

DEPARTMENT OF THE TREASURY**31 CFR Part 33**

RIN 1505-AC72

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 155 and 156**

[CMS-9914-F]

RIN 0938-AU18

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations

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

ACTION: Final rule.

SUMMARY: This final rule sets forth provisions related to user fees for federally-facilitated Exchanges and State-based Exchanges on the Federal Platform. It includes changes related to acceptance of payments by issuers of individual market Qualified Health Plans and clarifies the regulation imposing network adequacy standards with regard to Qualified Health Plans that do not use provider networks. It also adds a new direct enrollment option for federally-facilitated Exchanges and State Exchanges and implements changes related to section 1332 State Innovation Waivers.

DATES: These regulations are effective on March 15, 2021.

FOR FURTHER INFORMATION CONTACT:

Jeff Wu, (301) 492-4305, Rogelyn McLean, (301) 492-4229, Usree Bandyopadhyay, (410) 786-6650, Grace Bristol, (410) 786-8437, or Kiahana Brooks, (301) 492-5229, for general information.

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

Robert Yates, (301) 492-5151, for matters related to the direct enrollment option for federally-facilitated Exchange states, State-based Exchanges on the Federal Platform, and State Exchanges.

Erika Melman, (301) 492-4348, for matters related to network adequacy standards.

Emily Ames, (301) 492-4246, for matters related to acceptance of payments by QHP issuers.

Lina Rashid, (443) 902-2823, Michelle Koltov, (301) 492-4225, or Kimberly Koch, (202) 622-0854, for matters related to State Innovation Waivers.

SUPPLEMENTARY INFORMATION: In the December 4, 2020 **Federal Register**, HHS and the Department of the Treasury 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 (85 FR 78572) (hereinafter referred to as the “proposed 2022 Payment Notice” or “proposed rule”) that proposed revisions to regulations in 31 CFR part 33 and 45 CFR parts 147, 150, 153, 155, 156, 158, and 184, and policies that would reduce fiscal and regulatory burdens across related program areas and provide stakeholders with greater flexibility. This final rule addresses only a subset of the policies and proposed regulatory revisions addressed in the proposed 2022 Payment Notice, including certain policies and related proposed revisions to regulations in 31 CFR part 33 and 45 CFR parts 155 and 156. HHS continues to review comments to the proposed 2022 Payment Notice and intends to address the remaining provisions in future rulemaking.

Table of Contents

- I. Executive Summary
- II. Background
 - A. Legislative and Regulatory Overview
 - B. Stakeholder Consultation and Input
 - C. Structure of Proposed Rule
- III. Summary of the Proposed Provisions to the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule
 - A. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act
 - B. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges
- IV. Summary of the Proposed Provisions for State Innovation Waivers, Analysis of and Responses to Public Comments, and Provisions of the Final Rule
 - A. 31 CFR Part 33 and 45 CFR Part 155—State Innovation Waivers
- V. Collection of Information Requirements
 - A. ICRs Regarding State Innovation Waivers
 - B. ICRs Regarding Exchange Direct Enrollment Option
 - C. Submission of PRA-Related Comments
- VI. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Overall Impact
 - C. Impact Estimates of the Payment Notice Provisions and Accounting Statement
 - D. Regulatory Alternatives Considered
 - E. Regulatory Flexibility Act
 - F. Unfunded Mandates
 - G. Federalism
 - H. Congressional Review Act

I. Reducing Regulation and Controlling Regulatory Costs

I. Executive Summary

American Health Benefit Exchanges, or “Exchanges,” are entities established under the Patient Protection and Affordable Care Act (PPACA)¹ through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs). Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services.

On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS (hereinafter referred to as “Secretary”) and heads of all other executive departments and agencies with authorities and responsibilities under PPACA should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of PPACA that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. In the December 4, 2020 **Federal Register**, we² published the proposed 2022 Payment Notice, which proposed to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility.

In previous rulemaking, we established provisions and parameters to implement many PPACA requirements and programs. In this final rule, we are amending some of these provisions and parameters, with a focus on providing states with additional flexibilities, reducing unnecessary regulatory burdens on stakeholders, empowering consumers, and improving affordability.

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

² As this rule is jointly published by HHS and the Department of the Treasury, HHS clarifies that throughout this final rule, the term “we” refers only to HHS.

As we do every year in the HHS notice of benefit and payment parameters (Payment Notice), we are finalizing the user fee rates for issuers offering plans through the Exchanges using the federal platform. For the 2022 plan year, we are lowering the federally-facilitated Exchange (FFE) and State-based Exchange on the Federal Platform (SBE-FP) user fees rates to 2.25 and 1.75 percent of total monthly premiums, respectively, in order to reflect enrollment, premium and HHS contract estimates for the 2022 plan year. We are also finalizing a user fee rate for 2023 of 1.5 percent of total monthly premiums for FFE and SBE-FP states that elect in 2023 the direct enrollment option discussed later in the preamble.

We are updating the standards related to QHP issuers' acceptance of payments for premiums and cost sharing to require individual market QHP issuers to accept premium payments made by or on behalf of an enrollee in connection with an individual coverage health reimbursement arrangement (individual coverage HRA) or qualified small employer health reimbursement arrangement (QSEHRA). We are also providing a clarification to the network adequacy rules to reflect the longstanding interpretation that § 156.230 does not apply to plans seeking QHP certification that do not differentiate benefits based on whether or not enrollees receive covered services from providers that are members of the plan's provider network.

We are establishing a new direct enrollment option under which a State Exchange, SBE-FP, or an FFE state can elect to rely on direct enrollment to offer individual market consumers an enhanced QHP shopping experience. Under this option, instead of operating a centralized enrollment website, states may, with HHS approval, use direct enrollment technology to establish pathways to QHP issuers, web-brokers, and agents and brokers, to allow consumers to apply for and receive a determination or assessment of eligibility for insurance affordability programs and enroll in a QHP, or if applicable, be transferred to Medicaid or the Children's Health Insurance Program (CHIP).

The Secretaries of HHS and the Treasury (collectively, the Secretaries) are finalizing the proposal regarding State Innovation Waivers under section 1332 of PPACA, with modifications in response to comments, to codify many of the policies and interpretations outlined in the 2018 "State Relief and Empowerment Waivers" guidance (83

FR 53575)³ (hereinafter referred to as the 2018 Guidance) into section 1332 regulations governing waiver application procedures, monitoring and compliance, and periodic evaluations in order to give states certainty regarding the requirements to receive and maintain approval by the HHS and the Department of the Treasury (collectively, the Departments) for State Innovation Waivers under section 1332 of PPACA.

We intend to address the other topics and proposed policies outlined in the proposed 2022 Payment Notice in future rulemaking, taking into account comments received on those proposals.

II. Background

A. Legislative and Regulatory Overview

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

These provisions of the PHS Act were later augmented by other laws, including PPACA. Subtitles A and C of title I of PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans⁴ and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.

Sections 1311(b) and 1321(b) of PPACA 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 PPACA. Section 1321(c)(1) of PPACA 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 PPACA 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 PPACA. Section 1311(d) of PPACA describes the minimum functions of an Exchange. Section

1311(e)(1) of PPACA 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 PPACA, 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 1312(e) of PPACA 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 PPACA 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 PPACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of PPACA. Section 1321(a)(1) of PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of PPACA for, among other things, the establishment and operation of Exchanges. When operating an FFE under section 1321(c)(1) of PPACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of PPACA 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 PPACA provides that nothing in title I of PPACA must be construed to preempt any state law that does not prevent the application of title I of PPACA. Section 1311(k) of PPACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1332 of PPACA provides the Secretaries with the discretion to approve a state's proposal to waive specific provisions of PPACA, provided the state's section 1332 waiver plan meets certain requirements. The Departments finalized implementing

³ <https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf>.

⁴ 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 PPACA. The term "health plan" does not include self-insured group health plans.

regulations on February 27, 2012 (76 FR 13553) and published detailed guidance on the Departments' application of section 1332 to proposed state waivers on October 24, 2018 (83 FR 53575).

The 21st Century Cures Act (Cures Act), Public Law 114–255, 130 Stat. 1033, was enacted on December 13, 2016. Section 18001 of the Cures Act amends the Internal Revenue Code (Code), the Employee Retirement Income Security Act of 1974, and the PHS Act to permit an eligible employer to provide a QSEHRA to its eligible employees. Section 9831(d) of the Code, as amended by the Cures Act, establishes requirements for providing a QSEHRA. On October 31, 2017, the Department of the Treasury and the Internal Revenue Service (IRS) issued Notice 2017–67, 2017–47 IRB 517, to provide guidance on the requirements for providing a QSEHRA.

1. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. In the July 15, 2011 **Federal Register** (76 FR 41865), we 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 was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

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

2. Health Reimbursement Arrangements

On October 29, 2018, the Departments of HHS, Labor, and the Treasury published proposed regulations in the **Federal Register** (83 FR 54420) on health reimbursement arrangements (HRAs) and other account-based group health plans including individual

coverage HRAs. On June 20, 2019, the Departments of HHS, Labor, and the Treasury published final regulations in the **Federal Register** (84 FR 28888) on HRAs and other account-based group health plans.

3. State Innovation Waivers

Section 1332(a)(4)(B) of PPACA requires the Secretaries to issue regulations regarding procedures for State Innovation Waivers. On March 14, 2011, the Departments published the “Application, Review, and Reporting Process for Waivers for State Innovation” proposed rule⁵ in the **Federal Register** (76 FR 13553) to implement section 1332(a)(4)(B) of PPACA. On February 27, 2012, the Departments published the “Application, Review, and Reporting Process for Waivers for State Innovation” final rule⁶ in the **Federal Register** (77 FR 11700) (hereinafter referred to as the “2012 Final Rule”). On October 24, 2018, the Departments issued the 2018 Guidance, which superseded the previous guidance⁷ published on December 16, 2015 in the **Federal Register** (80 FR 78131) 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. On November 6, 2020, the Departments issued an interim final rule⁸ in the **Federal Register** (85 FR 71142), which revised regulations relating to public notice procedures to set forth flexibilities in the public notice requirements and post-award public participation requirements for State Innovation Waivers under section 1332 of PPACA during the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE).

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges. We have held a number of listening sessions with consumers, providers, employers, health plans, advocacy groups and the actuarial community to gather public input. We have solicited input from state representatives on numerous topics,

⁵ <https://www.govinfo.gov/content/pkg/FR-2011-03-14/pdf/2011-5583.pdf>.

⁶ <https://www.govinfo.gov/content/pkg/FR-2012-02-27/pdf/2012-4395.pdf>.

⁷ <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

⁸ <https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency>.

particularly the direct enrollment option for FFE states and State Exchanges.

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

C. Structure of Final Rule

The regulations outlined in this final rule are codified in 45 CFR parts 155 and 156. In addition, the regulations outlined in this final rule governing State Innovation Waivers under section 1332 of PPACA are codified in 31 CFR part 33 and 45 CFR part 155.

We establish a new direct enrollment option for State Exchanges, SBE–FPs and FFE states 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.

As we do every year in the annual HHS notice of benefit and payment parameters, we set forth the user fee rates for the 2022 benefit year for all issuers participating on the Exchanges using the federal platform. We also finalize modifications to the regulations addressing network adequacy standards for non-network plans. Finally, we require individual market QHP issuers to accept premium payments made by or on behalf of an enrollee in connection with an individual coverage HRA or QSEHRA.

The changes in 31 CFR part 33 and 45 CFR part 155 related to State Innovation Waivers finalize with modifications the proposals to codify many of the policies and interpretations outlined in the existing 2018 Guidance into the section 1332 waiver implementation regulations in order to give states certainty regarding the requirements to receive and maintain approval of State Innovation Waivers by the Departments.

III. Summary of the Proposed Provisions of the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule—Department of Health and Human Services

In the December 4, 2020 **Federal Register** (86 FR 78572), we 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. We received 542 comments in response to the policies in the proposed 2022 Payment Notice. Comments were received from members of Congress, 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 of or opposition to the proposed provisions to specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule that are not addressed in this final rule.

In this final rule, we provide a summary of the proposed provisions we are addressing in this final rule, a summary of the public comments received that relate to those proposals, our responses to these comments, and a description of the provisions we are finalizing.

We first address comments regarding the publication of this final rule and the comment period.

Comment: Multiple commenters criticized 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 also expressed concern that HHS would not adequately review and consider all comments before issuing a final rule; that HHS appears to be rushing to finalize substantial changes to regulations that would hamper access to coverage through the Exchanges; and that HHS should defer any major policy decisions affecting access to Exchange coverage to the incoming Administration.

Response: We disagree that the comment period was not long enough to allow stakeholders to provide meaningful comments. Each year, we generally have set a 30-day comment period to accommodate issuer filing deadlines for the upcoming plan year and to avoid creating significant challenges for states, Exchanges, issuers, and other entities operating under strict deadlines related to approval of products. Moreover, we found commenters’ submissions to be thoughtful and reflective of a detailed review and analysis of the proposed rule. We further recognize the importance of federal agencies reviewing and considering all relevant comments before issuing a final rule.

For this reason, HHS determined that it was appropriate to address in this final rule only those policies in the proposed 2022 Payment Notice that were most important to advancing the policy goals of reducing fiscal and regulatory burdens across related program areas and providing stakeholders with greater flexibility. Limiting the policies addressed in this final rule allowed us to review all relevant comments and expedite the publication of this final rule.

For reasons more fully reviewed in the preamble discussions related to specific policies in this final rule, we also disagree that the rule will hamper access to Exchange coverage. The policies we finalize in this rule have the potential to increase access to Exchange coverage. For example, the Exchange DE option we finalize in this rule has the potential to increase incentives for licensed agents, brokers, and web-brokers to promote Exchange enrollment through improvements to the consumer application and enrollment experience. The policies this final rule adopts in relation to section 1332 waivers are designed to provide flexibilities that will allow states to propose and implement waiver plans to increase access to Exchange coverage by reducing premiums. In addition, the policies related to individual coverage HRAs and QSEHRAs are being finalized to remove obstacles and ensure individuals offered these types of coverage have seamless access to enroll in individual market QHP coverage.

Finally, we disagree that major policy decisions should be deferred until a new Administration is in place, as this final rule constitutes a valid exercise of the Departments’ rulemaking authorities.

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

1. Standards for Direct Enrollment Entities (§ 155.221)

a. FFE, SBE–FP, and State Exchange Direct Enrollment Option

Classic Direct Enrollment (Classic DE) and Enhanced Direct Enrollment (EDE) are pathways offered as part of the FFE’s DE program under which third-party entities (issuers, agents and brokers, and web brokers) are approved by HHS to assist consumers with QHP plan selection and enrollment through a non-Exchange website in a manner considered to be through the Exchange.⁹

⁹ Classic DE is the original version of DE, which utilizes a “double redirect” from a DE entity’s non-Exchange website to *HealthCare.gov* where the

The Classic DE and EDE pathways are available in FFE and SBE–FP states. In light of the success of the FFEs’ DE program in improving the consumer experience, we proposed to provide additional options for states that wish to promote more flexible and lower-cost private sector approaches for assisting consumers with shopping and enrolling in individual market QHP coverage offered through Exchanges.

