payments as required by statute and to maintain the segregation of funds from intake to expenditure. Commenters also stated that, according to Merriam-Webster Dictionary, the word “separate” means “to set or keep apart” and that this warrants an interpretation of section 1303 as requiring only separate bills. Objecting commenters also argued that section 1303(b)(2)(B)(i) of the ACA demonstrates that section 1303 requires separate billing by elaborating that in the case of a payroll deposit, a separate deposit is required. Commenters therefore assert that the fact that section 1303 expressly requires separate deposits for certain abortion coverage in the case of premiums paid through employee payroll deposits further supports the interpretation that issuers must collect all separate payments from individuals through separate transactions.

Response: HHS again emphasizes that multiple Federal district courts have already invalidated the separate billing regulation, preventing HHS from requiring its implementation.¹³⁰ HHS also continues to believe the changes to § 156.280(e)(2)(ii) offer issuers options for

¹²⁸ U.S. Government Accountability Office, “Health Insurance Exchanges: Coverage of Nonexcepted Abortion Services by Qualified Health Plans,” (Sept. 15, 2014), available at <http://www.gao.gov/products/GAO-14-742R>.

¹²⁹ Letter from Chris Smith, Member of Congress, to Alex Azar, Secretary, U.S. Department of Health and Human Services (Aug. 6, 2018), available at https://chrissmith.house.gov/uploadedfiles/2018-08-06_-_smith_letter_on_section_1303_-_abortion_funding_transparency.pdf.

¹³⁰ *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB-20-00361 (D. Md. July 10, 2020); *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020); *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

meaningful compliance with section 1303 and ensure appropriate segregation of funds required by statute, without imposing the operational and administrative burdens of the separate billing regulation and without causing additional consumer confusion and unintended losses of coverage, a position that is supported by the Federal district courts invalidating the separate billing regulation. HHS therefore disagrees with commenters' assertions that the other methods for complying with the separate payment requirement HHS is finalizing at § 156.280(e)(2)(ii) are in conflict with the requirements in section 1303.

Indeed, the preamble to the 2019 Program Integrity Rule acknowledged that receipt by a QHP issuer of a single premium payment for the entirety of the policy holder's coverage including abortion services for which Federal funds are prohibited did not preclude QHP issuer compliance with the section 1303 separate payment requirement. Although the separate billing regulation required QHP issuers to bill separately and make reasonable efforts to collect the payment separately, it also specified that QHP issuers would not be permitted to refuse a combined payment or terminate the policy on the basis of combined payment. The separate billing regulation is therefore ultimately nonessential to QHP issuer compliance with the separate payment requirement in section 1303 of the ACA, which does not expressly require that a separate bill be sent for coverage of abortions for which Federal funding is prohibited. Upon receiving a single premium payment inclusive of the portion of premium attributable to coverage of such services, the QHP issuer may treat that portion as a separate payment and disaggregate the amounts into the separate allocation accounts, consistent with § 156.280(e)(2)(iii). HHS believes this provides the requisite segregation of funds required by statute. HHS therefore believes that requiring QHP issuers to acquire the separate payment through sending separate bills and instructing consumers to pay in separate transactions is more restrictive than necessary, especially in light of the issuer and stakeholder burden and adverse consumer impacts the separate billing regulation could impose.

Although sending a separate bill to enrollees for these services is one way in which an issuer may satisfy the separate payment requirement as finalized at § 156.280(e)(2)(ii), it is not the only method contemplated by the plain reading of section 1303. HHS therefore agrees with commenters that it is unnecessary to restrict the acceptable methods for collecting these payments, especially in light of the substantial anticipated burden from the separate billing regulation, the risk of inadvertent coverage terminations that could result from consumer confusion due to receiving two monthly bills, the stakeholder reliance on the prior acceptable methods, and Federal district court concerns with barriers to appropriate and timely medical care as well as a lack of corresponding benefits.

The section 1303 provision that is colloquially referred to as the separate payment requirement is titled “Establishment of allocation accounts,” and is a subsection of a section titled “Prohibition on the use of Federal funds.”¹³¹ These sections detail issuer requirements for calculating the AV for the portion of the premium attributable to coverage of abortion services for which Federal funds are prohibited, and require issuers to collect separate payments for this portion of the premium, segregate the funds, and deposit such funds into separate allocation accounts. Notably, these sections do not require that issuers satisfy these requirements by separately billing policy holders or instructing them to pay in separate transactions.

Lastly, HHS notes that not only is the 2014 U.S. GAO report that objecting commenters state is evidence of HHS non-enforcement of section 1303 of the ACA outdated, but also there is no evidence of ongoing issuer compliance issues with section 1303 of the ACA. In fact, the 2014 U.S. GAO report predates the 2016 Payment Notice, which is where HHS first clarified for issuers the acceptable methods for complying with the separate payment requirement which HHS is reinstating and codifying today. Further, the research to inform that report was conducted between February 2014 and September 2014, prior to the 2016 Payment Notice and during the first full year that the Exchanges began operating. As such, issuers were less likely to have fully

¹³¹ Section 1303(b)(2) and (b)(2)(B) of the ACA.

implemented the compliance standards required under the ACA and were not yet aware of how HHS would further clarify and implement the separate payment requirement in the 2016 Payment Notice.

Section 1303 does not specify the method a QHP issuer must use to collect the separate payment.¹³² Consistent with the Federal district court decisions invalidating the separate billing regulation, HHS is therefore finalizing a revised policy at § 156.280(e)(2)(ii) that repeals the separate billing regulation and instead allows issuers to satisfy the separate payment requirement through methods consistent with section 1303 of the ACA. As finalized, § 156.280(e)(2)(ii) imposes no more burden on issuers, states, Exchanges, and consumers than is necessary, and removes unreasonable barriers to obtaining appropriate medical care.

IV. Provisions of the Proposed Rule for Section 1332 Waivers – Department of Health and Human Services and Department of the Treasury

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

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 coverage.

Under section 1332 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 will provide 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 will provide coverage and cost-sharing protections

¹³² 84 FR 71674, 71683.

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 will provide 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 will not increase the Federal deficit. The Secretaries retain their discretionary authority under section 1332 to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrails.

The Departments are also responsible under section 1332 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 of the ACA requires that the Secretaries provide for and conduct periodic evaluations of approved section 1332 waivers.¹³³ The Secretaries must also provide for a process under which states with approved section 1332 waivers must submit periodic reports concerning the implementation of the state's waiver program.¹³⁴

In October 2018, the Departments issued the 2018 Guidance,¹³⁵ which provided additional guidance for states wishing to submit section 1332 waiver proposals regarding the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations.¹³⁶ The 2018 Guidance also included information regarding how the Departments will apply and interpret the section 1332 statutory guardrails when evaluating waiver applications. Furthermore, in part 1 of the 2022 Payment Notice final rule,¹³⁷ the Departments codified many of the major policies and interpretations outlined in the 2018 Guidance into the text of relevant section 1332 implementing regulations.

¹³³ See section 1332(a)(4)(B)(v) of the ACA.

¹³⁴ See section 1332(a)(4)(B)(iv) of the ACA.

¹³⁵ 83 FR 53575 (Oct. 24, 2018).

¹³⁶ The 2018 Guidance superseded guidance issued by the Departments in December 2015, which similarly provided information regarding the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, operational considerations, and interpretations of the statutory guardrails. See 80 FR 78131, available at <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

¹³⁷ See 86 FR 6138.

On January 28, 2021, President Biden issued EO 14009,¹³⁸ directing the Secretaries and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether such agency actions are inconsistent with the policy set forth in section 1 of EO 14009. As part of this review, EO 14009 directed agencies to look at demonstrations and waivers, as well as demonstration and waiver policies that may reduce coverage under or otherwise undermine Medicaid or the ACA. As such, the Departments reviewed the 2012 Final Rule, the 2015 Guidance, the 2018 Guidance, and the policies implemented in part 1 of the 2022 Payment Notice final rule on section 1332 waivers to determine whether they are inconsistent with the policy intention of EO 14009 to protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American.

In addition, on January 20, 2021, President Biden issued EO 13985,¹³⁹ directing that, as a policy matter, the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. As such, the Departments also reviewed the 2012 Final Rule, the 2015 Guidance, the 2018 Guidance, and the policies implemented in part 1 of the 2022 Payment Notice final rule on section 1332 waivers to assess whether, and to what extent, these policies may perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups.

Upon review, the Departments determined that the 2012 Final Rule was generally consistent with the policy intentions of EO 14009 and EO 13985. However, the Departments determined that the 2018 Guidance and the policies implemented in part 1 of the 2022 Payment Notice final rule on section 1332 waivers were generally inconsistent with the policy intentions

¹³⁸ 86 FR 7793 (Feb. 2, 2021).

¹³⁹ 86 FR 7009 (Jan. 25, 2021).

of EO 14009 and EO 13985. As explained in part 1 of the 2022 Payment Notice final rule and the proposed rule, the majority of commenters on both the 2018 Guidance and the 2022 Payment Notice Proposed Rule noted that both the 2018 Guidance and the incorporation of its guardrail interpretations into regulations could result in the Departments approving section 1332 waivers that would result in fewer residents in those states enrolling in comprehensive and affordable coverage, and that those interpretations do not represent the best fulfillment of Congressional intent behind the statutory guardrails. After further consideration of these comments as part of the Departments' reviews under EO 14009 and EO 13985, the Departments proposed to modify 31 CFR 33.108(f)(3)(iv)(A)-(C) and 45 CFR 155.1308(f)(3)(iv)(A)-(C) to generally remove the language incorporating the interpretation of the statutory guardrails first set forth in the 2018 Guidance from the text of the section 1332 regulations, including those that were finalized in part 1 of the 2022 Payment Notice final rule. In addition, the Departments proposed new interpretations and proposed amendments to regulations to provide supplementary information about the requirements that must be met for the approval of a section 1332 waiver, the Secretaries' application review procedures, certain analytical requirements, operational considerations, the calculation of pass-through funding, and amendments and extensions of approved waiver plans. The Departments discussed that the new proposed policies and interpretations, if adopted, would supersede those outlined in the 2018 Guidance and, where applicable, the preamble to part 1 of the 2022 Payment Notice final rule. The Departments also proposed amendments to the regulations that align with the revised interpretations of the guardrails.

In this final rule, the Departments are finalizing policies, interpretations, and regulatory amendments to provide clarity to states regarding the requirements and expectations of the section 1332 waiver program for the approval, as well as for ongoing oversight, of approved waivers. The Departments received 262 comments on the section 1332 waiver proposals from a mix of stakeholders, including general advocacy organizations, disease advocacy organizations,

states, issuers, providers, individuals, and other entities. The overwhelming majority of stakeholders supported the section 1332 waiver proposals and encouraged the Departments to finalize the policies as proposed. The Departments are generally finalizing the policies, interpretations, and regulatory amendments as proposed in order to encourage states to develop innovative waivers. Specifically, the Departments are finalizing modifications to 31 CFR 33.109(f)(3)(iv)(A)-(C) and 45 CFR 155.1308(f)(3)(iv)(A)-(C) to codify in regulation the manner in which the Departments will apply the comprehensiveness, affordability, and coverage guardrails. Relatedly, the Departments are adopting the proposed policy clarifications relating to the deficit neutrality guardrail. In addition, the Departments are adopting policy clarifications as outlined in the preamble to the proposed rule relating to coordinated waivers, application timing, requirements for the actuarial and economic analyses, implementation timeline and operational concerns, and public input on waiver proposals. The Departments are also finalizing modifications to 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320 to extend flexibilities in the public notice requirements and post-award public participation requirements for waivers under section 1332 beyond the COVID-19 PHE to allow similar flexibilities in the event of future emergent situations. The Departments also are finalizing the modifications to 31 CFR 33.120(a)(1) and (2) and 45 CFR 155.1320(a)(1) and (2) relating to waiver monitoring and compliance, to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. Similarly, the Departments are finalizing the modifications to 31 CFR 33.128(a) and 45 CFR 155.1328(a) relating to periodic evaluation requirements, to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. This rule also finalizes new regulation text at 31 CFR 33.122 and 45 CFR 155.1322 to codify in regulation details regarding the Departments' determination of pass-through funding for approved section 1332 waivers. Through this rule, the Departments also finalize the addition of new regulation text at 31 CFR 33.130 and 45 CFR 155.1330 governing waiver amendment

requests for approved section 1332 waivers and at 31 CFR 33.132 and 45 CFR 155.1332 governing waiver extension requests for approved section 1332 waivers.

As discussed in the proposed rule, the Departments are of the view that rescinding the 2018 Guidance, repealing the previous codification of its guardrail interpretations in part 1 of the 2022 Payment Notice final rule, and finalizing new policies and interpretations will align with the Administration's goals to strengthen the ACA and increase enrollment in comprehensive, affordable health coverage among the remaining underinsured and uninsured. These policies will further advance this Administration's goal of increasing access to coverage by empowering states to develop innovative health coverage options for their residents through section 1332 waivers that best fit the states' individual needs. The policies are also intended to provide more information and clarity regarding the interpretations, processes, and procedures the Departments would apply when reviewing new waiver applications and waiver amendment and extension requests, as well as making pass-through funding determinations for approved waivers. The Departments noted that all of the policies were designed to align with the Administration's commitment to protect and expand Americans' access to high-quality, comprehensive, and affordable health care coverage, and to ensure that systemic barriers to opportunities and benefits for people of color and other underserved groups are not perpetuated. In addition, the policies will further support the Administration's efforts to build on the ACA by meeting the health care needs created by the COVID-19 PHE, reducing individuals' health care costs, and making our health care system less complex to navigate. The Departments noted that, through section 1332 waivers, they aim to assist states with developing health insurance markets that expand coverage, lower costs, and make high-quality health care accessible for every American.¹⁴⁰ In light of EO 13985, the Departments also encourage states to develop waiver proposals that diminish barriers to opportunities and benefits, such as health insurance coverage, for people of color and other

¹⁴⁰ <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/15/statement-by-president-joe-biden-on-the-2021-special-health-insurance-enrollment-period-through-healthcare-gov/>.

underserved groups. For example, states may propose waiver programs that increase plan options for comprehensive coverage, reduce premiums, improve affordability, and address social determinants of health.

As under similar waiver authorities,¹⁴¹ the Departments note that the Secretaries reserve the right to further evaluate an approved waiver and suspend or terminate an approved waiver, in whole or in part, any time before the date of expiration, if the Secretaries determine that the state materially has failed to comply with the terms and conditions of the waiver, the section 1332 guardrails,¹⁴² or applicable laws and regulations, unless specifically waived.¹⁴³ In addition, states with approved waivers must come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.¹⁴⁴

1. Coordinated Waiver Process (31 CFR 33.102 and 45 CFR 155.1302)

Regulations at 31 CFR 33.102 and 45 CFR 155.1302 permit, but do not require, states to submit a single application for a section 1332 waiver and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Social Security Act (the Act), or under any other Federal law relating to the provision of health care items or services, provided that the application is consistent with the procedures outlined in the 2012 Final Rule,¹⁴⁵ the procedures for demonstrations under section 1115 of the Act (section 1115 demonstrations), if applicable, and the procedures under any other applicable Federal law or regulations under which the state seeks a waiver.

Similar to the policies outlined in the 2018 Guidance, as well as in guidance previously published in December 2015 (2015 Guidance), the Departments' determination of whether a section 1332 waiver proposal satisfies the statutory guardrails set forth in section 1332 takes into

¹⁴¹ Section 1115 Waiver Demonstrations have similar authority.

¹⁴² See 31 CFR 33.120(d) and 45 CFR 155.1320(d) and STC 16 at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-NH-Approval-STCs.pdf>.

¹⁴³ See 31 CFR 33.120(a)(1) and 45 CFR 155.1320(a)(1).

¹⁴⁴ Ibid.

¹⁴⁵ See 77 FR 11700.

consideration the projected impact of waivers of certain ACA provisions made pursuant to the section 1332 waiver. The Departments also consider related changes to the state's health care system that, under state law, are contingent only on the approval of the section 1332 waiver. For example, the Departments, in making their determination, would take into account the impact of a new, related state-run health benefits program that, under legislation enacted by the state, would be implemented only if the section 1332 waiver were approved.

The Departments did not propose any regulatory changes to 31 CFR 33.102 and 45 CFR 155.1302, but reiterated in the proposed rule the policy relating to the coordinated waiver process so states understand the process for submission and review of a coordinated waiver. As explained in the preamble to the proposed rule, the Departments are of the view that the policies outlined, which are in line with both the 2018 and 2015 Guidance, further advance EO 14009 because these policies aim to protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American by specifying how a state may submit a coordinated waiver. Specifically, the Departments will not consider the potential impact of policy changes that are contingent on further state action, such as state legislation that is proposed but not yet enacted that would be in effect during the timeframe for the section 1332 waiver. For example, the Departments will not consider the potential impact of state legislation to expand Medicaid that is not yet enacted. The Departments also will not consider the impact of changes contingent on other Federal determinations, including approval of Federal waivers (such as waivers under section 1115 or titles XVIII, XIX, or XXI of the Act) pursuant to statutory provisions other than section 1332 of the ACA. Therefore, as proposed, the Departments will not take into account proposed changes to Medicaid or CHIP state plans, waivers, or demonstration projects that require separate Federal approval, such as changes in coverage or Federal Medicaid or CHIP spending that would result from a proposed section 1115 demonstration, regardless of whether the section 1115 demonstration proposal is submitted as part of a coordinated waiver application with a section 1332 waiver. Savings accrued under either proposed or current

Medicaid or CHIP section 1115 demonstrations will not be factored into the assessment of whether a proposed section 1332 waiver meets the deficit neutrality requirement. The Departments' determination also will not take into account any proposed changes to the Medicaid or CHIP state plan that are subject to Federal approval.

As proposed, the Departments will take into account changes in Medicaid or CHIP coverage or in Federal spending on Medicaid or CHIP that would result directly from the proposed waiver of ACA provisions pursuant to section 1332, holding state Medicaid and CHIP policies constant. For example, if a state section 1332 waiver would result in more or less Medicaid spending, this impact will be considered in the Departments' assessment of the section 1332 waiver for the deficit neutrality guardrail.

Nothing in the proposed rule proposed to alter a state's authority to make changes to its Medicaid and CHIP policies consistent with applicable law. In addition, the proposed rule did not propose to alter the Secretary of HHS's authority or CMS's policy regarding review and approval of section 1115 demonstrations, and states should continue to work with the Center for Medicaid and CHIP Services (CMCS) on issues relating to section 1115 demonstrations or other Medicaid or CHIP authorities. A state may submit a coordinated waiver application as provided in 31 CFR 33.102 and 45 CFR 155.1302. The waiver applications included in a coordinated waiver application would each be reviewed by the applicable agency component independently according to the Federal laws and regulations that apply to each waiver application.

As the Departments receive and review waiver proposals, the Departments will continue to examine the types of changes, contingent on Federal approval, that will be considered in reviewing section 1332 waiver applications.

The following is a summary of the comments received and the Departments' responses related to the coordinated waiver process (31 CFR 33.102 and 45 CFR 155.1302).

Comment: The Departments received a few comments on coordinated waivers expressing general support of the policy clarifications regarding coordinated waivers. Some of the

commenters also encouraged the Departments to consider additional flexibilities to further support coordinated waivers and reduce the burden on states. Commenters recommended allowing states to coordinate section 1115 demonstration projects and section 1332 waivers so that deficit neutrality is considered in light of both programs to result in greater savings. Commenters also recommended that the Departments provide additional flexibility to states to demonstrate overall savings across both programs and for consumers/enrollees. The commenters contended that the proposal would otherwise have a negative impact on any new state-led innovation efforts through the section 1332 waiver process. Furthermore, another commenter encouraged the Departments to explore options for combined section 1115 demonstrations/1332 waivers to address affordability concerns for states, and to coordinate between Medicaid and Exchange programs to avoid gaps in coverage and ensure a seamless enrollment process.

Response: The Departments appreciate the comments and welcome the opportunity to work with states interested in pursuing coordinated waivers. States with specific proposals for coordinated waivers are encouraged to discuss proposals with the Departments early in the coordinated waiver development process. In regard to the commenter's suggestion that the Departments consider additional flexibilities concerning deficit neutrality (for the purposes of section 1332 waivers) and budget neutrality (for the purposes of section 1115 demonstrations) to further support coordinated waivers, the Departments note that there are differences between the section 1115 demonstration budget neutrality requirement and the section 1332 waiver deficit neutrality requirement. Section 1115 demonstrations are required to be budget neutral, meaning that Federal spending under the section 1115 demonstration cannot exceed the aggregate budget neutrality limit of what Federal spending would have been in absence of the section 1115 demonstration, and states are liable for additional demonstration spending over the budget neutrality limit. Section 1332 waivers are required by statute to not increase the Federal deficit. With regard to commenters' concerns that state innovation would be hindered without flexibility for states to demonstrate overall savings across Medicaid and Exchange programs, the

Departments remind states that the Departments are committed to providing technical assistance to states and encourage innovative waiver proposals. Proposals may range from addressing affordability concerns, to closing gaps in coverage and ensuring a seamless enrollment process, and the particular approach taken will depend on each state's unique needs and circumstances.

As previously noted, the Departments did not propose any regulatory changes to 31 CFR 33.102 and 45 CFR 155.1302 in the proposed rule. After consideration of the comments received, the Departments are adopting the proposed policies and interpretations related to the coordinated waiver process.

2. Section 1332 Application Procedures – Application Timing (31 CFR 33.108(b) and 45 CFR 155.1308(b))

Consistent with regulations at 31 CFR 33.108(b) and 45 CFR 155.1308(b), states are required to submit initial section 1332 waiver applications sufficiently in advance of the requested waiver effective date to allow for an appropriate implementation timeline. As explained in the proposed rule, the Departments did not propose any regulatory changes to 31 CFR 33.108(b) and 45 CFR 155.1308(b), but did propose through preamble policies related to the timing of initial section 1332 waiver application submissions that are consistent with policies outlined in the 2018 Guidance. As the Departments noted in the proposed rule, the proposed policies were intended to help states understand the requirements for submitting a section 1332 waiver application sufficiently in advance of the requested waiver effective date to allow for enough time for Federal review and to maintain smooth operations of the Exchange in the state. In addition, the proposed policies were intended to help states allow for enough time for implementation of their section 1332 waiver plan, and for affected stakeholders, including issuers of health insurance plans that may be affected by the waiver plan, to take necessary actions based on the approval of the waiver plan, particularly when the waiver impacts premium rates, if approved. As discussed in the proposed rule, some section 1332 waiver plans may require operational changes or accommodations to the Federal information technology platform

or its operations, and the proposed policies would help ensure the state and the Departments are able to sufficiently plan in advance of the effective waiver date. The Departments proposed the following policies:

The Departments strongly encourage states interested in applying for section 1332 waivers, including coordinated waivers with section 1115 demonstrations, to engage with the Departments promptly for assistance in formulating an approach to a section 1332 waiver that meets the requirements of section 1332.

In order to help ensure timely decision-making regarding approval, the Departments advise that states should plan to submit their initial section 1332 waiver applications with enough time to allow for public comment (as required by 31 CFR 33.112, 31 CFR 33.116(b), 45 CFR 155.1312, and 45 CFR 155.1316(b)), review by the Departments, and implementation of the section 1332 state plan as outlined in the waiver application. For example, for section 1332 waivers that impact the individual market, submission before or during the first quarter of the year prior to the year health plans affected by the section 1332 waiver would take effect would generally permit sufficient time for review and implementation of both the waiver application and affected plans, depending on the complexity of the proposal. The Departments note that they cannot guarantee approval of a section 1332 waiver submission or a state's request for expedited review and will continue to review applications consistent with the timeline requirements outlined in the regulations and statute.¹⁴⁶ The Departments encourage states to work with the Departments on formulating timeframes that take into account the states' legislative sessions and timing of health plan rate filings if the section 1332 waiver is projected to have any impact on premiums. If a state's section 1332 waiver application includes potential operational changes or accommodations to the Federal information technology platform or its operations, the Departments note that additional time for review and implementation of the waiver application may be needed. The Departments also encourage states to engage with the Departments early in

¹⁴⁶ 31 CFR 33.108 and 45 CFR 155.1308; Section 1332(d)(1) of the ACA.

the process to determine whether Federal infrastructure can accommodate technical changes that support their requested flexibilities, as discussed elsewhere in this preamble.

The following is a summary of the comments received regarding the Departments' proposed policies and the Departments' responses.

Comment: The Departments received one comment, which was in support of the proposal. The commenter applauded the Departments for encouraging states to engage with the Departments early in the waiver process and consider the implementation timeline as part of the waiver development and application process.

Response: The Departments appreciate the commenter's support. After consideration of the comments received, the Departments are adopting the proposed policies relating to section 1332 application procedures and timing.

3. Section 1332 Application Procedures – Statutory Guardrails (31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv))

The Departments proposed to modify 31 CFR 33.108(f)(3)(iv)(A)-(C) and 45 CFR 155.1308(f)(3)(iv)(A)-(C) to set forth revised interpretations of the comprehensiveness, affordability, and coverage guardrails. In addition, the Departments proposed to adopt new policies and interpretations with regard to the statutory guardrails that, if finalized, would supersede and rescind those outlined in the 2018 Guidance. The proposed guardrail interpretations were largely in line with those in the 2015 Guidance. The Departments also proposed to modify 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments.

As discussed in the proposed rule, the 2018 Guidance aimed to allow states to pursue section 1332 waivers with the goals of increasing consumer choice and promoting private market competition. In particular, in the 2018 Guidance, the Secretaries explained that their interpretations of the statutory guardrails were meant to remove restrictions that could limit

consumer choice by allowing states to provide access to health insurance coverage at different price points and benefits levels, including less comprehensive plans that states considered to be better suited to consumer needs. Specifically, the 2018 Guidance interpreted the comprehensiveness and affordability guardrails to be satisfied if comprehensive and affordable coverage were *available* to consumers, without regard to who would actually enroll in such coverage. In addition, the 2018 Guidance instructed that these two guardrails must be evaluated together. The 2018 Guidance explained that it is not enough to make available some coverage that is comprehensive but not affordable, while making available other coverage that is affordable but not comprehensive. Thus, the Departments stated that a state plan would comply with the comprehensiveness and affordability guardrails, consistent with the statute, if it makes coverage that is both comprehensive and affordable *available* to a comparable number of otherwise qualified residents as would have had such coverage available absent the waiver.

In the 2018 Guidance, the Departments also stated that section 1332(b)(1)(C) of the ACA requires that a state's plan under a section 1332 waiver will provide coverage "to at least a comparable number of its residents" as would occur without the waiver.¹⁴⁷ The 2018 Guidance further noted that the text of the coverage guardrail provision of the statute is silent as to the type of coverage that is required. Accordingly, in the 2018 Guidance, the Departments explained they would consider section 1332 waivers to satisfy the coverage guardrail requirement if at least as many state residents were projected to be enrolled in comprehensive and less comprehensive health plans combined under the waiver as would be enrolled without the waiver. Under that interpretation, the Departments could approve a state's section 1332 waiver designed to promote residents' enrollment in less comprehensive or less affordable coverage to promote choice. As

¹⁴⁷ 83 FR at 53577.

long as a comparable number of residents were projected to be covered as would have been covered absent the waiver, the coverage guardrail would be met.¹⁴⁸

In part 1 of the 2022 Payment Notice final rule, the Departments codified the 2018 Guidance interpretation of the guardrails into the text of the section 1332 implementing regulations. Specifically, the Departments added regulatory language in 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A), explaining that the Departments would consider the comprehensive coverage guardrail to be met by a state section 1332 waiver plan if the plan would provide consumers access to coverage options that are at least as comprehensive as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. The final rule also added language to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) providing that the Departments would consider the affordability requirement to be met by a state section 1332 waiver plan that would provide consumers access to coverage options that are at least as affordable as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. These modifications also provided, consistent with the 2018 Guidance and the Administration's priorities at the time, that the Departments would consider the comprehensiveness and affordability guardrails met if a section 1332 waiver plan provides *access* to coverage that is as comprehensive and affordable as coverage forecasted to have been available in the absence of the waiver, and is projected to be available to a comparable number of people under the waiver, as opposed to the actual number of people enrolled in comprehensive and affordable coverage as under the 2015 Guidance. The final rule also added regulatory language to 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) providing that, for purposes of the coverage guardrail, "coverage" refers to

¹⁴⁸ The Departments note that the policies and interpretations in the 2018 Guidance were in line with the Administration's priorities at the time. In particular, the 2018 Guidance noted that the Secretaries would consider favorably section 1332 waiver applications that advanced specific principles and noted that the Secretaries aimed to provide states maximum flexibility. See 83 FR at 53576.

minimum essential coverage as defined in 26 U.S.C. 5000A(f) and 26 CFR 1.5000A-2, and health insurance coverage as defined in 45 CFR 144.103.

As noted in the proposed rule, a majority of commenters on both the 2018 Guidance and the 2022 Payment Notice proposed rule were concerned that the 2018 Guidance and its proposed codification would undermine the congressional intent underlying the section 1332 guardrails and effectively codify policy they believe is based on a misapplication of the statutory guardrails. The commenters were concerned that the interpretation of the availability of comprehensive and affordable coverage in the 2018 Guidance would result in fewer residents enrolled in comprehensive and affordable coverage. Other commenters asserted that the interpretation of the availability of comprehensive and affordable coverage for the coverage guardrail allows for a disjointed application of the guardrails whereby a state can meet the coverage guardrail, while its waiver plan reduces the overall comprehensiveness and affordability of coverage in a state. A few commenters recommended rescinding and abandoning the 2018 Guidance completely in favor of returning to the prior interpretation of the guardrails in the 2015 Guidance. In addition, some commenters also expressed concern that alternative coverage options, which would qualify for the purposes of meeting the coverage guardrail under the 2018 Guidance, are not subject to the same limitations as comprehensive coverage in terms of consumer protections. For instance, alternative plan options generally lack financial limitations like out-of-pocket maximums and annual/lifetime limits, and, if consumers covered by alternative plan options experience unexpected, potentially-catastrophic health events, they are likely to pay substantially more out-of-pocket to cover incurred costs. Further, commenters also raised concerns that alternative plans can terminate or deny coverage based on health status, which would tend to affect high-risk individuals. Coupled with the diminished affordability of comprehensive coverage, this possibility puts high-risk individuals at great risk of going without effective coverage.