While we have taken a number of actions to reduce the burden on states of establishing State Exchanges, we wish to maximize flexibility for all states to oversee their own health care markets and to address unique state market dynamics. In the Exchange Final Rule,¹⁰ we recognized that states are best equipped to adapt Exchange functions to their local markets and the unique needs of their residents.¹¹ In addition, we recognized that for decades, issuers, licensed agents and brokers, and web-brokers have been engaging directly with consumers in offering health insurance and assisting consumers in selecting, enrolling in, and managing their coverage. We believe that the proposal to establish a new DE option for Exchanges would allow states to continue to more effectively exercise their traditional oversight authority over health insurance markets, while enhancing the consumer experience, increasing competition, and lowering costs.

To date, Exchange eligibility application and enrollment activities have been supported through Exchange-operated websites. One of the primary advantages of this design is that consumers can access one-stop shopping for all QHPs offered through an Exchange and can access relevant details on such plans in a standardized format. Before Exchanges existed, consumers shopping for individual health insurance coverage who searched for this information would generally have to contact multiple issuers or visit

eligibility application is submitted and an eligibility determination is made by the Exchange, and then back to the DE entity’s non-Exchange website for QHP shopping and plan selection consistent with applicable requirements in §§ 155.220(c)(3)(i), 155.221, 156.265, or 156.1230(b). EDE is the version of DE which allows consumers to complete all steps in the application, eligibility and enrollment processes on the DE entity’s non-Exchange website consistent with applicable requirements in §§ 155.220(c)(3)(ii), 155.221, 156.265, or 156.1230(b). EDE uses application programming interfaces (APIs) that are made available, owned, and maintained by CMS to transfer data between *HealthCare.gov* and the DE entity’s non-Exchange website.

¹⁰ 77 FR 18310 (March 27, 2012). Available at <https://www.govinfo.gov/content/pkg/FR-2012-03-27/pdf/2012-6125.pdf>.

¹¹ See, for example, 77 FR at 18313.

multiple websites, and the information would often be presented inconsistently, preventing true apples-to-apples comparison shopping. Exchange-run eligibility application and enrollment websites also help to manage coordination of coverage between private health insurance coverage and Medicaid and CHIP by offering full eligibility and enrollment integration between the programs or by providing connections to those public programs for individuals who may qualify for participation.

While Exchange-operated eligibility application and enrollment websites have undoubtedly helped many consumers shop for and compare plans, they also present some significant potential disadvantages given historical and current implementations of Exchange-operated websites. First, as we explained in the proposed rule, it can be costly and burdensome to create and operate Exchanges, including not only the cost of designing and maintaining a complex website, but also the burden of staffing and operating call centers that must be scaled up during each annual Open Enrollment Period (OEP), and then scaled down during lower-traffic periods.

Second, the design of Exchange-operated websites also tends to result in choke points when a large number of consumers use the same website at the same time to apply, shop for, and enroll in coverage. For example, on high traffic days near the end of the annual OEP, some consumers trying to access *HealthCare.gov* have been redirected to the FFE call center or told to come back to the website at a later time to complete their enrollment due to high volume. The ability for consumers to shop for coverage through any one of the websites operated by Classic DE and EDE entities with which HHS partners during these high traffic days provides an important, additional avenue to ensure consumers complete their plan selection and enroll in coverage. Although we recognize that without robust participation and competition among DE entities, a DE entity's website may experience similar choke points due to high consumer traffic, we believe that providing Exchanges in states that elect this option with the flexibility to partner with more than one DE entity mitigates this risk.

Third, we believe it is inherently difficult for Exchanges to keep up with the rapid pace of innovation in e-commerce and the ever-evolving preferences of online shoppers, who are accustomed to shopping for the products they buy in a manner that is not only tailored to their specific needs,

but is also aesthetically appealing and constantly refreshed. Federal and state governments, for example, can be limited in their ability to frequently refresh and update the consumer experience due to the length of time it can take to award vendor contracts.¹² Finally, we have heard criticisms from some stakeholders, including agents, brokers, and web-brokers, that the Exchange-operated eligibility application and enrollment website model competes directly with and may crowd out market players such as web-brokers, licensed agents and brokers, and issuers, dampening commercial investments in outreach and marketing by these market players to reach new consumers, including those who are currently uninsured.

We believe that both the FFE's DE and EDE pathways have promoted innovation and competition in states whose consumers use *HealthCare.gov* and have ultimately led to better experiences for consumers in these states. The FFE's Classic DE pathway has been in operation since the launch of the FFE in 2013. The FFE EDE pathway has been in operation since 2018. Together, for the 2020 Plan Year, the Classic DE and EDE pathways were responsible for approximately 29 percent of FFE enrollments. The recent experience from the 2021 Open Enrollment Period shows substantial growth in the use of the EDE pathway. The number of consumers who enrolled through the EDE pathway more than doubled from the prior 2020 Open Enrollment Period—increasing from approximately 521,000 to 1,130,000 plan selections, representing 37 percent of FFE enrollments.

Currently, the *HealthCare.gov* eligibility application and enrollment website and approved private sector non-Exchange websites operate in parallel to enroll consumers in

¹² For example, Federal contracting rules generally require full and open competitions under which federal agencies must seek proposals to fulfill an agency's needs for contractor services. See 10 U.S.C. 2304 and 41 U.S.C. 3301. These competitions generally last for months and may impede an agency's ability to quickly engage a vendor for the information technology services like those that may be necessary to update, improve, or otherwise address issues with the consumer shopping, eligibility, and enrollment experience. Moreover, even if a federal or state agency has a suitable contract in place that covers such services, there may not be sufficient funds allocated to the contract or otherwise available to the agency to cover the services at the time they are needed or desired. In these situations, government agencies like State Exchanges and HHS may be required to delay the services until a future funding cycle. Commercial entities like DE and EDE entities generally do not face such impediments and may more readily respond to consumer needs and preferences.

individual market QHPs offered through the FFEs and SBE-FPs. Like Exchange-operated websites, non-Exchange websites operated by Classic DE and EDE entity partners in FFE and SBE-FP states are required to provide standardized comparative information to assist consumers shopping for coverage.¹³ DE entities are also able to provide assistance with a broader array of plan options, including both on- and off-Exchange plan options and ancillary products. These additional coverage options are important for many consumers who do not qualify for premium tax credits or have less incentive to enroll in Exchange coverage, including employees with an offer of an affordable individual coverage HRA who may wish to opt into that coverage, as well as employees offered both an individual coverage HRA and a cafeteria plan because section 125(f)(3) of the Code specifically prohibits using salary reduction contributions under a cafeteria plan to purchase on-Exchange coverage.¹⁴ Finally, the FFE's EDE pathway helps to reduce costs to the federal government by enrolling many consumers without using the FFEs' eligibility application intake and enrollment resources (for example, the Marketplace call center and the *HealthCare.gov* website).

To build on the success of the FFE's Classic DE and EDE pathways in FFE and SBE-FP states that use *HealthCare.gov*, and to offer additional flexibility to all Exchanges, we proposed a new opportunity for states to adapt Exchange activities to the needs of local state markets and leverage the benefits of direct enrollment to enhance the consumer experience through a private sector-focused consumer engagement and enrollment strategy. We proposed to add § 155.221(j) to establish a process for states to elect a new Exchange Direct Enrollment option (Exchange DE option) in which a state can request to allow private sector entities (including QHP issuers, web-brokers, agents and brokers) to operate enrollment websites through which consumers can apply, receive an eligibility determination from the Exchange, and purchase an individual market QHP offered through the Exchange with advance payments of the premium tax credit (APTC) and cost-sharing reductions (CSRs), if otherwise eligible.

¹³ See, for example, 45 CFR 155.220(c)(3)(i)(A) (for web-brokers) and 156.1230(a)(1)(ii) (for QHP issuers).

¹⁴ As detailed in the proposed 2022 Payment Notice, there is a growing cohort of consumers who may be interested in off-Exchange coverage options. See 85 FR 78616–78619.

We proposed in § 155.221(j) that, subject to HHS approval, a state may elect for the Exchange in the state to engage one or more entities described in paragraph (a) ¹⁵ to facilitate QHP enrollments through its Exchange. Under this option, similar to the current FFE DE program, approved DE entities would enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange ¹⁶ and would also assist individuals in applying for, and receiving eligibility determinations from the Exchange, for APTCs and CSRs.

In § 155.221(j)(1), we proposed requirements that would apply to traditional State Exchanges that do not rely on the federal eligibility and enrollment platform that want to pursue the Exchange DE option and become an SBE–DE. In § 155.221(j)(2), we proposed requirements that would apply to states with an FFE or SBE–FP ¹⁷ that want to pursue the Exchange DE option and become an FFE–DE or SBE–FP–DE. We proposed that, subject to HHS approval, the Exchange DE option may be implemented in states with a State Exchange starting in plan year 2022. We proposed that, subject to HHS approval, the Exchange DE option may be implemented in states with an FFE or SBE–FP starting in plan year 2023.

Under the Exchange DE option, states would be able to request to adopt a private sector-based enrollment approach as an alternative to the consumer-facing enrollment website

operated by the Exchange (for example, *HealthCare.gov* for the FFEs). This decentralized, private sector-focused approach would transition application and enrollment functions to websites operated by approved partners (DE partners) to serve as the online platform(s) through which consumers apply for and enroll in individual market QHPs offered through the Exchange in their state, as well as apply for and receive determinations of APTC and cost-sharing reduction (CSR) eligibility for QHP coverage offered through the Exchange. The Exchange in a state that elects this option would implement a direct enrollment pathway (or pathways) with secure connections between its back-end eligibility determination system and the websites (or systems) of approved issuers, web-brokers, or agents and brokers that enable consumers to complete and submit the single streamlined eligibility application as described in § 155.405, receive an eligibility determination from the Exchange, select a plan and enroll in a QHP, with or without APTC and CSRs (if otherwise eligible). Exchanges would continue to be responsible for meeting, and ensuring its approved DE partners meet, all applicable statutory and regulatory requirements governing application for and enrollment in QHPs and other applicable state health subsidy programs.¹⁸ Under the Exchange DE option, the Exchange would also remain the entity responsible for making all determinations of whether an applicant is eligible for QHP enrollment, APTC, and CSRs, assessing or determining whether an applicant is eligible for Medicaid or CHIP, and conducting required verifications of consumer eligibility against trusted data sources. The Exchange would also continue to be responsible for sharing eligibility determination and enrollment information in coordination with issuers and HHS in accordance with 45 CFR 155.400, 155.430, and 155.340. The Exchange will continue to issue the applicable APTC to carriers on behalf of qualified individuals, and continue to be responsible for sharing this information with the IRS to support reconciliation of APTC on individual tax returns.

Consistent with section 1311(d)(4)(F) of PPACA and 45 CFR 155.302, under the Exchange DE option, the Exchange would also continue to be responsible for conducting assessments or determinations of eligibility for

Medicaid and CHIP, and where appropriate, for referring individuals who are assessed or determined eligible for Medicaid or CHIP to the appropriate state Medicaid agency for enrollment in those programs.¹⁹

In proposing the Exchange DE option, we noted that the applicable statutory provisions do not require Exchanges to operate an enrollment website. Rather, section 1311(d)(4)(C) of PPACA provides that an Exchange must maintain an internet website through which enrollees and prospective enrollees of QHPs may obtain standardized comparative information on QHPs available in the state. Within the statutory framework, these are some of the specific minimum functions an Exchange must undertake to facilitate the purchase of QHPs under section 1311(b)(1)(A) of PPACA and make available QHPs to qualified individuals and employers under section 1311(d)(2)(A) of PPACA. These minimum functions facilitate the purchase of QHPs by helping to make the purchase of QHPs easier and administering elements of the structure necessary to make QHPs available. An Exchange can continue to meet these obligations without operating a singular consumer-facing eligibility and enrollment website. In the context of operating an internet website, we interpret the statutory language at section 1311(c)(5) and (d)(4)(C) of PPACA to require that Exchanges provide consumers with the ability to view comparative information on QHP options, but that the Exchange may direct consumers to other entities or resources for purposes of submitting applications for eligibility and enrolling in QHPs, with APTC and CSRs, if otherwise eligible. We further explained that Exchanges, rather than DE entities, in states that elect to pursue this new option would continue to be responsible for determining eligibility for, and granting, exemption certifications under section 1311(d)(4)(H) of PPACA, as applicable; making available an electronic calculator consistent with section 1311(d)(4)(G) of PPACA; establishing a Navigator program as required under section 1311(d)(4)(K) of PPACA; and providing for the operation of a toll-free telephone hotline under section 1311(d)(4)(B) of PPACA.

¹⁹ Section 1311(d)(4)(F) of PPACA requires Exchanges to inform individuals of eligibility requirements for Medicaid, CHIP, or any applicable state or local public programs and, if through screening of the application the Exchange determines such individuals are eligible for any such program and refer such individuals to the appropriate state Medicaid agency for enrollment in such program(s).

¹⁵ Section 155.221(a) identifies QHP issuers and web-brokers as eligible direct enrollment entities.

¹⁶ Section 1401(a) of PPACA added new section 36B to the Code, which provides for PTCs for eligible individuals, while section 1402 of PPACA provides for CSRs for eligible individuals. For individuals to be eligible to receive PTCs, among other requirements, PPACA requires that individuals be enrolled in a QHP through an Exchange. CMS has interpreted this statutory language to allow a QHP issuer to enroll an applicant who initiates enrollment directly with the QHP issuer. See § 156.1230, whereby individuals enrolling directly on the site of a QHP issuer are considered enrolled “through an Exchange” so long as the issuer meets applicable requirements. We adopted a similar approach to allow a web-broker to enroll an applicant who seeks to enroll through the web-broker’s website. See § 155.220(a)(2) and (c), whereby individuals enrolling directly through the site of a web-broker are considered enrolled “through an Exchange” so long as the web-broker meets applicable requirements.

¹⁷ As detailed further below, states with an SBE–FP can request to pursue the Exchange DE option as an SBE–FP–DE. If a state that currently operates an SBE–FP is interested in transitioning to a full State Exchange that implements this Exchange DE option, it would need to update its Blueprint accordingly, and meet statutory and regulatory requirements to become a State Exchange implementing the Exchange DE option (an SBE–DE). Such requirements include operating its own eligibility and enrollment platform rather than relying on the federal platform.

¹⁸ See section 1413(e) of PPACA for a definition of the term “applicable state health subsidy program.”

In connection with the Exchange DE option, the Exchange would also be required to make available a website listing basic QHP information for comparison, and a listing with links to approved partner websites for consumer shopping, plan selection, and enrollment activities. Consistent with section 1311(d)(4)(E) of PPACA, the comparative plan information presented on the Exchange website would need to continue to utilize a standardized format, including the use of the uniform summary of benefits and coverage established under section 2715 of the PHS Act.²⁰ The standardized comparative information displayed on Exchange websites must also continue to include the quality ratings assigned to each QHP offered through the Exchange.²¹ Finally, the Exchange, along with its issuers and registered agents and brokers, which may also function as DE entities, would continue to be responsible for meeting federal accessibility standards under 45 CFR 155.205(c) for individuals living with disabilities and for individuals who have limited English proficiency.²²

Through private sector partners such as web-brokers and issuers, states may pursue alternatives to *HealthCare.gov* or other centralized, publicly-operated Exchange enrollment websites to enhance the consumer experience and provide additional incentives for insurers and licensed agents and brokers to conduct marketing and outreach to enroll more consumers in coverage. While states may consider creating enhanced commission structures or providing other market-based incentives, we also recognize the inherent incentive to issuers, web-brokers, and agents and brokers that will result from removing what some stakeholders view as a dominant public-sector competitor, making them the primary channels through which individuals shop for and enroll in individual market QHPs in those

states.²³ In the proposed rule we recognized that consumers who apply and enroll through a DE partner will have the benefit of assistance from a state-licensed agent or broker if they so choose. These agents and brokers will have been recognized by the relevant state as possessing the specialized expertise necessary to help consumers choose between health insurance options.

(1) Federally-Facilitated Exchange Direct Enrollment (FFE–DE) and State Exchange on the Federal Platform Direct Enrollment (SBE–FP–DE) Option

We proposed an option for any FFE or SBE–FP state to request the use of direct enrollment as the avenue through which individual market consumers and qualified individuals can shop for and purchase a QHP offered through the Exchange in the state, and apply and receive determinations of eligibility for APTC and CSRs. While SBE–FP states have the authority and responsibility for certifying QHPs and performing consumer outreach and assistance activities, because they rely on the federal eligibility and enrollment platform and consumer-facing website, in this respect they are more similar to the FFE–DE model than the SBE–DE model. In addition, the current FFE DE program and accompanying requirements also apply in SBE–FP states.²⁴

Under the proposed FFE–DE and SBE–FP–DE option, *HealthCare.gov* would continue to provide the same standardized comparative information on QHP options that is available today. The FFE would post and maintain an up-to-date list on *HealthCare.gov* of approved direct enrollment partners operating in the state. As such, consumers would still be able to view comparative information on *HealthCare.gov* for all QHP options available in their area and would also be

able to access information to connect with approved direct enrollment partners in that state. In the event that any approved direct enrollment partner does not have the technical capability to process a consumer eligibility application, *HealthCare.gov* would process that application. The Exchange would continue to have responsibility for operating a toll-free call center to provide eligibility and enrollment support for all consumers, pursuant to 45 CFR 155.205(a). However, under the Exchange DE option, there may be some cases where the DE partner may be best able to provide additional support to a consumer in completing their enrollment through the DE partner's website. We proposed to codify requirements at 45 CFR 155.221(j)(2)(ii), whereby a state that elects to implement the Exchange DE option must execute a federal agreement with HHS that defines the division of responsibilities between HHS and the state. This would include the Exchange's responsibilities, as well as DE partners' responsibilities for various activities, such as those pertaining to operating a toll-free call center to provide eligibility and enrollment support for consumers that enroll in coverage through an approved DE partner's website.

By leveraging private sector entities and directing consumers to approved direct enrollment partners, the vast majority of consumer traffic would flow to direct enrollment partners, leaving the *HealthCare.gov* structure in place primarily to provide the supporting functions that it does today, like the processing of data matching issues and special enrollment period verification documentation, casework, and eligibility appeals.

As noted above, the FFE would remain the entity responsible for making eligibility determinations and verifying whether an applicant is eligible for QHP enrollment, APTC and CSRs. The FFE would also continue to reconcile eligibility and enrollment information with issuers, in accordance with 45 CFR 155.340, 155.400, and 155.430, in order for HHS to issue the applicable APTC to carriers on behalf of qualified individuals, and would share similar information with the IRS to facilitate the IRS' reconciliation of APTC on individual tax returns. Under this option, given that an FFE–DE state or SBE–FP–DE state would use one or more participating, federally-approved Classic DE and EDE entities, at a minimum, the FFE privacy and security standards²⁵ and the FFE DE program

²⁰ See 45 CFR 155.205(b).

²¹ See section 1311(d)(4)(D) of PPACA and 45 CFR 155.205(b). Also see sections 1311(c)(3) and (c)(4) of PPACA and 45 CFR 155.1400 and 1405.

²² Covered entities such as States, recipients of Federal financial assistance from HHS, programs or activities administered by HHS under title I of PPACA (such as the FFE), and programs or activities administered by any entity established under Title I (such as State Exchanges), must comply with applicable federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex, age, and disability. These laws include Section 1557 of PPACA (42 U.S.C. 18116) (Section 1557), Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) (Title VI), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (Section 504), and the Americans with Disabilities Act of 1990 (29 U.S.C. 12101 *et seq.*) (ADA).

²³ Removing this public-sector competitor may be of particular interest due to the competitive advantage Exchanges hold over web-brokers under federal user fee and medical loss ratio (MLR) regulations. Consumers pay for both Exchange user fees and web-broker commissions indirectly through higher premiums. However, Exchange user fees and web-broker commissions are accounted for differently in the MLR calculation. Exchange user fees, a portion of which are used to fund Exchange-operated eligibility and enrollment websites that could be considered to be competitive with EDE interfaces, are treated as taxes, which makes it easier to meet the MLR requirement. In contrast, web-broker commissions count toward administrative costs, which makes it harder for issuers to meet the MLR requirements. This MLR accounting disparity on that portion of the Exchange user fees arguably disadvantages EDE entities.

²⁴ See, for example, 45 CFR 155.220(l) and 155.221(h).

²⁵ See 45 CFR 155.260 through 155.285.

requirements²⁶ would continue to apply.

We proposed in § 155.221(j)(2) that a state with an FFE or SBE-FP may request to pursue the FFE-DE or SBE-FP-DE option starting in plan year 2023, as applicable. We proposed that, pursuant to a request from the state, HHS may partner with the requesting state to implement the direct enrollment option described in paragraph (j). The FFE or SBE-FP must meet all applicable federal statutory and regulatory requirements for the operation of an Exchange, including maintaining the single, streamlined eligibility application required under § 155.405. To obtain HHS approval to implement this option, the state must coordinate with HHS on an implementation plan and timeline that allows for a transition period, developed at the discretion of HHS in consultation with the state, necessary to operationalize the required changes to implement this option. We proposed to codify these new requirements at paragraph (j)(2)(i). Additionally, we proposed to codify requirements at paragraph (j)(2)(ii), whereby the state must execute a federal agreement with HHS that includes the terms and conditions for the arrangement and that defines the division of responsibilities between HHS and the state. Further, to obtain HHS approval to implement the FFE-DE or SBE-FP-DE option, we proposed at § 155.221(j)(2)(iii) that the state must agree to procedures developed by HHS for the collection and remittance of the monthly user fee described in § 156.50(c) in support of the responsibilities undertaken by the state and HHS. Finally, we proposed at paragraph (j)(2)(iv) that the state would be required to perform and cooperate with activities established by HHS related to oversight and financial integrity requirements in accordance with section 1313 of PPACA, including complying with reporting and compliance activities required by HHS and described in the Federal agreement entered into pursuant to paragraph (j)(2)(ii).

(2) State Exchange Direct Enrollment Option (SBE-DE)

We proposed that a State Exchange that does not rely on the federal eligibility and enrollment platform can also elect the Exchange DE option to engage approved private-sector entities as the pathway (or pathways) for consumers in their state to apply for, and enroll in, QHPs offered through the Exchange. Under this option, the State

Exchange would remain responsible for continuing to operate an internet website to provide the same standardized comparative information on QHP options that is available today and for making eligibility determinations via its eligibility rules engine for consumers applying for APTC, CSRs, and enrollment in QHPs offered through the Exchange. However, this new option would permit multiple private entities, such as a combination of web-brokers and QHP issuers, to provide the consumer-facing resources for consumers to apply for and enroll in individual market coverage offered through the Exchange. State Exchanges that pursue this option could thereby leverage direct enrollment technology and direct consumers to approved partner non-Exchange websites to apply for APTC and CSRs, as well as select and enroll in a QHP offered through the Exchange (if otherwise eligible). In the event that direct enrollment partners in the state do not have the technical capability to process any consumer's application, the State Exchange would be required to maintain the capability to process that application through its own consumer-facing website.

We proposed in § 155.221(j)(1) that a state with a State Exchange that does not rely on the federal eligibility and enrollment platform may request approval to pursue the SBE-DE option by submitting a revised Exchange Blueprint within 90 days of their targeted launch date, in accordance with § 155.105(e) to do so.²⁷ We also proposed that the State Exchange must meet all other applicable federal statutory and regulatory requirements for the operation of an Exchange, including establishing and maintaining the single, streamlined eligibility application under § 155.405. Following submission of a revised Exchange Blueprint, HHS would have up to a total of 90 days²⁸ to review this revised submission and render a decision as to approval. We proposed to codify the new requirement at § 155.221(j)(2)(ii)

²⁷ This approach is consistent with the framework established in prior rulemakings that require a state to notify HHS and receive written approval from HHS before significant changes are made to the Exchange Blueprint. See, for example, 77 FR at 18316. Significant changes could include altering a key function of Exchange operations or other changes to the Exchange Blueprint that would have an impact on the operation of the Exchange. This includes, but is not limited to the process for enrollment in a QHP. See, for example, 76 FR at 41871.

²⁸ As detailed in § 155.105(e), HHS generally has 60 days after receipt of a completed request to complete its review of a significant change to an Exchange Blueprint and, for good cause, may extend the review period by an additional 30 days up to a total of 90 days.

that, to obtain HHS approval, the state would need to provide HHS an implementation plan and timeline that details the key activities, milestones, and communication and outreach strategy to support the transition of enrollment operations to direct enrollment entities. Additionally, in accordance with § 155.105(c) and the new requirement proposed at § 155.221(j)(1)(ii), a State Exchange that implements the SBE-DE option would be required to demonstrate to HHS operational readiness for the State Exchange and its proposed direct enrollment entities to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and to enable individuals to apply for APTC and cost sharing for QHPs.

While we proposed that State Exchanges that elect to implement the Exchange DE option would retain the flexibility to determine their own business controls, as well as to decide the state-specific requirements and mechanisms for approval and oversight of direct enrollment entities operating in the state, we would encourage these states to review and adopt processes and standards similar to those in the existing FFE federal direct enrollment and EDE framework, as described in 45 CFR 155.220, 155.221, 156.1230, and in sub-regulatory guidance.²⁹ Moreover, we proposed to codify a new requirement at § 155.221(j)(1)(iii) whereby State Exchanges that elect to implement the Exchange DE option are obligated to ensure that a minimum of one state-approved direct enrollment entity meets the minimum federal requirements applicable to DE entities that seek approval to participate in the FFE DE program, including requirements at 45 CFR 155.220 and 155.221, and is capable of enrolling all consumers in the state. In particular, we explained that we believe it is critical that State Exchanges that elect to implement the Exchange DE option ensure, at a minimum, that at least one approved web-broker DE entity meets requirements that align with the FFE standards under 45 CFR 155.220(c)(3)(i)(A) and (D)³⁰ to ensure

²⁹ See generally CMS guidance for becoming a web-broker in the FFEs, available at: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf>.

³⁰ In addition to ensuring there is at least one website available in the state that satisfies all accessibility requirements under § 155.205(c), we proposed that there must also be at least one website available in the state through which consumers can view and enroll in all available QHPs in the state.

²⁶ See 45 CFR 155.220, 155.221, and 156.1230.

consumers have at least one option through which to view detailed QHP information for all available QHPs in the state that also meets accessibility requirements under 45 CFR 155.205(c). Therefore, we proposed that if no direct enrollment partner in an SBE-DE state meets these requirements, the state would be required to continue operation of its own Exchange website to ensure there is one enrollment pathway in the state that does. To assist states in meeting requirements to become an SBE-DE, we noted that states would have the flexibility to partner with an existing, HHS-approved web-broker direct enrollment partner as a starting point to develop their own direct enrollment programs, as these entities would have already met requirements for HHS approval to participate in the FFE's DE program.

We requested comment on all aspects of these proposals, including any comments related to timing, governance, and any other considerations needed to effectively operationalize these proposed FFE-DE, SBE-FP-DE, and SBE-DE options. The following is a summary of the comments we received and our responses.

Comment: We received several comments that expressed support for the proposed Exchange DE option because of the flexibility it provides, noting that the Exchange DE option will increase consumer choice and competition among DE entities, potentially leading to reduced costs for consumers. These comments also included caveats or recommendations. For example, one commenter recommended delaying implementation of the proposed Exchange DE option pending additional stakeholder consultation to further explore potential advantages or disadvantages of the proposed Exchange DE option, including conducting consumer focus groups, accounting for operational considerations for QHPs and stand-alone dental plans (SADP), and conducting an assessment of the potential impact of the Exchange DE option on enrollment and premiums. One commenter recommended additional consumer support options be made available, namely the adoption of controls to ensure non-QHP options are readily-identifiable. Another commenter recommended that HHS work closely with DE entities, including issuers, in advance of implementation of the proposed Exchange DE option to further develop operational requirements. This commenter also recommended that there be one primary website available to consumers to enter their information

so that they do not have to complete multiple eligibility applications.

Response: We appreciate commenters' support for this option and are finalizing with some minor clarifying edits to the regulatory text. We believe the Exchange DE option will provide states and Exchanges with additional flexibility to tailor consumers' health insurance shopping experience, allowing states and their residents to reap the expected potential benefits of leveraging private sector DE partners, including increased choice in consumer experience to complete the enrollment process, access to information on additional plan options, and lower costs. We also underscore that this option is strictly permissive for states, and we welcome states that are interested in pursuing these options to undertake research, stakeholder consultation particularly with issuers and web-brokers, and data gathering at the state level to inform any operational requirements related to how the Exchange DE option is implemented to ensure it is tailored to meet the needs of their residents.

We also believe it is important for consumers to have access to tools and resources to compare their coverage options. Under the Exchange DE option, consumers will be able to view standardized information to compare QHPs using the website of their choice, and will still be able to access *HealthCare.gov* (or similar information technology infrastructure in a state with a State Exchange) should they choose to, or if necessary. Consumers will also continue to have access to other Exchange tools and resources—such as the single, streamlined eligibility application, a toll-free telephone number to request assistance, an electronic calculator to determine the actual cost of coverage after the application of any APTC and CSRs, as well as Navigators, other Assistors, and licensed agents and brokers. As detailed elsewhere in this final rule, at a minimum, the existing FFE DE program requirements will continue to apply in any state that is approved to implement an FFE-DE or SBE-FP-DE. These existing requirements include several safeguards to ensure non-QHP options are readily identifiable.³¹ For SBE-DE states, we finalize in § 155.221(j)(1)(iii)

³¹ See, for example, 45 CFR 155.221(b)(1)–(3). In the proposed rule, we proposed to provide additional flexibilities regarding the plan display standards currently captured at 45 CFR 155.221(b)(1) and (3) in certain circumstances. See 85 FR at 78616–78618. We intend to address these proposals in future rulemaking and, if finalized, would also consider and address the intersection with the new Exchange DE option as necessary or appropriate.

the requirement for the state to ensure that a minimum of at least one DE entity approved by the state meets minimum federal requirements to participate in the FFE DE program (including the FFE's plan display requirements) and we encourage these states to more broadly adopt standards similar to the existing FFE DE program for all DE partners approved by the state.