In the proposed rule, the Departments proposed changes to 31 CFR 33.108 and 45 CFR 155.1308 to incorporate revised interpretations of the statutory guardrails. The decision to

rescind those interpretations was based on further consideration of commenters' concerns that the proposals are a better interpretation of section 1332(b)(1)(A)-(C), and the Departments' reviews under EO 14009, which was intended to strengthen the ACA and expand access to high-quality health care, and EO 13985, which was intended to pursue a comprehensive approach to advancing equity for all. The Departments concluded that the interpretations of section 1332's comprehensiveness, affordability, and coverage guardrails codified in part 1 of the 2022 Payment Notice final rule could permit section 1332 waivers that do not result in a comparable number of residents overall being enrolled in coverage that is at least as affordable and as comprehensive as they would have enrolled in without the waiver. As discussed in more detail later in this preamble, the Departments' changes are intended to align with the President's instruction in EO 14009 to adopt policies to strengthen the implementation of the ACA and remove any barriers that those policies may create for expanding coverage, lowering costs, and making high-quality health care accessible for every American.

The Departments determined that the guardrail interpretations codified in part 1 of the 2022 Payment Notice final rule were inconsistent with the Departments' goal of ensuring that the guardrails should be focused on the types of coverage residents actually purchase such that individuals *are enrolled* in affordable, comprehensive coverage and not just that there is generalized *access* to such coverage. The Departments note that plans that could be offered to individuals under section 1332 waivers applying the interpretations codified in the part 1 of the 2022 Payment Notice final rule could allow state section 1332 waivers that would result in more individuals enrolling in medically underwritten plans¹⁴⁹ that offer only limited benefits, charge

¹⁴⁹ Health insurance issuers medically underwrite policies to try to ascertain prospective enrollees' health statuses when they are applying for health insurance coverage in order to determine whether to offer these individuals coverage, or at what price, and with what exclusions or limits, to offer coverage. (<https://www.healthcare.gov/glossary/medical-underwriting/>). Since 2014, however, medical underwriting is no longer permitted in the individual or small group markets with respect to non-grandfathered health insurance coverage, due to ACA rules. Instead, all such individual and small group plans are guaranteed issue. Guaranteed issue is a requirement that health insurance issuers must permit any individual to enroll regardless of health status, age, gender, or other factors that might predict the use of health services, subject to certain specified exceptions. Guaranteed issue does not limit how much individuals can be charged if they enroll in coverage. <https://www.healthcare.gov/glossary/guaranteed-issue/>. However, the ACA's community rating protections prevent health insurance issuers from varying premiums within a geographic area based on gender, health status or other factors not specified in the statute with respect to non-grandfathered individual and small group plans. <https://www.healthcare.gov/glossary/community-rating/>.

higher out-of-pocket costs, or both, which is inconsistent with the goal of the EO 14009 to reduce barriers for expanding comprehensive affordable coverage. Allowing more individuals to be in medically underwritten plans could also have a disparate impact on vulnerable populations, especially people of color and those who are in poverty, those who are underserved, and those with pre-existing conditions, which is inconsistent with the goal of EO 13985.

Additionally, the Departments are of the view that the section 1332 waiver proposals that could be available under the guardrail interpretations in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule may also conflict with EO 14009. For example, the *Section 1332 State Relief and Empowerment Waiver Concepts Discussion Paper* (November 2018 Discussion Paper)¹⁵⁰ included waiver concepts that were intended to foster discussion with states by illustrating how states might take advantage of new flexibilities provided in the 2018 Guidance. The Departments also are of the view that some of these waiver concepts, which rely upon the 2018 Guidance interpretation of the guardrails, are not in line with EO 14009 goals to protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American. For example, the *Adjusted Plan Options* section 1332 waiver concept included in the 2018 Discussion Paper would permit states to have the flexibility to provide state financial assistance for non-QHPs. A section 1332 waiver proposal that includes this concept could potentially increase coverage in non-QHPs and potentially decrease enrollment in comprehensive coverage plans by allowing consumers to use a state subsidy towards catastrophic plans, individual market plans that are not QHPs, or plans that do not fully meet ACA requirements. This waiver concept is inconsistent with EO 14009, as it would likely result in consumers enrolling in non-QHPs and plans that do not fully meet ACA requirements, thereby increasing barriers for expanding comprehensive affordable coverage and potentially decreasing enrollment in comprehensive coverage. Further, commenters to the 2018 Guidance

¹⁵⁰ <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Waiver-Concepts-Guidance.PDF>.

expressed generalized concern that the 2018 Guidance permitted alternative coverage options that can be underwritten and do not meet EHB standards. In addition, commenters were concerned that measures taken to facilitate coverage in alternative plan options (for example, allowing the use of subsidies for such coverage) would result in fewer comprehensive plans on the market, and that those comprehensive plans would become less affordable. In light of EOs 13985 and 14009 and concerns raised by commenters, the Departments proposed new policies that would allow states flexibility to develop waiver plans to meet their needs and expand coverage, lower costs, and increase access to high-quality health care with comprehensive benefits.

Given current policy goals, as well as the Departments' further consideration of comments received on the 2022 Payment Notice, the Departments proposed to revise policies for how the Departments would evaluate whether a state's section 1332 waiver plan satisfies each of the guardrails, as outlined in more detail later in this section. Overall, the Departments proposed that the "coverage" to be provided and evaluated in each guardrail should be interpreted the same way in each subparagraph of section 1332(b)(1)(A)-(C) of the ACA for consistency. Thus, the Departments proposed in 31 CFR 33.108(f)(3)(iv)(A) through (C) and 45 CFR 155.1308(f)(3)(iv)(A) through (C) that, to be approved, a waiver must be projected to provide coverage that is as comprehensive and affordable as would have been provided absent the waiver and to the same number of residents.

Similarly, given the current COVID-19 PHE, this Administration is focused on the response to the PHE and on helping increase enrollment in comprehensive, affordable health insurance coverage. The ARP made numerous changes to the ACA to expand access to comprehensive health insurance coverage and lower costs. Specifically, the ARP temporarily expanded eligibility for and increased the value of APTC/PTC, enabling previously ineligible consumers to qualify for help paying for Exchange coverage and increasing assistance to eligible individuals already enrolled in Exchange plans. As discussed in the proposed rule, these changes

have already increased enrollment through the Exchanges,¹⁵¹ and the Departments are of the view that this law will continue to increase enrollment through the Exchanges as the ARP's enhanced subsidies lower the costs of coverage for millions of Americans and change the incentives to seek and maintain comprehensive health insurance coverage. In addition, increased affordability and expansion of access to comprehensive health insurance coverage will better support enrollment of historically uninsured communities – especially those who have faced significant health disparities – in such coverage, thereby improving access to health care during and beyond the COVID-19 PHE. This Administration has also sought to strengthen the ACA and increase enrollment by directing the establishment of a special enrollment period, which was open from February 15, 2021 through August 15, 2021, for Exchanges using the HealthCare.gov platform (COVID-19 special enrollment period). Over 1.5 million Americans had already signed up for coverage on HealthCare.gov during the COVID-19 special enrollment period at the time of the proposed rule and that number has increased to 2.5 million.¹⁵² To promote the special enrollment period, CMS spent approximately \$100 million on outreach and education, including broadcast, radio, and digital advertising to reach the uninsured, and also launched parallel outreach efforts through stakeholders and partners to increase education and awareness across communities on the COVID-19 special enrollment period.¹⁵³ Earlier this year, CMS made approximately \$2.3 million in additional funding available to current Navigator grantees in FFEs to support the outreach, education, and enrollment efforts around the COVID-19 special enrollment period.¹⁵⁴ Additionally, on August 27, 2021, CMS awarded \$80 million in grant

¹⁵¹ 2021 Marketplace Special Enrollment Period Report, June 14, 2021 <https://www.cms.gov/newsroom/fact-sheets/2021-marketplace-special-enrollment-period-report-2>.

¹⁵² See <https://www.cms.gov/newsroom/fact-sheets/2021-marketplace-special-enrollment-period-report-3> and <https://www.cms.gov/newsroom/fact-sheets/2021-marketplace-special-enrollment-period-report-4>.

¹⁵³ On January 28, 2021, CMS announced \$50 million for outreach and marketing for the COVID-19 special enrollment period: <https://www.cms.gov/newsroom/fact-sheets/2021-special-enrollment-period-response-covid-19-emergency>. On April 1, 2021 HHS announced an additional \$50 million to further bolster the COVID-19 special enrollment period campaign and promote the lower premiums under the ARP: <https://www.cms.gov/newsroom/press-releases/hhs-secretary-becerra-announces-reduced-costs-and-expanded-access-available-marketplace-health>.

¹⁵⁴ <https://www.cms.gov/newsroom/press-releases/cms-announces-additional-navigator-funding-support-marketplace-special-enrollment-period>.

funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year.¹⁵⁵ This represents an eight-fold increase in funding from the previous year. Taken together, these policies, including the increased subsidies available under the ARP, the COVID-19 special enrollment period, and the increased Federal investment in the FFE Navigator program, have already led to, and are expected to continue to lead to, increased enrollment through the Exchanges.

As noted in the proposed rule, the Departments are of the view that rescinding the 2018 Guidance, repealing the previous codification of its guardrail interpretations in part 1 of the 2022 Payment Notice final rule, and proposing new policies and restoring prior interpretations aligns with the Administration's goals to strengthen the ACA and increase enrollment in comprehensive, affordable health coverage among the remaining underinsured and uninsured. The Departments also noted that they are of the view that during a pandemic, as Americans continue to battle COVID-19 and millions of Americans are facing uncertainty and experiencing new health problems, it is even more critical that Americans have meaningful access to high-quality, comprehensive and affordable health coverage options.

The Departments also proposed to modify 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. The Departments noted that they are of the view that the proposal aligns with the Departments' efforts to provide supplementary information about the requirements that must be met for the approval of a section 1332 waiver and the Secretaries' application review procedures. Because the Departments are of the view that the 2018 Guidance and its incorporation into regulations could result in the Departments approving section 1332 waivers that would result in fewer residents in those states enrolling in comprehensive and affordable coverage, that those interpretations do not represent

¹⁵⁵ <https://www.cms.gov/newsroom/press-releases/cms-announces-80-million-funding-opportunity-available-navigators-states-federally-facilitated-0>
<https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open>.

the best fulfillment of congressional intent behind the statutory guardrails, that they are inconsistent with the policy intentions of EO 14009 and EO 13985, and that it is appropriate to address concerns raised by commenters on the 2018 Guidance, the Departments proposed to remove references to the 2018 Guidance.

As proposed, the Departments would rely upon the statute and regulations, as well as the Departments' interpretive policy statements as outlined in the applicable notice and comment rulemaking, in reviewing section 1332 waiver applications.

The Departments sought comment on the proposals. The Departments also solicited comment on whether there are policies that meet the statutory guardrails of section 1332 waivers that the Departments could consider that would encourage states to find innovative ways to use section 1332 waivers to focus on equity and expand access to comprehensive coverage for their residents. In addition, the Departments considered whether any affected parties could be impacted by the proposed changes in policy interpretations outlined in this rule. This rule does not alter any of the requirements related to state innovation waiver applications, compliance and monitoring, or evaluation in a way that would create any additional costs or burdens for states submitting proposed waiver applications or those states with approved waiver plans that has not already been captured in prior burden estimates. As such, the Departments are of the view that both states with approved section 1332 waivers and states that are considering section 1332 waivers would continue to comply with the requirements noted earlier without creating any additional costs or burdens that have not already been accounted for in prior impact estimates of benefits and costs.

The following is a summary of the general comments received and the Departments' responses related to the section 1332 application procedures – statutory guardrails (31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv)).

Comment: The overwhelming majority of commenters were supportive of the proposed changes to the policies and interpretations related to the statutory guardrails. Commenters

encouraged the Departments to finalize the statutory guardrail proposals in order to establish strong protections for consumers so that states are not able to use section 1332 waivers to take away coverage or force people into high-cost health plans. Furthermore, commenters supported the policies and interpretations relating to the Departments' commitment to ensuring that waivers must not adversely affect vulnerable and underserved populations. A few commenters noted that the change in policies and interpretations would not affect approved waivers and supported the Departments finalizing the statutory guardrail policies and interpretations as proposed.

Response: The Departments appreciate commenters' support and agree that it is important to adopt policies that strengthen the ACA and increase enrollment in comprehensive, affordable health coverage. After consideration of the comments received, the Departments are finalizing as proposed regulation text at 31 CFR 33.108(f)(3)(iv)(A)-(C) and 45 CFR 155.1308(f)(3)(iv)(A)-(C), as well as adopting the new underlying statutory guardrail policies and interpretations described in this preamble.

Comment: A few commenters were concerned that the proposed changes to the policies and interpretations related to the statutory guardrails would be overly restrictive. These commenters were concerned that these proposed changes would limit state innovation and would be too restrictive for states to meet. Instead, these commenters expressed support for the 2018 Guidance guardrail interpretations, in particular the *access* standard. One commenter recommended that the 2018 Guidance guardrail interpretation for the access standard be expanded to the coverage guardrail as well.

Some of these commenters also took the position that the proposed changes to the policies and interpretations related to the statutory guardrails would undermine Congress' intent to give states a meaningful level of flexibility to develop and implement new health programs. They contended that the proposals only allow a waiver from the requirements of the ACA if the waiver meets the requirements of the ACA, thereby significantly diminishing state flexibility. Additionally, one commenter expressed concern that, by limiting consumer choice, the proposal

would have a detrimental impact on vulnerable populations and “ignores how waiver flexibility may allow states to better tailor plans for people with greater health needs.”¹⁵⁶

Response: The Departments appreciate these comments, but disagree that the proposed guardrail policies and interpretations are overly restrictive and will limit state flexibility to provide access to comprehensive, affordable coverage. These policies and interpretations only limit states’ flexibility to adopt section 1332 waiver plans that promote coverage that is not comprehensive (such as medically underwritten plans) at the expense of comprehensive coverage options. The Departments are of the view that the policies and interpretations finalized in this rule will allow states to develop proposals to promote comprehensive affordable coverage and restrict waiver proposals that would result in enrollment in less comprehensive coverage that may leave consumers exposed to high out-of-pocket costs. The Departments are committed to working with states to develop innovative waiver plans to address health care needs in a particular state. As discussed in the preambles to the proposed rule and this final rule, the Departments have determined that the guardrail interpretations codified in part 1 of the 2022 Payment Notice final rule are inconsistent with the Departments’ goal of ensuring individuals are enrolled in affordable, comprehensive coverage and not just that there is generalized access to such coverage. The decision to rescind these interpretations is based on the Departments’ goal to ensure enrollment in comprehensive coverage and further consideration of previous comments and whether the replacement proposals are a better interpretation of section 1332(b)(1)(A)-(C), as well as the Departments’ reviews under EO 14009, which is intended to strengthen the ACA and expand high-quality health care, and EO 13985, which is intended to pursue a comprehensive approach to advancing equity for all. The Departments’ proposed statutory guardrail policies and interpretations, which are being finalized as proposed, are intended to align with the President’s instruction in EO 14009 to adopt policies to strengthen the implementation of the ACA and remove any barriers that those policies may create for

¹⁵⁶ Center of the American Experiment comment letter on proposed rule.

expanding coverage, lowering costs, and making high-quality health care accessible for every American. Furthermore, in line with EO 14009, this Administration is focused on ensuring high-quality health care is accessible and affordable for every American. Therefore, as explained in the preambles to the proposed rule and this final rule, the Departments are of the view that the comprehensiveness and affordability guardrails should focus on the types of coverage residents actually purchase, rather than the types of coverage to which residents have access.

The Departments are also of the view that the policies and interpretations adopted in this preamble do not limit consumer choice and instead further the goal of ensuring individuals are enrolled in affordable, comprehensive coverage and not just that there is generalized access to such coverage. As discussed in the preambles to the proposed rule and this final rule, the plans that could be offered to individuals under section 1332 waivers when applying the interpretations codified in the part 1 of the 2022 Payment Notice final rule could allow state section 1332 waivers that would result in more individuals enrolling in medically underwritten plans that offer only limited benefits, charge higher out-of-pocket costs, or both, which is inconsistent with the goal of the EO 14009 to reduce barriers for expanding comprehensive affordable coverage. Allowing more individuals to enroll in medically underwritten plans could also have a disparate impact on vulnerable populations, especially people of color and those who are in poverty, those who are underserved, and those with pre-existing conditions, which is inconsistent with the goal of EO 13985. Further, waivers that result in more individuals enrolling in medically underwritten plans could also be detrimental to those who have chronic conditions or greater health needs. The policies and interpretations adopted in this preamble and regulations finalized in this rule will help decrease barriers for expanding comprehensive affordable coverage and potentially increase access to and enrollment in high-quality health care with comprehensive benefits. However, at the same time, the Departments note that the changes in policies and interpretations adopted in this preamble do not limit or otherwise establish new requirements or restrictions on other currently available coverage options. Therefore, the Departments generally disagree with

commenters' assertions that the new statutory guardrail policies and interpretations will limit consumer choice, as consumers will continue to have access to the same coverage options, both on and off Exchange, as they do today.

After consideration of the comments received, the Departments are adopting the new policies and interpretations described in this preamble with regard to the statutory guardrails and are finalizing the regulatory changes relating to the statutory guardrails (31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv)) as proposed. Each of the statutory guardrails is addressed further later in this section of this preamble, along with summaries of and responses to comments on each of the individual guardrails.

a. Comprehensive Coverage (31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A))

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) to set forth a revised interpretation of the comprehensiveness guardrail. In addition, the Departments proposed, through preamble, policies and interpretations relating to the requirements for the comprehensive coverage guardrail that are similar to the policies and interpretations outlined in the 2015 Guidance. Specifically, the Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) such that to satisfy the comprehensive coverage requirement, the Departments, as applicable, must determine that the section 1332 waiver will provide coverage that is at least as comprehensive overall for residents of the state as coverage absent the waiver.

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) for the comprehensiveness guardrail as follows:

To meet the comprehensiveness guardrail, health care coverage under a section 1332 waiver is required to be forecast to be at least as comprehensive overall for residents of the state as coverage absent the waiver.

As proposed, the Departments' policies and interpretations related to the comprehensiveness guardrail are as follows: Comprehensiveness refers to the scope of benefits provided by the coverage and would be measured by the extent to which coverage meets the requirements for EHBs as defined in section 1302(b) of the ACA and offered through Exchanges established by Title I of the ACA, or, as appropriate, Medicaid or CHIP standards. The impact on all state residents would be considered, regardless of the type of coverage they would have had absent the section 1332 waiver.

Comprehensiveness will be evaluated by comparing coverage under the section 1332 waiver to the state's EHB -benchmark plan applicable for the plan year pursuant to 45 CFR 156.111, as well as to, in certain cases, the coverage provided under the state's Medicaid or CHIP programs.¹⁵⁷ A section 1332 waiver will not satisfy the comprehensiveness requirement if the waiver decreases: (1) the number of residents with coverage that is at least as comprehensive as the EHB-benchmark plan in all ten EHB categories; (2) for any of the ten EHB categories, the number of residents with coverage that is at least as comprehensive as the benchmark in that category; or (3) the number of residents whose coverage includes the full set of services that would be covered under the state's Medicaid or CHIP programs, holding the state's Medicaid and CHIP policies constant. That is, the section 1332 waiver cannot decrease the number of individuals with coverage that satisfies EHB requirements, the number of individuals with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services covered under the state's Medicaid or CHIP programs.

Assessment of whether a section 1332 waiver proposal meets the comprehensiveness requirement will also take into account the effects across different groups of state residents, and, in particular, effects on vulnerable and underserved residents, including low-income individuals,

¹⁵⁷ In the 2019 Payment Notice, HHS provided states with substantially more options in the selection of an EHB-benchmark plan. Instead of being limited to 10 options, states are now be able to choose from the 50 EHB-benchmark plans used for the 2017 plan year in other states or select specific EHB categories, such as drug coverage or hospitalization, from among the categories in the EHB-benchmark plan used for the 2017 plan year in other states. Additionally, states are able to build their own set of benefits that could potentially become their EHB-benchmark plan, subject to certain scope of benefits requirements.

older adults, those with serious health issues or who have a greater risk of developing serious health issues, and people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.¹⁵⁸ A section 1332 waiver will be highly unlikely to be approved by the Secretaries under the interpretation outlined in the preambles to the proposed rule and this final rule if the waiver would reduce the comprehensiveness of coverage provided to these types of vulnerable or underserved groups, even if the waiver maintained comprehensiveness in the aggregate. This condition generally must be forecast to be met in each year that the section 1332 waiver would be in effect.

Consistent with 31 CFR 33.108(f) and 45 CFR 155.1308(f), the section 1332 waiver application must include analysis and supporting data that establishes that the section 1332 waiver satisfies this requirement. This includes an explanation of how the benefits offered under the section 1332 waiver differ from the benefits provided absent the waiver (if the benefits differ at all) and how the state determined the benefits to be as “comprehensive.”

As discussed previously in the preamble to the proposed rule, the policies and interpretations of the comprehensiveness guardrail outlined in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule were in line with the Administration’s priorities at the time to promote private market competition and increase consumer choice. Under those policies, analysis of comprehensiveness and affordability of coverage under a section 1332 waiver focused on the nature of coverage that is made available to state residents (access to coverage), rather than on the coverage that residents actually purchase. The plans that could be offered to individuals under section 1332 waivers as codified in part 1 of the 2022 Payment Notice final rule could therefore allow for more individuals to enroll in medically underwritten

¹⁵⁸ These groups include individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government/>.

plans that only offer limited benefits, which is inconsistent with the goal of EO 14009 to reduce barriers for expanding comprehensive affordable coverage.

In response to the proposal in the 2022 Payment Notice proposed rule, commenters raised concerns that alternative plan options (which could include medically underwritten plans) can terminate or deny coverage based on health status, which would tend to affect high-risk individuals. Commenters asserted that this possibility puts individuals with greater medical needs at risk of going without effective coverage for their health care needs. Some commenters expressed concern that the potential market effects would have a disparate impact on vulnerable populations, especially low-income consumers and those with pre-existing conditions. Additionally, these commenters expressed concern that a disparate impact on any particular group would not necessarily cause the Departments to deny a section 1332 waiver application, even though the impact on vulnerable population groups would be taken into account.

The Departments noted that they are of the view that the current interpretation of the comprehensiveness guardrail is inconsistent with the goal of EO 14009 to reduce barriers for expanding comprehensive affordable coverage. The Departments also noted that they are of the view that the current interpretation of the comprehensiveness guardrail is inconsistent with the goal of EO 13985 to pursue a comprehensive approach to advancing equity and could create barriers to health coverage for people of color and underserved groups.

As noted in the proposed rule, the proposed changes are intended to align with the President's instructions in EO 14009 and EO 13985 to adopt policies to strengthen the implementation of the ACA and ensure high-quality health care coverage is accessible and affordable for every American. The Departments note that they are of the view that the provisions outlined in the proposed rule would further support states providing consumers with comprehensive, high-quality health care coverage that will better protect consumers with pre-existing conditions and will help protect consumers from unexpected and expected medical needs. Further, the Departments note that the provisions outlined in the proposed rule would

further the goal that consumers with pre-existing conditions, particularly racial and ethnic minorities who are 1.5 to 2.0 times more likely than whites to have major chronic diseases¹⁵⁹ and as such pre-existing conditions, maintain comprehensive coverage.

The Departments sought comment on the proposed policies and interpretations related to the comprehensiveness guardrail. The Departments noted that they are of the view that the proposed provisions would have minimal impact on both states with section 1332 waivers under development and states with approved waivers. The Departments solicited comment on the impact to stakeholders.

The following is a summary of the comments received and the Departments' responses related to 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A), the comprehensiveness guardrail.

Comment: The Departments received a few comments specifically focused on the comprehensiveness guardrail. Several commenters supported the proposal to use EHB and Medicaid coverage as a standard of comparison for the comprehensiveness guardrail. Furthermore, these commenters supported the modifications to the rule text to evaluate this guardrail based on coverage that is provided under the waiver, not just coverage that is available. One commenter recommended adding rule text to capture that the waiver cannot decrease the number of people with coverage that satisfies EHB requirements, the number of people with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services covered under the state's Medicaid or CHIP programs. Furthermore, this commenter recommended that the rule text should reaffirm that these criteria must be met in each year of the waiver.

Response: After consideration of the comments received, the Departments are adopting the proposed policies and interpretations related to the comprehensiveness guardrail, as well as

¹⁵⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3794652/#:~:text=more%20chronic%20diseases,-,Racial%2Fethnic%20minorities%20are%201.5%20to%202.0%20times%20more%20likely,seem%20to%20be%20getting%20worse.>

the proposed amendments to 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A). As finalized, to meet the comprehensiveness guardrail, coverage under a section 1332 waiver must be forecast to be at least as comprehensive overall for residents of the state as coverage absent the waiver. For this purpose, comprehensiveness refers to the scope of benefits provided and will be measured by the extent to which coverage meets EHB or, as appropriate, Medicaid or CHIP standards. The impact on all state residents will be considered as part of this analysis, regardless of the type of coverage they would have had absent the section 1332 waiver. As explained in this preamble, the Departments will evaluate this guardrail in each year that the section 1332 waiver would be in effect to ensure that a waiver will not decrease the number of people with coverage that satisfies EHB requirements, the number of individuals with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services covered under the state's Medicaid or CHIP programs. The Departments remain committed to approving waivers that promote health insurance coverage and health equity.

Regarding the comprehensiveness guardrail regulatory provisions, the Departments are not finalizing additional changes to the rule text at this time. The Departments are of the view that codifying more specific requirements and guidelines in regulation is unnecessary, given the policies and interpretations already discussed in this preamble and the amendments to the comprehensiveness guardrail regulations finalized in this rule, which provide states and the Federal Government the information to reasonably evaluate whether a section 1332 waiver meets the coverage guardrail and relevant policy goals.

Comment: One commenter opposed the proposal due to concerns it would stifle a state's ability to innovate through plan design. This commenter raised concerns that as proposed, the proposal "leaves no room for plan and benefit design" and encouraged the Departments to use an "overall" standard for comprehensiveness as they do for the affordability guardrail.¹⁶⁰

¹⁶⁰ Oregon Department of Consumer and Business Services, the State of Oregon's insurance regulator, and the Oregon Health Authority comment letter on proposed rule.

Response: The proposed policies and interpretations related to the statutory guardrails require that coverage be available for a comparable number of people that is as affordable and comprehensive as coverage would have been available in the absence of the waiver. The Departments disagree that the proposed policies and interpretations of the comprehensiveness guardrail will stifle a state's ability to innovate through plan design. Under the 2019 Payment Notice final rule, states have increased flexibility to change their EHB -benchmark plan.¹⁶¹ States interested in changing their EHB -benchmark plan can do so without pursuing a section 1332 waiver, following the approach finalized in the 2019 Payment Notice final rule, or they can elect to make those changes while also pursuing a section 1332 waiver to make other changes. For example, a state could select another state's EHB -benchmark plan that was applicable for the 2017 plan year, replace one or more of categories in its EHB-benchmark plan with the same categories from another state's EHB -benchmark plan that was applicable for the 2017 plan year, or select a set of benefits that would become the state's new EHB -benchmark plan.

States could also consider increasing the generosity of an EHB-benchmark plan's benefits to address health equity. Further, the Departments are of the view that the "overall" standard incorporated in the comprehensiveness guardrail analysis, which looks at the number of residents with coverage that is at least as comprehensive as the benchmark in all ten EHB categories, any of the ten EHB categories, and full set of services under the state's Medicaid or CHIP programs, is critical to ensure that consumers continue to have comprehensive affordable coverage under a waiver. As such, the Departments are of the view that states could consider current policy flexibilities and utilizing section 1332 waivers to innovate through plan design and benefit design.

After consideration of the comments received, the Departments are adopting the proposed policies and interpretations relating to the comprehensiveness guardrail and finalizing the proposed modifications to 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A).

¹⁶¹ 45 CFR 156.111.

b. Affordability (31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B))

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) to set forth a revised interpretation of the affordability guardrail. In addition, the Departments proposed, through preamble, policies and interpretations relating to the requirements for the affordability coverage guardrail that are similar to the policies and interpretations outlined in the 2015 Guidance. Specifically, the Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) such that to satisfy the affordability requirement, the Departments, as applicable, must determine that the section 1332 waiver would provide coverage that is at least as affordable overall for residents of the state as coverage absent the waiver.

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) for the affordability guardrail as follows: To meet the affordability guardrail, health care coverage under the section 1332 waiver will be required to be forecast to be as affordable overall for state residents as coverage absent the waiver.

As proposed, the Departments' policies and interpretations related to the affordability guardrail are as follows:

Affordability refers to state residents' ability to pay for health care expenses relative to their incomes and will generally be measured by comparing each individual's expected out-of-pocket spending for health coverage and services to their incomes. Out-of-pocket spending for health care includes premiums (or equivalent costs for enrolling in coverage), and spending such as deductibles, co-pays, and co-insurance, associated with the coverage or direct payments for health care. Spending on health care services that are not covered by a health plan or health coverage could also be taken into account if they are affected by the section 1332 waiver proposal. The impact on all state residents will be required to be considered, regardless of the type of coverage they would have had absent the section 1332 waiver. Under the proposed

provisions and interpretation, this condition generally must be forecast to be met in each year that the section 1332 waiver would be in effect.

Section 1332 waivers will be evaluated not only based on how they affect affordability on average, but also on how they affect the number of individuals with large health care spending burdens relative to their incomes. Increasing the number of state residents with large health care spending burdens will cause a section 1332 waiver proposal to fail the affordability requirement, even if the waiver would increase affordability for many other state residents. Given that eligibility for comprehensive coverage among the uninsured varies across racial and ethnic groups, the Departments' assessment of whether the proposal meets the affordability requirement will also take into account the effects across different groups of state residents, and, in particular, effects on vulnerable or underserved residents, including low-income individuals, older adults, those with serious health issues or who have a greater risk of developing serious health issues, and people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.¹⁶² A section 1332 waiver will be highly unlikely to be approved by the Secretaries under the policies and interpretations set forth in the preambles to the proposed rule and this final rule if it reduces affordability for these vulnerable or underserved groups, even if the waiver would maintain affordability in the aggregate. In addition, a section 1332 waiver will fail to meet the affordability guardrail if it would reduce the number of individuals with coverage that provides a minimal level of protection against excessive cost sharing. In particular, section 1332 waivers that reduce the number of people with insurance coverage that provides both an AV equal to or greater than 60 percent and an out-of-pocket maximum that complies with section 1302(c)(1) of the ACA, will fail to meet this guardrail under the policies and interpretations set forth in this rule. Section 1332 waivers that

¹⁶² These groups include individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. See <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government/>.

reduce the number of people with coverage that meets the affordability requirements set forth in sections 1916 and 1916A of the Act, as codified in 42 CFR part 447, subpart A, while holding the state's Medicaid policies constant will also fail under the affordability guardrail.