We believe that the Exchange DE option will drive the private sector to make consumer-centric investments that will improve consumers' shopping experiences, as these private entities are incentivized to provide the best possible consumer experience to retain their consumer base year-over-year and to attract new consumers each year. While the Exchange DE option is not available today, with an expanded available customer base, issuers, web-brokers, and individual agents and brokers will have an increased incentive to invest in providing the resources necessary to serve a majority of consumers, and in focusing marketing and outreach activities to attract new consumers, including the currently uninsured population. We believe these increased incentives to invest in the consumer enrollment experience will, over time, increase consumer enrollment by persons who would not otherwise have enrolled, a potentially healthier population who may improve the health of the risk pool and lead to lower premiums.

Comment: Nearly all commenters on this rulemaking cautioned about potential harmful impacts to consumers from the introduction of the Exchange DE option. Commenters asserted that the Exchange DE option may effectively eliminate access to *HealthCare.gov* and State Exchange websites, by allowing access to apply and enroll for QHP coverage through multiple private websites operated by DE entities. Commenters believed that because existing Exchange consumers have established relationships with, and have relied on, the centralized Exchange enrollment website in their state to serve as an unbiased resource to provide eligibility determinations, enroll in QHPs, and receive APTC/CSR eligibility determinations, the Exchange DE option would result in a new, fragmented process that would likely lead to consumer confusion and mistrust. They further stated that the negative impacts of effectively eliminating the Exchange-run enrollment websites as an option would outweigh the benefits of making this new option available to consumers. One commenter, which operates as an EDE entity, noted that while DE entities account for a significant volume of

HealthCare.gov enrollment today, elimination of the centralized FFE or SBE enrollment platforms would lead to various forms of disruption for the majority of consumers who already are accustomed to relying on an Exchange-operated website for enrollment.

Response: We understand commenters' concerns about the potential impact of the Exchange DE option and acknowledge that any transition or change can be unsettling and disruptive. However, we disagree that the potential negative impacts of the Exchange DE option outweigh the benefits given the success of the Federal DE and EDE pathways, and we note that the Exchange DE option is not a requirement for states, and that states have ample flexibility to tailor operational requirements and any transition steps to the needs of their health care markets. We also note that several states have made full transitions from the FFE to become an SBE, providing models of successful transitions to new enrollment platforms with minimal disruptions. In addition, an Exchange in a state that elects this option must at a minimum continue to operate an internet website that provides the same standardized comparative QHP information that is available today, along with an up-to-date listing of approved DE entities operating in the state. We believe that the continued availability of this website will mitigate any potential consumer confusion caused by the availability of multiple enrollment pathways. We further note that in states that choose to implement the Exchange DE option, the Exchange will remain available to consumers whose eligibility applications cannot be processed by an approved DE entity. States choosing the Exchange DE option also have the flexibility to continue making available its Exchange eligibility and enrollment website despite the availability of DE partner websites, or to define other instances in which the Exchange enrollment website would be available to consumers, including instances in which a consumer makes a request to apply through an Exchange-run website. We are also requiring that Exchanges in states choosing to implement the Exchange DE option continue to meet all applicable statutory and regulatory requirements. This includes, but is not limited to, the Exchange retaining responsibility for making all determinations of whether an applicant is eligible for QHP enrollment, APTC, and CSRs, conducting required verifications of consumer eligibility against trusted data sources, and

conducting assessments or determinations of eligibility for Medicaid and CHIP for all applicants, and where appropriate, refer individuals assessed or determined eligible for such coverage to the appropriate state Medicaid agency for enrollment in those programs. Consumers will therefore continue to have access to an unbiased resource for comparative QHP information and eligibility determinations in states that elect this option. We also strongly encourage DE entities to undergo appropriate coordination efforts with the Exchange. In particular, additional coordination will be required to ensure consumer communications, particularly consumer eligibility notices sent by the Exchange regarding coverage obtained by enrolling through a DE entity website do not result in consumer confusion.

The FFE already has experience transitioning consumers already enrolled in Exchange coverage through *HealthCare.gov* between enrollment platforms to new State Exchange platforms as evidenced by the successful transitions of SBE-FP states to SBE states. Most recently, ahead of the plan year 2021 open enrollment period, New Jersey and Pennsylvania transitioned from SBE-FPs to SBEs. Among the most critical work streams associated with these transitions was the migration of these states' consumer eligibility and enrollment data from *HealthCare.gov* to the respective State Exchange eligibility and enrollment platforms such that existing Exchange consumers could re-enroll directly through the State Exchange. We believe that any consumer disruptions can be minimized during a transition process by incorporating safeguards during the transition, such as robust stakeholder consultation with issuers and other partners, proactive coordination with other state agencies, targeted consumer outreach and education, and contingency planning to ensure consumers can fall back on *HealthCare.gov* if needed. The implementation plans developed under § 155.221(j)(1)(ii) and (j)(2)(i) should include details on any such measures. In addition, for states pursuing the SBE-DE option, HHS intends to examine these types of issues as part of the operational readiness assessment under § 155.221(j)(1)(i). Based on the FFE's experience, we expect that given the ability of existing DE entities to meet consumer needs and reduce burden on Exchanges, introducing DE entities as the primary consumer-facing pathway to enroll in coverage in states that elect

this new option will be beneficial to all stakeholders.

Comment: An overwhelming majority of commenters on this rulemaking argued that there are potential conflicts of interest, particularly financial incentives, that would put DE entities at odds with consumers seeking coverage and the policy goals of PPACA. Commenters noted that the proposed Exchange DE option will increase the incentive for DE entities, particularly agents and brokers, to compete among each other for commissions, which could lead to consumers being directed to the most profitable products, rather than those best-suited for their health care needs. Several commenters emphasized that, in many cases, the most profitable product for DE entities is non-QHP coverage. Commenters thus fear that the Exchange DE option could lead to deceptive marketing practices and an increase in fraud, as well as more consumers who are uninsured, or who enroll in coverage even if it does not adequately meet their health care needs. Commenters were also concerned that the Exchange DE option could result in consumers being steered toward less robust non-comprehensive coverage (for instance, short-term limited duration insurance (STLDI) plans) that generally bring higher commissions to agents and brokers and web-brokers, but do not meet PPACA requirements. Commenters also asserted that consumers could be required to pay higher out-of-pocket costs because they did not receive information related to, or were misinformed about, the availability of Exchange financial assistance. A few commenters raised similar concerns related to Navigators and other Exchange assisters using DE entity websites to enroll consumers since consumers could be misled by the inclusion of non-QHP products on the DE entity websites, by the omission of critical information related to coverage options, or by confusion that could result when consumers are required to visit multiple DE entity websites to review comprehensive information on all available QHPs in a state.

Several commenters also raised concerns about protecting consumer privacy and security under the Exchange DE option, under which a consumer must share personally identifiable information with a private DE entity that could be misused in the absence of a robust regulatory framework to protect against this abuse.

We also received many comments that cautioned against potential negative impacts of working with DE entities to coordinate coverage with other insurance affordability programs. In

particular, commenters noted that DE entities generally do not have the incentive or expertise to ensure consumers receive a Medicaid eligibility assessment or determination, and to subsequently transfer them to the appropriate state website to complete the enrollment process. These commenters requested additional information on how HHS would ensure that this coordination of coverage will occur in order for HHS to maintain its “no wrong door” policy.

Response: We acknowledge that there must be sufficient oversight of all states approved to implement the Exchange DE option, as well as oversight of the DE entities themselves, to ensure the proper alignment and management of incentives. The many comments we received that raised concerns around potential misalignment of incentives and conflicts of interest serve to highlight key areas where HHS and the states can be proactive to implement additional controls and work closely with DE entities to prevent fraud, waste, and abuse, particularly with respect to protecting against deceptive marketing and inappropriate steering. We reiterate that, at a minimum, the existing FFE DE program requirements will continue to apply in any state that is approved to implement an FFE-DE or SBE-FP-DE. These existing requirements include safeguards to protect against deceptive marketing practices and ensure consumers have the information they need to make informed decisions.³² For SBE-DE states, we finalize in § 155.221(j)(1)(iii) the requirement for the state to ensure that a minimum of at least one DE entity approved by the state meets minimum federal requirements to participate in the FFE DE program (including the FFE’s safeguards to protect against deceptive marketing practices and ensure consumers have the information needed to make informed decisions) and we encourage these states to more broadly adopt standards similar to the existing FFE DE program for all DE partners approved by the state. We note too that recent federal legislation addressing surprise billing³³ generally requires issuers of STLDI plans to disclose to potential enrollees any broker commissions for STLDI plans prior to plan selection. This transparency requirement should further mitigate risk presented by any misalignment of

incentives that could result in inappropriate steering. Other controls could also be implemented by states to check misalignment of incentives and mitigate the risk that DE entities will improperly steer consumers toward non-QHP products and allow consumers to make informed choices.

We also reiterate that DE entities operating under the FFE-DE and SBE-FP-DE options would be required to meet FFE privacy and security standards while SBE-DEs have the flexibility to ensure similar standards are in place to protect consumer information. HHS intends to continue to strengthen the regulatory and operational controls that would apply to DE entities operating in FFE and SBE-FP states that elect this option to ensure that sufficient protections are in place. Generally, assuming due diligence and appropriate regulatory and operational safeguards to ensure oversight over DE entities, and taking into account that these organizations have a strong business interest in serving their customers effectively to maintain their customers, we believe that the balance of risk is acceptable. Thus, we believe that the potential benefits of the Exchange DE option outweigh the burdens of oversight and the risk of fraud, waste, and abuse.

We also agree that it is important for consumers to continue receiving Medicaid and CHIP eligibility assessments or determinations when they apply for Exchange QHP enrollment and financial assistance through DE entities. In states implementing the Exchange DE option, the Exchange would still be required to establish and maintain the single, streamlined eligibility application as required under § 155.405, and make eligibility assessments and determinations of Medicaid or CHIP eligibility as required under § 155.302. Exchanges would also remain the entity responsible for making all determinations of whether an applicant is eligible for QHP enrollment, APTC, and CSRs, conducting required verifications of consumer eligibility against trusted data sources, and SBE-FPs and FFEs that elect this option can choose among HHS-approved entities already operating through the FFE’s DE program, and we are requiring SBE-DEs to have at least one DE entity with whom they partner that can display and allow for enrollment in all QHPs available in the state. We also intend to work closely with states electing this option to ensure that they meet these and other applicable requirements, and that there are appropriate back-end application interfaces in place between

the Exchange’s eligibility platform and approved DE entities to ensure that all consumers have a seamless experience completing the single, streamlined eligibility application and receiving an eligibility determination just as if they were applying for coverage directly through the Exchange website. These are examples of the areas HHS intends to focus on when assessing an SBE-DE state’s operational readiness under § 155.221(j)(1)(i) and implementation plan under § 155.221(j)(1)(ii). For states interested in pursuing the FFE-DE or SBE-FP-DE option, these are areas that would need to be considered and addressed, as appropriate, as part of the implementation plan under § 155.221(j)(2)(i) and the Federal agreement under § 155.221(j)(2)(ii). While we acknowledge comments that the Exchange DE option could produce a disjointed enrollment process to a certain degree for some consumers, we believe that the benefits of providing consumers with more options outweigh the drawbacks, especially since they will still be completing the single, streamlined eligibility application on an approved DE partner’s website in order to access APTCs and CSRs, or access Medicaid and CHIP coverage, if eligible. We also believe our focus on coordinating closely with states as part of the rollout process and transition to the Exchange DE option will help mitigate any risk of a reduction in Exchange or Medicaid and CHIP enrollment, as well as any potential increase in the uninsured.

Finally, the availability of the Exchange DE option does not directly affect the existence or operation of Navigator and other assister programs created by PPACA. As indicated above and detailed in the proposed rule, states that implement the Exchange DE option (DE states) will still be required to establish a Navigator program as required under section 1311(d)(4)(K) of PPACA. In all states that are approved to implement the DE option, the Exchange in the state must continue to make available an internet website that provides the same standardized comparative information on QHP options that is available on Exchange websites today. Therefore, Navigators and certified application counselors (collectively assisters), as well as agents and brokers, in DE states will still be able to view on State Exchange websites or *HealthCare.gov*, as applicable, comparative information for all QHP options available in the state, and will also be able to access information to connect with approved DE entities in their states. Moreover, each DE state

³² See, for example, 45 CFR 155.220(j)(2)(i) and 156.1230(b)(2). Also see *supra* note 30.

³³ See Sec. 202 of Division BB of Public Law: 116–260, the Consolidated Appropriations Act, 2021, signed into law on 12/27/2020. <https://www.congress.gov/bills/116th-congress/house-bill/133>.

must ensure that at least one DE entity website is capable of processing all eligibility applications, including those that present complex enrollment scenarios, or else the state must continue to make available its own website that possesses such capability.

Finally, we note that the DE option requirements we finalize in this rule will provide Navigators and certified application counselors greater flexibility to effectively assist consumers than currently exists under the FFE's assister programs. For instance, in 2015 the FFE issued guidance (the 2015 guidance) instructing that FFE assisters should not use non-Exchange websites when providing enrollment assistance except as reference tools to supplement information on *HealthCare.gov*. But given the consumer protections that will apply in DE option states to ensure ready access to information on all QHPs available in a state (which include consumer-protective requirements that were not in place at the time we published the 2015 guidance),³⁴ there is no need to similarly limit assisters' ability to use DE entity websites to assist consumers.³⁵ We appreciate that actual implementation of the DE option will require states and HHS to closely monitor the program to ensure that consumers are receiving complete and accurate information and effective assistance. In the event HHS becomes aware of the need for additional or different DE option requirements, or greater clarity regarding DE option requirements, HHS may issue future guidance or pursue future rulemaking.

Comment: Many commenters argued that HHS does not have the legal authority under sections 1103, 1302, 1311, or 1312 of PPACA to permit states and Exchanges to implement the Exchange DE option. Some commenters also argued that the Exchange DE option violates the spirit and intent of PPACA and represents an attempt to replace congressional legislation in violation of the Administrative Procedure Act (APA). Other commenters argued that the Exchange DE option is not based on a reasonable interpretation of specific aspects of PPACA and implementing regulations. In particular, some commenters argued that the Exchange DE option violates Section 1311(d)(1) of

PPACA that requires that Exchanges be operated by a "governmental agency or nonprofit entity that is established by a State." Some commenters also argued that HHS does not have the authority to delegate essential government functions currently performed by Exchanges to private entities.

Response: We disagree. The Exchange DE option requires that participating states and HHS continue to meet all applicable requirements of PPACA, including applicable requirements under section 1311 of PPACA. This is captured in the regulatory text at § 155.221(j)(1) and (2), which states that Exchanges must meet all federal statutory and regulatory requirements for the operation of an Exchange. As detailed above and in the proposed rule, Exchanges in states that elect this option must continue to provide the required minimum functions established in PPACA and comply with applicable requirements. This includes the responsibility to make all determinations of whether an applicant is eligible for QHP enrollment, APTC, and CSRs; conducting required verifications of consumer eligibility against trusted data sources; conducting assessments or determinations of eligibility for Medicaid and CHIP, and where appropriate, referring individuals who are assessed or determined eligible for Medicaid or CHIP to the appropriate state agency for enrollment in those programs; certifying plans as QHPs, making QHPs available to consumers, and facilitating the purchase of QHPs; granting exemption certifications, as applicable; making an electronic calculator available; establishing a Navigator program; and providing for the operation of a toll-free telephone hotline. In the context of operating an internet website, we interpret the statutory language at section 1311(c)(5) and (d)(4)(C) of PPACA to require that Exchanges provide consumers with the ability to view comparative information on QHP options, but that the Exchange may direct consumers to other entities or resources for purposes of submitting applications for eligibility and enrolling in QHPs, with APTC and CSRs, if otherwise eligible. An Exchange can continue to meet these obligations without operating a consumer-facing enrollment website and Exchanges in states that elect this option must continue to operate a website that provides the same standardized comparative information about QHPs that is available today.³⁶ In addition, we

maintain that states choosing to transition to the SBE-DE or SBE-FP-DE option must still meet the requirements of Section 1311(d)(1) of PPACA.³⁷ The arrangements that states would make with the DE entities approved to provide a consumer shopping and enrollment portal would be no different than the current contracting arrangements that HHS enters into today with approved partners who participate in the FFE DE program. It is also similar to the arrangements Exchanges may enter into today to provide other services, such as a call center, to their consumers.³⁸ Finally, we note how the Exchange DE option aligns with the general structure of how PPACA assigns states substantial authority to administer provisions of the law—including giving states the primary responsibility to create Exchanges and relying on states as the primary enforcers of PPACA's insurance regulations and Exchange requirements.³⁹ Accordingly, HHS is of the view that the Exchange DE option is consistent with the language, spirit, and intent of PPACA and its implementing regulations and there is sufficient authority to permit states to pursue this option. Moreover, consumers would still have available to them a centralized website, operated by the Exchange, to obtain standardized comparative information about available QHPs, as

format to be used for the presentation of information on coverage option by July 1, 2010. See, for example, Health Care Reform Insurance Web Portal Requirements; Interim Final Rule with Comment Period, 75 FR 24470 (May 5, 2010). We also disagree with commenters who suggested that sections 1302 or 1312 of PPACA are legal obstacles to the adoption of the Exchange DE option. Section 1302 relates to the development of the essential health benefits package and accompanying benefit requirements (for example, requirements related to cost-sharing and actuarial value levels of coverage). Section 1312 establishes requirements related to consumer choice and the establishment of single risk pools by issuers. As such, section 1302 and section 1312's single risk pool provisions generally outline benefits, plan design, and rating requirements applicable to issuers of non-grandfathered health insurance coverage, and issuers must continue to comply with these requirements in any state that elects to adopt the Exchange DE option. The other provisions in section 1312, such as those related to consumers' choice of whether to enroll in coverage through an Exchange, the continued operation of the market outside the Exchanges, the option for states to allow agents or brokers to assist with Exchange enrollments, and the enrollment of members of Congress in plans offered through an Exchange also would continue to apply in states that elect to adopt the Exchange DE option and do not preclude our finalizing the Exchange DE option.

³⁷ For FFE states that elect and are approved to transition to the FFE-DE option, CMS, on behalf of HHS will continue to be responsible for operation of the Exchange consistent with section 1321(c)(1).

³⁸ See, for example, section 1311(f)(3).

³⁹ See section 2723(a)(1) of the PHS Act and section 1321(c)(2).

³⁴ See 85 FR 78613.

³⁵ As detailed in the proposed rule, we are also revisiting our policy regarding the ability of FFE assisters' use of web-broker non-Exchange websites. See 85 FR at 78611–78614. If finalized as proposed, this policy change would permit assisters in FFEs and SBE-FPs to also use web-broker non-Exchange websites to assist consumers with QHP selection and enrollment, provided certain conditions are met.

³⁶ We further note that HHS met its obligations under section 1103 of PPACA when it established the internet Portal and developed the standardized

well as information about and links to approved partners' enrollment websites. Finally, they would still have access to the Exchange itself to apply for, and enroll in, coverage should that be necessary. Given that states electing the Exchange DE option remain subject to the requirements of PPACA and its implementing regulations, we further disagree that the flexibility we are providing to meet those requirements constitutes an attempt to replace congressional legislation in violation of the APA.

Comment: Many commenters argued that the Exchange DE option is not legally permissible in the absence of a section 1332 waiver, and should only be approved through the section 1332 waiver process. Some commenters highlighted in particular the benefits of the section 1332 waiver public notice and comment process as an additional safeguard that they asserted would be beneficial to any state interested in pursuing the Exchange DE option. Some commenters further argued that Georgia's recent section 1332 waiver proposal to implement activities similar to those proposed under the Exchange DE option was wrongfully approved and that even if another state were to apply for a section 1332 waiver to implement the Exchange DE option, such a waiver plan would violate section 1332's coverage guardrail because they believe enrollment would generally be reduced.

Response: The merits of the Departments' decision to approve Georgia's section 1332 waiver is not in the scope of this rulemaking. However, we clarify that a section 1332 waiver is not required for a state to be approved for and to implement the Exchange DE option. Georgia's section 1332 waiver is distinguishable from the Exchange DE option we finalize here because states that elect and implement the Exchange DE option would still be required to meet all Exchange requirements under PPACA, while under its section 1332 waiver plan Georgia waived certain Exchange requirements under section 1311.⁴⁰ Moreover, under Georgia's section 1332 waiver, consumers in Georgia will no longer be able to access and utilize *HealthCare.gov*, and a state statute expressly prohibits the state from implementing a State Exchange and

from establishing a Navigator program or its equivalent.⁴¹

In contrast, in states that elect the FFE-DE or SBE-FP-DE option, consumers will continue to have the *HealthCare.gov* website available to them to view standardized comparative information about QHPs and the Exchange will be required to continue to operate its respective Navigator program. States that elect to become or transition to an SBE-DE would similarly be required to maintain and make available the State Exchange website for standardized comparative information, the state's respective Navigator program to assist consumers, and the state's associated eligibility rules engine to make eligibility determinations, as well as the state's enrollment platform, in the event that there is not a DE entity capable of processing a consumer's application. We also recognize the importance of a meaningful public notice and comment process, and note that states that elect to pursue the Exchange DE option have the discretion to provide for a state public notice and comment process should they deem it to be beneficial.

Comment: Many commenters noted that programmatic guardrails or operational parameters are not adequately defined and incorporated into the rule to allow for effective implementation of the Exchange DE option, particularly with respect to ensuring oversight over DE entities. In particular, commenters noted a lack of clarity about the responsibilities of DE entities regarding administering consumer education and assistance to ensure consumers are not confused or misled about their coverage options. In particular, commenters noted that it is not clear how HHS would ensure DE entities operate in an unbiased, transparent manner such that consumers can effectively compare and make an informed choice among all available QHP options, know when they are viewing non-QHP options, and receive information on public coverage options they may be determined eligible for, such as Medicaid and CHIP. Several commenters noted that we should be more definitive about the responsibilities of the DE entities regarding display of QHPs and choice of Exchanges should handle the scenario where a consumer wishes to enroll in an issuer's QHP when a particular DE entity is not appointed to sell products by that issuer.

Response: In proposing the Exchange DE option, we wanted to strike an appropriate balance to provide states with appropriate flexibility to implement the Exchange DE option in a manner that is tailored to the needs of their unique health care markets while still meeting the applicable federal requirements. We have included a broad framework of baseline federal requirements governing the Exchange DE option in this final rule and welcome states interested in pursuing this option to adopt any additional state-specific requirements they deem necessary to effectively oversee DE entities and protect consumers. It is important to note that the framework of programmatic parameters and federal requirements governing the Exchange DE option included in this final rule is meant to serve as a floor and not a ceiling. We also share commenters' concerns about ensuring effective oversight over DE entities and protecting consumers. As explained in the proposed rule, given that an FFE-DE or SBE-FP-DE state would use one or more DE entities approved to participate in the FFE DE program, at a minimum, the FFE privacy and security standards⁴² and the FFE DE program requirements⁴³ would continue to apply. This includes the requirement for web brokers under § 155.220(c)(3)(i)(B) to provide consumers with the ability to view all QHPs offered through the Exchange and the corresponding similar requirement for issuers at § 156.1230(a)(1)(ii); the requirement for web brokers under § 155.220(c)(3)(i)(A) to display QHP information comparable to information available on the Exchange website or display a subset of QHP information and a disclaimer with a link to the Exchange and the corresponding similar requirement for issuers at § 156.1230(a)(1)(iv); as well as the requirements at §§ 156.1230(b)(2) and 155.220(j)(2)(i) applicable to all DE entities to provide consumers with correct information, without omission of material fact, and refrain from marketing or conduct that is misleading, coercive, or discriminatory.

For SBE-DE states, we codify in § 155.221(j)(1)(iii) the requirement for the state to ensure that a minimum of at least one DE entity approved by the state meets minimum federal requirements for HHS approval to participate in the FFE DE program (including the examples highlighted in the prior sentence) and we encourage these states to more broadly adopt processes and standards similar to the

⁴⁰ As detailed in Georgia's approval letter and Specific Terms and Conditions (STCs), the Exchange requirements in sections 1311(b), (c), (d), (e) and (i) are waived to the extent they conflict with the Georgia Access Model as described in the state's approved waiver. See https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-1332-GA-Approval-Letter-STCs.pdf.

⁴¹ See O.C.G.A. sec. 33-1-23, available at: <https://law.justia.com/codes/georgia/2019/title-33/chapter-1/section-33-1-23>.

⁴² See 45 CFR 155.260 through 155.285.

⁴³ See 45 CFR 155.220, 155.221 and 156.1230.

existing FFE DE program for all DE partners approved by the state. At the same time, however, SBE-DE states would retain general flexibility to determine their own business controls, as well as to decide the state-specific requirements and mechanisms for approval and oversight of direct enrollment entities operating in the state. HHS would review and assess an SBE-DE state's process, standards and oversight approach for DE entities as part of the operational readiness assessment under § 155.221(j)(1)(i). We also intend to continue engaging stakeholders on, and develop, additional programmatic and operational requirements through future rulemaking and sub-regulatory guidance, as necessary or appropriate. Furthermore, additional technical assistance and operational details related to implementation of the FFE-DE and SBE-FP-DE options may be best defined and addressed during the development of the implementation plan under § 155.221(j)(2)(i) and the federal agreement that states electing to implement the FFE-DE or SBE-FP-DE option must execute with HHS under § 155.221(j)(2)(ii). This approach allows HHS to be responsive to programmatic and operational concerns in real time, as well as tailor the implementation to meet a state's unique market conditions or needs of its residents.

Comment: Several supportive commenters recommended that CMS delay implementation of the Exchange DE option pending further research, evidence gathering, stakeholder consultation, and a more robust public comment process to quantify potential impacts and adequately inform programmatic and operational parameters. Many opposing commenters requested that we strike it from this rulemaking entirely for the same reasons. In particular, commenters noted interest in potential impacts on premiums, as well as how enrollment in various insurance affordability programs and the uninsured could impact the risk pool. Other commenters noted that it is not clear that the Exchange DE option represents a better value proposition than the current centralized Exchange enrollment model and requested that HHS gather additional data to quantify the value of this new option. Commenters questioned the premise that a centralized consumer-facing website is less efficient than fracturing the consumer-facing pathway and consumer experience among multiple platforms, potentially leading to increased cost and burden on consumers. Many commenters also

contend that a centralized consumer-facing website is the more efficient and effective model for states and Exchanges, as well, rather than the state or an Exchange having to manage multiple DE entity relationships and their associated technical infrastructure, including multiple DE entity websites and their interfaces to the back-end Exchange eligibility and enrollment platform that must be managed under the Exchange DE option.

Response: We proposed and are finalizing this new Exchange DE option in response to our experience operating the *HealthCare.gov* platform and stakeholder feedback, including the comments about challenges related to Exchanges becoming a dominant public-sector competitor that can crowd out other market players. We also emphasize this option is strictly permissive for states. Whether the Exchange DE option or a centralized Exchange website is more efficient, or provides better value, for a given state is contingent on the unique circumstances of that state's health care market and the needs of its residents. Therefore, we do not believe that one or the other can be characterized as generally more efficient, or a better value, across all states. As states consider and elect the Exchange DE option, we will coordinate and engage in information sharing with these states as appropriate to assess the efficacy and value of this option from the federal perspective. This will help inform our continued consideration and development of programmatic and operational parameters and any additional regulatory requirements related to these options. Given that the health care market of each state is unique, we also welcome states that are interested in pursuing the Exchange DE option to undertake their own research, stakeholder consultation, and data gathering to determine whether it represents a sensible value proposition for their consumers. We also welcome the sharing of any information and data on findings, best practices, and lessons learned. Finally, expected impacts to the premiums and the risk pool have been addressed in the Regulatory Impact Analysis (RIA) in this rulemaking.

Comment: A few commenters noted that the potential consequences of the Exchange DE option, including Exchanges no longer serving as the single pathway for many to get covered, present potential barriers to accessing QHP or Medicaid coverage, and risks of being underinsured or becoming uninsured would disproportionately impact various vulnerable groups, namely historically-marginalized

populations, individuals with pre-existing conditions, individuals with substance-abuse disorders, rural and low-income populations, non-English-speaking populations, and others. One commenter noted that it could encourage health inequities between white communities and communities of color particularly with respect to substance abuse addiction.

Response: We share concerns about health disparities and the disproportionate impact on vulnerable population groups or the creation of inequity that exist in today's health care system, and commend commenters for identifying these issues as particular areas where HHS and states can remain proactive and diligent. States that elect to pursue the SBE-DE option should consider these issues and detail their communication and outreach strategy to target vulnerable populations as part of the implementation plan required under § 155.221(j)(1)(ii). Similarly, HHS will partner with FFE-DE and SBE-FP-DE states to consider these issues when developing the implementation plan under § 155.221(j)(2)(i). Through the various requirements and controls we are finalizing, particularly accessibility and non-discrimination requirements, the requirement that the Exchange remain available to consumers who need it, as well as the flexibility states will have to implement additional requirements and controls to protect consumers, we believe that such disproportionate impacts can be prevented or mitigated. We note that the Exchange DE option offers a platform for multiple DE entities to compete to serve consumers, which creates an opportunity for DE entities to specialize to serve specific populations, including vulnerable populations. As such, the Exchange DE option holds potential to better connect vulnerable populations to coverage than a centralized one-size-fits-all Exchange model. Again, we welcome the sharing of any information and data on findings, best practices, and lessons learned.

Following our review of the comments, we are finalizing this proposal but have amended the regulatory text to underscore our requirement that State Exchanges electing the DE option must ensure at a minimum, that at least one approved web-broker DE entity meets requirements that align with the FFE standards under §§ 155.220 and 155.221 to ensure consumers have at least one option through which to view detailed QHP information for all available QHPs in the state and enroll in a QHP. We have also incorporated minor clarifying edits throughout the regulatory text. We

will also continue to assess the need for any additional programmatic and operational parameters, as well as any additions to the regulatory requirements, to ensure necessary protections for consumers in states that implement the Exchange DE option.