Consistent with 31 CFR 33.108(f) and 45 CFR 155.1308(f), the section 1332 waiver application must include analysis and supporting data that establishes that the waiver satisfies this requirement. This includes information on estimated individual out-of-pocket costs (premium and out-of-pocket expenses for deductibles, co-payments, co-insurance, co-payments and plan differences) by income, health expenses, health insurance status, and age groups, absent the section 1332 waiver and with the waiver. The expected changes in premium contributions and other out-of-pocket costs and the combined impact of changes in these components should be identified separately. The application should also describe any changes in employer contributions to health coverage or in wages expected under the section 1332 waiver. The application should identify any types of individuals for whom affordability of coverage would be reduced by the section 1332 waiver.

As discussed previously in the preamble of the proposed rule, the affordability guardrail interpretation outlined in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule aimed to increase consumer choice to allow states to provide access to health insurance coverage at different prices points and benefits levels. The Departments noted that they are of the view that this interpretation of the affordability guardrail is inconsistent with the goal of EO 14009 to reduce barriers for expanding comprehensive affordable coverage. The current interpretation could allow for more individuals, including potentially those with pre-existing conditions, to enroll in medically underwritten plans that charge higher out-of-pocket costs, which is inconsistent with the goal of the EO to reduce barriers for expanding comprehensive affordable coverage. As proposed, the changes were intended to align with the President's instruction in EO 14009 to adopt policies to strengthen the implementation of the ACA and ensure high-quality health care is accessible and affordable for every American. The

Departments noted that they are of the view that the provisions outlined in the proposed rule would further support states providing consumers with comprehensive, high-quality affordable health care coverage that will better protect consumers with pre-existing conditions, and will help protect consumers from unexpected and expected medical needs.

The Departments sought comment on these proposed policies and interpretations related to the affordability guardrail. The Departments noted that they are of the view the proposal would have minimal impact on both states with section 1332 waivers under development and states with approved waivers. The Departments solicited comment on the impact to stakeholders.

The following is a summary of the comments received and the Departments' responses related to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B), the affordability guardrail.

Comment: Commenters were generally supportive of the proposals related to the affordability guardrail. These commenters supported the modifications to require coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of title I of the ACA. Commenters were supportive of the policies outlined in the preamble to the proposed rule, including the Departments' policy under which they would evaluate whether consumers would have large health care spending burdens relative to their incomes and will examine the effects on various vulnerable groups. Additionally, one commenter recommended that the rule text should similarly require examination of the effect of a proposed waiver on vulnerable groups and the groups now eligible for the largest premium credits and cost sharing reductions.

Response: The Departments appreciate commenters' support and are finalizing the amendments to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) and the affordability guardrail policies and interpretations as proposed. As finalized, to meet the affordability guardrail, a section 1332 waiver must be forecast to be as affordable overall for state residents as coverage absent the waiver. The impact on all state residents will be considered

as part of this analysis, regardless of the type of coverage they would have had absent the section 1332 waiver. Section 1332 waivers will be evaluated not only based on how they affect affordability on average, but also on how they affect the number of individuals with large health care spending burdens relative to their incomes. As previously explained, in applying this guardrail, the Departments will examine the impact the waiver has on state residents' ability to pay for health care expenses relative to their incomes and will generally measure compliance by comparing each individual's expected out-of-pocket spending for health coverage and services to their incomes. This approach allows the Departments to evaluate the affordability guardrail across various FPL levels, including for those newly eligible or eligible for expanded PTC as a result of the ARP, which impacts various FPLs differently, an issue that was raised by a commenter. Regarding the waiver's impact on the affordability of coverage for vulnerable populations, the Departments' analysis of compliance with the affordability guardrail will also take into account the effects on low-income individuals, older adults, those with serious health issues or who have a greater risk of developing serious health issues, and people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. The Departments also note that, under the proposals finalized in this rule related to the Actuarial and Economic Analysis section of the regulation,¹⁶³ states should compare comprehensiveness, affordability, coverage, and deficit neutrality with and without the section 1332 waiver. States should also include in their analysis of the aforementioned guardrails whether the proposed section 1332 waiver would increase health equity in keeping with goals of with EO 13985, which will provide the Departments with information to evaluate the impact on vulnerable populations.

The Departments decline to finalize additional changes to the rule text at this time. The Departments are of the view that codifying more specific requirements and guidelines in regulation is unnecessary, given the policies and interpretations already discussed in this

¹⁶³ See 31 CFR 33.108(f)(4)(i)-(iii) and 45 CFR 155.1308(f)(4) (i)-(iii).

preamble and the amendments to the affordability guardrail regulations finalized in this rule, which provide states and the Federal Government the information needed to reasonably evaluate the ability of a section 1332 waiver to meet the affordability guardrail and relevant policy goals.

The Departments remain committed to approving waivers that promote health insurance coverage and health equity and are adopting the proposed policies and interpretations relating to the affordability guardrail, as well as finalizing as proposed the modifications to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B).

c. Coverage (31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C))

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) to remove the coverage guardrail interpretations codified in part 1 of the 2022 Payment Notice final rule. In addition, the Departments proposed, through preamble, policies and interpretations relating to the requirements for the coverage guardrail that are similar to the policies and interpretations outlined in the 2015 Guidance. Specifically, the Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) such that to satisfy the scope of coverage requirement, the Departments, as applicable, must determine that the section 1332 waiver would provide coverage to a comparable number of state residents under the waiver as would have coverage absent the waiver.

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) for the coverage guardrail as follows: To meet the coverage guardrail, a comparable number of state residents must be forecast to have coverage under the section 1332 waiver as would have had coverage absent the waiver.

As proposed, the Departments' policies and interpretations related to the coverage guardrail are as follows:

Coverage refers to MEC as defined in 26 USC 5000A(f). For this purpose, "comparable" means that the forecast of the number of covered individuals is no less than the forecast of the

number of covered individuals absent the section 1332 waiver. This condition generally will be required to be forecast to be met in each year that the section 1332 waiver would be in effect.

The impact on all state residents will be considered, regardless of the type of coverage they would have had absent the section 1332 waiver. For example, while a section 1332 waiver may not change the terms of a state's Medicaid coverage or change existing Medicaid demonstration authority, changes in Medicaid enrollment – whether increases or decreases – that result from a section 1332 waiver, holding the state's Medicaid policies constant, will be considered in evaluating the number of residents with coverage under a waiver.

Assessment of whether the section 1332 waiver application covers a comparable number of individuals will also take into account the effects across different groups of state residents, and, in particular, effects on vulnerable or underserved residents, including low-income individuals, older adults, those with serious health issues or who have a greater risk of developing serious health issues, and people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.¹⁶⁴ A section 1332 waiver will be highly unlikely to be approved by the Secretaries if it would reduce coverage for these populations, even if the waiver would provide coverage to a comparable number of residents in the aggregate. Finally, analysis under the coverage requirement will take into account whether the section 1332 waiver sufficiently prevents gaps in or discontinuations of coverage.

Consistent with 31 CFR 33.108(f) and 45 CFR 155.1308(f), the section 1332 waiver application must include analysis and supporting data that establishes that the waiver satisfies this requirement, including information on the number of individuals covered by income, health expenses, health insurance status, and age groups, under current law and under the waiver,

¹⁶⁴ These groups include individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. See <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government/>.

including year-by-year estimates. The application should identify any types of individuals, including vulnerable and underserved individuals, who are more or less likely to be covered under the waiver than under current law.

As discussed previously in the preamble to the proposed rule, under the interpretation outlined in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule, the coverage guardrail would be met if at least as many residents are enrolled in health coverage, including both comprehensive and less comprehensive health plans, as would be enrolled absent the waiver. That interpretation was intended to promote choice among a wide range of plans to ensure that consumers can enroll in coverage that is right for them. As such, the Departments noted that the interpretations set forth in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule permit states to provide access to less comprehensive or less affordable coverage as an additional option for their residents to choose. Under the current policy, as long as a comparable number of residents are projected to be covered as would have been covered absent the section 1332 waiver, the coverage guardrail would be met. The Departments noted that this interpretation of the coverage guardrail is inconsistent with the goal of EO 14009 to reduce barriers for expanding comprehensive affordable coverage. The interpretation could allow for more individuals to enroll in medically underwritten plans that offer limited benefits, charge higher out-of-pocket costs, or both, which is inconsistent with the goal of EO 14009 to reduce barriers for expanding comprehensive, high-quality, affordable coverage. As discussed in the preamble to the proposed rule, the proposed provisions are intended to align with the President's instruction in EO 14009 to adopt policies to strengthen the implementation of the ACA and ensure high-quality health care is accessible and affordable for every American. The Departments are of the view that the proposals outlined in the proposed rule will further support states providing consumers with comprehensive, high-quality affordable health care that will better protect consumers with pre-existing conditions and will help protect consumers from unexpected and expected medical costs.

The Departments sought comment on the proposed policies and interpretations related to the coverage guardrail. The Departments are of the view that the proposed provisions would have minimal impact on both states with section 1332 waivers under development and states with approved waivers. The Departments solicited comment on the impact to stakeholders.

The following is a summary of the comments received and the Departments' responses related to 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C), the coverage guardrail.

Comment: Commenters were generally supportive of the proposals related to the coverage guardrail. One commenter recommended that the regulatory language be clarified to indicate that the coverage it references is comprehensive coverage, meeting the standards set forth in 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A).

Response: The Departments appreciate commenters' support and are adopting the policies and interpretations related to the coverage guardrail policy and finalizing the amendments to 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) as proposed. The Departments confirm that for purposes of the coverage guardrail, the term "coverage" refers to minimum essential coverage as defined in 26 USC 5000A(f), which aligns with the policies and interpretations described in this preamble for the comprehensiveness guardrail analysis under 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A). As explained in this preamble, the Departments will evaluate waiver proposals against this guardrail to ensure that, under the waiver, a comparable number of state residents are forecast to have coverage under the section 1332 waiver as would have had coverage absent the waiver. The impact on all state residents will be considered, regardless of the type of coverage they would have had absent the section 1332 waiver. The Departments remain committed to approving waivers that promote health insurance coverage and health equity.

Regarding the coverage guardrail regulations, the Departments are not finalizing additional changes to the rule text at this time. The Departments are of the view that codifying more specific requirements and guidelines in regulation is unnecessary, given the policies and

interpretations already discussed in this preamble and the amendments to the coverage guardrail regulations finalized in this rule, which provide states and the Federal Government the information necessary to reasonably evaluate the ability of a section 1332 waiver to meet the coverage guardrail and relevant policy goals.

After consideration of the comments received, the Departments are adopting the policies and interpretations related to the coverage guardrail and finalizing the modifications to 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) as proposed.

d. Deficit Neutrality (31 CFR 33.108(f)(3)(iv)(D) and 45 CFR 155.1308(f)(3)(iv)(D))

The Departments did not propose to modify the regulations at 31 CFR 33.108(f)(3)(iv)(D) and 45 CFR 155.1308(f)(3)(iv)(D) for the deficit neutrality guardrail, but proposed, through preamble, policies and interpretations relating to the requirements for the deficit neutrality guardrail consistent with the policies outlined in the 2015 and 2018 Guidance. As proposed, the Departments' policies and interpretations related to the deficit neutrality guardrail are as follows:

Under the deficit neutrality guardrail, the projected Federal spending net of Federal revenues under the section 1332 waiver is required to be equal to or lower than projected Federal spending net of Federal revenues in the absence of the waiver.

The estimated effect on Federal revenue is required to include all changes in income, payroll, or excise tax revenue, as well as any other forms of revenue (including user fees), that would result from the proposed section 1332 waiver. Estimated effects include, for example, changes in the amounts the Federal Government pays in PTC, small business tax credits, or other health coverage tax credits; changes in the amount of employer shared responsibility payments and excise taxes on high-cost employer-sponsored plans collected by the Federal Government; and changes in income and payroll taxes resulting from changes in tax exclusions for employer-sponsored insurance and in deductions for medical expenses.

The effect on Federal spending includes all changes in Federal financial assistance (PTC, small business tax credits, and CSRs) and other direct spending, such as changes in Medicaid spending (while holding the state's Medicaid policies constant) that would result from the changes made through the proposed section 1332 waiver. Projected Federal spending under the section 1332 waiver proposal also includes all administrative costs to the Federal Government, including any changes in IRS administrative costs, Federal Exchange administrative costs, and other administrative costs associated with the waiver or alleviated by the waiver.

Under the policies and interpretations outlined in the proposed rule, section 1332 waivers must not increase the Federal deficit over the period of the waiver (which may not exceed 5 years unless renewed) or in total over the 10-year budget plan submitted by the state as part of the section 1332 waiver application. Consistent with the policies in the 2015 Guidance and in the 2018 Guidance, the 10-year budget plan would be required to describe, for both the period of the waiver and for the 10-year budget window, the projected Federal spending and changes in Federal revenues under the section 1332 waiver and the projected Federal spending and changes in Federal revenues in the absence of the waiver for each year of the 10 years.

The 10-year budget plan should assume the section 1332 waiver would continue permanently, but should not include Federal spending or savings attributable to any period outside of the 10-year budget window. A variety of factors, including the likelihood and accuracy of projected spending and revenue effects and the timing of these effects, will be considered when evaluating the effect of the section 1332 waiver on the Federal deficit. A section 1332 waiver that increases the deficit in any given year is less likely to meet the deficit neutrality requirement than one that does not.

The Departments note that the approach outlined in part 1 of the 2022 Payment Notice final rule for the deficit neutrality guardrail is consistent with EO 14009 as it would not reduce coverage or otherwise undermine the ACA and Medicaid.

The Departments sought comment on the proposed policies and interpretations related to the deficit neutrality guardrail. The Departments noted that the proposal would have minimal impact on both states with section 1332 waivers under development and states with approved waivers. The Departments solicited comment on the impact to stakeholders.

The following is a summary of the comments received and the Departments' responses related to 31 CFR 33.108(f)(3)(iv)(D) and 45 CFR 155.1308(f)(3)(iv)(D), the deficit neutrality guardrail. The summary of comments and the Departments' responses that follow also address comments regarding pass-through funding that were made in connection with the Departments' proposals related to the deficit neutrality guardrail.

Comment: The Departments received two specific comments that were generally supportive of the proposals related to the deficit neutrality guardrail. One commenter noted that the "Departments' longstanding approach... appropriately carries out this statutory requirement by specifying that the Federal Government's projected spending net of revenues under a section 1332 waiver would need to be equal to or lower than would occur in the absence of a waiver."¹⁶⁵ Another commenter noted that while it supports the policies and interpretation of the deficit neutrality guardrail, "the Departments should calculate pass-through funding differently and in a way that would allow states to share more of the Federal savings that a section 1332 waiver could generate."

Response: The Departments appreciate commenters' support and are finalizing the policies and interpretations related to the deficit neutrality guardrail policy as proposed. Regarding pass-through funding, states with approved section 1332 waivers may only receive pass-through funding associated with resulting reductions in Federal spending on certain types of Federal financial assistance specified in the statute and reduced, as necessary, to ensure deficit neutrality, as required by the statute.¹⁶⁶

¹⁶⁵ Center on Budget and Policy Priorities comment letter on proposed rule.

¹⁶⁶ See section 1332(a)(3) of the ACA, which refers to premium tax credits, cost-sharing reductions, and small business credits under section 36B of the Code or under Part I of subtitle E of the ACA.

Comment: The Departments received several comments requesting that the Departments revisit their proposed policies and interpretations of the deficit neutrality guardrail. These commenters expressed concern that as proposed, the policies and interpretations are overly strict and narrow, which may prevent states from pursuing innovative new models that would expand coverage, and are inconsistent with the original intent of the waiver program and the Administration's goal of increasing enrollment in comprehensive coverage. Furthermore, these commenters contended that the Departments' overall proposed interpretation of deficit neutrality is inconsistent with the other statutory guardrails and the ACA more broadly. Other commenters were of the view that these policies and interpretations were also contrary to EO 14009 and EO 13985 and should be updated to explicitly allow state efforts to experiment with improving on the ACA while reducing racial disparities due to a lack of coverage or barriers to affordability.

These commenters expressed concern that the proposed policies and interpretations of the deficit neutrality guardrail could result in a scenario where a state that pursues a section 1332 waiver that successfully results in an increase in ACA-eligible enrollment would fail to meet the deficit neutrality requirement because the increase in enrollment would increase Federal spending on PTC, thereby increasing the Federal deficit. The commenters stated that this creates a disincentive for states to pursue innovative health care reform under a section 1332 waiver, since, if a state were to pursue an innovative health care proposal outside the section 1332 process which resulted in increased enrollment, the Federal Government would bear the cost of any increased enrollment. Further, commenters noted that the Departments' overall interpretation of the deficit neutrality guardrail is contrary to the goals of the ACA and EOs 14009 and 13985 as people who are eligible but not enrolled are disproportionately from communities of color. As such, commenters contended that the policies and interpretations as proposed would penalize states seeking to innovate through a section 1332 waiver and contradict the Departments' stated goal to expand coverage.

The commenters recommended that the Departments instead consider three alternative ways to evaluate the deficit neutrality guardrail. One recommendation is that the Departments take into account those who are currently eligible for coverage, but unenrolled, in the baseline coverage for evaluating the deficit neutrality guardrail and costs used to compute pass-through funding. Commenters noted that this alternate interpretation of “deficit neutrality” aligns with the aims of the ACA to expand coverage and would grant states the flexibility to create new waiver designs, including a state-level public option, to meet those goals. Commenters noted utilizing this approach for section 1332 waivers would align with the statutory interpretation for section 1115 demonstrations and Medicaid waivers that a law should be interpreted to promote rather than undermine the accomplishment of its core objectives. Further, the commenters noted that CMS has permitted states to juxtapose waiver spending against baselines reflecting state implementation of alternative policies permitted without any waiver in the context of section 1115 demonstrations to promote statutory objectives and increased enrollment of eligible people.

Another commenter recommended that instead of looking at deficit neutrality on an annual basis for each and every year of the waiver, the Departments should instead consider the deficit neutrality guardrail over a 10-year period to allow states greater opportunity for innovation, such as creating a public option. The commenter noted that this approach would be consistent with existing requirements for section 1332 waivers to include a 10-year budget projection in 1332 waiver applications. In other rulemaking, commenters have also noted that this approach would be consistent with how the Congressional Budget Office (CBO) scores are generally analyzed for deficit neutrality over a 10-year period.

Another recommendation from commenters was that the Departments evaluate deficit neutrality and compute pass-through funding on a per capita basis. These commenters explained that a per capita basis would provide a sustainable funding source in the event future enrollment exceeds current levels. These commenters further noted that under section 1115 demonstration projects, the calculation of the without waiver budget neutrality expenditure limit(s) is based on

spending per eligible individual, per month (PMPM). Using this PMPM approach, the commenters explained that the state is not at risk for increased costs associated with increases in enrollment, and does not accrue savings from decreases in enrollment. Unexpected increases in enrollment could be a consequence of factors outside the demonstration and beyond the state's complete control—such as changing economic conditions and natural disasters. The state is at risk only for increases to the PMPM cost growth—not for the increases in enrollment.¹⁶⁷

Response: The Departments appreciate these commenters' recommendations and acknowledge stakeholders' interest in pursuing innovative strategies to increase enrollment. After consideration of the comments received, the Departments are finalizing as proposed their interpretation of the requirement that waivers must not increase the Federal deficit.¹⁶⁸ Thus, the projected Federal spending net of Federal revenues under the section 1332 waiver is required to be equal to or lower than projected Federal spending net of Federal revenues in the absence of the waiver to meet the deficit neutrality guardrail requirement. The Departments also clarify that the evaluation of whether a section 1332 waiver increases the Federal deficit will include consideration of the projected impact of the waiver over the period of the waiver (which may not exceed 5 years unless renewed) and over the 10-year budget plan. However, the Departments reiterate that under the policies and interpretations finalized in this rule, a section 1332 waiver that increases the Federal deficit in any given year is less likely to meet this guardrail than one that does not.

The Departments appreciate commenters' suggestions on the deficit neutrality guardrail, as well as suggestions related to the affordability, comprehensiveness, and coverage guardrails and pass-through funding. The Departments reaffirm their aim to promote health equity and increase health insurance coverage through section 1332 waivers and are of the view that the proposed policies and interpretations related to the deficit neutrality guardrail are consistent with

¹⁶⁷ SMD # 18-009 RE: Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects available online at <https://www.medicaid.gov/Federal-policy-guidance/downloads/smd18009.pdf>.

¹⁶⁸ See section 1332(b)(1)(D) of the ACA.

the goals of the ACA, and align with EO 14009 and EO 13985, as states are still encouraged to consider ways to experiment with improving coverage and affordability for vulnerable populations. Thus, after consideration of the comments received, the Departments are adopting the proposed policies and interpretations related to the deficit neutrality guardrail. The Departments are also finalizing the accompanying pass-through funding policies and interpretations, as well as the codification of 31 CFR 33.122 and 45 CFR 155.1322, as proposed.

4. Section 1332 Application Procedures (31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4))

a. Actuarial and Economic Analysis (31 CFR 33.108(f)(4)(i)-(iii) and 45 CFR 155.1308(f)(4)(i)-(iii))

As required under 31 CFR 33.108(f)(4)(i)-(iii) and 45 CFR 155.1308(f)(4)(i)-(iii), states must include actuarial analyses and actuarial certifications, economic analyses, and the data and assumptions used to demonstrate and support the state's estimates that the proposed section 1332 waiver will comply with the statutory guardrails. The Departments did not propose any regulatory changes to 31 CFR 33.108(f)(4)(i)-(iii) and 45 CFR 155.1308(f)(4)(i)-(iii), but did propose, through preamble, policies relating to the requirements for the actuarial and economic analyses that are similar to the policies outlined in the 2015 and 2018 Guidance. The Departments proposed these policies to help ensure that the Departments have the appropriate and necessary information to measure the impact of waivers on the guardrails, particularly related to coverage. This information is especially important in light of the goal of EO 14009 to provide more comprehensive affordable coverage to consumers. In addition, the Departments encouraged states to include in their analysis whether the proposed section 1332 waiver would increase health equity in line with EO 13985. As proposed, the policies are as follows:

Consistent with the 2015 and 2018 Guidance, the determination of whether a proposed section 1332 waiver meets the requirements under section 1332 and the calculation of the pass-through funding amount will be made using generally accepted actuarial and economic analytic methods, such as micro-simulation. The analysis will rely on assumptions and methodologies

that are similar to those used to produce the baseline and policy projections included in the most recent President's Budget (or Mid-Session Review), but adapted as appropriate to reflect state-specific conditions. As provided in 31 CFR 33.108(f)(4)(i) and 45 CFR 155.1308(f)(4)(i), the state must include actuarial analyses and actuarial certifications to support the state's estimates that the proposed section 1332 waiver will comply with the comprehensive coverage requirement, the affordability requirement, and the scope of coverage requirement. Consistent with the 2018 Guidance, these actuarial analyses and certifications should be conducted by a member of the American Academy of Actuaries.

The Departments' analysis of whether a proposed section 1332 waiver meets the requirements under section 1332 will be based on state-specific estimates of the current level and distribution of population by the relevant economic and demographic characteristics, consistent with the 2015 and 2018 Guidance, including income and source of health coverage. It will generally use Federal estimates of population growth, and economic growth as published in the Analytical Perspectives volume released as part of the President's Budget¹⁶⁹ and health care cost growth¹⁷⁰ to project the initial state variables through the 10-year budget plan window. However, in limited circumstances where it is expected that a state will experience substantially different trends than the nation as a whole in the absence of a section 1332 waiver, the Secretaries may determine that state-specific assumptions will be used.

Consistent with the 2018 Guidance and largely similar to the 2015 Guidance, estimates of the effect of the section 1332 waiver will assume, in accordance with standard estimating conventions, that macroeconomic variables like population, output, and labor supply are not affected by the waiver. However, estimates will take into account, as appropriate, other changes in the behavior of individuals, employers, and other relevant entities induced by the section 1332 waiver where applicable, including employer decisions regarding what coverage (and other

¹⁶⁹ https://www.whitehouse.gov/omb/budget/Analytical_Perspectives.

¹⁷⁰ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/NationalHealthExpendData/>.

compensation) they offer and individual decisions regarding whether to take up coverage. The same state-specific and Federal data, assumptions, and model are used to calculate comprehensiveness, affordability, and coverage, and relevant state components of Federal taxes and spending under the section 1332 waiver and under current law.

The analysis and information submitted by the state as part of the section 1332 waiver application must conform to these standards. Consistent with the 2015 and 2018 Guidance, the application would describe all modeling assumptions used, sources of state-specific data, and the rationale for any deviation from Federal forecasts. A state may be required under 31 CFR 33.108(f)(4)(vii) and 45 CFR 155.1308(f)(4)(vii) to provide to the Secretaries copies of any data used for their section 1332 waiver analyses that are not publicly available so that the Secretaries can independently verify the analysis produced by the state.

Consistent with the 2018 Guidance, for each of the guardrails, the state must clearly explain its estimates with and without the section 1332 waiver. The actuarial and economic analyses would be required to compare comprehensiveness, affordability, coverage, and deficit neutrality with and without the section 1332 waiver. The deficit neutrality analysis will specifically examine net Federal spending and revenues under the section 1332 waiver to those measures absent the waiver (the baseline) for each year of the waiver. If the state is submitting a section 1332 waiver application for less than a 5-year period, the actuarial analysis could be submitted for the period of the waiver. The Departments, in accordance with their regulations,¹⁷¹ could request additional information or data in order to conduct their assessments.

The state should also provide a description of the models used to produce these estimates, including data sources and quality of the data, key assumptions, and parameters for the section 1332 waiver. Consistent with the 2018 Guidance, the Departments will not prescribe any particular method of actuarial analysis to estimate the potential impact of a section 1332 waiver. However, the state should explain its modeling in sufficient detail to allow the Secretaries to

¹⁷¹ See 31 CFR 33.108(g) and 45 CFR 155.1308(g).

evaluate the accuracy of the state's modeling and the comprehensiveness and affordability of the coverage available under the state's section 1332 waiver proposal. As permitted under 31 CFR 33.108(g) and 45 CFR 155.1308(g) the state may be required to provide, upon request by the Secretaries, data or other information that it used to make its estimates, including an explanation of the assumptions used in the actuarial analysis.

The Departments sought comment on the proposals, and did not receive any comments in response to these proposals regarding 31 CFR 33.108(f)(4)(i)-(iii) and 45 CFR 155.1308(f)(4)(i)-(iii). The Departments are finalizing these policies as proposed.

b. Implementation Timeline and Operational Considerations (31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv))

As required under 31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv), states must include in their applications for initial approval of a section 1332 waiver a detailed draft timeline for the state's implementation of the proposed waiver. The Departments did not propose any regulatory changes to 31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv). Rather, the Departments proposed the operational considerations in preamble that states should take into account when developing a waiver application, waiver plan, and implementation timeline. Specifically, the Departments proposed these operational considerations to provide additional information regarding how HHS and the IRS may be able to support a state in implementing a section 1332 waiver plan so states can take this information into consideration as it relates to their implementation timelines. The Departments noted that the proposals would help to ensure that the Departments have the appropriate and necessary information to measure the impact of proposed waivers on the statutory guardrails, particularly related to coverage. This information is especially important in light of the goal of EO 14009 to provide more comprehensive affordable coverage to consumers. In addition, the Departments encouraged states to include in their analysis whether the proposed section 1332 waiver would increase health equity in line with EO 13985. Upon consideration, the approach proposed with regard to operational considerations was

revised from the 2018 Guidance with regard to the use of the Exchange information technology platform (the Federal platform) and IRS operational considerations to maintain smooth operations of the Exchanges consistent with EO 14009 and this Administration's goals to protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American. A discussion of operational considerations for waivers that use the Federal platform for FFE states and IRS functionality follows, as well as comments on the proposals.

i. Use of Federal Platform Technology

HHS operates the Federal platform utilized by FFEs and by some State Exchanges for eligibility and enrollment functions. For technical, operational, and fiscal efficiency, the Federal platform is generally designed to support uniform administration across the states that utilize it. With that noted, HHS would be open to inquiries and further discussion with states that are developing section 1332 waiver proposals and are interested in potential technical collaboration. For example, over the past few years HHS has offered assistance to states implementing state-based reinsurance programs.¹⁷² Currently, states can request that the Federal Government assist with the calculation of issuers' eligible state reinsurance payments based on the state reinsurance parameters as part of the state's approved section 1332 waiver plan. Under this arrangement, states are still responsible for making reinsurance payments to issuers and otherwise administering and overseeing their programs.

The Departments noted that states that are interested in this assistance should notify HHS early in the process about the state's interest and the state's parameters (that is, claims cost-based, conditions-based, or other) for HHS to assess the feasibility of providing this support. Should a final proposal involve any customized or specialized Federal technical or operational capabilities, the Departments noted that states would be responsible for funding the development

¹⁷² For plan year 2021, HHS is providing this support for six states: Colorado, Delaware, Maryland, New Hampshire, North Dakota, and Pennsylvania.

and operation of these capabilities under the Intergovernmental Cooperation Act (ICA).¹⁷³ Under the ICA, a Federal agency generally may provide certain technical and specialized services to state governments, so long as the state covers the full costs of those services. Accordingly, where a state intends to rely on HHS for technical services related to its section 1332 waiver proposal, the state would be required to cover HHS's costs. For example, states implementing state-based reinsurance programs that request technical or specialized services from HHS with respect to calculating state reinsurance payments are responsible for the Federal costs associated with providing this service, including development, implementation, maintenance, operations, and customer support. For this reason, the Departments noted that should HHS and a state agree to such technical or specialized services to support an approved section 1332 waiver plan, the Departments would not consider costs for HHS services covered under the ICA as an increase in Federal spending resulting from the state's waiver plan for purposes of the deficit neutrality analysis.

As outlined in the preamble of the proposed rule for the deficit neutrality guardrail, costs associated with changes to Federal administrative processes that are not covered under the ICA would be taken into account in determining whether a waiver application satisfies the deficit neutrality requirement. Regulations at 31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4) require that such costs be included in the 10-year budget plan submitted by the state. As specific section 1332 waiver proposals are submitted, the Departments noted that HHS would work closely with states to determine which Federal costs are covered under the ICA (and thus are not subject to deficit neutrality guardrail), and which are not covered under the ICA (and thus are subject to the deficit neutrality guardrail).

ii. IRS Functionality

Certain changes that affect IRS administrative processes may make a section 1332 waiver proposal infeasible for the Departments to accommodate. The IRS generally is not able to

¹⁷³ Pub. L. 90-577.

administer different sets of Federal tax rules for different states. As a result, the Departments noted that while a state may propose to entirely waive the application of one or more of the Federal tax provisions listed in section 1332 for taxpayers in the state, it would generally not be feasible to design a section 1332 waiver that would require the IRS to administer a program that alters these provisions for taxpayers in the state.