B. 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)

a. FFE and SBE–FP User Fee Rates for the 2022 Benefit Year (§ 156.50(c))

Section 1311(d)(5)(A) of PPACA requires states to ensure that Exchanges are self-sustaining, which may include the state allowing 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 PPACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specify 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 charges under other statutes and applies to the extent permitted by law. Furthermore, OMB Circular 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 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.

For the 2022 benefit year, issuers participating in an FFE will receive special benefits from the following federal activities:

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

Activities through which FFE issuers receive a special benefit also include the Health Insurance and Oversight System (HIOS) and Multidimensional Insurance Data Analytics System (MIDAS) platforms, which are partially funded by Exchange user fees. Based on estimated costs, enrollment (accounting for anticipated establishment of state Exchanges in certain states in which FFEs are currently operating), and premiums for the 2021 plan year, we proposed a 2022 user fee rate for all participating FFE issuers at 2.25 percent of total monthly premiums. This proposed user fee rate reflects our estimates for the 2022 benefit year of costs for operating the FFEs, premiums, enrollment, and transitions in Exchange models (from the FFE and SBE–FP models to either the SBE–FP, FFE–DE or State Exchange models (state transitions)). The proposed FFE user fee rate is lower than the 3.0 percent FFE user fee rate that we established for benefit years 2020 and 2021, and the 3.5 percent FFE user fee rate that we established for benefit years 2014 through 2019. After accounting for the impact of the lower user fee rate, we estimated that we would have the necessary funding available to fully fund user-fee eligible Exchange activities in 2022. We sought comment on this proposed 2022 FFE 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), we specify that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable

benefit year, 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 SBE–FP issuers by the federal government include use of the federal information technology platform and call center infrastructure used to support eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs as defined at section 1413(e) of PPACA, and QHP enrollment functions under § 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. Based on this methodology, we proposed to charge issuers offering QHPs through an SBE–FP a user fee rate of 1.75 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP. This proposed rate is lower than the 2.5 percent user fee rate that we had established for the 2021 benefit year. The lower proposed user fee rate for SBE–FP issuers for the 2022 benefit year reflects our estimates of costs for operating the Federal Exchanges, premiums, enrollment, as well as state Exchange transitions for the 2022 benefit year, and the costs associated with performing these services that benefit SBE–FP issuers. We sought comment on the proposed 2022 SBE–FP user fee rate.

We received public comments on the proposed FFE and SBE–FP user fee rates for the 2022 benefit year (§ 156.50(c)). The following is a summary of the comments we received and our responses.

Comment: Several commenters supported lowering the FFE and SBE–FP user fee rates as proposed, with some commenters supporting the lower user fee rates so long as the reduction does not adversely impact FFE operations. Other commenters opposed the proposed user fee rates and asked that HHS raise the user fee rates to previous levels, 3.5 percent for FFE issuers and 2.5 percent for SBE–FP issuers, and use any excess user fees for education, consumer outreach, improving *HealthCare.gov*, or to otherwise increase funding levels for these activities. Some commenters asked that HHS maintain the current 2021 user fee rates of 3.0 percent for FFE issuers and 2.5 percent for SBE–FPs issuers. Other commenters recommended HHS finalize a lesser reduction to the user fee rates than the 0.75 percentage point reductions we

proposed. Several other commenters opposed the proposed user fee rates, noting that the reduction in user fee rates could negatively affect State Exchanges by limiting the funding available for national marketing and outreach, which those states rely on to encourage enrollment in all Exchange types. However, one commenter suggested further lowering the FFE and SBE-FP user fee rates to 2 percent and 1.5 percent respectively. This commenter stated that the additional reductions would better align the user fee rates with the reduced scope of operations performed by HHS.

Several commenters asked that HHS use user fees to improve Exchange services for populations facing heightened barriers to enrollment, such as those in rural areas and those with limited English proficiency. One commenter questioned whether lowering the user fee rate was sound budgeting practice.

Response: We are finalizing the 2022 benefit year user fee rates at 2.25 percent for FFE issuers and 1.75 percent for SBE-FP issuers, which is lower than the user fee rates for the 2021 benefit year. We estimate that these user fee rates will provide the necessary funding for the full functioning of the federal platform for the 2022 benefit year. Based on future projected changes in costs, enrollment, and premiums, we project that HHS can fully fund federal platform costs associated with providing special benefits to these issuers.

HHS remains committed to providing a seamless enrollment experience for consumers who enroll in coverage through an Exchange that uses the federal platform and to providing a value based approach to outreach and marketing activities. We believe that the services offered by the FFEs are sufficient to support all consumers seeking to enroll in coverage through the FFEs and SBE-FPs. The experience from the recently closed 2021 Open Enrollment Period shows *HealthCare.gov* and the call center operated well with the investments made over recent years to improve stability and the consumer experience on the federal platform. Specifically, the reduced user fee rates we adopt in this final rule will not impede federal platform services and will continue to apply resources to cost-effective, high-impact outreach and marketing activities that offer the highest return on investment. We will continue to evaluate consumer outreach and education needs within the normal budget process. Additionally, we will continue to evaluate the user fee rates

and the associated costs to operate the federal platform for future benefit years.

Comment: Some commenters requested more transparency and data on how user fees are calculated and allocated, and information on how funding for *HealthCare.gov* is allocated. Several commenters noted that without data transparency, it is difficult to meaningfully comment on the proposed user fee reductions. One commenter requested that HHS delay finalization of the 2022 benefit year user fee rates until more data is made publicly available.

Response: We believe that the information provided in the proposed rule in support of the user fee rate proposals was sufficient to allow commenters to meaningfully assess and comment on the appropriateness of our user fee rate proposals. As we explained in the preamble to the proposed rule, 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 evaluation of expected enrollment and premiums for the 2022 benefit year. To calculate these expected costs, we make reasonable assumptions about the expected market for the upcoming benefit years and we reconsider these assumptions and re-estimate these costs on an annual basis with the most recent data available. For example, for the 2022 benefit year, we considered whether we needed to make changes to our cost, premium, and enrollment assumptions based on data from the 2020 benefit year and made updates to our projections as appropriate.

User fee-eligible costs are estimated in advance of the benefit year and are based upon cost targets for specific contracting activities that are not yet finalized, and therefore, proprietary. We 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 the FFE user fee-eligible functions. The categories that are considered user fee-eligible include activities that provide special benefits to issuers offering QHPs through the federal platform, and do not include activities that are provided to all QHP issuers. For example, functions related to risk adjustment program operations and operations associated with APTC calculation and payment, which are provided to all issuers in states where HHS operates the risk adjustment program (all 50 states and the District of Columbia for the 2022 benefit year), are not included in the FFE or SBE-FP user fee-eligible costs. However, costs related to Exchange-

related information technology, health plan review, management and oversight, eligibility and enrollment determination functions including the call center, and consumer information and outreach are considered FFE user fee-eligible costs. SBE-FPs conduct their own health plan certification reviews and consumer information and outreach, and therefore, the SBE-FP user fee rate is determined based on the portion of FFE costs that are also applicable to issuers offering QHPs through SBE-FPs.

Based on our estimates and after considering comments, we continue to believe that a user fee rate of 2.25 percent for FFE issuers and 1.75 percent for SBE-FP issuers will provide the necessary funding for the full functioning of the federal platform for the 2022 benefit year, and therefore, we are finalizing the FFE and SBE-FP user fee rates as proposed.

b. FFE-DE and SBE-FP-DE User Fee Rates for the 2023 Benefit Year (§ 156.50(c)(3))

In the proposed rule, we proposed to allow states served by an FFE or SBE-FP to implement the proposed direct enrollment option under § 155.221(j) beginning with plan year 2023, under which one or more private direct enrollment entities approved by the FFE would operate non-Exchange websites through which consumers may apply for and enroll in a QHP, with or without APTC or CSR (if otherwise eligible), in a manner considered to be through the Exchange. Under the Exchange DE option, QHP issuers offering plans through an FFE-DE or SBE-FP-DE would continue to receive some of the benefits received by FFE and SBE-FP issuers; however, some consumer outreach, education, and support activities would be provided by the state or through the approved DE partners.⁴⁴ 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. As such, we proposed in new § 156.50(c)(3) to charge issuers offering QHPs through an FFE-DE or an SBE-FP-DE a user fee for the services and benefits provided to those issuers by HHS as the administrator of the FFE. We proposed to charge issuers offering QHPs through an FFE-DE or SBE-FP-DE a user fee rate calculated based on the proportion of FFE user fee-eligible costs incurred by HHS that are

⁴⁴ See above for more information on the direct enrollment option under § 155.221(j).

associated with implementation and operation of the FFE–DE or SBE–FP–DE. We assumed that the use of FFE services will be less for FFE–DE and SBE–FP–DE states in 2023 than for FFE and SBE–FP states during the same time period. Therefore, to provide some certainty for states that consider a transition to a proposed FFE–DE or SBE–FP–DE, we proposed a 2023 user fee rate of 1.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an FFE–DE or SBE–FP–DE in plan year 2023.

In a state that implements the Exchange DE option, the Exchange in the state would no longer provide many of the consumer-facing enrollment-related activities that are currently being performed through the federal platform, or such activities would be substantially reduced. For example, the use of the Marketplace call center and *HealthCare.gov* website will be substantially diminished. Because of the role of the state in operating SBE–FPs, the value to issuers and the associated costs of operating these functions in FFEs are typically higher. The reduction of these functions and costs is reflected by a larger proposed reduction in the user fee rate for issuers in FFE–DEs from the rate applicable in FFEs (from 2.25 percent to 1.5 percent) than the reduction in the user fee rate for issuers in SBE–FP–DEs from the rate applicable in SBE–FPs (from 1.75 percent to 1.5 percent), resulting in the same proposed user fee rate for FFE–DEs and SBE–FP–DEs. We sought comment on the FFE–DE or SBE–FP–DE user fee rate, including whether the rate should be state-specific or higher or lower depending on whether the Exchange is an FFE–DE or SBE–FP–DE. We also sought comment on the specific services HHS will provide consistent with the Federal agreement we proposed to require under new § 155.221(j)(2)(ii). We sought comment on the FFE–DE and SBE–FP–DE user fee rates for the 2023 benefit year.

We are finalizing the 2023 FFE–DE and SBE–FP–DE user fee rate as proposed. We also make clear that HHS intends to collect these user fees on a monthly basis as it does with the FFE and SBE–FP user fees, consistent with the netting regulations at 45 CFR 156.1210. The following is a summary of the public comments we received on the FFE–DE and SBE–FP–DE user fee rate proposal for the 2023 benefit year and our responses.

Comment: We received several comments in support of a lower user fee rate for FFE–DE and SBE–FP–DE states. Other commenters expressed a general skepticism or disapproval of this user

fee rate as an extension of their disapproval of the proposed Exchange DE option. One commenter believed that increased reliance on agents and brokers calls for increased spending on their oversight, and thus a higher FFE–DE and SBE–FP–DE user fee rate than that proposed would be appropriate.

Response: We are finalizing the proposed 1.5 percent of premium user fee rate for issuers offering plans through FFE–DEs and SBE–FP–DEs for the 2023 benefit year. We proposed this user fee rate to provide clarity and predictability regarding the user fee rate HHS would assess in FFE–DE and SBE–FP–DE states in order to allow states to evaluate whether to elect the Exchange DE option beginning with the 2023 benefit year. As discussed earlier in the preamble, this user fee rate is reflective of the costs incurred by HHS to support FFE–DE and SBE–FP–DE operations. Changes to HHS’s costs, such as those related to oversight of agents and brokers, changes to underlying estimates of premiums and enrollment, or changes to the models adopted by states for their Exchanges could impact the user fee rate for 2023 or future benefit years. Therefore, we will continue to evaluate our estimates and will revisit the 2023 FFE–DE and SBE–FP–DE user fee rates in the 2023 Payment Notice proposed rule in compliance with our regulations.⁴⁵

Comment: One commenter questioned the validity of a single user fee rate for issuers in FFE–DE and SBE–FP–DE states. The commenter asserted that even where differences between the services provided to FFE–DE and SBE–FP–DE issuers were minimized, a single user fee rate may not be justified.

Response: The 1.5 percent of premium user fee rate we proposed for FFE–DE and SBE–FP–DE issuers was calculated based on the proportion of FFE user-fee eligible costs that HHS anticipates it would incur to support the operation of an FFE–DE or SBE–FP–DE. We assumed that the use of federal platform services will be less for FFE–DEs and SBE–FP–DEs in 2023 than for an FFE or SBE–FP during the same time period.

Under the Exchange DE option, an Exchange would no longer provide many of the consumer-facing enrollment-related activities that are currently being performed through the federal platform for FFEs and SBE–FPs,

or such activities would be substantially reduced. For example, the use of the Marketplace call center and *HealthCare.gov* website will be substantially diminished. Because of the role of the state in operating SBE–FPs, the value to issuers and the associated costs of operating these functions in FFEs is typically higher. The reduction of these functions and costs is reflected by a larger proposed reduction in the user fee rate for issuers in FFE–DEs from the rate applicable in FFEs (from 2.25 percent to 1.5 percent) than the reduction in the user fee rate for issuers in SBE–FP–DEs from the rate applicable in SBE–FPs (from 1.75 percent to 1.5 percent). These reductions resulted in the same user fee rate for issuers offering QHPs through FFE–DEs and SBE–FP–DEs.

2. Network Adequacy Standards (§ 156.230)

We are finalizing the proposed revisions to 45 CFR 156.230, which implements section 1311(c)(1)(B) of PPACA and describes network adequacy standards for plans seeking certification as QHPs. As we stated in the proposed rule, we have received questions regarding whether § 156.230 requirements apply to a plan that does not vary benefits based on whether enrollees receive services from an in-network or out-of-network provider.

As we stated in the proposed rule, nothing in PPACA requires a QHP issuer to use a provider network and § 156.230 does not impose any network adequacy certification requirement for QHPs that do not use a provider network. Accordingly, an issuer might design and seek QHP certification for a plan that does not use a provider network and provides equal benefits for the same covered services without regard to whether the issuer has a network participation agreement with the provider that furnishes the covered services. To address any ambiguity in this section, we proposed to codify this longstanding interpretation at paragraph (f) to provide that a plan that does not vary benefits based on whether the issuer has a network participation agreement with a provider that furnishes covered services is not required to comply with the network adequacy standards at paragraphs (a) through (e) of § 156.230 to qualify for certification as a QHP. In the proposed rule, we explained that this proposal would simply clarify existing QHP requirements and would not add to, change, or remove any QHP certification requirements.

We received public comments on the proposed updates to the QHP network

⁴⁵ We note that even if this further consideration does not lead us to propose a change to the FFE–DE or SBE–FP–DE user fee rates applicable for the 2023 benefit year, we intend to address the 2023 FFE–DE and SBE–FP–DE user fee in the 2023 Payment Notice proposed rule in compliance with our regulations. See 45 CFR 156.50(c).

adequacy standards under § 156.230. The following is a summary of the comments we received and our responses.

Comment: Of the comments received addressing this provision, a plurality supported this clarification, asserting that it will encourage variety in the kinds of plans certified as QHPs, lower costs by fostering more competition between issuers, increase enrollee access to providers, and reduce pressure on providers to enter into network agreements with issuers.

Response: We agree with commenters and are finalizing this clarification as proposed. Since plan year 2016, § 156.230(a) has applied only to QHPs that utilize a provider network.⁴⁶ The provision finalized here only clarifies this existing policy by adding explicit regulatory text reflecting the regulation's inapplicability to plans that do not utilize a provider network and do not vary benefits for covered services based on whether or not they are provided by an in-network or out-of-network provider.

Comment: A few commenters opposed the proposed clarification, asserting that it would reduce CMS's ability to oversee QHP issuers and ensure issuer accountability. A few commenters requested clarification on whether plans that do not utilize a provider network must comply with other QHP certification and market-wide requirements, such as requirements related to maximum out-of-pocket limits, cost-sharing protections, coverage of essential health benefits (EHB), actuarial value standards, inclusion of essential community providers, and non-discrimination standards under § 156.125. Some of these commenters opposed finalization of this provision until CMS could be assured that such plans would comply with these requirements.

Response: The provision finalized here only clarifies that plans that do not utilize a provider network are not required to satisfy the network adequacy standards at § 156.230 to obtain QHP certification. This final rule does not add to, change, or remove QHP certification requirements, nor does it add to, change, or remove any requirement for these plans to comply with the market reform provisions under title I of PPACA. Plans that do not utilize a provider network must still comply with all applicable QHP certification requirements to obtain QHP

certification, which ensures that any plan that does not comply with applicable QHP certification requirements will be denied QHP certification.

Comment: A few commenters cautioned about the potential proliferation of QHPs that do not utilize a provider network, which could place consumers in the middle of payment disputes between issuers and providers. One commenter asserted that, while CMS should do more to encourage issuers to develop plans that do not utilize a provider network, QHP certification should be reserved for plans that utilize adequate provider networks and meet all other QHP certification requirements.

Response: We proposed no substantive changes to QHP certification requirements and decline to disqualify plans that do not utilize provider networks from obtaining QHP certification. Since plan year 2016, the text of § 156.230(a) has stated that the section only applies to QHPs that utilize a provider network.⁴⁷ While plans that do not utilize a provider network have always been eligible to apply for QHP certification, only 12 plans that did not utilize a provider network have ever been approved as QHPs in the FFEs.⁴⁸

Comment: One commenter requested that CMS disclose the plans that do not utilize a provider network that have sought or received certification as QHPs.

Response: CMS releases QHP certification information in Public Use Files (PUFs) at <https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf>. The Plan Attributes PUF lists the plan type for each plan approved as a QHP. There were 12 plans certified as QHPs in Wisconsin for plan year 2016 that did not utilize a provider network. No such plans have been granted QHP certification in an FFE since.

We are finalizing this policy as proposed.

3. Enrollment Process for Qualified Individuals (§ 156.1240)

We are finalizing the proposed revisions to § 156.1240, with a

modification in response to comments. Under § 156.1240(a), QHP issuers are required to accept a variety of payment methods so that individuals without a bank account or a credit card will have readily available options for making monthly premium payments. Specifically, paragraph (a)(1) of § 156.1240 requires QHP issuers to follow the premium payment process established by an Exchange in accordance with 45 CFR 155.240. Paragraph (a)(2) requires QHP issuers to accept for all payments in the individual market, at a minimum, paper checks, cashier's checks, money orders, EFT, and all general-purpose pre-paid debit cards as methods of payment and to present equally all payment method options to allow a consumer to select their preferred payment method. We proposed to add new paragraph (a)(3) to require individual market QHP issuers to also accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA. As explained in the proposed rule, we received questions indicating that there is some confusion over whether issuers must accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA. Individual coverage HRAs are a new type of health reimbursement arrangement that employers may offer to employees as of January 1, 2020.⁴⁹ QSEHRAs are another new type of HRA that qualified small employers can provide to their employees pursuant to section 9831 of the Code. In general, employers may offer individual coverage HRAs or provide QSEHRAs to their employees as a means of providing tax-advantaged reimbursements for medical care expenses, including premiums for individual health insurance coverage that they purchase for themselves and their families. Reimbursement from individual coverage HRAs and QSEHRAs may include employee-initiated payments made through use of financial instruments, such as pre-paid debit cards, as well as direct payments (individual or aggregate) by the employer, employee organization, or other plan sponsor to the health insurance issuer.⁵⁰

We proposed to add a new § 156.1240(a)(3) to require issuers offering individual market QHPs to accept payments of premiums that are received directly from an individual

⁴⁶ 80 FR at 10830 (February 27, 2015). Available at <https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf>.

⁴⁷ See 80 FR at 10830, 10873 (February 27, 2015) (explaining HHS's proposal to modify § 156.230(a) "to specify that this section only applies to QHPs that use a provider network" and finalizing § 156.230(a) to state that "[e]ach QHP issuer that uses a provider network must ensure that the provider network consisting of in-network providers, as available to all enrollees, meets . . . standards [under § 156.230(a)] . . ." (italics added)). Available at <https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf>.

⁴⁸ Twelve such plans were approved as QHPs in Wisconsin for plan year 2016. See plan type data for QHPs, available at: <https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf>.

⁴⁹ See 84 FR 28888.

⁵⁰ See 84 FR at 28950–51 ("[E]mployer funds paid from an HRA go directly to a participant or a health insurance issuer because the economic substance of the transaction is the same—that is, the funds are being used to discharge an employee's premium payment obligations.").

coverage HRA or QSEHRA that are made on behalf of an enrollee who is covered by the individual coverage HRA or QSEHRA. We proposed that QHP issuers would be required to accept such payments when they are made using a method of payment described in § 156.1240(a)(2). We recognized some individual coverage HRAs and QSEHRAs prefer to make aggregate payments on behalf of multiple employees to a QHP issuer. We further encouraged QHP issuers to work with employers and administrators of individual coverage HRAs and QSEHRAs to facilitate these aggregate payments, as this approach could ease administration of individual coverage HRAs and QSEHRAs. We also explained that this proposal would help ensure that individual coverage HRAs or QSEHRAs operate as intended, and would address potential stakeholder confusion regarding whether QHP issuers must accept payments made from individual coverage HRAs or QSEHRAs. However, we did not propose to require QHP issuers to accept payments from individual coverage HRAs or QSEHRAs when made using a form of payment that is not described in § 156.1240(a)(2) or to accept aggregate payments from an individual coverage HRA or QSEHRA made on behalf of multiple enrollees.

We are finalizing this policy, but with a modification to clarify that QHP issuers not only must accept payments made on behalf of an enrollee directly from an individual coverage HRA or QSEHRA, but must also accept payments made directly by an enrollee using funds from an individual coverage HRA or QSEHRA, so long as such payments are made using a form of payment that is described in § 156.1240(a)(2).

We received public comments on the proposed updates to § 156.1240. The following is a summary of the comments we received and our responses.

Comment: Most commenters who commented on this proposal supported it. Several commenters noted that it would help overcome issuer confusion about whether they must accept payments from an individual coverage HRA or QSEHRA, which commenters stated has been an obstacle to the implementation of these options. One commenter reported that some issuers have refused to accept payments from an individual coverage HRA or QSEHRA when it was used to purchase coverage through a special enrollment period, and that this change would ensure that individuals offered an individual coverage HRA or provided a QSEHRA would be able to enroll in

individual market QHP coverage. A few commenters encouraged CMS to require that QHP issuers accept aggregate payments from individual coverage HRAs or QSEHRAs made on behalf of multiple enrollees.

A smaller number of commenters opposed the proposal and stated that whether to accept premium payments made by an individual coverage HRA or QSEHRA on behalf of an enrollee should be at the option of the issuer, rather than required by HHS. A few commenters were concerned that accepting these payments, particularly aggregate payments, was not issuer standard practice and would be operationally difficult to implement. They raised concerns about the issuer burden associated with building the IT infrastructure to facilitate roster, or list, billing.

Response: We did not propose and are not finalizing a requirement for QHP issuers to accept aggregate payments from individual coverage HRAs or QSEHRAs.⁵¹ We also did not propose and are not finalizing any requirement that QHP issuers facilitate roster, or list, billing. We instead encourage QHP issuers to work with employers and administrators of individual coverage HRAs and QSEHRAs to facilitate acceptance of aggregate payments from these HRA vehicles. We are not inclined to require more at this time given the relative infancy of individual coverage HRAs and QSEHRAs, but we expect the proposal we are finalizing that requires QHP issuers to accept premium payments received directly from an individual coverage HRA or QSEHRA to ease administration of individual coverage HRAs and QSEHRAs. This rule will also make the individual coverage HRA and QSEHRA experience more seamless for employees by ensuring that individual coverage HRAs and QSEHRAs may pay employee premiums directly, rather than only reimbursing employees after they have paid first out of their own pockets.

We understand that some QHP issuers are working to build IT systems to accommodate aggregate payments. However, because not all QHP issuers can accept aggregate payments using their existing IT infrastructure, it could be costly and time-consuming to require all QHP issuers to accept them. As individual coverage HRAs and QSEHRAs grow in popularity, we anticipate the benefits of making such an IT investment may outweigh the costs for most QHP issuers. However, at this time, with individual coverage HRAs and QSEHRAs still in their

infancy, the final rule does not require QHP issuers to accept such aggregate payments, even if such payments are made using a form of payment that is described in § 156.1240(a)(2).

Additionally, we recognize that it may not previously have been standard practice for every individual market QHP issuer to accept payments of premiums that are received directly from an individual coverage HRA or QSEHRA. Although some QHP issuers may incur administrative costs for operational changes necessary to comply with the payment acceptance requirement adopted in this final rule, such costs should be minimal because QHP issuers are already required to accept the forms of payment described in § 156.1240(a)(2) for all payments in the individual market. Therefore, we believe the benefits of requiring individual market QHP issuers to accept payments from individual coverage HRAs and QSEHRAs, rather than employees having to pay premiums out-of-pocket and then seek reimbursement at a later time, outweighs these administrative costs and is in the best interests of consumers.

Comment: Several commenters stated that individual coverage HRAs and QSEHRAs constitute third party payments, which issuers are not required to accept under § 156.1250.

Response: Individual coverage HRAs and QSEHRAs are structured to reimburse an employee for eligible medical care expenses that are paid by the employee. HHS considers any payments for eligible medical care expenses that are reimbursed by an employer through an individual coverage HRA or a QSEHRA per the terms of the employee's compensation package, including payments for eligible individual market premiums, to be payments by the employee, not the employer. This remains true regardless of whether funds from an individual coverage HRA or QSEHRA are transmitted directly by an enrollee or by an employer. As such, payments from these HRA vehicles for individual market coverage do not constitute third party payments. To ensure that QHP issuers do not erroneously reject payments as third party payments when the payments are made in connection with an individual coverage HRA or QSEHRA that are transmitted directly by an enrollee or by an employer, we are finalizing revisions to § 156.1240(a)(3) that make clear that all such payments must be accepted so long as they are made using a form of payment described in § 156.1240(a)(2).

We recognize that individual coverage HRAs and QSEHRAs may differ in how

⁵¹ 85 FR 78572, 78644.

they are administered. While some individual coverage HRAs and QSEHRAs may pay premiums directly to issuers on behalf of covered individuals, others may reimburse covered individuals for incurred or paid covered expenses. It is important that, regardless of how an individual coverage HRA or QSEHRA is administered, individuals covered by individual coverage HRAs and QSEHRAs be able to use HRA funds to enroll in QHP coverage. We can identify no compelling reason to treat payments from an individual coverage HRA and QSEHRA differently based on whether the payments are made directly to the QHP issuer or to the covered individual. In either case, the payment functions as a reimbursement to the employee for the employee's premium payment as part of the employee's compensation package.⁵²

After considering comments, we are finalizing § 156.1240(a)(3) to require issuers offering individual market QHPs to accept payments of premiums that are received directly from an individual coverage HRA or QSEHRA that are made on behalf of an enrollee who is covered by the individual coverage HRA or QSEHRA. To address potential confusion about the payment acceptance requirements, in response to comments, we specify in the regulation text that QHP issuers must also accept payments that are made directly by an enrollee in connection with an individual coverage HRA or QSEHRA. These requirements apply so long as such premium payments are made using a payment method described in § 156.1240(a)(2).

IV. Summary of the Proposed Provisions of the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule—Department of Health and Human Services and Department of the Treasury

A. 31 CFR Part 33 and 45 CFR Part 155—State Innovation Waivers

1. Section 1332 Application Procedures (31 CFR 33.108 and 45 CFR 155.1308), Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320), and Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

Section 1332 of PPACA permits states to apply for a State Innovation Waiver (also referred to as a section 1332 waiver or State Relief and Empowerment Waiver) to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. The overarching goal of section 1332 waivers is to give all Americans the opportunity to obtain high value and affordable health coverage regardless of income, geography, age, sex, or health status, while simultaneously empowering states to develop health coverage strategies that best meet the needs of their residents. In the proposed rule, the Departments sought to provide states with consistency and predictability by proposing to codify the Departments' interpretative guidance published in the **Federal Register** in 2018, regarding how the Departments will apply section 1332 of PPACA to determine whether applications for section 1332 waivers will be approved. In this final rule, the Departments are finalizing these policies, with modifications to explicitly incorporate major policies outlined in the 2018 Guidance into the text of relevant section 1332 regulations.

Under section 1332 of PPACA, 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 PPACA section 1302(b) and offered through Exchanges established by title I of PPACA, 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 PPACA and the provisions of PPACA that would be waived; (2) the proposal will provide coverage and cost-sharing protections

against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided under title I of PPACA; (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 PPACA; 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 of PPACA for monitoring a waiver's compliance with the statutory guardrails and for conducting evaluations to determine the impact of the waiver. Specifically, section 1332 of PPACA requires that the Secretaries provide for and conduct periodic evaluations of approved section 1332 waivers. The Secretaries must also provide for a process under which states with approved waivers must submit periodic reports concerning the implementation of the state's waiver program.

In October 2018, the Departments issued the 2018 Guidance,⁵³ which provides additional guidance for states that wish to submit section 1332 waiver proposals regarding the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. The 2018 Guidance also includes information regarding how the Departments will apply the section 1332 statutory guardrails to evaluate whether a waiver is approvable. Section 1332 of PPACA and the 2018 Guidance empower states to address problems with their individual insurance markets and increase coverage options for their residents, and to encourage states to evaluate and adopt innovative strategies to reduce future overall health care spending. Together, the statutory guardrails and the 2018 Guidance provide states a reliable roadmap to follow in designing section 1332 waiver programs that will promote a stable health insurance market that offers more choice and affordability to state residents.

In this final rule, the Departments provide certainty to states that the requirements and expectations of the section 1332 program will not change abruptly, or without notice to states and the public, and an opportunity to comment. Specifically, the Departments proposed to incorporate by reference the 2018 Guidance in full in the regulations

⁵² See 84 FR at 28951 (“[U]nder the [HRA] final rules, ‘reimbursement’ may include employee-initiated payments made through use of financial instruments, such as pre-paid debit cards, as well as direct payments, individual or aggregate, by the employer, employee organization, or other plan sponsor to the health insurance issuer.”).