The Departments noted that in some limited circumstances, the IRS may be able to accommodate small adjustments to the existing systems for administering Federal tax provisions. However, the Departments noted that it is generally not feasible to have the IRS administer a different set of PTC eligibility or PTC computation rules for individuals in a particular state. Thus, states contemplating a waiver proposal that includes a modified version of a Federal tax provision could consider waiving the provision entirely and creating a subsidy program administered by the state as part of a section 1332 waiver proposal.

In addition, a section 1332 waiver proposal that partly or completely waives one or more Federal tax provisions in a state may create administrative costs for the IRS. As noted in the preamble for the deficit neutrality guardrail of the proposed rule, costs associated with changes to Federal administrative processes would be taken into account in determining whether a waiver application satisfies the deficit neutrality requirement. Regulations at 31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4) require that such costs be included in the 10-year budget plan submitted by the state. States contemplating to waive any part of a Federal tax provision should engage with the Departments early in the section 1332 waiver application process to assess whether the waiver proposal is feasible for the IRS to implement, and, if applicable, to assess the administrative costs to the IRS of implementing the waiver proposal.

The Departments did not receive any public comments in response to these proposals regarding 31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv), Implementation Timeline and Operational Considerations, and are finalizing these policy clarifications and operational considerations as proposed.

5. Public Input on Waiver Proposals (31 CFR 33.112 and 45 CFR 155.1312)

Section 1332(a)(4)(B)(i) of the ACA, and regulations at 31 CFR 33.112 and 45 CFR 155.1312, require states to provide a public notice and comment period for a section 1332 waiver application sufficient to ensure a meaningful level of public input prior to submitting an application. Under the current requirements, as part of the state's public notice and comment period, a state with one or more federally-recognized tribes must conduct a separate process for meaningful consultation with such tribes.¹⁷⁴ In addition, a state must make available, at the beginning of its public notice and comment period, through its website or other effective means of communication, a public notice that includes all of the information outlined in 31 CFR 33.112(b) and 45 CFR 155.1312(b). The state must also update this information, as appropriate. After issuance of this notice and prior to submission of a new section 1332 waiver application, the state must conduct public hearings and provide interested parties an opportunity to learn about and comment on the contents of the state's section 1332 waiver application.¹⁷⁵ Because section 1332 waiver applications may vary significantly in their complexity and breadth, the regulations provide states with flexibility in determining the length of the comment period required to allow for meaningful and robust public engagement. 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 posted online in a manner that is accessible to individuals with disabilities. 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"),¹⁷⁶ or alternatively, the World Wide Web Consortium's Web Content Accessibility Guidelines (WCAG)¹⁷⁷ 2.0 Level AA standards.

¹⁷⁴ See 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2).

¹⁷⁵ See 31 CFR 33.112(c) and 45 CFR 155.1312(c).

¹⁷⁶ For more information on section 508 standards, see: <https://section508.gov/manage/program-roadmap>. See also: <https://www.hhs.gov/sites/default/files/ocr-guidance-electronic-information-technology.pdf>.

¹⁷⁷ For more information, see the WCAG website at <http://www.w3.org/TR/WCAG20/>.

While the Departments did not propose any regulatory changes to 31 CFR 33.112 and 45 CFR 155.1312, through the preamble, the Departments proposed policies and interpretations for the state public notice requirements. More specifically, the Departments proposed to maintain the current standard that the state comment period for a section 1332 waiver application should generally be no less than 30 days.¹⁷⁸ The Departments explained that a general standard requiring a minimum 30-day comment period would be sufficient to allow for meaningful and robust public engagement on a state's waiver application and reiterated that a longer period may be appropriate for complex proposed waiver plans.

Section 1332(a)(4)(B)(iii) of the ACA and its implementing regulations¹⁷⁹ also require the Federal Government to provide a public notice and comment period once the Secretaries receive an application. The period must be sufficient to ensure a meaningful level of public input and must not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedure Act, or requirements that are unreasonable or unnecessarily burdensome with respect to state compliance.¹⁸⁰ Under existing regulations, 31 CFR 33.108(f) and 45 CFR 155.1308(f), a submitted section 1332 waiver application will not be deemed received until the Secretaries have made the preliminary determination that the application is complete. As with the state comment period described earlier, the Departments did not propose regulatory amendments and instead proposed adoption of policies and interpretations related to the Federal comment period. More specifically, the Departments explained that the length of the Federal comment period should also reflect the complexity of the section 1332 waiver proposal

¹⁷⁸ Notwithstanding this policy, the Departments clarified that states with approved waivers and states seeking approval for proposed waivers continue to have flexibility to submit requests to the Departments to modify certain public participation requirements during the COVID-19 PHE. See 31 CFR 33.118 and 45 CFR 155.1318. Also see the November 2020 IFC, 85 FR 71142. As detailed below, in this rulemaking, the Departments are finalizing the proposal to extend similar flexibilities during future emergent situations. As such, states with approved waivers and state seeking approval for proposed waivers will have similar flexibilities to submit requests to the Departments to modify certain public participation requirements during future emergent situations.

¹⁷⁹ See 31 CFR 33.116 and 45 CFR 155.1316.

¹⁸⁰ See section 1332(a)(4)(B)(iii) of the ACA, 31 CFR 33.116(b) and 45 CFR 155.1316(b).

and similarly proposed that the Federal comment period should also generally not be less than 30 days.¹⁸¹

The Departments did not receive any public comments on the proposals related to 31 CFR 33.112 and 45 CFR 155.1312, Public Input on Waiver Proposals, and are finalizing these policy clarifications and interpretations as proposed.

6. Modification from the normal public notice requirements (31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320)

In the November 2020 IFC,¹⁸² the Departments revised regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for waivers under section 1332 during the COVID-19 PHE. The Departments proposed to extend these 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. The Departments proposed to consider a situation to be "emergent" if it is both unforeseen and urgent. The Departments did not propose any changes with respect to the flexibility made available in the November 2020 IFC during the COVID-19 PHE. The Departments further clarified that states with approved section 1332 waivers and states seeking approval for proposed waivers will continue to have flexibility to submit requests to the Departments to modify certain public participation requirements during the COVID-19 PHE.¹⁸³

The Departments also explained in the 2022 Payment Notice proposed rule¹⁸⁴ that CMS similarly proposed an extension of COVID-19 policy flexibilities, specifically the calculation of

¹⁸¹ Notwithstanding this policy, the Departments clarified that states with approved waivers and states seeking approval for proposed waivers continue to have flexibility to submit requests to the Departments to modify certain public participation requirements during the COVID-19 PHE. See 31 CFR 33.118 and 45 CFR 155.1318. Also see the November 2020 IFC, 85 FR 71142. As detailed below, in this rulemaking, the Departments are finalizing the proposal to extend similar flexibilities during future emergent situations. As such, states with approved waivers and state seeking approval for proposed waivers will have similar flexibilities to submit requests to the Departments to modify certain public participation requirements during future emergent situations.

¹⁸² 85 FR 71142. See <https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency>.

¹⁸³ See 85 FR 71142.

¹⁸⁴ See 85 FR at 78597 – 78598 and 78608 - 78609.

plan average premium and state average premium requirements for extending future premium credits (“temporary premium credits”), which was originally published in the November 2020 IFC.¹⁸⁵ In part 2 of the 2022 Payment Notice final rule, HHS finalized these policies to extend beyond the COVID-19 PHE, to be available, if permitted by HHS, during a future declared PHE.¹⁸⁶ In developing the policies in the proposed rule, the Departments considered extending the section 1332 flexibilities adopted in the November 2020 IFC only to future declared PHEs, but are of the view that these flexibilities, as proposed to be available on a broader basis in different times of emergent situations, would allow states to use or modify their waivers to respond to state or local emergent situations that may not rise to the level of a national declared PHE. The Departments further explained they are of the view that this best aligns with the overall statutory purpose and goals for section 1332 waivers, which are meant to allow states to craft their own unique solutions to respond to the specific health care needs in their respective markets. If the Departments were to limit these flexibilities only to future declared national PHEs, states may not be able to utilize or modify their section 1332 waivers as a tool to address state or local emergent situations or state designated emergencies which may similarly threaten consumers’ access to health insurance coverage, consumers’ access to health care, or human life.

In addition, the flexibilities outlined in the proposed rule are similar to those available under section 1115 demonstrations. Existing regulations at 42 CFR 431.416(g), relating to demonstration projects under section 1115 of the Act, provide that CMS may waive, in whole or in part, the state and Federal public notice requirements to expedite a decision on a proposed section 1115 demonstration application or section 1115 demonstration extension request that addresses a natural disaster, PHE, or other sudden emergency threat to human life, under certain circumstances described in the regulation. The Departments explained they are of the view that using a similar standard for section 1332 waivers would provide states the necessary flexibility to

¹⁸⁵ 85 FR 54820.

¹⁸⁶ 86 FR at 24182 – 24183 and 24202 - 24203.

enable them to quickly respond to various emergent situations. For example, some states have used flexibilities for section 1115 demonstrations in emergent situations to address threats to human life such as mudslides and wildfires that were state-designated emergencies.

The Secretaries value the importance of the public input process, but also intend to propose to provide reprieve from certain requirements, where appropriate, in emergent situations. Allowing the Secretaries to modify the public notice and post award requirements would allow states to seek emergency relief in support of the development of quick and innovative ways to ensure consumers across the country have access to health care coverage in the face of unforeseen threats to that coverage. As was noted in the November 2020 IFC and the proposed rule, HHS and the Department of the Treasury are concerned that past trends that threaten the stability of the individual market risk pool may return, leading some issuers to cease offering coverage on the Exchanges in some states and counties and leading other issuers to increase their rates, leaving some geographic areas with limited or no affordable Exchange coverage options. Permitting the Secretaries to modify the public notice procedures, in part, will help states seeking section 1332 waivers to address such circumstances more quickly and develop innovative ways to ensure consumers have access to affordable health care coverage. Specifically, the Departments proposed to modify 31 CFR 33.118 and 45 CFR 155.1318 to broaden the Secretaries' authority to modify, in part, the otherwise applicable public notice procedures to expedite a decision on a proposed section 1332 waiver request that is submitted or would otherwise become due during emergent situations, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. The proposed amendments to these regulations further clarify that these proposed flexibilities would be available in future natural disasters; PHEs; and other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life, rather than being limited to only the duration of the COVID-19 PHE.

The Departments also proposed to modify 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2) to provide the Secretaries with similar authority to modify, in part, otherwise applicable post award public notice requirements for an approved waiver outlined in 31 CFR 33.120(c) and 45 CFR 155.1320(c) when the application of the post-award public notice procedures would be contrary to the interests of consumers during a natural disaster; PHE; or other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life, rather than limiting this flexibility only to the duration of the COVID-19 PHE. These proposals would expand on policies published in the November 2020 IFC that are limited to the COVID-19 PHE.

a. Public Notice Procedures and Approval (31 CFR 33.118 and 45 CFR 155.1318)

Section 1332(a)(4)(B) of the ACA provides that the Secretaries shall issue regulations providing 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, 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 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 requirements under the accompanying Federal process.

As explained in the November 2020 IFC, the Departments recognize that the current section 1332 waiver regulations regarding state and Federal public notice procedures and comment period requirements may impose barriers for states pursuing a proposed waiver request during an emergent situation, such as the COVID-19 PHE or a future natural disaster; PHE; or other emergent situation that threatens consumers' access to health insurance coverage, consumers' access to health care, or human life. It is the mission of the Departments to enhance and protect the health and well-being of all Americans. As such, the Departments proposed to extend the existing flexibilities codified in regulations to protect public health and access to

health insurance coverage and care during the COVID-19 PHE to also apply in the event of a future emergent situation, such as a natural disaster; a PHE; or other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life. These flexibilities have been important during the COVID-19 PHE and support efforts to prevent the spread of COVID-19 by limiting the need for in-person gatherings related to section 1332 waivers during the PHE. Extending these flexibilities beyond the COVID-19 PHE to future emergent situations is important to similarly help states as they may face uncertainty as to whether their waiver request will be approved in time, given the otherwise applicable state and Federal public notice procedures or public participation requirements, to expeditiously reform their health insurance markets and to protect consumers during a future emergent situation. Some states may not consider more robust changes because they are concerned that the current section 1332 waiver application requirements are too time-consuming or burdensome to pursue during a future emergency or other emergent situation. Therefore, the Departments explained they are of the view that providing similar flexibility to modify certain public notice procedures and participation requirements during a future emergent situation will protect public health and health insurance markets, and will increase flexibility and reduce burdens for states seeking to use section 1332 waivers as a means of innovation for providing coverage, lowering premiums, and improving their health care markets.

Permitting the Secretaries to modify the public notice procedures, in part, when a delay would undermine or compromise the purpose of the proposed section 1332 waiver request and be contrary to the interests of consumers will help states seeking section 1332 waivers to address such circumstances more quickly to ensure consumers have access to affordable health care coverage throughout the emergent situation. As such, the Departments explained they are of the view that, if certain safeguards are met, it is in the best interest of the public to provide states applying for section 1332 waivers with the option to request to modify otherwise applicable public notice procedures during an emergent situation. Based on the experience with the current

COVID-19 PHE, the Departments noted they are of the view that it is appropriate and reasonable to propose to make similar flexibilities available in future emergent situations.

The Departments proposed to modify 31 CFR 33.118(a) and 45 CFR 155.1318(a) to provide that the Secretaries may 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 requirements specified at 31 CFR 33.116(b) and 45 CFR 155.1316(b) to expedite a decision on a proposed section 1332 waiver request during an emergent situation, when a delay would undermine or compromise the purpose of the proposed waiver request and would be contrary to the interests of consumers. As proposed, the amendments to 31 CFR 33.118(a) and 45 CFR 155.1318(a) further specified that these flexibilities would be limited to emergent situations, including natural disasters; PHEs; or other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life.

As noted earlier in this section of the preamble, under the proposal, the existing flexibility made available in the November 2020 IFC¹⁸⁷ for the COVID-19 PHE would continue to apply. The Departments also clarified that, similar to the November 2020 IFC, they were *not* proposing to allow states to waive 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2), which require states to conduct a separate process for meaningful consultation with federally-recognized tribes. The Departments noted that tribal consultation is subject to separate requirements in accordance with EO 13175,¹⁸⁸ which mandates the establishment of regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications.

In addition, the Departments clarified that a state cannot use this flexibility to request to eliminate public notice and participation procedures. Instead, this is a targeted proposal intended to extend the existing COVID-19 PHE flexibilities to future emergent situations to remove

¹⁸⁷ See 85 FR 71142, <https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency>.

¹⁸⁸ See 85 FR 71142, 71178.

potential barriers and allow both the Federal Government and states flexibility to respond to emergent situations as they unfold. It is limited to permitting states to request to modify, in part, certain otherwise applicable public notice and participation requirements, not to eliminate the requirements all together.

Examples of the public notice and participation procedures that currently apply that, under this proposal, a state may seek to have waived or modified during a future emergent situation include the requirement that the state notifies the public and holds hearings prior to submitting an application, that the state hold more than one public hearing in more than one location, and that the Departments provide for public notice and comment after an application is determined to be complete. States may also seek to modify the state and/or Federal comment periods to be less than 30 days and to host public hearings virtually rather than in person.

In addition, the Departments explained they are of the view that these flexibilities are necessary to allow states flexibility to respond to rapid changes in the event of a future emergent situation and noted that these proposals align with existing flexibilities available for public health programs that do not apply to section 1332 waivers. For example, when the President declares a disaster or emergency under the Stafford Act or the National Emergencies Act and the Secretary of HHS declares a PHE under section 319 of the PHS Act, section 1135 of the Act allows the Secretary of HHS to temporarily waive or modify certain Medicare, Medicaid, and CHIP requirements to ensure: (1) sufficient health care items and services are available to meet the needs of individuals enrolled in these programs in the emergency area(s) and time periods; and (2) providers who give such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud and abuse). However, section 1135 of the Act does not apply to or otherwise provide the Departments with authority to waive or modify requirements regarding section 1332 waivers when similar events cause similar impacts in the private health insurance markets. As proposed, the modifications to the Departments' section 1332 waiver regulations outlined in the proposed rule were designed to generally align with the

section 1135 flexibilities, but would be available in broader circumstances than emergencies or disasters declared under the Stafford Act or the National Emergencies Act and PHEs declared under section 319 of the PHS Act. The Departments proposed to apply this flexibility to include other emergencies at the state or local level to allow states to better address all of the various emergent situations that may impact their state health insurance markets and residents access to coverage and care.

Consistent with the existing framework for state modification requests related to the COVID-19 PHE, for a state request to modify the state or Federal public notice requirements to expedite a decision on a proposed section 1332 waiver request during an emergent situation to be approved, the state must meet the requirements outlined in 31 CFR 33.118(b) and 45 CFR 155.1318(b). As proposed, the Secretaries could approve a state's request to modify the Federal and/or state public notice procedures, in part, in future emergent situations if the state meets all of the following requirements:

- The state requests a modification in the form and manner specified by the Secretaries.
- The state acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the request for the modification for the section 1332 waiver, and the waiver application request, as applicable.
- The state details in its request for a modification, as applicable, the justification for the requested modification from the state public notice procedures, and the alternative public notice procedures it proposes to implement at the state level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the state's request for a modification.
- The state details in its request for a modification, as applicable, the justification for the request and the alternative public notice procedures it requests to be implemented at the Federal level.

The Departments also proposed that the state, as applicable, must implement the alternative public notice procedures at the state level if the state's modification request is approved and, if required, amend the section 1332 waiver application to specify that it is the state's intent to comply with those alternative public notice procedures in the state's modification request. These are the same requirements that apply under the existing framework for state modification requests related to the COVID-19 PHE and are currently captured in 31 CFR 33.118(b)(1) through (4) and (f) and 45 CFR 155.1318(b)(1) through (4) and (f).¹⁸⁹

Any state submitting a proposed section 1332 waiver application during a future emergent situation could submit a separate request to the Secretaries to modify, in part, certain otherwise applicable state and/or Federal public notice and public participation requirements or could include such a request in its section 1332 waiver application request.

Consistent with the framework for COVID-19 PHE state modification requests, the Secretaries' review and consideration of a modification request for future emergent situations would vary based on the state's circumstances, its modification request, and the complexity and breadth of the state's proposed section 1332 waiver request. For example, during the COVID-19 PHE, many states prohibited in-person public gatherings or established stay-at-home orders due to the public health threat.¹⁹⁰ States seeking new section 1332 waiver(s) that had such prohibitions in effect at the time they would have otherwise had to conduct public notice were unable to hold two in-person public hearings prior to submission of their section 1332 waiver applications. In similar future emergent situations, this approach would allow the Secretaries to grant the state's request to hold the two public hearings virtually, rather than in person, or to hold one public hearing at the state level, rather than two public hearings at the state level, if the state's request meets other applicable requirements. As another example, the Secretaries may

¹⁸⁹ To effectuate the extension of these flexibilities to future emergent situations, the Departments proposed to amend 31 CFR 33.118(b)(3) and 45 CFR 155.1318(b)(3) to replace the current reference to "public health emergency" with "the emergent situation." This criterion otherwise remains the same.

¹⁹⁰ <https://khn.org/morning-breakout/states-declare-emergencies-ban-large-gatherings-as-coronavirus-sweeps-the-nation/>; <https://www.axios.com/states-shelter-in-place-coronavirus-66e9987a-a674-42bc-8d3f-070a1c0ee1a9.html>.

agree with a state's determination that, due to emergent circumstances that have arisen related to a natural disaster, there is insufficient time for the state to provide public notice and hold any public hearings at the state level prior to submitting its section 1332 waiver application as would otherwise be required by 31 CFR 33.112(a) and 45 CFR 155.1312(a), and grant the state's request to provide public notice and hold public hearings at the state level after the state's submission of its application if the state's request meets other applicable requirements.

In situations where the Departments approve a state's modification request to provide public notice and host the state-level hearings on a different timeframe or setting, such as after the submission of a state's waiver application request, the state would be required to amend the application request as necessary to reflect public comments or other relevant feedback received during the alternative state-level public notice procedures. The Departments would evaluate a state's request for a modification of the public participation requirements and issue their modification determination within approximately 15 calendar days after the request is received. In assessing whether a state acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the modification request for the waiver, and for the section 1332 waiver application, the Departments would evaluate whether the relevant circumstances are sufficiently emergent. The Departments proposed in new proposed 31 CFR 33.118(g) and 45 CFR 155.1318(g) that the Departments will consider circumstances to be emergent when they could not have been reasonably foreseen. In addition, the Departments proposed to assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and would not make this assessment based solely on the number of days a state may have been aware of such issues. Other relevant factors that the Departments would consider include the specific circumstances involved, the nature and extent of the future emergent situation, and whether the state could have predicted the situation. To assist the Departments with making this assessment, the Departments also proposed to capture a new requirement at 31 CFR 33.118(b)(5) and 45 CFR 155.1318(b)(5) to require a state submitting a

modification request must also explain in its request how the circumstances underlying its request result from a natural disaster; PHE; or other emergent situation that threatens consumers' access to health insurance coverage, consumers' access to health care, or human life that could not be reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interests of consumers.

The Departments reminded states that any public participation processes must continue to comply with applicable Federal civil rights laws,¹⁹¹ including taking reasonable steps to provide meaningful access for individuals with LEP and taking appropriate steps to ensure effective communication with individuals with disabilities, including accessibility of information and communication technology. It is also important for states to remember that virtual meetings may present additional accessibility challenges for people with communication and mobility disabilities, as well as those who lack broadband access. The Departments noted that they expect states to take these considerations into account when seeking flexibility to modify the public participation requirements, as the overall statutory and regulatory obligation to ensure a meaningful level of public input during the public notice and comment period would continue to apply. By way of example, ensuring effective communication during a future emergent situation when the otherwise applicable public notice and participation requirements are modified may include providing American Sign Language interpretation and real-time captioning as part of a virtual hearing, and ensuring that the platform used to host the hearing is interoperable with assistive technology for those with mobility difficulties. The Departments especially encouraged states to strive to obtain meaningful input from potentially affected populations, including low-income residents, residents with high expected health care costs, persons less likely to have

¹⁹¹ 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), 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. 1213 et.seq., 28 CFR Part 35). The HHS Office for Civil Rights enforces applicable Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex, age, or disability, as well as laws protecting the exercise of conscience and religious freedom, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb-4).

access to care, and members of federally-recognized tribes, if applicable, as part of any alternative public participation process.

Consistent with the framework for COVID-19 PHE state modification requests, the Secretary of HHS would publish on the CMS website any modification determinations within 15 calendar days of the Secretaries making such a determination, as well as the approved revised timeline for public comment at the state and Federal level, as applicable.¹⁹² In addition, the state would be required to publish on its website any modification requests and determinations within 15 calendar days of receipt of the determination, as well as the approved revised timeline for public comment at the state and Federal level, as applicable.¹⁹³

The Departments sought comment on these proposals. The Departments summarize and respond to comments on the proposals related to Public Notice Procedures and Approval requirements captured in 31 CFR 33.118 and 45 CFR 155.1318 below alongside comments on the accompanying proposals to the Monitoring and Compliance requirements captured in 31 CFR 33.120 and 45 CFR 155.1320. As detailed further later in this section of the preamble, the Departments are finalizing the amendments to 31 CFR 33.118(a), (b)(3), (b)(5) and (g) and 45 CFR 155.1318(a), (b)(3), (b)(5) and (g) with one modification. In response to comments and to align the regulations with the intended policy, we are replacing the reference to “health insurance coverage” with “comprehensive coverage” in the description of emergent situations in 31 CFR 33.118(a) and (b)(5) and 45 CFR 155.1318(a) and (b)(5).¹⁹⁴

b. Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320)

As section 1332 waivers are likely to have a significant impact on individuals, states, and the Federal Government, the 2012 Final Rule established processes and methodologies to

¹⁹² See 31 CFR 33.118(d) and 45 CFR 155.1318(d).

¹⁹³ See 31 CFR 33.118(e) and 45 CFR 155.1318(e).

¹⁹⁴ As finalized, the new regulatory text provides these flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers’ access to comprehensive coverage, consumers’ access to health care, or human life. Similarly, state requests to modify otherwise applicable public notice and participation requirements must explain how the emergent circumstances underlying the request result from a natural disaster; public health emergency; or other emergent situation that threatens consumers’ access to comprehensive coverage, consumers’ access to health care, or human life and could not reasonably have been foreseen.

ensure that the Secretaries receive adequate and appropriate information regarding section 1332 waivers (consistent with section 1332(a)(4)(B)(iv) of the ACA). As part of the Departments' monitoring and oversight of approved section 1332 waivers, the Secretaries monitor the state's compliance with the specific terms and conditions of the waiver, including, but not limited to, compliance with the guardrails, reporting requirements, and the post award forum requirements.¹⁹⁵ Under 31 CFR 33.120(c) and 45 CFR 155.1320(c), to ensure continued public input within at least 6 months after the implementation date, and annually thereafter, states are required to hold a public forum at which members of the public have an opportunity to provide comments on the progress of the program authorized by the section 1332 waiver and to provide a summary of this forum to the Secretary of HHS for the Departments' review as part of the quarterly and annual reports required under 31 CFR 33.124 and 45 CFR 155.1324. Under 31 CFR 33.120(c)(1) and 45 CFR 155.1320(c)(1), states are required to 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. In the November 2020 IFC, the Departments added 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2) to provide that the Secretaries may waive, in part, post award public notice requirements during the COVID-19 PHE when certain criteria were met.

The Departments proposed to modify 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2), to extend the flexibilities currently provided during the COVID-19 PHE to permit the Secretaries to modify in part, certain post award public notice requirements in 31 CFR 33.120(c) and 45 CFR 155.1320(c) for approved waivers during a future emergent situation when the application of the post award public notice procedures would be contrary to the interests of consumers. Extending these flexibilities beyond the COVID-19 PHE to future emergent situations is important to help states as they may face similar uncertainty as to whether they are able to comply with the otherwise applicable post award requirements in such situations. For example,

¹⁹⁵ See section 1332(a)(4)(iv) and (v). Also see 31 CFR 33.120 and 45 CFR 155.1320.

the state post award procedures generally require an in-person gathering. Based on the experience with the current COVID-19 PHE, the Departments explained they are of the view that it is appropriate and reasonable to propose to make similar flexibilities available in future emergent situations as those circumstances may also limit the ability for the state to host in-person gatherings. The Departments did not propose any changes with respect to the flexibility made available in the November 2020 IFC in response to the COVID-19 PHE and clarified that states with approved section 1332 waivers continue to have flexibility to submit requests to the Departments to modify certain post award public notice requirements during the COVID-19 PHE.¹⁹⁶

Consistent with the framework for state modification requests related to the COVID-19 PHE, as proposed, the Secretaries could similarly approve a state request to modify the post award public notice procedures, in part, when the application of the post award public notice requirements would be contrary to the interest of consumers during the future emergent situation. The Departments proposed to amend the title in 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2) and to amend the text at 31 CFR 33.120(c)(2)(i) and 45 CFR 155.1320(c)(2)(i) to replace the references to “the public health emergency” with “an emergent situation.” The Departments also proposed amendments to the last sentence of 31 CFR 33.120(c)(2)(i) and 45 CFR 155.1320(c)(2)(i) to replace the language that limits these flexibilities to the COVID-19 PHE to reflect the broader proposed applicability to emergent situations, including natural disasters; PHEs; or other emergent situations that threaten consumers’ access to health insurance coverage, consumers’ access to health care, or human life. In addition, the Departments proposed that the Secretaries could approve a state’s post award modification request if the state meets all of the following requirements:

- The state requests a modification in the form and manner specified by the Secretaries.

¹⁹⁶ See 85 FR 71142.

- The state acts in good faith, and in a diligent, timely, and prudent manner to comply with the monitoring and compliance requirements under the regulations and specific terms and conditions of the section 1332 waiver and to submit and prepare the request for a modification.

- The state details in its request for a modification the reason(s) for the alternative post award public notice procedures it proposes to implement at the state level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergent circumstances underlying the state's request for a modification.

These are the same requirements that apply under the existing framework for state post award modification requests related to the COVID-19 PHE currently captured in 31 CFR 33.120(c)(2)(ii)(A) through (C) and 45 CFR 155.1320(c)(2)(ii)(A) through (C).

As proposed, a state may request to modify the otherwise applicable public participation requirements to host the public forum for an approved section 1332 waiver that would take place or become due during an emergent situation virtually rather than as an in-person gathering. When reviewing state modification requests, the Departments would remain focused on ensuring the public is informed about the implementation of programs authorized by section 1332 waivers and has a meaningful opportunity to comment on its implementation.

Consistent with the framework for COVID-19 state modification requests, the Secretaries would evaluate a state's request for a modification of certain post award public participation requirements during a future emergent situation and issue their modification determination within approximately 15 calendar days after the request is received.¹⁹⁷ The state would be required to publish on its website any modification requests and determinations by the Departments within 15 calendar days of receipt of the determination, as well as information on the approved revised timeline for the state's post award public notice procedures, as

¹⁹⁷ See 31 CFR 33.120(c)(2)(ii)(D) and 45 CFR 155.1320(c)(2)(ii)(D).

applicable.¹⁹⁸ Since the state is already required to post materials as part of post award annual reporting requirements, such as the notice for the public forum and annual report, states would be responsible for ensuring that the public is aware of the determination to modify the public notice procedures and would be required to include this information along with the other information required under 31 CFR 33.120(c)(1) and 45 CFR 155.1320(c)(1) for the alternative procedures in a prominent location on the state's public website.

The Departments explained they are of the view that post award public forums are critical to ensure that the public has a regular opportunity to learn about and comment on the progress of section 1332 waivers. Based on the experience during COVID-19 PHE, the Departments explained they are of the view that it is appropriate and reasonable to propose to provide similar flexibilities and permit states to request to modify certain post award public participation requirements in future emergent situations. States that receive approval to modify, in part, these post award public notice procedures would still need to meet all other applicable requirements specified in 31 CFR 33.120(c) and 45 CFR 155.1320(c). For example, if the state receives a modification approval that permits it to hold the post award public forum virtually instead of in person, the state must still publish the notice of its post award public forum on the state's public website and use other effective means to communicate the required information to the public. The public notice must include the website, date, and time of the public forum that will be convened by the state, information related to the timeframe for comments, and how comments from the public on the section 1332 waiver must be submitted. The Departments reminded states that they still must also comply with applicable Federal civil rights requirements, including laws pertaining to accessibility, if the Secretaries approve a modification from post award public notice procedures. For example, a state that receives approval to host the required public hearing(s) virtually would need to ensure the hearings are accessible to individuals with

¹⁹⁸ See 31 CFR 33.120(c)(2)(ii)(E) and 45 CFR 155.1320(c)(2)(ii)(E).

disabilities and individuals with LEP so members of the public can participate and submit comments. The state should also track how many people are attending these forums, if possible.

In assessing whether a state acted in good faith, and in a diligent, timely, and prudent manner when reviewing a state's post award modification request, the Departments would evaluate whether the relevant circumstances are sufficiently emergent. The Departments proposed in 31 CFR 33.120(c)(2)(iii) and 45 CFR 155.1320(c)(2)(iii) that the Departments will consider circumstances to be emergent when they could not have been reasonably foreseen. In addition, the Departments proposed to assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and would not make this assessment based solely on the number of days a state may have been aware of such issues. Other relevant factors that the Departments would consider include the specific circumstances involved, the nature and extent of the emergent situation, and whether the state could have predicted the situation. To assist the Departments with making this assessment the Departments also proposed to capture a new requirement at 31 CFR 33.120(c)(2)(ii)(F) and 45 CFR 155.1320(c)(2)(ii)(F) to require a state submitting a post award modification request to also explain in its request how the circumstances underlying its request result from a natural disaster; PHE; or other emergent situation that threatens consumers' access to health insurance coverage, consumers' access to health care, or human life and could not be reasonably have been foreseen and how application of the post award public notice requirements would be contrary to the interests of consumers.

The Departments sought comment on this proposal.

The following is a summary of the comments received and the Departments' responses to our proposals to amend 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320 to permit the Secretaries to modify, in part, the normal public notice requirements for section 1332 waivers in future emergent situations.

Comment: The Departments received comments in support of the proposals to modify 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320. In addition, one commenter recommended that the Departments codify as part of the regulatory text the “reasonably foreseeable” definition for emergent situations. Another commenter recommended that the section 1332 waiver process should more closely mirror the section 1115 demonstration program emergency process. This commenter had concerns about the vagueness of both the definition of “emergency” and the definition of “health insurance coverage” - specifically, the latter not being defined as comprehensive - and that the proposed flexibilities could be “subject to misuse” as a result. Another commenter requested that the Departments provide further guidance or examples of situations the Departments will consider unforeseeable and urgent threats to consumers’ access to health insurance coverage, consumers’ access to health care, or human life so states can better understand when these flexibilities may be available. One commenter recommended that the Departments extend the flexibilities demonstrated during the COVID-19 PHE, not just for other emergent situations, but regardless of whether the circumstances are emergent or not. This commenter explained that extending these policies beyond emergencies would foster the goals of the statute by providing the public an opportunity for meaningful access and participation in the public notice process. This commenter noted that extending this policy more generally would help individuals with LEP and individuals with disabilities since online tools make participation possible and may exceed what is available at a time- and space-restricted in-person forum.

Response: The Departments appreciate commenters’ support for the proposals to extend the COVID-19 flexibilities to modify, in part, the otherwise applicable public participation requirements and are finalizing these policies and clarifications as proposed. The Departments are not finalizing additional changes to the rule text at this time.

The Departments considered but did not propose extending these flexibilities regardless of whether the circumstances are emergent or not. The Departments proposed and are finalizing

the extension of these flexibilities to address when current requirements are barriers for states during emergent situations. This policy is targeted at providing a reprieve from certain requirements to allow the Federal Government and states to respond to emergent situations as they unfold. States will be required to meet the otherwise applicable public participation requirements in all other circumstances. Furthermore, there is also no requirement that precludes states from utilizing online tools for their public participation requirements forums in addition to in-person forums to better meet the needs of populations such as those with disabilities or LEP.

The Departments decline to adopt a specific definition for “reasonable foreseeability” or further define the exact number of days that the state must not have been aware of such issues. The Departments are of the view that such a determination would depend heavily on the specific facts and circumstances involved, including the nature and extent of the emergent situation. The Departments are finalizing the proposal to assess “reasonable foreseeability” based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and would not make this assessment based solely on the number of days a state may have been aware of such issues. Other relevant factors that the Departments will consider include the specific circumstances involved, the nature and extent of the future emergent situation, and whether the state could have predicted the situation. The justification and other information submitted by the state as part of its modification request will also be considered. The Departments are of the view that this general framework allows the Departments to strike a balance in accounting for states experiencing different kind of emergencies, while also providing states with information on the factors the Departments will use when making this determination. For example, a state that experiences a hurricane, which often happens quickly and may impact the state’s ability to hold an in-person hearing, would likely have little lead time to request and plan for a change. Furthermore, a state could experience a new emergent situation that could lead to limited or no Exchange plan options in a geographic area—perhaps from a very recent and sudden economic downturn, issuer insolvency, or other reasons—that could threaten consumers’ access to health

insurance coverage or care. In this scenario, the state would likely have more lead time compared to a natural disaster, such as a hurricane or flooding, but the issue could become emergent at various points during the rate submission or QHP certification process. For example, the Departments would not consider an ongoing recession, by itself, to be an emergent situation. The Departments further note that existing threats to consumers' access to health coverage or care—such as in geographic areas in which issuer participation has been historically low—would not be considered emergent situations for purposes of applying the flexibilities finalized in this rule. After receipt of a state's modification request, the Departments will also examine what is in the best interest of the public and whether allowing the state to modify the full public participation requirements would do undue harm to the public. This evaluation will also take into account other relevant factors and information, including information provided by the state regarding how the emergent situation could not reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interest of consumers.

The Departments are not providing additional examples of situations they may consider “reasonably unforeseen” at this time but will consider doing so in the future. States that may be interested in using these flexibilities during an emergent situation should reach out to the Departments as soon as practicable to help determine if the situation would meet the requirements outlined in this rule.

While section 1115 demonstration projects do not have emergency processes for situations that threaten access to health insurance coverage, it is the Departments' view that these flexibilities for an emergent situation are important for section 1332 waivers for the private health insurance market. In addition, the Departments clarify that for the purposes of this flexibility to address emergent situations that threaten consumers' access to health insurance coverage, the reference to “health insurance coverage” was intended to capture comprehensive coverage as defined under 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) such that situations that threaten consumers' access to comprehensive coverage that meets the

requirements for EHBs as defined in section 1302(b) of the ACA and offered through Exchanges established by title I of the ACA, or, as appropriate, Medicaid or CHIP, may be considered emergent under this rule. Similarly, the reference was intended to align with the policies and interpretations finalized in this rule regarding the coverage guardrail and to capture the different forms of MEC as defined in 26 USC 5000A(f). In response to comments and to align the regulations with the intended policies and interpretations, we are updating 31 CFR 33.118(a) and (b)(5), 31 CFR 33.120(c)(2)(i) and (c)(2)(ii)(F), 45 CFR 155.1318(a) and (b)(5), and 45 CFR 155.1320(c)(2)(i) and (c)(2)(ii)(F) to replace the references to “health insurance coverage” with “comprehensive coverage” in the description of emergent situations.¹⁹⁹

Comment: The Departments received several comments encouraging the Departments to withdraw the proposals to modify 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320 related to extending the COVID-19 PHE flexibilities to future emergent situations. These commenters voiced concerns that the proposals would allow states to avoid providing the public a meaningful opportunity to provide input on waiver plans, as required by the statute. Some of these commenters were concerned that the revised public notice requirements risk unintended negative consequences for consumers. They noted that various stakeholders, including state advocates, rely on these public comment periods to provide feedback on how waiver proposals will impact consumers and other key stakeholders. The commenters expressed the view that the proposed flexibilities would allow states to cut short the notice and comment periods, thereby not allowing for a meaningful level of public input. Furthermore, these commenters were of the view that the proposed flexibilities would delay the public notice procedures until after the Departments make a decision on a waiver application request. These commenters also noted that section 1332 waivers are designed to implement

¹⁹⁹ As finalized, the new regulatory text provides these flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers’ access to comprehensive coverage, consumers’ access to health care or human life. Similarly, state requests to modify otherwise applicable public notice and participation requirements must explain how the emergent circumstances underlying the request result from a natural disaster; public health emergency; or other emergent situation that threatens consumers’ access to comprehensive coverage, consumers’ access to health care or human life and could not reasonably have been foreseen.

health system innovations, not to respond to disasters and other emergencies. They also cited that Congress has provided other authorities to respond to natural disasters and other emergencies.

Response: The Departments appreciate and understand the concerns raised by these commenters; however, as explained earlier and in the proposed rule, the flexibilities provided under this rule do not allow states to avoid providing notice and an opportunity to comment on proposed waiver applications. Consistent with section 1332(a)(4)(B)(i) of the ACA and regulations at 31 CFR 33.112 and 45 CFR 155.1312, states will continue to be required to provide a public notice and comment period for section 1332 waiver applications sufficient to ensure a meaningful level of public input prior to approval or denial of an application. States with approved section 1332 waivers will similarly be required to provide a meaningful opportunity to comment during post award public forums. Stakeholders and the general public will continue to be able to provide feedback on the impact of waiver proposals. As explained in this preamble, the Departments value the importance of the public input process, but are finalizing the flexibility to permit the adjustment of certain requirements, where appropriate, in emergent situations.

In finalizing these policies, the Departments intend to permit states to request to modify the public notice procedures for proposed waiver applications, *in part*, when a delay would undermine or compromise the purpose of the proposed section 1332 waiver request and be contrary to the interests of consumers. States will also be permitted to request to modify the post award requirements, *in part*, when the application of those requirements would be contrary to the interests of consumers. The Departments again reiterate that a state cannot use this flexibility to eliminate public notice and participation procedures.²⁰⁰ In addition, states cannot waive the requirement to conduct a separate process for meaningful consultation with federally-recognized tribes. States must also continue to comply with applicable civil rights laws, including

²⁰⁰ The state's request must detail the justification for and the alternative public notice procedures it seeks to implement that are designed to provide the greatest opportunity and level of public input from impacted stakeholders practicable given the emergent circumstances underlying the state's request. See 31 CFR 33.118(b)(3) and 45 CFR 155.1318(b)(3).

requirements related to providing meaningful access for individuals with LEP and effective communication with individuals with disabilities. This rule is a targeted policy to extend the existing COVID-19 PHE flexibilities to future emergent situations to remove potential barriers and allow both the Federal Government and states flexibility to respond to emergent situations as they unfold. States can seek to use these flexibilities to modify the requirement to hold more than one public hearing in more than one location, to hold public hearings before submission of the waiver application to the Departments, or to hold the hearings virtually rather than in-person. The Departments expect states will take into account relevant considerations when seeking flexibility to modify the public participation requirements and that states will address these considerations in modification requests. For example, when evaluating a state's request to conduct a virtual hearing during a future emergent situation, the Departments may evaluate, among other relevant factors, what steps the state outlines in its modification request in response to the additional accessibility challenges that such hearings entail.

The Departments also reiterate that in situations where the Departments approve a state's modification request to provide public notice and host the state-level hearings on a different timeframe or in a different setting, such as after the submission of a state's waiver application request, the state would be required to amend the application request as necessary to reflect public comments or other relevant feedback received during the alternative state-level public notice procedures. The state would also be required to publish on its website any modification requests and determinations, as well as publish information on the approved revised timeline to inform the public about the alternative timeline or procedures. The Departments further clarify and affirm that they do not intend to approve or deny a waiver application request until after completion of the modified public notice procedures at the state or Federal level, as applicable, and consideration of timely submitted public comments

Finally, these flexibilities have been important during the COVID-19 PHE and have furthered efforts to prevent the spread of COVID-19 by limiting the need for in-person

gatherings related to section 1332 waivers. During the COVID-19 PHE, 14 states with approved section 1332 waivers have utilized the flexibilities outlined in the November 2020 IFC to meet the section 1332 public notice requirements while ensuring the safety of state residents by holding virtual forums.²⁰¹ Furthermore, states have found virtual forums more beneficial in terms of reaching more rural or hard-to-reach populations, when compared to in-person gatherings. Finally, the Departments acknowledge there are similar flexibilities available under section 1115 demonstrations for Medicaid and CHIP, as well as under section 1135 waivers for Medicare, Medicaid, and CHIP. These amendments to 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320 provide for similar treatment of section 1332 waivers.

The Departments appreciate commenters' concern that section 1332 waivers are not intended to respond to disasters and other emergencies, but are of the view that these situations could lead to an acute need for health insurance coverage and that section 1332 waivers can be used to help address these challenges and promote market stability.

After consideration of these comments, the Departments are finalizing the modifications to 31 CFR 33.118(a), (b)(3), (b)(5) and (g); 31 CFR 33.120(c)(2); 45 CFR 155.1318(a), (b)(3), (b)(5) and (g); and 45 CFR 155.1320(c)(2) and the adoption of the accompanying policies, interpretations, and clarifications as explained in this section of this preamble.

7. Monitoring and compliance (31 CFR 33.120 and 45 CFR 155.1320)

The Departments proposed to modify 31 CFR 33.120(a)(1) and (2) and 45 CFR 155.1320(a)(1) and (2) to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. The proposal aligns the Departments' efforts to provide supplementary information about the requirements that must be met for the continued oversight and monitoring of an approved section 1332 waiver. Because the Departments are of the view that the 2018 Guidance and the incorporation of its guardrail

²⁰¹ States with approved waivers that have held public notice requirements virtually during the COVID-19 PHE include Alaska, Colorado, Delaware, Hawaii, Maine, Maryland, Minnesota, Montana, New Hampshire, North Dakota, Oregon, Pennsylvania, Rhode Island, and Wisconsin.

interpretations into regulations could result in the Departments approving section 1332 waivers that would result in fewer residents in those states enrolling in comprehensive and affordable coverage, that those interpretations do not represent the best fulfillment of congressional intent behind the statutory guardrails, that they are inconsistent with the policy intentions of EO 14009 and EO 13985, and that it is appropriate to address concerns raised by commenters on the 2018 Guidance, the Departments proposed to remove the reference to the 2018 Guidance. As proposed, the Departments would rely upon the statute and regulations, as well as the Departments' interpretive policy statements as outlined in the applicable notice and comment rulemaking, in monitoring approved section 1332 waivers.

The following is a summary of the comments received and the Departments' responses to our proposals to amend 31 CFR 33.120(a)(1) and (2) and 45 CFR 155.1320(a)(1) and (2).

Comment: The Departments received some comments expressing general support for removing the reference to guidance from the rule text. In addition, one commenter specifically supported the proposal to monitor approved section 1332 waivers according to the statute, regulations, and interpretative policy described in notice and comment rulemaking, and removing the reference to the 2018 guidance.

Response: The Departments appreciate commenters' support. After consideration of these comments, the Departments are finalizing these proposed modifications to 31 CFR 33.120(a)(1) and (2) and 45 CFR 155.1320(a)(1) and (2).

8. Pass-through Funding (31 CFR 33.122 and 45 CFR 155.1322)

Section 1332(a)(3) of the ACA directs the Secretaries to pay pass-through funding to the state for the purpose of implementing the state section 1332 waiver plan and outlines accompanying requirements for making the pass-through funding determination. The Departments proposed new regulation text at 31 CFR 33.122 and 45 CFR 155.1322 to codify in regulation details regarding the Departments' determination of pass-through funding for approved section 1332 waivers. More specifically, the Departments proposed to codify in

regulation that, with respect to a state's approved section 1332 waiver, the amount of Federal pass-through funding would equal the amount, determined annually by the Secretaries, of the PTC under section 36B of the Code, the small business tax credit (SBTC) under section 45R of the Code, or CSRs under ACA part I of subtitle E (collectively referred to as Federal financial assistance), that individuals and small employers in the state would otherwise be eligible for had the state not received approval for its section 1332 waiver. This calculation would include any amount not paid due to an individual not qualifying for Federal financial assistance or qualifying for a reduced level of such financial assistance. The pass-through amount would not be increased to account for any savings other than the reduction in Federal financial assistance. The pass-through amount would be reduced by any net increase in Federal spending or net decrease in Federal revenue if necessary to ensure deficit neutrality. The pass-through estimates take into account experience in the relevant state and the experience of other states with respect to participation in an Exchange and credits and reductions provided under such provisions to residents of the other states. This amount would be calculated annually by the Departments and could be updated by the Departments as necessary to reflect applicable changes in Federal or state law. The proposed regulations further state, consistent with the statute,²⁰² that any pass-through funding can only be used for purposes of implementing the state's approved section 1332 waiver plan.

Consistent with the Departments' existing regulations at 31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4), section 1332 waiver applications are required to provide analysis and supporting data to inform the Department's estimate of the pass-through funding amount and the waivers' predicted impact on the deficit neutrality guardrail. For states that do not utilize an FFE, this includes information about enrollment, premiums, and Federal financial assistance in the state's Exchange by age, income, and type of policy, and other information as may be required by the Secretaries. Consistent with the Departments' existing regulations at 31 CFR 33.124 and 45 CFR

²⁰² See section 1332(a)(3) of the ACA.

155.1324, states with approved section 1332 waivers must comply with state reporting requirements in accordance with the terms and conditions of the state's section 1332 waiver. If pass-through funding is being sought as part of the state's section 1332 waiver plan, states may also be required to submit data as outlined in the specific terms and conditions for the state's approved waiver in order for the Departments to calculate pass-through funding. The Departments did not propose any changes to these waiver requirements.

In addition, the proposals do not change the existing requirements codified in 31 CFR 33.108(f)(3)(iii) and 45 CFR 155.1308(f)(3)(iii) for the state's section 1332 waiver application to include a description of the provisions for which the state seeks a section 1332 waiver and how the waiver is necessary to facilitate the state's waiver plan. The Departments proposed that, if the state is seeking pass-through funding, the state waiver application should include an explanation of how, due to the structure of the section 1332 state plan and the statutory provisions waived, the state anticipates that individuals would no longer qualify for Federal financial assistance or would qualify for reduced Federal financial assistance, as a result of the section 1332 waiver.²⁰³ In addition, the Departments proposed the state would also need to explain in its application how the state intends to use that funding for the purposes of implementing its section 1332 state plan.

The Departments sought comment on the proposals, including the proposed adoption of the new regulatory text on pass-through funding for approved section 1332 waivers. The Departments received some comments regarding pass-through funding in connection with the Departments' proposals related to the deficit neutrality guardrail and those comments are summarized and responded to in this preamble at section IV(3)(d) of this final rule.

Comment: The Departments received a comment expressing general support for codifying the proposed interpretation related to pass-through funding.

²⁰³ While this rule generally finalizes the proposal to supersede and rescind the 2018 Guidance, the Departments are finalizing these standards which align with the approach outlined in the 2018 Guidance.

Response: The Departments appreciate this commenter's support. After consideration of the comments on pass-through funding, the Departments are finalizing the adoption of these proposed policies and the codification of these new regulations.

9. Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

The Departments proposed to modify 31 CFR 33.128(a) and 45 CFR 155.1328(a) to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. The proposal aligns the Departments' efforts to provide supplementary information about the requirements that must be met for the periodic evaluation requirements of an approved section 1332 waiver. Because the Departments are of the view that the 2018 Guidance and the incorporation of its guardrail interpretations into regulations could result in the Departments approving section 1332 waivers that would result in fewer residents in those states enrolling in comprehensive and affordable coverage, that those interpretations do not represent the best fulfillment of Congressional intent behind the statutory guardrails, that they are inconsistent with the policy intentions of EO 14009 and EO 13985, and that it is appropriate to address concerns raised by commenters on the 2018 Guidance, the Departments proposed to remove the reference to the 2018 Guidance. As proposed, the Departments would rely upon the statute and regulations, as well as the Departments' interpretive policy statements as outlined in the applicable notice and comment rulemaking, in conducting periodic evaluations of approved section 1332 waivers.

The following is a summary of the comments received and the Departments' responses to the proposals to amend 31 CFR 33.128(a) and 45 CFR 155.1328(a).

Comment: The Departments received some comments expressing general support for removing the reference to guidance from the rule text.

Response: The Departments appreciate commenters' support. After consideration of these comments, the Departments are finalizing the proposed modifications to 31 CFR 33.128(a) and 45 CFR 155.1328(a).

10. Waiver Amendment (31 CFR 33.130 and 45 CFR 155.1330)

The Departments proposed new regulations at 31 CFR 33.130 and 45 CFR 155.1330 to delineate the process by which a state is permitted to submit an amendment to an approved section 1332 waiver. The proposed new regulations also capture a proposed definition of a section 1332 waiver amendment. While the statute does not specifically mention amendment requests, some states with approved section 1332 waivers have indicated interest in amending their current approved waiver plans. Further, in response to previously received comments on the 2012 Final Rule, the Departments acknowledged that information regarding section 1332 waiver amendments and renewals would be needed in the future,²⁰⁴ and the Departments have received several inquiries from states on these topics. In addition, there may be situations where states pursuing proposed section 1332 waiver plans are interested in amending an application that has been submitted to the Departments for review. The Departments proposed that the framework would only apply to amendments to approved section 1332 waiver plans and would not apply to changes to an initial section 1332 waiver application submitted to the Departments but unapproved.²⁰⁵ Under this proposal, a state would not be authorized to implement any aspect of the proposed amendment without prior approval by the Departments.

In the proposed rule, the Departments set forth a proposed procedural framework for submission and review of amendment requests for an approved section 1332 waiver. The Departments explained they are of the view that this additional information will help states with approved section 1332 waiver plans better plan for and prepare for potential amendments to their state waiver plans. The Departments also noted they intend to continue providing information and details regarding the section 1332 waiver amendment process in the specific terms and conditions for an approved waiver plan. The proposals were intended to align with the current

²⁰⁴ See 77 FR 11700.

²⁰⁵ In circumstances where a state wants to amend its waiver application before the Departments have approved the waiver plan, the Departments intend to work with the state to ensure there is an adequate, meaningful opportunity for public notice and comment taking into account the particular circumstances of the situation and the state's waiver application (such as the changes to the proposed waiver, timing, etc.).

amendment request process outlined in recent specific terms and conditions (STCs) for states with approved waivers.²⁰⁶

a. Definition of Waiver Amendment

For purposes of these requirements, the Departments proposed to define the term “section 1332 waiver amendment” as a change to a section 1332 waiver plan that is not otherwise allowable under the STCs of an approved waiver, a change that could impact any of the section 1332 statutory guardrails, or a change to the program design for an approved waiver. Such potential changes include, but are not limited to, changes to eligibility, coverage, benefits, premiums, out-of-pocket spending, and cost sharing. The Departments proposed to codify this definition in new proposed 31 CFR 33.130(a) and 45 CFR 155.1330(a).

b. Waiver Amendment Process

To request a waiver amendment, the Departments proposed that the state must submit a letter in electronic format to the Departments to notify them in writing of its intent to request an amendment to its approved section 1332 waiver plan(s). The state would be required to include a detailed description of all of the intended change(s), including the proposed implementation date(s), in its letter of intent. The Departments explained they would encourage the state to submit the letter of intent at least 15 months prior to the section 1332 waiver amendment’s proposed implementation date and to engage with the Departments early in its development of a potential waiver amendment. The state may want to submit this letter of intent more than 15 months prior to the section 1332 waiver amendment’s proposed implementation date, depending on the complexity of the amendment request and the timeline for implementation, among other factors.

The Departments would review the state’s letter of intent request. The Departments proposed that, within approximately 30 days of the Departments’ receipt of the letter of intent,

²⁰⁶ For example, see STC 9 in New Hampshire’s Approval Letter and STCs: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-NH-Approval-STCs.pdf>.

the Departments would respond to the state and confirm whether the change requested is a section 1332 waiver amendment, as well as identify the information the state needs to submit in its waiver amendment request. This written response would also include whether or not the proposed section 1332 waiver amendment(s) would be subject to any additional or different requirements. For example, depending on the complexity of the section 1332 amendment request, scope of changes from the approved waiver plan, operational/technical changes, or implementation considerations, the Departments may impose requirements similar to those specified in 31 CFR 33.108(f) and 45 CFR 155.1308(f) for initial section 1332 waiver applications. The preamble regarding section 1332 waiver amendment content that follows further describes the proposed content requirements for section 1332 waiver amendment requests.

Under the proposed section 1332 waiver amendment framework, the state should generally plan to submit its waiver amendment request no later than 9 months prior to when the proposed amendment would take effect in order to allow for sufficient time for review of the waiver amendment request. Similar to the regulations at 31 CFR 33.108(a) and 45 CFR 155.1308(a) for new section 1332 waiver applications, the Departments proposed that applications for waiver amendments of a section 1332 waiver must be submitted in electronic format to the Departments. Similar to the regulations at 31 CFR 33.108(b) and 45 CFR 155.1308(b) for new section 1332 waiver applications, the Departments proposed that the state would be required to submit the section 1332 waiver amendment request sufficiently in advance of the requested waiver implementation date, particularly when the waiver plan impacts premium rates, to allow for an appropriate review and implementation timeframe. Depending on the complexity of the section 1332 amendment request, the state may want to submit the amendment request earlier than 9 months prior to implementation. In developing the implementation timeframe for its section 1332 waiver amendment request, the Departments proposed that the state must maintain uninterrupted operations of the Exchange in the state and provide adequate

notice to affected stakeholders and issuers of health insurance plans that would be (or may be) affected by the amendment to take necessary action based on approval of the section 1332 waiver amendment request. As detailed later in this section of this preamble, these are operational details that the state would be required to address as part of its waiver amendment request. In addition, as reflected in the new proposed regulations at 31 CFR 33.130(a) and 45 CFR 155.1330(a), a state would not be authorized to implement any aspect of the proposed amendment without prior approval from the Secretaries.

The Departments proposed a similar process for section 1332 waiver amendment requests as is outlined for new section 1332 waiver applications in 31 CFR 33.108 and 45 CFR 155.1308. In line with these requirements, the Departments proposed to define the type of information and what information a state is required to provide to the public prior to the submission of a section 1332 waiver amendment request to the Departments. Similar to new section 1332 waiver applications, the Departments proposed to evaluate the state's section 1332 waiver amendment request and may approve the request if the waiver, as amended, meets the statutory guardrails as defined in section 1332(b)(1)(A)-(D) of the ACA and other applicable requirements. In general, states are permitted to have a waiver plan that consists of different components or parts. As proposed, states would be permitted to propose an amendment, which could build on an approved section 1332 waiver plan. The Departments proposed that a state's approved section 1332 waiver plan and the proposed waiver amendment request should be analyzed together, and the state would receive pass-through funding for implementation of the amended waiver plan (including the amendment, if approved) if the amended waiver plan yields Federal financial assistance savings, net of any reductions necessary to ensure deficit neutrality. For example, if a state has an approved reinsurance program for plan year 2021 through 2025, and is seeking approval for a waiver amendment request to begin in 2023, the analysis in the section 1332 waiver amendment request should demonstrate that the reinsurance program combined with any proposed amendments meets the guardrails. In comparing scenarios with and without the section

1332 waiver, the Departments proposed to consider the without-waiver scenario to include neither the reinsurance program nor the section 1332 waiver amendment request and the with-waiver scenario to include the combined impact of the reinsurance program and the section 1332 waiver amendment request. In terms of pass-through funding, the Departments proposed that, if the section 1332 waiver amendment request described in the example is approved and determined to yield additional reductions in Federal financial assistance (in the form of PTC, CSR, or SBTC), the state would continue to receive pass-through funding annually for combined reductions in Federal financial assistance for the entire section 1332 waiver plan, rather than receiving a separate pass through funding amount for the reinsurance component of the waiver and a separate pass-through funding amount for the waiver amendment component. As noted in the earlier in preamble on pass-through funding, such amounts could be updated by the Departments, as necessary, to reflect applicable changes in state or Federal law.

Similar to the requirements in 31 CFR 33.108 and 45 CFR 155.1308, the Departments also proposed that the public must have a meaningful opportunity to provide input at the state and Federal level on waiver amendment requests. Section 1332(a)(4)(B) of the ACA requires the Secretaries to issue regulations that provide a process for public notice and comment at the state level, including public hearings, that is sufficient to ensure a meaningful level of public input. The Departments propose that a state pursuing a section 1332 waiver amendment must conduct the state public notice process that is specified for new applications at 31 CFR 33.112 and 45 CFR 155.1312. As such, to ensure a meaningful level of public input, the comment period would generally need to be no less than 30 days. The Departments also proposed that it would be permissible for a state to use its annual public forum required under 31 CFR 33.120(c) and 45 CFR 155.1320(c) for the dual purpose of soliciting public input on a proposed section 1332 waiver amendment request and on the progress of its approved waiver plan. This policy proposal is in line with the flexibility the Departments permitted in the 2012 Final Rule section 1332

regulations²⁰⁷ to allow for states to use Medicaid tribal consultation to also satisfy the requirements as set forth in 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2), that require a state with one or more federally-recognized tribes within its borders to conduct a separate process for meaningful consultation with the tribes as part of the state section 1332 waiver public notice and comment process. The Departments explained they are of the view that allowing states to use the annual public forum for the dual purpose of soliciting public input on the state's proposed section 1332 waiver amendment request and on the progress of its approved waiver plan would create a more efficient process for both the state and the public to provide a meaningful level of input. Furthermore, the proposal would allow a state to explain to the public how the state's proposed section 1332 waiver amendment would interact with the state's approved waiver plan, and thus would be beneficial to the public in understanding the impact of the state's proposed waiver amendment.

The Departments proposed a similar Federal public notice and approval process for section 1332 waiver amendment requests as is outlined for new section 1332 waiver applications in 31 CFR 33.116 and 45 CFR 155.1316. In line with these requirements, the Departments proposed that following a determination that a state's section 1332 waiver application request for a section 1332 waiver is complete, the Secretaries will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input, and the comment period would generally be no less than 30 days. The Departments would make available through an HHS website the complete section 1332 waiver amendment request, information relating to how and where written comments may be submitted, and the timeframe during which comments will be accepted. Additionally, the Departments will make available public comments received on the section 1332 waiver amendment request during the Federal public notice and comment period. The Departments explained they are of the view that these proposals would increase transparency of the Federal review process and create a clear path for states and the Departments

²⁰⁷ See 77 FR at 11706.

to determine if the information submitted is sufficient to continue review and when to start a Federal public comment period on the state's proposed waiver amendment. In addition, the Departments noted these proposals provide the public with a meaningful opportunity to provide input on a section 1332 waiver request in line with the intent of the statute.

c. Waiver Amendment Content

The Departments proposed that a state that wants to pursue a section 1332 waiver amendment request must furnish information and analysis regarding the state's proposed waiver amendment that is necessary to permit the Departments to evaluate the request. The proposed information and analysis are similar to the existing requirements for new section 1332 waiver applications.²⁰⁸ As such, the Departments proposed that a section 1332 waiver amendment request must include the following:

(1) A detailed description of the requested amendment, including the impact on the guardrails, and related changes to the section 1332 waiver program elements as applicable, including sufficient supporting documentation;

(2) An explanation and evidence of the process used by the state to ensure meaningful public input;

(3) Evidence of sufficient authority under state law(s) in order to meet the ACA section 1332(b)(2)(A) requirement for purposes of pursuing the section 1332 waiver amendment;

(4) An updated actuarial and/or economic analysis demonstrating how the section 1332 waiver, as amended, will meet the section 1332 statutory guardrails;

(5) An explanation of the estimated impact, if any, of the section 1332 waiver amendment on pass-through funding; and

(6) Any further requested information and/or analysis that is determined necessary by the Departments to evaluate the section 1332 waiver amendment.

²⁰⁸ See 31 CFR 33.108 and 45 CFR 155.1308.

For the required updated actuarial and/or economic analysis, the Departments proposed that such analysis must identify the “with waiver” impact of the requested amendment on the statutory guardrails. Such analysis would also be required to include a “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using data from recent experience, as well as a summary of and detailed projections of the change in the “with waiver” scenario. In addition, as described earlier, the Departments proposed that the analysis submitted by the state with its section 1332 waiver amendment request must demonstrate how the state’s approved section 1332 waiver plan, combined with any proposed amendments, impacts the guardrails.

The Departments solicited comments on the proposals, including whether the proposed framework for section 1332 waiver amendment requests should be codified in regulation.

The following is a summary of the comments received and the Departments’ responses to the waiver amendment request proposals and the proposed adoption of 31 CFR 33.130 and 45 CFR 155.1330.

Comment: The Departments received some comments on the proposals regarding waiver amendments. Commenters were supportive of the proposals overall and appreciated the clarification on what is required for a state with an approved waiver to request to make changes to the approved waiver. Several commenters sought further clarification on the definition of a waiver amendment under various scenarios. One commenter requested clarification regarding whether a state may have two separate section 1332 waivers or if any additional waiver request, while a state has an approved waiver, would be considered a waiver amendment. Another commenter relatedly asked if, for example, a state with an approved waiver plan were to seek both an extension and an amendment to its waiver plan, whether the state would be able to accomplish the two requests through one submission, rather than by making separate requests under 31 CFR 33.130 and 45 CFR 155.1330 for the amendment request and 31 CFR 33.132 and 45 CFR 155.1332 for the extension request. As another example, the commenter questioned

whether a second waiver request submitted by a state with an approved waiver plan would automatically be considered an amendment request; or alternatively, whether the second waiver request would only be considered an amendment request if it was closely enough related to the state's approved waiver plan. Two commenters requested that the Departments minimize the burden on states seeking a section 1332 waiver amendment and only request from states the minimum documentation necessary to review the state's proposal. One commenter did not support the amendment provision because the commenter did not support the requirement for states to submit an amendment proposal at least 15 months prior to the waiver's implementation date, which in the commenter's view is too long and inflexible.

Response: The Departments appreciate these comments and look forward to working with states on potential amendments to approved waivers, extensions of approved waivers, and new waiver application requests. The Departments note that state waiver proposals may present novel approaches for providing coverage to a state's residents, such that by nature, the outcomes may be difficult to predict and must be analyzed based on a state's specific proposal and circumstances. For example, as seen in each state's section 1332 waiver application, the required actuarial and economic analyses take into account various state-specific characteristics and data, such as historical and current information on premiums, target enrollee populations, market conditions, and other economic factors, in order to project the potential outcomes of implementing a section 1332 waiver under different scenarios. It would be difficult to ascertain whether a proposal is a waiver amendment, technical change to the existing waiver, or a new waiver application request without sufficient information and analysis. Accordingly, the Departments encourage states seeking to amend or otherwise modify a section 1332 waiver to contact the Departments early in their processes to discuss their plans and receive guidance on whether the request would be considered an amendment, a technical change, or a new waiver, taking into account their approved waiver plans and their proposals. This rulemaking provides a general framework for amendment requests, including the establishment of a definition for this

key term, to provide states and other stakeholders with sufficient information to reasonably evaluate whether the state's proposal is an amendment. More specifically, as finalized, the term 'section 1332 waiver amendment' is defined as a change to a section 1332 waiver plan that is not otherwise allowable under the STCs of an approved waiver, a change that could impact any of the section 1332 statutory guardrails, or a change to the program design for an approved waiver. Regarding the specific questions related to whether a state could seek an amendment and an extension (defined later in this preamble) through a single submission, the Departments encourage states with approved waiver plans to discuss specific waiver proposals with the Departments, as that determination will depend on the details of the waiver proposal(s) and the state's approved waiver plan.

As discussed earlier in this preamble and in the proposed rule, the Departments will respond to the state and confirm whether the change requested is a section 1332 waiver amendment, as well as identify the information the state needs to submit in its waiver amendment request if the state's proposal is determined to be a waiver amendment. Depending on the complexity of the proposed waiver amendment request, the scope of changes from the approved waiver plan, operational/technical changes, and implementation considerations, the Departments may impose requirements similar to those specified in 31 CFR 33.108(f) and 45 CFR 155.1308(f) for initial section 1332 waiver applications. In general, a waiver amendment request must include a detailed description of the requested amendment, including the impact on the guardrails; an explanation and evidence of the process used by the state to ensure meaningful public input; evidence of sufficient authority under state law to pursue the section 1332 waiver amendment; an updated actuarial and/or economic analysis; and an explanation of the estimated impact of the amendment on pass-through funding. This information is necessary to permit the Departments to evaluate the waiver amendment request. However, the Departments agree with certain commenters' concerns about minimizing the burden on states and will aim to request the minimum documentation and analysis necessary from states to review waiver amendment

requests. For example, the Departments intend to use available data and resources, including the data and analysis in the periodic reports submitted by states with approved waivers under 31 CFR 33.124 and 45 CFR 155.1324, if appropriate, to minimize the burden on states. The Departments also clarify that the Departments are not requiring that states submit the letter of intent at least 15 months prior to the section 1332 waiver amendment's proposed implementation date, but that the Departments are encouraging states to follow that timeline and submit the letter of intent at least 15 months prior to the section 1332 waiver amendment's proposed implementation date to allow enough time for submission and review of the amendment request and to allow for an appropriate timeline for implementation of the already approved waiver and amendment, if approved.

After consideration of these comments, the Departments are finalizing the adoption of the waiver amendment framework along with clarifications outlined in this section of this preamble and the addition of 31 CFR 33.130 and 45 CFR 155.1330.

11. Waiver Extension (31 CFR 33.132 and 45 CFR 155.1332)

Section 1332(e) of the ACA provides that no section 1332 waiver may extend over a period of longer than 5 years unless the state requests continuation of its waiver, and such request shall be deemed granted unless the Departments, within 90 days after the date of its submission, either deny such request in writing or inform the state in writing with respect to any additional information which is needed in order to make a final determination with respect to the request. Recognizing that several of the existing section 1332 waivers were approved in 2016 and 2017 to begin in plan years 2017 and 2018, respectively, the Departments proposed new regulations at 31 CFR 33.132 and 45 CFR 155.1332 to codify section 1332(e) of the ACA and also proposed, in preamble, the proposed framework for section 1332 waiver extensions. In response to previously received comments, the Departments acknowledged that information regarding section 1332 waiver amendments and renewals would be needed in the future²⁰⁹ and

²⁰⁹ See 77 FR 11700.

noted they received several inquiries from states on these topics. As such, the Departments proposed new regulations at 31 CFR 33.132 and 45 CFR 155.1332 to permit, but not require, states to submit a section 1332 waiver extension request to continue an approved waiver plan. The proposed new regulations also provide that an extension request shall be deemed granted unless the Secretaries, within 90 days after the date of the state's submission of a complete section 1332 waiver extension request, either deny such request in writing or inform the state in writing with respect to any additional information needed to make a final determination with respect to the request. The proposed rule also set forth, in preamble, a proposed procedural framework for submission and review of extension requests for approved section 1332 waiver plans. The Departments explained they are of the view that this additional information would help states with approved section 1332 waiver plans better plan for and prepare for potential extensions to their waiver plans. The Departments also noted they intend to provide information and details regarding the section 1332 waiver extension process in the STCs for an approved waiver plan. The proposals were intended to align with the extension request process outlined in recent STCs for states with approved section 1332 waivers.²¹⁰

The Departments proposed to define a section 1332 waiver extension as an extension of an approved waiver under the existing waiver terms. As detailed further later in this section of this preamble, if a state wants to make changes to the existing terms of an approved section 1332 waiver, the proposed waiver amendment request framework would apply. The Departments proposed that states with approved section 1332 waivers that want to pursue a waiver extension would be required to inform the Departments if the state will apply for extension of its waiver at least one year prior to the waiver's end date. To request a section 1332 waiver extension, the Departments proposed that the state must submit a letter of intent in an electronic format to the Departments to notify them in writing of its intent to request a waiver extension of its approved

²¹⁰ For example, see STC 10 in New Hampshire's Approval Letter and STCs: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-NH-Approval-STCs.pdf>.

waiver plan(s). The Departments would then review the state's letter of intent request. The Departments proposed that, within approximately 30 days of the Departments' receipt of the letter of intent, the Departments would respond to the state and confirm whether the extension request would be considered as an extension request or whether any changes requested result in the need for a waiver amendment request instead. The Departments would also identify the information the state needs to submit in its section 1332 waiver extension request. The Departments also proposed that section 1332 waiver extension requests must also be submitted in electronic format to the Departments, consistent with the format and manner requirements applicable to initial waiver applications under 31 CFR 33.108(a) and 45 CFR 155.1308(a).

The Departments also proposed that they may request an updated economic or actuarial analysis for the requested extension period in a section 1332 waiver extension request. Given that the Departments receive periodic reports from states with approved section 1332 waivers under 31 CFR 33.124 and 45 CFR 155.1324, in some circumstances the Departments may not need, and therefore, would not require full new analysis (as required under 31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4) for initial section 1332 waiver applications) and instead may rely on the updated analyses provided as part of these periodic reports. In other instances, depending on the complexity of the section 1332 waiver and the extension request, the Departments may require additional data and information to be submitted to review the extension request.

The Departments proposed to evaluate the state's section 1332 waiver extension request and may approve the request if it meets the statutory guardrails as defined in section 1332 (b)(1)(A)-(D) and meets other applicable requirements. The Departments proposed that a state waiver extension request may be required to include the following information:

(1) Updated economic or actuarial analyses for the requested extension period in a format and manner specified by the Departments;

(2) Preliminary evaluation data and analysis from the existing section 1332 waiver program;

- (3) Evidence of sufficient authority under state law(s) to meet the ACA section 1332(b)(2)(A) requirement for purposes of pursuing the requested extension;
- (4) An explanation of the process followed by the state to ensure meaningful public input on the extension request at the state level; and
- (5) Other information as requested by the Departments that is necessary to reach a decision on the requested extension.

As noted earlier in this preamble, the Departments would identify the specific information a state needs to include as part of its section 1332 waiver extension request in the response to the state's letter of intent. Further, the Departments proposed that the updated economic or actuarial analyses for the requested extension period would be in a format and manner specified by the Departments. The Departments would also rely on available data, such as the analyses provided as part of the periodic reports required under 31 CFR 33.124 and 45 CFR 155.1324, when evaluating a state's waiver extension request if appropriate.

The Departments also proposed that it would be permissible for a state to use its annual public forum required under 31 CFR 33.120(c) and 45 CFR 155.1320(c) for the dual purpose of soliciting public input on a proposed section 1332 waiver extension request and on the progress of its approved waiver plan. This policy proposal is in line with the flexibility the Departments permitted in the 2012 Final Rule²¹¹ to allow states to use Medicaid tribal consultation to also satisfy the requirements as set forth in 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2), that require a state with one or more federally-recognized tribes within its borders to conduct a separate process for meaningful consultation with such tribes as part of the state section 1332 waiver public notice and comment process. The Departments explained they are of the view that allowing states to use the annual public forum for the dual purpose of soliciting public input on an extension request and on the progress of its approved section 1332 waiver would create a more efficient process for both the state and for the public to provide a meaningful level of input.

²¹¹ See 77 FR at 11706.

The Departments proposed a similar Federal public notice and review process for a section 1332 waiver extension request as is outlined for new section 1332 waiver applications in 31 CFR 33.116 and 45 CFR 155.1316. The Departments proposed that the Departments would review a state's section 1332 waiver extension request and make a preliminary determination as to whether it is complete within approximately 30 days after it is submitted. In line with these requirements, the Departments proposed that after determining that the section 1332 waiver extension request is complete, the waiver extension request would be made public through the CMS website, and a 30-day Federal public comment period would commence while the extension request is under review. The Departments would make available through the CMS website the information relating to how and where written comments may be submitted and the timeframe during which comments will be accepted. Additionally, the Departments would make available public comments received on the section 1332 waiver amendment request during the Federal public notice and comment period. The determination that the section 1332 waiver extension request is complete would also mark the beginning of the 90-day clock outlined in section 1332(e) of the ACA for the Secretaries to deny or request more information regarding the continuation, or extension, of the state's approved waiver plan. If, after the extension request has been determined complete, the Departments find that content is missing, additional information is required, or the state needs to respond to public comments received during the Federal comment period, the Departments would notify the state and an additional review period would begin once the Departments received the requested information or responses from the state. The Departments proposed that this additional review period would be no longer than 90 days. The Departments explained they are of the view that these proposals increase transparency of the Federal review process and create a clear path for states and the Departments to determine if the information submitted is sufficient to continue review and when to start a Federal public comment period. In addition, the Departments noted they are of the view that this proposal

provides the public with a meaningful opportunity to provide input on a section 1332 waiver extension request in line with the intent of the statute.

The proposed section 1332 waiver extension request process would be separate from the waiver amendment framework described earlier in this rulemaking. A section 1332 waiver extension request under proposed 31 CFR 33.132 and 45 CFR 155.1332 would only be available for an extension of the existing terms of an approved waiver plans and would not be applicable if the state was seeking to make substantive changes to its approved waiver plan beyond a continuation of the term of the waiver. If a state also seeks to make substantive changes to its approved section 1332 waiver plan along with seeking an extension, the Departments would treat those changes as amendments and the framework outlined in this preamble for waiver amendment requests would apply.

The Departments solicited comments on these proposals, including whether the proposed framework for section 1332 waiver extension requests should be codified in regulation.

The following is a summary of the comments received and the Departments' responses to the waiver extension request proposals and the proposed adoption of 31 CFR 33.132 and 45 CFR 155.1332.

Comment: The Departments received some comments on the proposals regarding waiver extensions. Commenters were supportive of the proposals overall and appreciated the clarification on what is required for a state with an approved waiver to request an extension of the approved waiver. Several commenters requested clarification regarding whether a waiver could be extended with one or more amendments through one submission, rather than by making separate waiver extension and amendment requests.

Response: The Departments appreciate commenters' support. As finalized, a section 1332 waiver extension is defined as an extension of an approved waiver under the existing waiver terms. For example, if a state with an approved section 1332 reinsurance waiver wanted to extend a reinsurance program for an additional three years, but was not seeking to make any

other changes beyond a technical change as allowable under the STCs, the request would be treated as a waiver extension request. Examples of allowable technical changes are revisions to a state's reinsurance program parameters or a state's authorized funding source.²¹² Any changes to an approved waiver not otherwise allowable under the STCs would be considered an amendment. As explained earlier in this preamble regarding waiver amendments (31 CFR 33.130 and 45 CFR 155.1330), the Departments will analyze state waiver proposals, including amendment and extension requests, based on a state's specific proposals and circumstances. Accordingly, the Departments encourage states seeking to amend or extend a section 1332 waiver to contact the Departments early in their processes to discuss their plans and receive guidance on whether the request would be considered an amendment or an extension, as well as confirm the applicable requirements. In general, the Departments aim to work with states in a manner that provides clarity and transparency on the waiver extension and amendment process.

After consideration of these comments, the Departments are finalizing the adoption of the waiver extension framework along with clarifications outlined in this section of this preamble and the addition of 31 CFR 33.132 and 45 CFR 155.1332.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, the Departments are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. In order 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 the Departments solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

²¹² Technical changes are changes that do not impact the guardrails or any obligations of the state or the Departments, such as changes to the state-approved program funding level or program parameters like altering the attachment point, cap, coinsurance rate, or eligible conditions.

- 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.

HHS solicited public comment on each of these issues for the following sections of this preamble that contain ICRs.

A. ICRs Regarding Navigator Program Standards (§ 155.210)

The data collection requirements for FFE Navigator grantees are currently approved under OMB control 0938-1215/Expiration date: October 31, 2023 (Cooperative Agreement to Support Navigators in federally-facilitated Exchanges). The proposal to once again require FFE Navigators to provide consumers with information and assistance with regard to certain post-enrollment topics does not increase the number of reports that Navigator grantees are required to submit. Additionally, HHS does not anticipate changes to the data elements related to the expansion of required Navigator duties to be significant. HHS notes that since the 2020 Payment Notice made assistance with the topics at § 155.210(e)(9) permissible, but no longer required, many Navigator grantees have continued to report on these activities as part of their weekly, monthly, and quarterly metric reports to HHS. Therefore, HHS does not project the information collection burden to increase.

B. ICRs Regarding Segregation of Funds for Abortion Services (§ 156.280)

HHS is finalizing amendments to § 156.280(e)(2)(ii) to repeal the separate billing regulation governing payments for QHPs that offer coverage of abortion services for which Federal funds are prohibited. As finalized, HHS is reverting to and codifying in amended regulatory text at § 156.280(e)(2)(ii) the prior policy in the 2016 Payment Notice such that QHP issuers offering coverage of abortion services for which Federal funds are prohibited again have flexibility in selecting a method to comply with the separate payment requirement in section 1303 of the ACA. Acceptable methods for satisfying the separate payment requirement include sending the policy holder a single monthly invoice or bill that separately itemizes the premium

amount for coverage of abortion services for which Federal funds are prohibited; sending the policy holder a separate monthly bill for these services; or sending the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. Repealing the separate billing regulation will remove the burden associated with the policy, as detailed below.

The 2019 Program Integrity Rule²¹³ estimated that the total one-time burden to implement the separate billing regulation for the 94 issuers that were offering coverage for abortion services for which Federal funds are prohibited at the time of finalization would be 2,961,000 hours for a total cost of approximately \$385 million. HHS anticipated the one-time burden for the 3 State Exchanges that performed premium billing and payment processing and had QHP issuers that offered coverage for abortion services for which Federal funds are prohibited to be 94,500 hours for a total cost of approximately \$12.3 million. In the May 2020 IFC,²¹⁴ HHS reaffirmed these one-time estimates and anticipated that this one-time burden would still be incurred primarily in 2020, despite the 60-day delay to the implementation deadline.

The 2019 Program Integrity Rule also estimated ongoing annual costs for implementing the separate billing regulation. HHS estimated the total annual burden in 2020 for all 94 issuers would be 1,133,640 hours with an equivalent cost of approximately \$50.1 million. From 2021 onwards, HHS estimated the total annual burden for all 94 issuers to be approximately 2,267,280 hours with an associated cost of approximately \$100.2 million. HHS estimated that for the 3 State Exchanges performing premium billing and payment processing, the total annual burden would be approximately 36,180 hours with an equivalent cost of approximately \$1.6 million in 2020 and 72,360 hours with an associated cost of approximately \$3.2 million starting in 2021. HHS predicted in the May 2020 IFC that delaying the implementation of the deadline for the separate billing regulation by 60 days would result in a reduction to this annual burden in 2020

²¹³ 84 FR 71674 (December 27, 2019).

²¹⁴ 85 FR 27550 (May 8, 2020).

of 389,940 hours with an equivalent cost reduction of approximately \$17.4 million for all 97 issuers and State Exchanges performing premium billing and payment processing.

In addition, the Program Integrity Rule estimated that issuers and State Exchanges performing premium billing and payment processing would need to print and send approximately 1.82 million separate paper bills per month in 2020, incurring monthly costs of approximately \$91,200. The Program Integrity Rule estimated the total cost for all issuers and State Exchanges to be approximately \$547,225 in 2020. In 2021, HHS estimated that the annual cost for all issuers and State Exchanges to send separate paper bills would be approximately \$1,070,129 and that, in 2022, the annual cost would be approximately \$1,045,808. In the May 2020 IFC, HHS anticipated that delaying the implementation of the deadline for the separate billing regulation by 60 days would reduce the cost of printing separate bills in 2020 by approximately \$182,400.

As described in further detail in the preamble to § 156.280, the majority of commenters agreed with these burden estimates, citing significant concerns that the separate billing regulation was unduly burdensome to issuers, states, Exchanges, and consumers and could create consumer confusion, resulting in significant harm to consumers who inadvertently lose their coverage.

HHS disagrees with comments contesting the validity of its burden estimates and suggesting that they are inflated. HHS again emphasizes that the 2019 Program Integrity Rule included a detailed account of the anticipated financial and operational burdens from the separate billing regulation, estimates which were based upon plan and premium data, actuarial estimates, public comments from issuers and states directly regulated by the separate billing policy, and consumer enrollment figures. Those burdens are discussed in further detail in sections III., “Collection of Information Requirements,” and IV., “Regulatory Impact Analysis,” of that rule, which explain from where such estimates are derived.

Some commenters noted that issuers have already incurred ongoing costs for printing and mailing, additional staffing, and reprogramming billing systems and that the separate billing regulation already resulted in increased burden for issuers and consumers, widespread confusion

by consumers and other stakeholders, and an increase in frustration and confusion around grace periods and terminations. HHS acknowledges that some costs may have already been incurred by issuers and that the actual cost savings, especially for one-time IT related costs, may be lower than HHS estimates. Unfortunately, HHS does not have an estimate of costs already incurred by issuers and can only estimate savings going forward. HHS continues to believe the timing of the courts' actions likely dissuaded most issuers from assuming further costly administrative and operational burdens required to build the separate billing policy into their billing and IT systems. Further, as the courts' nationwide invalidation of the policy prevented HHS from requiring initial implementation of the separate billing regulation, the potential consumer confusion over payment obligations, which could have inadvertently led to non-payment of enrollee premium and subsequent termination of consumer coverage, was also avoided.

Therefore, HHS believes repeal of the separate billing regulation removes the associated ICRs and the anticipated burden on QHP issuers and State Exchanges that perform premium billing and payment processing, which have not been approved by OMB. HHS will not pursue OMB approval of the ICRs associated with the repealed separate billing regulation (OMB control number: 0938–1358, Billing and Collection of the Separate Payment for Certain Abortion Services (CMS–10681)). As repeal of the separate billing regulation removes the associated ICRs with that regulation, the currently approved ICRs associated with issuer compliance with other longstanding requirements of § 156.280 in existence prior to finalization of the separate billing regulation apply and capture the associated burden with issuer compliance of § 156.280 (OMB control number: 0938-1156, Establishment of Exchanges and Qualified Health Plans (CMS-10400)). Those ICRs capture the estimated associated burden with issuer compliance under § 156.280(e)(5)(ii), which requires each QHP issuer offering coverage of abortion services for which Federal funding is prohibited to submit to the relevant state insurance commissioner a plan describing how the issuer will establish and maintain a separate payment account for any QHP that covers abortion services for which Federal funding is prohibited, and §

156.280(e)(5)(iii) which requires each QHP issuer to annually attest to compliance with section 1303 of the ACA and applicable regulations.

C. ICRs Regarding Section 1332 Waivers (31 CFR Part 33 and 45 CFR Part 155)

The Departments are finalizing modifications to the section 1332 waiver implementing regulations, including changes related to the interpretation of the statutory guardrails, the establishment of processes for section 1332 waiver amendment and extension requests, and the codification of new regulatory text related to pass-through funding for approved section 1332 waiver plans. In the proposed rule, the Departments discussed that the proposed policies and interpretations, if finalized, would supersede and replace prior finalized policies and interpretations. The Departments are also finalizing modifications to the regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers during emergent situations, building off of the flexibilities provided during the COVID-19 PHE. These altered requirements related to section 1332 waiver applications, compliance and monitoring, or evaluation do not 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. Therefore, the Departments do not expect that implementing these provisions will significantly change the associated burden currently approved under OMB control number: 0938-1389/Expiration date: February 29, 2024.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule implements revised FFE and SBE-FP user fees for the 2022 benefit year. It also repeals the Exchange DE option. The rule also includes changes related to the annual open enrollment period; Navigator program standards; and separate billing and segregation of funds for abortion services. In addition, it clarifies a provision related to special enrollment periods for enrollees that are newly eligible or ineligible for APTC , and establishes a monthly special enrollment period for qualified individuals who are eligible for APTC, and whose household

income is expected to be no greater than 150 percent of the FPL during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP. Finally, relating to section 1332 waivers, it implements several changes, including the repeal of the incorporation of many policies and interpretations from the 2018 Guidance into the section 1332 waiver implementing regulations. This rule also finalizes proposed policies and interpretations governing section 1332 waivers that are consistent with providing more accessible and affordable health care through the individual and small group markets.

HHS is extending the annual open enrollment period to provide individuals with a longer opportunity to enroll in coverage, which will expand access to health insurance coverage, and HHS is codifying flexibility for State Exchanges that operate their own eligibility and enrollment platform to set annual open enrollment period end dates no earlier than December 15. Similarly, HHS is reinstituting prior requirements that FFE Navigators provide information and assistance with regard to certain post-enrollment topics, including helping consumers understand basic concepts and rights related to health coverage and how to use it. In addition, HHS repeals the separate billing regulation at § 156.280(e)(2)(ii) that required individual market QHP issuers to send a separate bill for that portion of a policy holder's premium that is attributable to coverage for abortion services for which Federal funds are prohibited and to instruct such policy holders to pay for the separate bill in a separate transaction. This rule also reduces administrative burden on issuers, states, Exchanges, and consumers, as well as consumer confusion and unintended losses of coverage.

B. Overall Impact

HHS has examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980; Pub. L. 96354), section 1102(b) of the Act, section 202 of the Unfunded

Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), 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). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Based on HHS’s estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, HHS has prepared a Regulatory Impact Analysis that to the best of its ability presents the costs and benefits of the rulemaking.

The provisions in this final rule will expand consumer access to affordable health care. The provisions in this final rule will extend the annual open enrollment period and codify flexibility for State Exchanges that operate their own eligibility and enrollment platform to set annual open enrollment period end dates no earlier than December 15, expand Navigator duties,

repeal the Exchange DE option, provide more funding for FFE Navigators and consumer outreach and education, and reduce administrative burden and confusion for consumers. These provisions will also reduce regulatory burden for states and administrative costs for Exchanges and issuers. Through the improvements in enrollment accessibility and increased affordability for consumers, these provisions will increase access to affordable health coverage.

The user fee rates in this final rule are higher than those previously finalized for 2022 in part 1 of the 2022 Payment Notice final rule,²¹⁵ which could increase premiums for consumers. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Proposed Rule Provisions and Accounting Table

In accordance with OMB Circular A-4, Table 1 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including allowing consumers to have continued access to coverage and health care and stabilizing premiums in the individual and small group health insurance markets, including in the Exchanges. HHS is unable to quantify all benefits and costs of this final rule. The effects in Table 1 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers.

²¹⁵ 86 FR 6138.

TABLE 1: Accounting Statement

Benefits:				
Qualitative:				
<ul style="list-style-type: none"> Consumers will benefit from a longer annual open enrollment period, as they will have a greater opportunity to enroll in coverage. State Exchanges that operate their own eligibility and enrollment platform will benefit from flexibility to set annual open enrollment period end dates no earlier than December 15, as they will retain flexibility to determine the optimal annual open enrollment period length for their state. The special enrollment period clarification will benefit individuals who experience a decrease in household income that makes them newly eligible for an APTC amount of greater than zero dollars. Consumers will benefit from repeal of the separate billing regulation, as they will no longer be subject to the risk of confusing billing processes. APTC-eligible qualified individuals whose household income does not exceed 150 percent of the FPL will benefit from the new special enrollment period during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP, as they will have more opportunities to enroll in coverage throughout the year. 				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	-\$261.8 million	2020	7 percent	2021-2025
	-\$259.0 million	2020	3 percent	2021-2025
Quantitative:				
<ul style="list-style-type: none"> Reduction in costs to all issuers, states, State Exchanges performing premium billing and payment processing, Exchanges on the Federal platform, and consumers due to the separate billing regulation of approximately \$407.05 million in 2021, \$230.7 million in 2022, and \$229.3 million annually in 2023 and onwards. In addition to annual costs, the reduction in costs in 2021 includes the one-time implementation changes that issuers, states, States Exchanges performing premium billing and payment processing, and the Exchanges on the Federal platform would have incurred if the separate billing policy had been implemented in 2020. Because the separate billing policy was not implemented in 2020 due to courts invalidating the policy, these one-time costs could have been incurred in 2021, had the separate billing policy remained applicable. Increase in costs to Exchanges on the Federal platform of \$8.3 million annually to extend the annual open enrollment period to January 15. 				
Qualitative:				
<ul style="list-style-type: none"> Increased costs due to increases in provision of medical services (if health insurance enrollment increases). 				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$480.9 million to \$1.2309 billion	2021	7 percent	2022-2026
	\$481.5 million to \$1.2315 billion	2021	3 percent	2022-2026
Quantitative:				
<ul style="list-style-type: none"> Increase in transfers from issuers to Federal Government by approximately \$200 million in 2022 and approximately \$240 million in 2023 onwards due to changes in user fee rates and state transitions from FFEs to SBE-FPs or from SBE-FPs to State Exchanges. A potential 0.5 to 2 percent increase in premiums in 2022 and onwards as a result of the monthly special enrollment period for APTC-eligible qualified individuals whose household income does not exceed 150 percent of the FPL, during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP, with a corresponding potential increase in APTC/PTC annual outlays and decrease in income tax revenues of approximately \$250 million to \$1 billion. 				

This RIA expands upon the impact analyses of previous rules and utilizes the CBO analysis of the ACA's impact on Federal spending, revenue collection, and insurance enrollment. In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, HHS anticipates that

the quantitative effects of the provisions in this rule are consistent with its previous estimates in the 2021 Payment Notice for the impacts associated with APTC, expanded consumer outreach and education and Navigators, and FFE user fee requirements.

1. Navigator Program Standards (§ 155.210)

HHS is amending § 155.210(e)(9) to reinstitute the requirement that FFE Navigators provide consumers with information and assistance with regard to certain post-enrollment topics. In FFEs, Navigators will continue to be permitted to undertake the Navigator duties specified in § 155.210(e)(9) until this provision becomes effective. FFE Navigators will be required to perform the Navigator duties specified in § 155.210(e)(9) beginning with Navigator grants awarded in 2022, including non-competing continuation awards. As finalized in this rule, prior to Navigator grant funding being awarded in FY 2022, FY 2021 Navigator grantees will be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance. To the extent Navigators awarded grant funding in FY 2021 are not already performing these duties under their year one project plans when this provision becomes effective, they can revise their project plans to incorporate performance of the duties specified in § 155.210(e)(9) as part of their non-competing continuation application for their FY 2022 funding.

These duties were previously required of Navigators in all Exchanges before the 2020 Payment Notice amended § 155.210(e)(9) and made assistance with these post-enrollment topics permissible for FFE Navigators, but not required, beginning with FFE Navigator grants awarded in 2019. Despite no longer being required, the majority of FFE Navigators continue to provide information and assistance to consumers and report metrics on the post-enrollment topics outlined in § 155.210(e)(9). Additionally, by reinstituting the requirements at § 155.210(e)(9), HHS will be able to both require applicants to include plans for performing these post-enrollment activities as part of their annual applications for new or continued Navigator grant funding, as well as include Navigator assistance with these post-enrollment activities as part of their

performance evaluations. All costs associated with reaching these consumers in FFEs would be considered allowable costs that would be covered by the Navigator grants for the FFEs and that may be drawn down as the grantee incurs such costs.

2. Exchange Direct Enrollment Option (§ 155.221(j))

HHS is removing § 155.221(j) and repealing the Exchange DE option, which established a process for states to use direct enrollment technology to transition to private-sector-focused enrollment pathways operated by QHP issuers, web-brokers, and agents and brokers, instead of or in addition to a centralized eligibility and enrollment website operated by an Exchange. HHS believes that repealing the Exchange DE option will have minimal impact on stakeholders at this time since no resources have been expended by states or HHS on implementing it. Any potential costs and burdens associated with the Exchange DE option would be eliminated. These include costs to develop consumer-facing enrollment functionality and meet eligibility application technical requirements, as well as to maintain back-end eligibility determination functionality and other back-end eligibility services; start-up and implementation costs to develop the appropriate privacy and security infrastructure and business controls; as well as costs related to ongoing oversight and monitoring of DE entities and maintaining the individual interfaces and transactions with each DE entity. HHS also believes that repealing the Exchange DE option would mitigate potential negative downstream impacts, including consumer confusion and an increased uninsured and underinsured population. A more detailed discussion of potential impacts appears earlier in this preamble in the discussion of public comments on this provision.

3. Annual Open Enrollment Period Extension (§ 155.410(e))

HHS is extending the individual market annual open enrollment period from November 1 through January 15 for the 2022 coverage year and beyond, with a modification to codify flexibilities for State Exchanges not utilizing the Federal platform to choose an annual open enrollment period end date no earlier than December 15 and to adopt accelerated effective dates. HHS does not believe a significant impact on the Exchange risk pool will result from this

change. Consumers will benefit from a longer annual open enrollment period without additional demand placed on them. A lengthened annual open enrollment period may result in an increase of \$8.3 million in technical infrastructure costs to the FFEs annually to support extended Cloud and application services associated with the extension. A lengthened annual open enrollment period may also lead to increased enrollments which could impose additional costs on Exchanges and enrollment assisters to conduct outreach and assist new consumers. However, this change could also reduce outreach costs on Exchanges and enrollment assisters by spreading out enrollments over a greater length of time, resulting in opportunities for efficiency and increased health coverage.

4. Monthly Special Enrollment Period for APTC-Eligible Qualified Individuals with a Household Income No Greater than 150 Percent of the Federal Poverty Level whose Applicable Taxpayer has an Applicable Percentage of Zero (§ 155.420(d)(16))

HHS is finalizing the monthly special enrollment period for APTC eligible consumers with a projected annual household income no greater than 150 percent of the FPL with coverage effective dates and other eligibility parameters as proposed, but is finalizing it so that the special enrollment period is only available during periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP. HHS is also finalizing that plan category limitations apply to this special enrollment period, and in consideration of concerns from certain commenters as further discussed in preamble, HHS is also finalizing § 155.420(a)(4)(ii)(D) with revisions to reflect that an enrollee who is adding a qualified individual or dependent through this special enrollment period may add the newly enrolling household member to their current QHP; or, change to a silver-level QHP and add their newly enrolling household member to this silver-level QHP; or, change to a silver-level QHP and enroll the newly enrolling qualified individual or dependent in a separate QHP. HHS believes that this modification is appropriate to provide clarity on options and limitations for enrollees whose

household members newly enroll through this special enrollment period. In particular, HHS is finalizing that, while newly enrolling qualified individuals and dependents are not subject to plan category limitations, enrollees with a newly-enrolling dependent or other household member may not use the new monthly special enrollment period to change to a plan of any metal level to enroll together with their newly-enrolling household member, but can stay in the same plan or change to a silver plan to enroll together with the newly-enrolling household member.²¹⁶ Additionally, this special enrollment period will be available at the option of the Exchange, as proposed, in order to allow State Exchanges to decide whether to implement it based on their specific market dynamics, needs, and priorities. HHS is also finalizing that Exchanges on the Federal platform will implement this special enrollment period by providing qualified individuals who are eligible with a pathway to access it through the HealthCare.gov application.

To provide Exchanges with flexibility to prioritize ensuring that qualifying individuals are able to obtain coverage through this special enrollment period quickly following plan selection, or to implement this special enrollment period in keeping with their current operations, HHS is adding a new paragraph at § 155.420(b)(2)(vii) to provide that the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the month following plan selection, at the option of the Exchange. Finally, HHS is adding a new paragraph at § 147.104(b)(2)(i)(G) to specify that issuers are not required to provide this special enrollment period in the individual market with respect to coverage offered outside of an Exchange, because eligibility for the special enrollment period is based on eligibility for APTC, and APTC cannot be applied to coverage that is not a QHP offered through an Exchange.²¹⁷

This special enrollment period availability will provide more opportunities for certain low-income APTC- and CSR-eligible consumers to take advantage of the financial assistance available to them. As discussed in the preamble for this rulemaking, HHS believes that the

²¹⁶ As noted in the proposed rule, this provision does not prevent enrollees who qualify for the new special enrollment period from changing to a plan of any category through a special enrollment period that provides this flexibility, including the special enrollment periods at § 155.420(d)(4), (8), (9), (10), (12), and (14).

²¹⁷ See IRC 36B(b)(2)(A), (c)(2)(A)(i).

benefit to providing these opportunities outweighs adverse selection concerns. Further, HHS believes the risk of adverse selection is mitigated to some degree by most qualifying individuals having access to a premium-free silver plan with a 94 percent AV after application of APTC, because consumers eligible for a premium-free plan after application of APTC which, due to its 94 percent AV, covers such a significant portion of health care services, would likely already be enrolled if they were aware of their eligibility for such coverage. Additionally, HHS believes that those for whom this is the case are not likely to move in and out of coverage once they have enrolled, for example to end coverage once an immediate health care need is met, which may also limit some adverse selection risk. HHS also believes that applying plan category limitations to this special enrollment period will help to mitigate adverse selection because it will limit the ability of enrollees to change to a higher metal level plan based on a new health care need and then change back to a silver or bronze plan once the health issue is resolved. HHS also believes that enrollees who are interested in changing plans during the year through this special enrollment period will likely be deterred because such a change would generally mean they lose progress they have made toward meeting their deductibles and other accumulators. However, HHS acknowledges that enrollees may still choose to enroll in a silver level plan that is more expensive than their zero-dollar option, and, with a monthly special enrollment period, could make this change during the plan year based on a difference in provider network or prescription drug formulary.

HHS requested comment on practices, including education and outreach, that could help ensure that consumers who are eligible for this special enrollment period enroll in the silver plan with a zero-dollar premium after application of APTC that is available to them. HHS also sought comment on the remaining risk for issuers; for example, on the extent to which there is risk related to consumers who become aware of the availability of the special enrollment period after they become sick and seek to enroll because they need medical care. Based on the possibility that consumers could enroll through the special enrollment period only after they need to use health

care services, HHS sought comment on whether issuers may account for this risk through premium increases. HHS estimated a 0.5 to 2 percent increase in premiums when the enhanced APTC provisions of the ARP are in effect in states where this special enrollment period is implemented, due to increased adverse selection risk, resulting in an estimated \$250 million to \$1 billion increase in APTC/PTC outlays and decrease in income tax revenues nationwide, and HHS sought comment on this estimate.

HHS also sought comment on potential risk that individuals, including those who enroll in coverage due to a health event, later experience a household income change or change their primary place of residence such that they are no longer eligible for a silver plan with a zero-dollar premium, and that these individuals will end coverage at that point. Because this special enrollment period has the potential to introduce new adverse selection risk into the individual market, HHS also sought comment generally on the impact on premiums of this policy in Exchanges where it is implemented, and potential regulatory tools that could mitigate these risks.

For example, Exchanges that implement this special enrollment period could try to mitigate some risks with a robust outreach and education campaign to promote awareness of the special enrollment period. However, because the special enrollment period will be based on projected annual household income level, and Exchanges rely on applicants to report their most up to date household income information, it may be difficult for Exchanges to assess which individuals might be eligible for outreach and education purposes and could make targeted marketing and outreach difficult. HHS also sought comment on practices that could help mitigate this challenge, and ways to improve outreach to low-income consumers more generally.

Relatedly, HHS sought comment on how Exchanges could help to mitigate potential confusion on the part of stakeholders that provide enrollment assistance, such as HHS Navigator grantees, and agents and brokers. HHS sought comment on how Exchanges and stakeholders that provide enrollment assistance could develop effective outreach and education campaigns to target this population.

Finally, HHS requested comment on level of effort for Exchanges to implement this special enrollment period, especially within the amount of time required to make it available to consumers during the 2022 plan year.

The following is a summary of the comments received and HHS's responses to the comment solicitations related to the estimated impact of the monthly special enrollment period for APTC-eligible qualified individuals with a household income no greater than 150 percent of the FPL (§ 155.420(d)(16)).

Comment: As further discussed in preamble, some commenters supported the monthly special enrollment period and stated that the risk of adverse selection as a result of the policy would be limited due to the enhanced subsidy provisions of the ARP. Some of these commenters also stated that risk would be limited because younger and healthier individuals would be more likely to enroll when given additional opportunities to do so. As further discussed in preamble, many commenters also cited comparable state experiences as evidence of the low likelihood of adverse selection, such as the Massachusetts State Exchange's enrollment opportunity for individuals with a household income no higher than 300 percent of the FPL, and the ability of consumers up to 200 percent of the FPL to enroll in the Basic Health Program year-round in Minnesota and New York.

Some commenters added that State Exchange data on risk factors associated with enrollees who accessed coverage through a special enrollment period, including the special enrollment period that State Exchanges provided during the 2020 or 2021 plan years due to the COVID-19 pandemic, indicated that these enrollees did not pose significant additional risk and in some cases were younger than the average age of enrollees who did not access coverage through the special enrollment period. One of these commenters asked that CMS analyze data on special enrollment period enrollees in states that use the HealthCare.gov platform, and suggested that such analysis would yield a similar result. Other commenters suggested that HHS could

extend the special enrollment period to APTC-eligible individuals with household incomes up to 200 or 250 percent of the FPL with only a relatively small increase in adverse selection.

Response: HHS appreciates commenters' support of the monthly special enrollment period and agree that adverse selection will be mitigated during the period of enhanced subsidies due to the ARP. The goal of this policy is to increase access to affordable health care, consistent with EO 14009, and HHS appreciates comments stating that the monthly special enrollment period would increase the number of subsidized enrollees in the individual market. As further discussed in preamble, HHS also agrees that, in many cases, special enrollment periods may encourage consumers who are younger and healthier than average to enroll. Additionally, HHS acknowledges that some Exchanges that have expanded enrollment opportunities for consumers with a projected annual household income below a certain threshold have not experienced significant negative impacts from adverse selection. However, because HHS appreciates concerns that the risk of adverse selection may vary significantly based on market conditions specific to different Exchanges, and HHS's goal is also to achieve a balanced approach that takes into account these varying conditions as much as possible, HHS is finalizing this special enrollment period to limit it to be available only during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax year 2022, as provided by section 9661 of the ARP.

Comment: As noted in preamble, some commenters were concerned that the monthly special enrollment period would result in increased premiums, narrowed networks, fewer plan choices, and market instability due to adverse selection created by newly enrolling consumers but also, perhaps more significantly, by current enrollees using the special enrollment period to change plans mid-year based on provider network or other plan characteristics. Several of these commenters stated that HHS's estimated increase in premiums of 0.5 to 2 percent was an underestimate of the true impact of this policy and argued that adverse selection would increase if the special enrollment period extends beyond the current expiration date of the ARP.

Several commenters agreed that adverse selection and related increases in individual health insurance premiums would vary significantly by state based on specific market conditions such as Medicaid expansion status. A few commenters voiced concerns that the HHS-operated risk adjustment methodology does not adequately compensate for individuals with partial-year or short-term enrollment. Several commenters, including some that supported the proposal, asked that CMS monitor the individual market for impacts of adverse selection, and one commenter asked us to engage in additional rulemaking if evidence of significant adverse selection is found. One commenter stated that this special enrollment period would increase enrollment and the increased costs would be overwhelmingly borne by the Federal Government in the form of increased APTC, but that these costs would be an appropriate use of Federal resources. However, other commenters voiced the concern that adverse selection would drive up rates and that these increases would disproportionately impact unsubsidized consumers.

Response: As further discussed in preamble, HHS acknowledges the potential impacts to premiums and adverse selection as a result of this special enrollment period and appreciates comments on its estimates of potential premium increases related to adverse selection. HHS also clarifies that HHS calculated this estimate based on currently available data and internal analyses, and based on the assumption that the proposed special enrollment period would only be available for coverage for periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero; in particular, during tax year 2022, as provided by section 9661 of the ARP. Based on this internal analysis and the balance of public comments, including those that cite other Exchanges' experiences with open-ended special enrollment periods, HHS continues to believe the risk of adverse selection with respect to this new special enrollment period is limited and is outweighed by the gains in coverage that would result from this special enrollment period.

Further, as discussed in preamble and the proposed rule, HHS believes that applying plan category limitations to this special enrollment period will help to mitigate adverse selection, and

HHS has updated the proposed regulatory text at § 155.420(a)(4)(ii)(D) to clarify that an enrollee who is adding a qualified individual or dependent may add the newly enrolling household member to their current QHP; or, change to a silver-level QHP and add their newly enrolling household member to this silver-level QHP; or, change to a silver-level QHP and enroll the newly enrolling qualified individual or dependent in a separate QHP. HHS notes that per the time limitation HHS is finalizing, the special enrollment period will be available only for coverage for periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, which is currently limited to tax year 2022, as provided by section 9661 of the ARP. HHS believes that the time-limited nature of this special enrollment period and the applicable plan category limitations will help to mitigate concerns about adverse selection, especially when combined with robust outreach and education efforts to maximize the number of qualifying individuals who gain coverage through the special enrollment period based on an understanding of its availability as opposed to enrolling due to an emerging health care need.

However, as also noted in preamble, HHS appreciates that adverse selection will likely vary across different Exchanges based on a variety of factors, such as whether a state has expanded its Medicaid program, and HHS will work with stakeholders to monitor individual health insurance markets while the special enrollment period is in place to track potential adverse selection impacts of the special enrollment period, as well as access to coverage for higher-income individuals, in particular those who do not qualify for a monthly APTC payment of more than zero dollars, and to consider possible approaches to address any issues that arise.

Last, as discussed in this preamble, the HHS-operated risk adjustment methodology added enrollment duration factors to the adult risk adjustment models starting with the 2017 benefit year. These enrollment duration factors are used in the calculation of adult enrollee risk scores under the state payment transfer formula to account for additional risk associated with enrollees with partial-year enrollment. They do so through a set of 11 enrollment duration binary

indicatory variables that signify that an enrollee had exactly one to 11 months of enrollment in a given plan. The value of these indicators decreases monotonically from one to 11 months, reflecting the increased annualized costs associated with fewer months of enrollment. Adult enrollees who enrolled during this special enrollment period will receive the applicable enrollment duration factor in the risk score calculation. While HHS continues to evaluate the current enrollment duration factors, HHS generally disagrees with comments asserting the risk adjustment methodology does not adequately address partial year enrollees.

Comment: As also discussed in preamble, some commenters stated the concern that issuers had not had time to incorporate adverse selection risk related to the proposed special enrollment period into their rates for the 2022 plan year. However, no commenters recommended giving issuers an additional opportunity to adjust rates before the 2022 plan year. Several commenters requested that HHS delay making the proposed special enrollment period available until the 2023 plan year if HHS finalized the proposal, in order to provide issuers with adequate time to incorporate related risk into their rates.

Response: Based on HHS's determination that consumers who are eligible for free or very low-cost coverage provided by enhanced APTC through the ARP will benefit from additional opportunities to enroll in Exchange coverage while this enhanced assistance is in place, HHS is finalizing the special enrollment period to be available for the 2022 plan year, and to be limited to provide coverage for periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, including tax year 2022, as provided by section 9661 of the ARP.

5. Clarification of Special Enrollment Periods for Enrollees who are Newly Eligible or Newly Ineligible for Advance Payments of the Premium Tax Credit (§ 155.420(f))

HHS is finalizing new language to clarify, for purposes of the special enrollment period rules at § 155.420, that a qualified individual, enrollee, or his or her dependent, who qualifies for APTC because they meet the criteria at § 155.305(f), but who qualifies for a maximum APTC

amount of zero dollars, is not considered APTC eligible, even when they have previously been APTC ineligible for another reason, such as having other MEC. HHS believes that the special enrollment period rules that reference APTC eligibility at § 155.420(d)(6) could have permitted inconsistent interpretations of what it means to be newly eligible or ineligible for APTC when an individual is found to be eligible generally to receive APTC, but for a specific APTC amount of zero dollars. HHS believes that this clarification will help ensure that the special enrollment periods at § 155.420(d)(6) are available to individuals as intended: those determined to be newly eligible for an APTC amount greater than zero dollars.

HHS believes that this change will not be relevant to a significant number of individuals in Exchanges on the Federal platform, but that for the reasons described in preamble, it will be important in light of the removal of the upper APTC eligibility limit on household income at 400 percent of the FPL for taxable years 2021 and 2022 under the ARP.²¹⁸ More specifically, this definition makes clear that an individual who qualifies for a maximum APTC amount of zero dollars would qualify for a special enrollment period per § 155.420(d)(6)(i) or (ii) if, later in the plan year, they became newly eligible for an APTC amount greater than zero dollars based on a decrease in their household income. This clarification may be helpful for any individual who experiences a decrease in household income that makes them newly eligible for an APTC amount of greater than zero dollars.

As of March 1, 2021 (prior to the passage of the ARP), approximately 7.25 million enrollees through Exchanges on the Federal platform were APTC eligible, but only 36,000 (or 0.5 percent) were APTC eligible with a maximum APTC amount of zero dollars. However, just under 119,000 enrollees through Exchanges on the Federal platform reported a household income that was greater than 400 percent of the FPL. HHS analysis indicated that roughly 35,000 of this greater than 400 percent FPL population would automatically be considered APTC eligible with a maximum APTC amount of zero dollars once the 400 percent FPL limit on

²¹⁸ Pub. L. 117-2.

household income had been removed and these enrollees were no longer considered APTC ineligible simply by virtue of exceeding that limit, doubling the number of potentially impacted enrollees through Exchanges on the Federal platform even before to the passage of the ARP. Additionally, as of March 1, 2021, HHS identified roughly 501,000 enrollees that did not report any household income on their application; some of these enrollees may also be newly eligible for APTC under the new rules. After passage of the ARP and CMS's removal of the 400 percent FPL limit on household income regarding qualifying individuals applying for coverage through an Exchange on the Federal platform, the number of enrollees who did not provide household income decreased slightly, to just under 472,000, and the number of enrollees reporting a household income greater than 400 percent of the FPL has increased to over 191,000. The number of enrollees eligible for a maximum APTC amount of zero dollars has also increased slightly, to just under 42,000 individuals. More recently, the number of enrollees who did not provide household income decreased further, to just under 458,000, and the number of enrollees reporting a household income greater than 400 percent of the FPL has increased to over 280,000. The number of enrollees eligible for a maximum APTC amount of zero dollars has also increased, to just over 51,000 individuals.²¹⁹ As noted in the proposed rule, HHS expects these trends continue during 2022 in Exchanges on the Federal platform and likely in other State Exchanges, as well, making this clarification especially relevant at that time.

HHS sought comment on the proposal, including from State Exchanges regarding whether this definition of APTC eligibility reflects their current implementation of the special enrollment period qualifying events per § 155.420(d)(6), and if not, whether there are policy concerns about this clarification, or concerns about the burden of making related changes to State Exchanges' operations. HHS also sought comment on whether any group of individuals who

²¹⁹ Figures repeated here that were also included in the proposed rule were drawn from internal CMS analysis as of late May 2021, almost 2 months after CMS updated HealthCare.gov to reflect the removal of the 400 percent FPL limit on household income on applicants applying for coverage with APTC. New figures are from internal CMS analysis as of late August 2021.

may qualify for one or more of the special enrollment periods at § 155.420(d)(6) could be harmed by this clarification, and if so, how such harm could be mitigated.

The summary of the comments received and HHS's responses to the comment solicitations related to the clarification of special enrollment period for enrollees who are newly eligible or newly ineligible for advance payments of the premium tax credit (§ 155.420(f)) appears in that preamble section earlier in this rule.

6. FFE and SBE-FP User Fees (§ 156.50)

HHS is finalizing an increased FFE user fee rate of 2.75 percent for the 2022 benefit year, which is higher than the 2.25 percent FFE user fee rate finalized in part 1 of the 2022 Payment Notice. HHS is also increasing the SBE-FP user fee rate to 2.25 percent for the 2022 benefit year from the 1.75 percent SBE-FP user fee rate finalized in part 1 of the 2022 Payment Notice final rule.²²⁰ Based on HHS's estimated costs, enrollment (including anticipated transitions of states from the FFE and SBE-FP models to either the SBE-FP or State Exchange models), premiums for the 2021 and 2022 benefit years, and user fee rates, HHS expects transfers from issuers to Federal Government to be increased by approximately \$200 million in plan year 2022.

HHS is repealing the 2023 benefit year user fee rate for the Exchange DE option in FFE and SBE-FP states, which was finalized in part 1 of the 2022 Payment Notice final rule. No state entity has approached HHS to consider this option. Since this option has not been implemented in any state, HHS does not expect any changes to user fee transfers from issuers to the Federal Government due to this rescission.

7. Segregation of Funds for Abortion Services (§ 156.280)

HHS is amending the separate billing regulation at § 156.280(e)(2)(ii) that governs payments for QHPs that provide coverage of abortion services for which Federal funds are prohibited. As finalized, HHS reverts to codifies prior policy that allowed QHP issuers offering coverage of such abortion services flexibility in selecting a method to comply with the separate

²²⁰ 86 FR 6138.

payment requirement in section 1303 of the ACA. As finalized, the acceptable methods for satisfying the separate payment requirement include sending the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of such abortion services; sending the policy holder a separate monthly bill for these services; or sending the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge.

The 2019 Program Integrity Rule extensively detailed the anticipated financial and operational burdens from the separate billing regulation. HHS continues to believe removal of the separate billing regulation will remove the significant burden associated with the separate billing regulation. Those burdens included costly estimates for issuer implementation of the technical build to implement the necessary system changes to support separate billing and receipt of separate payments, which would require significant changes to current billing practice and pose increased challenges for some states and issuers given the mid-plan year implementation timeline. These activities included planning, assessment, budgeting, contracting, and building and testing their systems; as well as one-time changes such as billing-related outreach and call center training. The burdens also included ongoing costs related to sending a separate bill, such as those related to identifying impacted enrollees, ensuring billing accuracy, reconciliation, quality assurance, record keeping, document retention, support for enrollees who enter grace periods for non-payments, customer service, outreach, and compliance. Issuers would also be expected to assume annual materials costs related to printing of and sending the separate bill. HHS anticipated that State Exchanges would experience increased burden associated with one-time technical changes such as updating online payment portals to accept separate payments and updating enrollment materials and notices that reference binder payments, and ongoing costs related to increased customer service, outreach, and compliance.

HHS also stated in the 2019 Program Integrity Rule that QHP issuers were likely to consider these new costs when setting actuarially sound rates and that this would likely lead to

higher premiums for enrollees. Specifically, HHS estimated there would be an approximate premium impact of up to 1.0 percent in plan year 2021 and each year thereafter in states with QHP issuers offering coverage of abortion services for which Federal funds are prohibited. HHS also estimated that enrollment would be slightly reduced in the impacted states as a result of the increase to premiums. In plan year 2021 and each year after, HHS estimated that APTC amounts would increase up to \$146 million when premium rates reflect the projected additional administrative and operational expense burdens.

HHS also projected in the 2019 Program Integrity Rule that the FFEs would incur additional costs due to one-time technical changes and increased call volumes and additional customer service efforts. HHS estimated that the FFEs would incur a one-time cost of \$750,000 in 2020 and ongoing annual costs of approximately \$400,000 in 2020, \$800,000 in 2021, \$600,000 in 2022, and \$400,000 in 2023 onwards to implement the separate billing policy.

HHS also anticipated that all impacted State Exchanges would incur one-time costs of \$9 million in 2020 for necessary technical changes such as updating online payment portals to accept separate payments and updating enrollment materials. In addition, HHS estimated that State Exchanges would incur ongoing annual costs associated with increased customer service, outreach, and compliance totaling \$2.4 million in 2020, \$4.8 million in 2021, \$3.6 million in 2022, and \$2.4 million 2023 onwards for all impacted State Exchanges.

HHS also anticipated increased costs to consumers for the time required to read and understand the separate bills and seek help from customer service, and additional time to read and send separate payments in subsequent months. For the estimated 2 million policy holders in plans offering coverage of abortion services for which Federal funds are prohibited, the Program Integrity Rule estimated a total annual cost for of 2.9 million hours in 2020 with an associated annual cost of \$35.5 million. HHS decreased this estimated burden slightly in the May 2020 IFC to account for a burden reduction of approximately 337,793 hours with an equivalent cost savings of approximately \$4.2 million. For subsequent years, HHS estimated in the 2019

Program Integrity Rule that the annual enrollee burden would be approximately 2 million hours with an associated annual cost of approximately \$25.1 million.

In total, the projected burden to all issuers, states, State Exchanges performing premium billing and payment processing, the FFEs, and consumers due to the separate billing policy regulation totaled \$546.1 million in 2020, \$232.1 million in 2021, \$230.7 million in 2022, and \$229.3 million annually in 2023 and onwards.

HHS also believes the consumer confusion and new logistical obstacles due to the separate billing regulation would disproportionately harm and burden communities that already face barriers to accessing care and that any potential coverage losses caused by the separate billing regulation could further exacerbate existing health disparities and jeopardize health outcomes. Further, issuers dropping coverage of abortion services for which Federal funds are prohibited as a result of the burden associated with the separate billing regulation could transfer out-of-pocket costs for this coverage to enrollees, which may disproportionately impact low-income women who already face barriers to accessing quality health care.

Comment: Commenters supporting repeal of the separate billing regulation and codification of the prior policy confirmed these estimates and expressed support for removal of an onerous billing requirement on issuers, states, Exchanges, and consumers. Commenters stated that issuers would have had to redesign their billing systems for only a small portion of their business in the individual market Exchanges. Commenters agreed that the separate billing regulation would have imposed expensive IT changes on issuers and states, requiring creation of a billing system only for individual Exchanges and not for products sold in any other market. Commenters also agreed that the separate billing regulation would have required costly changes to other issuer operations such as invoice processing, collections, customer service support, and other transactions with Exchanges. Commenters also agreed there would be added administrative costs of mailing separate bills in separate envelopes and collecting separate payments. Some commenters noted that issuers have already incurred ongoing costs for printing and mailing,

additional staffing, and reprogramming billing systems and that the separate billing regulation already resulted in increased burden for issuers and consumers, widespread confusion by consumers and other stakeholders, and an increase in frustration and confusion around grace periods and terminations. Commenters also expressed concern that the highest costs from the separate billing regulation would have been concentrated in states that require abortion coverage.

For example, one commenter noted that many of its QHPs that offer abortion coverage for which Federal funding is prohibited are in states where the State Exchange operationalizes the premium billing and collections process on behalf of issuers, while others directly bill consumers. This commenter noted that for issuers operating in states that operationalize the billing and collections themselves, issuers expected that there would be an additional assessment to cover the costs to the state, which will ultimately be factored into premiums, as the 2019 Program Integrity Rule acknowledged. In other states, including those where abortion coverage for which Federal funding is prohibited is mandatory, the commenter explained that issuers would have been tasked with the complete operational and financial burden. This commenter asserted that the separate billing regulation therefore conflicted with the common goal among QHPs to keep costs and premiums low in order to provide affordable care for low-income and vulnerable populations.

Commenters also asserted that the separate billing regulation seemed to serve no discernible purpose beyond the introduction of easily-avoidable administrative complexity for health plans and red tape for consumers. As such, commenters believe that the separate billing regulation would have caused issuers to stop covering abortion services for which Federal funding is prohibited in states where such coverage is not mandated. Commenters agreed that, if issuers were to drop such abortion coverage, the costs would be transferred to consumers and would likely disproportionately impact low-income women that already face barriers to accessing health care services. Commenters also noted that the burden would have been particularly significant in states that require individual market QHP coverage of abortion

because, in such states, every QHP policy holder would have received two separate bills and been instructed to pay those bills in two separate transactions. Commenters assert that this would have caused significant harm to individual market enrollees and that implementation costs for issuers would have further harmed consumers by causing their premiums to increase.

Commenters again agreed that these negative impacts, including the widespread consumer confusion that could result in an increased number of consumers losing their health coverage, would have had a disproportionate impact on the state's most vulnerable residents.

Commenters objecting to repeal of the separate billing regulation argued that HHS has not shown how repeal of the separate billing regulation and codification of the prior policy will add a financial benefit to either consumers or insurers that outweighs the harm caused to consumer transparency, conscience protections, and statutory compliance with section 1303. Objecting commenters also broadly criticized HHS's cost estimates for the burden associated with the separate billing regulation, arguing that HHS failed to consider important factors, explore sufficient data, and make necessary estimates. Objecting commenters also alleged that, regardless of the extent of burden associated with the separate billing regulations on issuers, states, Exchanges, and consumers, that any such burden is not unreasonable, but necessary to ensure compliance with section 1303 of the ACA. Commenters also asserted that HHS did not provide sufficient evidence that certain groups of people are more likely to be impacted by the separate billing regulation than others and that, in any event, such arguments cannot justify violating the separate billing requirement that commenters argue is expressly required under section 1303 of the ACA.

Commenters objecting to repeal of the separate billing regulation asserted that the cost estimates fail to address or take into account recent changes in the law made by the ARP. Commenters stated that millions of Americans are newly eligible for zero-dollar coverage under ARP but that, in states where all or most ACA individual market plans cover abortion for which Federal funding is prohibited, consumers will not be able to purchase a zero-dollar premium plan

because of section 1303's funding restrictions. Commenters therefore argued that individuals in such situations are already paying, in effect, a "separate bill" for that coverage and would not face additional burdens established by the separate billing regulation. Commenters raising this objection asked HHS to explain how the Department will enforce section 1303's funding restrictions for otherwise zero-premium Exchange plans and to provide a state-by-state analysis of the effects of the proposed rule.

Response: HHS agrees with commenters concerns regarding the costs and burdens the separate billing policy would have imposed on stakeholders. As raised by some commenters, HHS also acknowledges that some costs may have already been incurred by issuers and that the actual cost savings, especially for one-time IT related costs, may be lower than HHS estimates. Unfortunately, HHS does not have an estimate of costs already incurred by issuers and can only estimate savings going forward. HHS disagrees with comments contesting the validity of these burden estimates. Further, as the courts' nationwide invalidation of the policy prevented HHS from requiring initial implementation of the separate billing regulation, the potential consumer confusion over payment obligations, which could have inadvertently led to non-payment of enrollee premium and subsequent termination of consumer coverage, was also avoided.

HHS acknowledges that consumers who live in states where premiums for Exchange coverage cannot be fully paid for with APTC, such as states that require coverage of abortion services for which Federal funding is prohibited, will not have access to a silver plan with a zero-dollar premium, as further explained in the preamble to § 155.420(d)(16) of the proposed rule.²²¹ However, HHS also notes that individual market QHP issuers covering abortion services for which Federal funds are prohibited offering coverage to consumers who qualify for zero-dollar premium plans are still required to comply with section 1303 of the ACA and all applicable requirements codified at § 156.280. HHS also notes that the ARP was enacted in 2021, and therefore, the consumer cost and burden estimates in each respective rule regarding the separate

²²¹ 86 FR 35156.

billing regulation were based on the estimated number of all consumers enrolled in QHPs offering coverage for abortion and are reflective of the anticipated burden at that time.

The 2019 Program Integrity Rule included a detailed account of the anticipated financial and operational burdens from the separate billing regulation, estimates which were based upon plan and premium data, actuarial estimates, public comments from issuers and states directly regulated by the separate billing regulation, and consumer enrollment figures. Those burdens are discussed in further detail in sections III., “Collection of Information Requirements,” and IV., “Regulatory Impact Analysis,” of that rule, which explain from where such estimates are derived. As explained in more detail in the preamble to § 156.280, HHS also agrees with commenters that the consumer confusion and new logistical obstacles from the separate billing regulation would disproportionately burden communities who already face barriers to accessing care.

Upon reassessing the separate billing regulation, and in light of the legal developments, HHS no longer sees a discernible benefit to requiring separate billing that would be sufficient to outweigh its burdens. Section 1303 does not specify the method a QHP issuer must use to collect the separate payment²²² and multiple Federal district courts have already invalidated the separate billing regulation, preventing HHS from requiring its implementation.²²³ HHS is therefore finalizing a policy that allows issuers to satisfy the separate payment requirement through methods consistent with section 1303 of the ACA; that imposes no more burden on issuers, states, Exchanges, and consumers than is necessary; and that removes unreasonable barriers to obtaining appropriate medical care. HHS anticipates repeal of the separate billing regulation will remove the associated burdens to issuers, states, Exchanges, and consumers by allowing issuers to continue the billing practices and collection methods previously adopted and relied upon since publication of the 2016 Payment Notice.

²²² 84 FR 71674, 71683.

²²³ *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB-20-00361 (D. Md. July 10, 2020); 5 U.S.C. § 706; *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020); *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

8. Section 1332 Waivers

In this rule, the Departments are finalizing modifications to the section 1332 waiver implementing regulations, including the adoption of new policies and interpretations of the statutory guardrails. The Departments also finalize new processes and procedures for amendment and extension requests for approved section 1332 waiver plans. As outlined in this final rule, the policies and interpretations in this rule will supersede and replace prior finalized policies and interpretations. The Departments are also modifying these regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers during future emergent situations. However, this rule does not alter any of the requirements related to state innovation waiver applications, compliance and monitoring, or evaluation in a way that would create any additional costs or burdens for states submitting proposed waiver applications or those states with approved waiver plans that has not already been captured in prior burden estimates. As such, the Departments are of the view that both states with approved section 1332 waivers and states that are considering section 1332 waivers would continue to comply with the requirements noted earlier without creating any additional costs or burdens that have not already been accounted for in prior impact estimates of benefits and costs. The Departments anticipate that implementing these provisions would 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 could help increase state innovation, which in turn could lead to more affordable health coverage for individuals and families in states that consider implementing a section 1332 waiver program.

9. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, HHS 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, HHS assumes that the total number of unique commenters on part three of the 2022 Payment Notice proposed rule will be the number of reviewers of this final rule. HHS acknowledges that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, HHS believed that the number of commenters on part three of the 2022 Payment Notice proposed rule, in addition to the number of states and issuers in the individual, small and large group markets nationwide, would be a fair estimate of the number of reviewers of the final rule. HHS welcomed any comments on the approach in estimating the number of entities which will review the proposed rule.

HHS also recognized that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of this estimate, HHS assumes that each reviewer reads approximately 50 percent of the rule. HHS sought comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11-9111), HHS estimates that the cost of reviewing this rule is \$114.24 per hour, including overhead and fringe benefits.²²⁴ Assuming an average reading speed, HHS estimates that it would take approximately 1 hour for the staff to review half of this final rule. HHS assumes 652 entities will review this final rule. For each entity that reviews the rule, the estimated cost is approximately \$114.24 (1 hour x \$114.24). Therefore, HHS estimates that the total cost of reviewing this regulation is approximately \$74,588.80 (\$114.24 x 652 reviewers).

²²⁴ https://www.bls.gov/oes/current/oes_nat.htm.

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, HHS considered numerous alternatives to the provisions. Below HHS discusses the key regulatory alternatives that HHS considered.

HHS considered taking no action related to adding a new paragraph at § 155.420(d)(16), to provide a monthly special enrollment period for qualified individuals or enrollees, or the dependent of a qualified individual or enrollee, who are eligible for APTC and whose household income is expected to be no greater than 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. HHS also considered whether, if HHS were to provide this special enrollment period, whether it should be limited to periods of time when enhanced APTC benefits were also available, such as those provided by the section 9661 of the ARP. Based on public comments and in order to help mitigate adverse selection concerns, HHS is limiting availability of this special enrollment period to periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP. Finally, HHS also considered and received comment on other strategies to help individuals who may benefit from the proposed special enrollment period, some of whom may qualify for another existing special enrollment period or could benefit from assistance with transitioning between Medicaid and Exchange coverage. HHS will continue to consider innovative and thoughtful steps that HHS and Exchanges may take to assist consumers with transitions between different coverage types and help them to maintain continuous coverage. However, HHS is also finalizing the proposed special enrollment period to maximize

opportunities for consumers to enroll in free or low-cost coverage of which they may not be aware.

HHS considered taking no action related to its clarification, for purposes of the special enrollment period rules at § 155.420, that a qualified individual, enrollee, or his or her dependent who qualifies for APTC because they meet the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is not considered APTC eligible. However, HHS is finalizing as proposed because, in consideration of generally supportive public comments, HHS continues to believe that consumers and other stakeholders will benefit from this clarification because it improves transparency of Exchanges' implementation of the special enrollment period qualifying events provided at § 155.420(d)(6).

HHS considered restoring user fee rates to their 2021 levels at 3 percent and 2.5 percent of total monthly premium for issuers in the FFEs and SBE-FPs, respectively. However, based on HHS's analysis of estimated 2022 enrollment, premiums, and contract costs, HHS determined that this increase would be unnecessary to finance the Exchange essential functions.

Regarding the section 1332 waiver provisions in this rule, the Departments considered rescinding the 2018 Guidance and the regulatory updates and policies finalized in part 1 of the 2022 Payment Notice final rule such that the Departments would rely on the statute for review and approval of section 1332 waiver applications. The Departments did not choose this option because not outlining policies, interpretations, and standards to help explain the section 1332 program requirements and the Departments' interpretations thereof would lead to uncertainty for states considering section 1332 waiver applications. The Departments also considered codifying the policies and interpretations in the 2015 Guidance in regulation, but determined finalizing new policies and interpretations (some of which align with previous guidance and rulemaking) was the clearest way to explain the requirements for submission and approval of section 1332 waivers.

E. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare a final regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience a change in revenues of more than 3 to 5 percent.

In this rule, HHS finalizes revised 2022 user fee rates, which will impact issuer rate setting. HHS believes that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$41.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$35 million or less.²²⁵ HHS believes that few, if any, insurance issuers 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 report²²⁶ submissions for the 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of \$41.5 million or less. This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 67 percent of

²²⁵ <https://www.sba.gov/document/support--table-size-standards>.

²²⁶ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding \$41.5 million. The user fee rates finalized in this rule are lower than the 2021 benefit year user fee rates by 0.25 percent, and these new rates are higher than the previously finalized 2022 benefit year user fee rates by 0.5 percent. Therefore, these user fee rates will only impact premium revenue for these issuers by approximately 0.25 percent, since no issuer has effectuated payments under the previously finalized user fee rates, and this impact is below HHS's 3 to 5 percent significance threshold stated earlier.

In this final rule, HHS also codifies a new monthly special enrollment period for certain APTC-eligible individuals. Because this special enrollment period has the potential to introduce new adverse selection risk into the individual market, HHS sought comment in the RIA on the impact on premiums of this policy in Exchanges where it is implemented. HHS estimates that this policy could result in an increase in premiums of 0.5 to 2 percent when the enhanced APTC provisions of the ARP are in effect, and this impact is below HHS's 3 to 5 percent significance threshold stated earlier in this preamble.

In addition, the other provisions in this rule will either reduce costs or have no cost impact. Therefore, HHS does not expect the provisions of this rule to affect a substantial number of small entities. HHS does not believe that this threshold will be reached by the requirements in this final rule. Therefore, the Secretary of HHS has determined 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 HHS to prepare a regulatory impact analysis in certain cases 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 purposes of section 1102(b) of the Act, HHS defines 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, HHS has determined that this final rule

would not affect small rural hospitals, as the policies finalized in this rule impact consumer assisters, Exchanges, states, issuers, and consumers, but do not directly pertain to providers or facilities. Therefore, the Secretary of HHS has determined that this 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) 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 2021, that threshold is approximately \$158 million. Although HHS has not been able to quantify all costs, HHS expects the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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 HHS's view, while this final rule does not impose substantial direct requirement costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, HHS has 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, HHS attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, HHS complied with the requirements of EO 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange. For states that elected previously to operate an Exchange, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. A user fee is assessed on issuers under all existing Exchange models, including State Exchanges where the user fee is assessed by the state, SBE-FPs, and the FFEs. HHS solicited comment on the proposed user fee rate of 2.75 percent of monthly premiums for issuers in FFEs and 2.25 percent of monthly premiums for issuers in SBE-FPs.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller for review. This final rule is a "major rule" as that term is defined in 5 U.S.C. 804(2), because it is likely to result in an annual effect on the economy of \$100 million or more.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 13, 2021.

List of Subjects

31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Age discrimination, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 155

Administrative practice and procedure, Advertising, Age discrimination, Brokers, Civil rights, Citizenship and naturalization, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Technical assistance, Taxes, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Age discrimination, Alaska, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Department of the Treasury amends 31 CFR 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. Amend § 33.108 by revising paragraphs (f)(3)(iv) introductory text and (f)(3)(iv)(A) through (C) to read as follows:

§ 33.108 Application procedures.

* * * * *

(f) * * *

(3) * * *

(iv) The analyses, actuarial certifications, data, assumptions, targets, and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of Health and Human Services, as applicable, with the necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with the provisions of this paragraph (f)(3)(iv):

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive. To satisfy the comprehensive coverage requirement, the Secretary and the Secretary of Health and Human Services, as applicable, must determine that the coverage under the State plan is forecasted to be at least as comprehensive overall for residents of the State as coverage absent the waiver;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide. To satisfy the affordability requirement, the Secretary and the Secretary of Health and Human Services, as applicable, must determine that the coverage under the State plan is forecasted to be as affordable overall for State residents as coverage absent the waiver;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide. To satisfy the scope of coverage requirement, the Secretary and the Secretary of the Health and Human Services, as applicable, must determine that the State plan will provide coverage to a comparable number of State residents under the waiver as would have coverage absent the waiver; and

* * * * *

3. Amend § 33.118 by revising the section heading and paragraphs (a) and (b)(3) and adding paragraphs (b)(5) and (g) to read as follows:

§ 33.118 Modification from the normal public notice requirements during an emergent situation.

(a) The Secretary and the Secretary of Health and Human Services may modify, in part, the State public notice requirements under § 33.112(a)(1), (b), (c), and (d) and the Federal public notice procedures under § 33.116(b) to expedite a decision on a proposed section 1332 waiver request during an emergent situation, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(b) * * *

(3) The State must, as applicable, detail in its request for a modification from State-level notice procedures under paragraph (a) of this section the justification for the request as it relates to the emergent situation and the alternative public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State's request for a modification.

* * * * *

(5) The State must explain in its request for a modification from State-level notice procedures under paragraph (a) of this section how the emergent circumstances underlying its request results from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life could not reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interests of consumers.

* * * * *

(g) The Departments will consider circumstances to be emergent when they could not have been reasonably foreseen. The Departments will assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

4. Amend § 33.120 by revising paragraphs (a) and (c)(2)(i) and adding paragraphs (c)(2)(ii)(F) and (c)(2)(iii) to read as follows:

§ 33.120 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of Health and Human Services, as applicable, a State must comply with all applicable Federal laws and regulations, unless expressly waived. A State must, within the timeframes specified in law and regulation come into compliance with any

changes in Federal law and regulation affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) The Secretary and the Secretary of Health and Human Services will examine compliance with Federal and regulatory requirements consistent with §155.1308(f)(3)(iv) when conducting implementation reviews under paragraph (b) of this section.

* * * *

(c) * * *

(2) * * *

(i) The Secretary and the Secretary of Health and Human Services may modify, in part, State post award requirements under this paragraph (c)(2) for an approved section 1332 waiver request during an emergent situation, when the application of the post award public notice requirements would be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(ii) * * *

(F) The State must explain in its request for modification under this paragraph (c)(2) how the emergent circumstances underlying its request results from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life and could not reasonably have been foreseen and how the application of the post-award public notice requirements would be contrary to the interests of consumers.

(iii) The Secretary and the Secretary of Health and Human Services will consider circumstances to be emergent when they could not have been reasonably foreseen. The Secretary and the Secretary of Health and Human Services will assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and

will not make this assessment based solely on the number of days a State may have been aware of such issues.

* * * * *

5. Section 33.122 is added to read as follows:

§ 33.122 Pass-through funding for approved waivers.

(a) *Pass-through funding.* With respect to a State's approved section 1332 waiver, under which, due to the structure of the approved State waiver plan, individuals and small employers in the State would not qualify for or would qualify for a reduced amount of premium tax credit under section 36B of the Internal Revenue Code, small business tax credit under section 45R of the Internal Revenue Code, or cost-sharing reductions under ACA part I of subtitle E for which they would otherwise be eligible, the Secretary and the Secretary of the Health and Human Services shall provide for an alternative means by which the aggregate amount of such credits or reductions that would have been paid on behalf of participants in the Exchanges had the State not received such waiver shall be paid to the State for purposes of implementing the approved State waiver plan. Such amount shall be determined annually by the Secretary and the Secretary of Health and Human Services, taking into consideration the experience of other States with respect to participation in an Exchange and credits and reductions provided under such provisions to residents of the other States. This amount can be updated to reflect applicable changes in Federal or State law.

(b) [Reserved]

6. Amend § 33.128 by revising paragraph (a) to read as follows:

§ 33.128 Periodic evaluation requirements.

(a) The Secretary and the Secretary of Health and Human Services, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with § 33.108(f)(3)(iv) and any terms and conditions governing the section 1332 waiver.

* * * * *

7. Section 33.130 is added to read as follows:

§ 33.130 Waiver amendment.

(a) *Amendment to an approved section 1332 waiver.* A State may request an amendment to an approved section 1332 waiver from the Secretary and the Secretary of Health and Human Services. A section 1332 waiver amendment is considered a change to an approved section 1332 waiver plan that is not otherwise allowable under the terms and conditions of an approved waiver, a change that could impact any of the section 1332 statutory guardrails or a change to the program design for an approved waiver. A State is not authorized to implement any aspect of the proposed amendment without prior approval by the Secretary and the Secretary of Health and Human Services.

(b) [Reserved]

8. Section 33.132 is added to read as follows:

§ 33.132 Waiver extension.

(a) *Extension.* A State may request continuation of an approved section 1332 waiver, and such request shall be deemed granted unless the Secretary and the Secretary of Health and Human Services, within 90 days after the date of submission of a complete waiver extension request to the Secretary and the Secretary of Health and Human Services, either denies such request in writing or informs the State in writing with respect to any additional information that is needed in order to make a final determination with respect to the request.

(b) [Reserved]

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, as set forth below.

PART 147 – HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL INSURANCE MARKETS

9. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended, and section 3203, Pub. L. 116-136, 134 Stat. 281.

10. Amend § 147.104 by revising paragraphs (b)(2)(i)(E) and (F) and adding paragraph (b)(2)(i)(G) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(E) Section 155.420(d)(12) of this subchapter (concerning plan and benefit display errors);

(F) Section 155.420(d)(13) of this subchapter (concerning eligibility for insurance affordability programs or enrollment in the Exchange); and

(G) Section 155.420(d)(16) of this subchapter (concerning eligibility for advance payments of the premium tax credit and household income, as defined in 26 CFR 1.36B-1(e), that is expected to be no greater than 150 percent of the Federal poverty level).

* * * * *

PART 155 – EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

11. 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.

12. Amend § 155.210 by revising paragraph (e)(9) to read as follows:

§ 155.210 Navigator program standards.

* * * * *

(e) * * *

(9) The Exchange may require or authorize Navigators to provide information and assistance with any of the following topics. In federally-facilitated Exchanges, FY 2021 Navigator grantees will be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance. Beginning with Navigator grants awarded in 2022, including non-competing continuation awards, Navigators are required to provide information and assistance with all of the following topics:

(i) Understanding the process of filing Exchange eligibility appeals;

(ii) Understanding and applying for exemptions from the requirement to maintain minimum essential coverage granted through the Exchange;

(iii) The Exchange-related components of the premium tax credit reconciliation process, and understanding the availability of IRS resources on this process;

(iv) Understanding basic concepts and rights related to health coverage and how to use it; and

(v) Referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, and premium tax credit reconciliations.

* * * * *

§ 155.221 [Amended]

13. Amend § 155.221 by removing paragraph (j).

14. Amend § 155.410 by—

- a. Revising paragraph (e)(3);
- b. Adding paragraph (e)(4);
- c. Revising paragraph (f)(2) introductory text; and
- d. Adding paragraph (f)(3).

The revisions and additions read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) * * *

(3) For the benefit years beginning on January 1, 2018 through January 1, 2021, the annual open enrollment period begins on November 1 and extends through December 15 of the calendar year preceding the benefit year.

(4) For the benefit years beginning on or after January 1, 2022--

(i) Subject to paragraph (e)(4)(ii) 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 not utilizing the Federal platform, for the benefit years beginning on or after January 1, 2022, an alternative annual open enrollment period end date may be adopted, provided the end date is no earlier than December 15 of the calendar year preceding the benefit year.

(f) * * *

(2) For the benefit years beginning on January 1, 2016 through January 1, 2021, the Exchange must ensure coverage is effective—

* * * * *

(3) For benefit years beginning on or after January 1, 2022, the Exchange must ensure that coverage is effective—

(i) Subject to paragraph (f)(3)(ii) of this section—

(A) January 1, for QHP selections received by the Exchange on or before December 15 of the calendar year preceding the benefit year.

(B) February 1, for QHP selections received by the Exchange from December 16 of the calendar year preceding the benefit year through January 15 of the benefit year.

(C) The first of the following month, for QHP selections received by the 15 of a month after January, if applicable under paragraph (e)(4)(ii) of this section.

(D) The first of the second following month, for plan selections received between the 16th and the end of a month, beginning January 16 of the benefit year, if applicable under paragraph (e)(4)(ii) of this section.

(ii) For State Exchanges not utilizing the Federal platform, for a QHP selection received by the Exchange during the open enrollment period for which effective dates specified in paragraph (f)(3)(i) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph.

* * * *

15. Amend § 155.420—

a. In paragraph (a)(4)(ii)(B), by removing the phrase “enrollment; or” and adding in its place “enrollment;”;

b. By revising paragraph (a)(4)(ii)(C);

c. By adding paragraph (a)(4)(ii)(D);

d. By revising paragraph (a)(4)(iii) introductory text; and

e. By adding paragraphs (b)(2)(vii), (d)(16), and (f).

The revision and additions read as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(4) * * *

(ii) * * *

(C) No later than January 1, 2024, if an enrollee or his or her dependents become newly ineligible for advance payments of the premium tax credit in accordance with paragraph (d)(6)(i) or (ii) of this section, the Exchange must allow the enrollee and his or her dependents to change to a QHP of any metal level, if they elect to change their QHP enrollment; or

(D) If an enrollee or his or her enrolled dependents qualify for a special enrollment period in accordance with paragraph (d)(16) of this section, the Exchange must allow the enrollee and his or her enrolled dependents to change to any available silver-level QHP if they elect to change their QHP enrollment. If a qualified individual or a dependent who is not an enrollee qualifies for a special enrollment period in accordance with paragraph (d)(16) of this section and has one or more household members who are enrollees, the Exchange must allow the enrollee to add the newly enrolling household member to his or her current QHP; or, to change to a silver-level QHP and add the newly enrolling household member to this silver-level QHP; or, to change to a silver level QHP and enroll the newly enrolling qualified individual or dependent in a separate QHP;

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (d)(4), and (d)(6)(i) and (ii) of this section for becoming newly eligible or ineligible for CSRs and paragraphs (d)(8), (9), (10), (12), (14), and (16) of this section:

* * * *

(b) * * *

(2) * * *

(vii) If 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 no greater than 150 percent of the Federal poverty level, enrolls in a QHP or changes from one QHP to another one time per month in accordance with paragraph (d)(16) of this section, the Exchange must ensure that coverage is

effective in accordance with paragraph (b)(1) of this section or on the first day of the month following plan selection, at the option of the Exchange.

* * * * *

(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 no greater than 150 percent of the Federal poverty level, may enroll in a QHP or change from one QHP to another one time per month 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 Internal Revenue Code, is set at zero.

* * * * *

(f) For purposes of this section, references to eligibility for advance payments of the premium tax credit refer to being eligible for such advance payments in an amount greater than zero dollars per month. References to ineligibility for advance payments of the premium tax credit refer to being ineligible for such payments or being eligible for such payments but being eligible for a maximum of zero dollars per month of such payments.

16. Amend § 155.1308 by revising paragraphs (f)(3)(iv) introductory text and (f)(3)(iv)(A) through (C) to read as follows:

§ 155.1308 Application procedures.

* * * * *

(f) * * *

(3) * * *

(iv) The analyses, actuarial certifications, data, assumptions, targets, and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of the Treasury, as applicable, with the necessary data to determine that the State's

proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with the provisions of this paragraph;

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive. To satisfy the comprehensive coverage requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the coverage under the State plan is forecasted to be at least as comprehensive overall for residents of the State as coverage absent the waiver;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide. To satisfy the affordability requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the coverage under the State plan is forecasted to be at least as affordable overall for State residents as coverage absent the waiver;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide. To satisfy the scope of coverage requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the State plan will provide coverage to a comparable number of State residents under the waiver as would have coverage absent the waiver; and

* * * * *

17. Amend § 155.1318 by revising the section heading and paragraphs (a) and (b)(3) and adding paragraphs (b)(5) and (g) to read as follows:

§ 155.1318 Modification from the normal public notice requirements during an emergent situation.

(a) The Secretary and the Secretary of the Treasury may modify, in part, the State public notice requirements under §155.1312(a)(1), (b), (c), and (d) and the Federal public notice procedures under §155.1316(b) to expedite a decision on a proposed section 1332 waiver request during an emergent situation, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(b) * * *

(3) The State must, as applicable, detail in its request for a modification from State-level notice procedures under paragraph (a) of this section the justification for the request as it relates to the emergent situation and the alternative public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State's request for a modification.

* * * * *

(5) The State must explain in its request for a modification from State-level notice procedures under paragraph (a) of this section how the emergent circumstances underlying its request result from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life could not reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interests of consumers.

* * * * *

(g) The Secretary and the Secretary of the Treasury will consider circumstances to be emergent when they could not have been reasonably foreseen. The Secretary and the Secretary of the Treasury will assess “reasonable foreseeability” based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

18. Amend § 155.1320 by—

- a. Revising paragraph (a);
- b. Revising the subject heading for paragraph (c)(2);
- c. Revising paragraph (c)(2)(i); and
- d. Adding paragraphs (c)(2)(ii)(F) and (c)(2)(iii).

The revisions and additions read as follows:

§ 155.1320 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, as applicable, a State must comply with all applicable Federal laws and regulations, unless expressly waived. A State must, within the timeframes specified in law and regulation come into compliance with any changes in Federal law and regulation affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) The Secretary and the Secretary of the Treasury will examine compliance with Federal and regulatory requirements consistent with §155.1308(f)(3)(iv) when conducting implementation reviews under paragraph (b) of this section.

* * * * *

(c) * * *

(2) *Modification from the normal post award requirements during an emergent situation.*

(i) The Secretary and the Secretary of the Treasury may modify, in part, State post award

requirements under this paragraph (c)(2) for an approved section 1332 waiver request during an emergent situation when the application of the post award public notice requirements would be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(ii) * * *

(F) The State must explain in its request for a modification under paragraph (c)(2) of this section how the emergent circumstances underlying its request results from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life and could not reasonably have been foreseen and how the application of the post award public notice requirements would be contrary to the interests of consumers.

(iii) The Secretary and the Secretary of the Treasury will consider circumstances to be emergent when they could not have been reasonably foreseen. The Secretary and the Secretary of the Treasury will assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

* * * * *

19. Section 155.1322 is added to subpart N to read as follows:

§ 155.1322 Pass-through funding for approved waivers.

(a) *Pass-through funding.* With respect to a State's approved section 1332 waiver, under which, due to the structure of the approved State waiver plan, individuals and small employers in the State would not qualify for or would qualify for a reduced amount of premium tax credit under section 36B of the Internal Revenue Code, small business tax credit under section 45R of the Internal Revenue Code, or cost-sharing reductions under ACA part I of subtitle E for which they would otherwise be eligible, the Secretary and the Secretary of the Treasury shall provide

for an alternative means by which the aggregate amount of such credits or reductions that would have been paid on behalf of participants in the Exchanges had the State not received such waiver shall be paid to the State for purposes of implementing the approved State waiver plan. Such amount shall be determined annually by the Secretary and the Secretary of the Treasury, taking into consideration the experience of other States with respect to participation in an Exchange and credits and reductions provided under such provisions to residents of the other States. This amount can be updated to reflect applicable changes in Federal or State law.

(b) [Reserved]

20. Amend § 155.1328 by revising paragraph (a) to read as follows:

§ 155.1328 Periodic evaluation requirements.

(a) The Secretary and the Secretary of the Treasury, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with §155.1308(f)(3)(iv) and any terms and conditions governing the section 1332 waiver.

* * * * *

21. Section 155.1330 is added to subpart N to read as follows:

§ 155.1330 Waiver amendment.

(a) *Amendment to an approved section 1332 waiver.* A State may request an amendment to an approved section 1332 waiver from the Secretary and the Secretary of the Treasury. A section 1332 waiver amendment is considered a change to a section 1332 waiver plan that is not otherwise allowable under the terms and conditions of an approved waiver, a change that could impact any of the section 1332 statutory guardrails or a change to the program design for an approved waiver. A State is not authorized to implement any aspect of the proposed amendment without prior approval by the Secretary and the Secretary of the Treasury.

(b) [Reserved]

22. Section 155.1332 is added to subpart N to read as follows:

§ 155.1332 Waiver extension.

(a) *Extension.* A State may request continuation of an approved section 1332 waiver, and such request shall be deemed granted unless the Secretary and the Secretary of the Treasury, within 90 days after the date of submission of a complete waiver extension request to the Secretary and the Secretary of the Treasury, either denies such request in writing or informs the State in writing with respect to any additional information that is needed in order to make a final determination with respect to the request.

(b) [Reserved]

PART 156 – HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

23. 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.

24. Amend § 156.115 by revising paragraph (a)(3) to read as follows:

§ 156.115 Provision of EHB.

(a) * * *

(3) With respect to the mental health and substance use disorder services, including behavioral health treatment services, required under § 156.110(a)(5), comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations.

* * * * *

25. Amend § 156.280 by revising the section heading and paragraph (e)(2)(ii) to read as follows:

§ 156.280 Segregation of funds for abortion services.

* * * * *

(e) * * *

(2) * * *

(ii) An issuer will be considered to satisfy the obligation in paragraph (e)(2)(i) of this section if it sends the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of abortion services described in paragraph (d)(1) of this section; sends the policy holder a separate monthly bill for these services; or sends the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services, and specifies the charge.

* * * * *

Xavier Becerra,

Secretary,

Department of Health and Human Services.

Mark J. Mazur,

Deputy Assistant Secretary (Tax Policy),

Department of the Treasury.