⁵³ 83 FR 53575 (Oct. 24, 2018).

governing section 1332 waiver application procedures, monitoring and compliance, and periodic evaluation requirements. The Departments are finalizing the policies, with modifications made in response to public comments to codify many of the policies and interpretations outlined in the 2018 Guidance specifically in the text of the section 1332 implementing regulations. The Departments are of the view that this rulemaking will give states greater certainty regarding how the Departments will apply section 1332's statutory guardrails when determining whether a state's waiver proposal can receive and maintain approval by the Departments.

31 CFR 33.108 and 45 CFR 155.1308 specify the application procedures a section 1332 waiver proposal must meet to be approved by the Secretaries. Under these regulations, an application for initial approval of a section 1332 waiver will not be considered complete unless the application complies with the application procedures under 31 CFR 33.108(f) and 45 CFR 155.1308(f), including written evidence of the state's compliance with the public notice requirements set forth in 31 CFR 33.112 and 45 CFR 155.1312. Furthermore, an application must provide a comprehensive description of the enacted state legislation and program to implement a plan meeting the requirements for a waiver under section 1332; a copy of the enacted state legislation authorizing such waiver request; a list of the provisions of law that the state seeks to waive including a brief description of the reason for the specific request; and the analyses, actuarial certifications, data, assumptions, targets and other information sufficient to provide the Secretaries with the necessary data to determine that the state's proposed waiver meets the statutory guardrails. The 2018 Guidance provides supplementary information about the Departments' analysis as to whether a proposed section 1332 waiver plan meets requirements for approval, the Secretaries' application review procedures, the calculation of pass-through funding, certain analytical requirements, and operational considerations. The 2018 Guidance also clarifies adjustments the Secretaries may make to maintain federal deficit neutrality, and explains how states may rely on existing legislative authority in certain circumstances as authorization for section 1332 waivers.

The Departments are of the view that formalizing these policies and interpretations through rulemaking will encourage more states to pursue waivers

without being concerned that some of the rules may change without sufficient notice after they have submitted a waiver application. As such, the Departments are finalizing modifications to 31 CFR

33.108(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 'section 1332 guardrails'⁵⁴ as outlined in the 2018 Guidance. Specifically, this final rule adds regulatory language to 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) explaining that the Departments will consider the comprehensive coverage guardrail to be met by a state waiver plan if the plan will 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. This final rule also adds language to 31 CFR

33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) providing that the Departments will consider the affordability requirement to be met by a state waiver plan that will 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 provide, consistent with the 2018 Guidance, that the Departments will consider the comprehensiveness and affordability guardrails met if a 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.

This final rule also adds 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 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. No changes are being made to the

⁵⁴ Under section 1332 of PPACA, the Departments may approve a state's section 1332 waiver application when the Departments determine the waiver plan will meet the four criteria specified in section 1332(b)(1), including the guardrails related to comprehensiveness, affordability, and coverage, as well as a fourth guardrail related to deficit neutrality.

Federal deficit neutrality guardrail under 31 CFR 33.108(f)(3)(iv)(D) and 45 CFR 155.1308(f)(3)(iv)(D), which prohibits approval of any waiver plan that is projected to increase the Federal deficit.

The Departments are also finalizing a modification to 31 CFR 33.108(f)(3)(i) and 45 CFR 155.1308(f)(3)(i) to provide that the Departments may consider existing legislation in analyzing whether the state has satisfied the requirement that the state enact a law under section 1332(b)(2)(A) of PPACA that provides statutory authority to enforce PPACA provisions or the state plan, combined with a duly-enacted state regulation or executive order. The Departments are of the view that these modifications will allow states to better plan for future section 1332 waiver applications and provide certainty to states as they invest significant state resources toward the submission of a section 1332 waiver application and the implementation of a section 1332 waiver plan, particularly waivers that require multi-year preparation.

In the proposed rule, the Departments proposed to incorporate the 2018 Guidance in full into the Departments' monitoring and compliance regulations at 31 CFR 155.1320 and 45 CFR 155.1320. Specifically, under the current regulations, the Secretaries reserve the right to suspend or terminate a waiver, in whole or in part, any time before the date of expiration, if the Secretaries determine that the state materially failed to comply with the terms and conditions of the waiver. The Departments will review and, when appropriate, investigate documented complaints that the state is failing to materially comply with requirements specified in the approved waiver and the specific terms and conditions (STCs) for the approval of the waiver signed by the Departments and the state. In addition, the Departments will promptly share with the state any complaint that they may receive and will notify the state of any applicable monitoring and compliance issues. States with approved section 1332 waivers must comply with all applicable federal laws and regulations (unless specifically waived) and must come into compliance with any changes in federal law or regulations affecting section 1332 waivers.

The Departments are finalizing a modification to 31 CFR 33.120(a)(1) and 45 CFR 155.1320(a)(1) to explicitly require that the Departments examine monitoring and compliance consistent with 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) and guidance published by the Departments. The

Departments are of the view that codifying many of the policies and interpretations outlined in the 2018 Guidance into the section 1332 waiver implementing regulations will provide certainty regarding how the Departments will evaluate and review section 1332 waiver programs, as states submit information concerning the implementation of their waiver programs.

In the proposed rule, the Departments also proposed to incorporate the 2018 Guidance in full in the periodic evaluation requirements regulations at 31 CFR 33.128 and 45 CFR 155.1328. Under current regulations, the Departments are responsible for evaluating the waiver using federal data, information reported by states, and the waiver application itself to ensure that the Departments can exercise appropriate oversight of the approved waiver. Per 31 CFR 33.120(f) and 45 CFR 155.1320(f), the state must fully cooperate with the Departments or an independent evaluator selected by the Departments, to undertake an independent evaluation of any component of the section 1332 waiver. As part of this required cooperation, the state must submit all requested data and information to the Departments or the independent evaluator. The state generally must meet the statutory requirements in each year that the waiver is in effect; as such the primary focus of the periodic evaluations will be the four statutory guardrails. However, the Departments will consider the longer-term impacts of a state's waiver plan.

The Departments are finalizing a modification to 31 CFR 33.128 and 45 CFR 155.1328 to require that the Departments periodically evaluate approved waivers to ensure the program is consistent with 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) and guidance published by the Departments. The Departments are of the view that codifying many of the policies and interpretations outlined in the 2018 Guidance into the section 1332 waiver implementing regulations will provide certainty regarding how the Departments will evaluate whether a state may maintain approval of its section 1332 waiver. The Departments also are of the view that this policy will help states to anticipate the data that will be most relevant and helpful to the Departments' analyses of a state's compliance with the specific terms and conditions approved by the Departments and other applicable requirements.

The Departments are finalizing the policies, as stated above, with modifications to 31 CFR 33.108, 31 CFR 33.120, 31 CFR 33.128, 45 CFR 155.1308, 45 CFR 155.1320, and 45 CFR 155.1328 to codify many of the policies and interpretations outlined in the 2018 Guidance in the section 1332 implementing regulations. The Departments are of the view that the increased certainty that would result from incorporating these policies in the 2018 Guidance into the section 1332 implementing regulations will allow states to have greater confidence that the significant time and monetary investments necessary to plan for, submit, and implement a section 1332 waiver will not result in wasted resources and taxpayer dollars. The Departments are also of the view that these modifications finalized in this final rule will help to increase state innovation, which could lead to more affordable health coverage for individuals and families in states that implement a section 1332 waiver program.

The Departments sought comments on these proposals. The Departments received public comments on the proposed updates to the regulations detailing the section 1332 application procedures (31 CFR 33.108 and 45 CFR 155.1308), monitoring and compliance (31 CFR 33.120 and 45 CFR 155.1320), and periodic evaluation requirements (31 CFR 33.128 and 45 CFR 155.1328). In addition, the Departments previously solicited public comments on the 2018 Guidance for a 60-day period (October 22, 2018 through December 24, 2018). During that period, the Departments received approximately 2,100 public comments.

Based on the Departments' review and consideration of comments in response to the proposed rule and the 2018 Guidance, their experience with section 1332 waivers, and the positive market effects that have been attained as a result of existing section 1332 waiver programs, the Departments will not revise the 2018 Guidance or otherwise modify the policies that they are now explicitly incorporating into regulation in this final rule. However, in response to comments, the Departments will not incorporate by reference the 2018 Guidance in the section 1332 implementing regulations, but are finalizing modifications to the text of those implementing regulations to codify many of the policies and interpretations outlined in the 2018 Guidance. Later in this section of the preamble, the Departments review and respond to comments received in 2018 in response to the 2018 Guidance, as

well as those received in response to the proposals to incorporate the 2018 Guidance into the section 1332 implementing regulations in the proposed rule, which were largely similar to comments submitted on the 2018 Guidance.

Comment: A few commenters stated that it is not proper to incorporate by reference the 2018 Guidance under 1 CFR 51.7(b) because it is an HHS publication or under 1 CFR 51.7(c)(1) because it has previously been published in the **Federal Register**. Another commenter stated that the 2018 Guidance is amorphous and imprecise, such that the proposed cross-references to the 2018 Guidance do not fit the definition of a rule under 5 U.S.C. 551. Other commenters asserted that it was bad policy to codify the 2018 Guidance by reference rather than by crafting concrete regulatory language.

One commenter stated that the Departments failed to comply with H.R. 3010, the Regulatory Flexibility Act of 2011, which the commenter believes to include a legal mandate that a federal agency, as part of an agency's evaluation of any proposed regulatory change, must analyze its distributional effects, which specifically refers to the impact of a regulatory action across the population and economy, divided up in various ways (for example, income groups, race, sex, industrial sector, geography).⁵⁵ The commenter further stated that the Departments failed to adequately identify and analyze the effects of codifying the 2018 Guidance. One commenter noted that the Department of the Treasury's participation was necessary for any regulation issued regarding section 1332 waivers and CMS cannot act alone.

Response: The Departments appreciate these commenters' concerns and want to ensure the requirements are clear to the public. The goal of the proposal to incorporate the 2018 Guidance into the section 1332 implementing regulations was to provide stability and certainty to states with existing waivers and to those who may be in the process of or interested in pursuing such a waiver. The Departments agree with commenters that suggested the Departments craft more specific regulatory text, rather than finalize the proposed incorporation of the 2018 Guidance by reference, to codify the Departments' interpretations in these regulations. As such, in this rule, the Departments are finalizing

⁵⁵The Departments' research shows that H.R. 3010, the Regulatory Flexibility Act of 2011, was never signed into law. Notwithstanding, the Departments respond to the commenter's concerns here and in the RIA, section VI.C.3 of this final rule.

modifications to 31 CFR 33.108, 31 CFR 33.120, 31 CFR 33.128, 45 CFR 155.1308, 45 CFR 155.1320, and 45 CFR 155.1328 to codify many of the policies and interpretations outlined in the 2018 Guidance in the section 1332 waiver program's implementing regulations. Specifically, the Departments are adding language to 31 CFR 33.108(f)(3)(i) and 45 CFR 155.1308(f)(3)(i) providing that the Departments may consider existing legislation in analyzing whether the state has satisfied the requirement that the state enact a law under section 1332(b)(2)(A) of PPACA if that legislation provides statutory authority to enforce PPACA provisions or the state plan, combined with a duly-enacted state regulation or executive order. Additionally, the Departments are finalizing changes to 31 CFR 33.108(f)(3)(iv)(A)–(C) and 45 CFR 155.1308(f)(3)(iv)(A)–(C) to codify many of the 2018 Guidance guardrail interpretations into regulations. The Departments are also finalizing changes to 31 CFR 33.120(a)(1) and 45 CFR 155.1320(a)(1) to explicitly require that the Departments examine monitoring and compliance requirements consistent with the guardrail interpretations outlined in 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) and guidance published by the Departments. Lastly, the Departments are finalizing changes to 31 CFR 33.128 and 45 CFR 155.1328 to require that the Departments periodically evaluate approved waivers to ensure the program is consistent with the guardrail interpretations outlined in 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) and guidance published by the Departments. As described below, the policies and interpretations outlined in the 2018 Guidance remain unchanged. These regulatory modifications are being made in response to commenters' recommendations to craft concrete regulatory language and to further ensure that these finalized requirements are clear to the public.

Regarding some commenters' concerns that the Departments' did not analyze the distributional effect on the population and economy across subgroups that could result from incorporating the 2018 Guidance into regulation, the Departments are of the view that the data and information necessary to such an analysis are unavailable at this time. In particular, the Departments are unable to estimate or determine how many or which states may apply for a waiver using the regulatory modifications finalized in this final rule. As discussed in detail in the RIA under section VI.C.3 of this

final rule, it would be difficult for the Departments to predict and analyze the impact of various state waiver plans that have not been submitted, including the distributional effects on various segments of the population. The Departments are of the view that meaningful analyses of the distributional effects of waiver proposals will be possible upon states' submissions to the Departments of complete section 1332 waiver applications. Pursuant to section 1332 of PPACA, the Departments must conduct reviews of section 1332 waiver applications on an individual basis. The distributional effects of each proposed waiver plan will be analyzed as part of the Departments' review, and members of the public and other stakeholders will have two distinct opportunities to comment on the distributional effects of a waiver during the state and federal public comment periods.

The Departments also agree that the Department of the Treasury's participation was necessary to the section 1332 proposals in the proposed rule. Thus, HHS did not act alone in developing or publishing the section 1332 proposals in the proposed rule. The proposed rule's section 1332 proposals were issued by both HHS and the Department of the Treasury, and in this final rule, the Departments are finalizing changes to relevant provisions in both 31 CFR part 33 (Treasury regulations) and 45 CFR part 155 (HHS regulations).

Comment: A few commenters expressed their support for the 2018 Guidance and its incorporation into the section 1332 implementing regulations. These commenters supported simplifying and streamlining the process for obtaining section 1332 waivers and affording states flexibility in meeting the guardrails for obtaining a waiver. Another commenter supported this proposal because it will provide certainty and allow states to utilize section 1332 waivers as intended, without adding unnecessary cost and time dealing with proposals that do not meet the necessary standards. The commenter further noted that such action is especially appreciated as state budgets are stretched thin due to the COVID-19 pandemic. One commenter noted that codifying the Departments' 2018 Guidance is especially important because of the significant time and taxpayer resources to develop and submit a waiver application. One commenter also noted that the process of developing a proposal and submitting it may take significant time and taxpayer resources, such that states may not want to undertake section 1332

waivers if the probability of success is low and the probability of the Departments changing requirements is high.

Furthermore, a few commenters noted that incorporating the 2018 Guidance into regulation will continue to improve the ability of states to access the flexibilities allowed by section 1332 waivers, empowering new innovation in the push to lower health costs. One commenter noted that a June 2020 CMS analysis of the effect of implemented section 1332 state-based reinsurance waivers found that premiums were an average of 17.7 percent lower during the 2020 plan year in the 12 states that had approved section 1332 waivers in place than they would have been without those waivers. The same commenter also noted that the results of 1332 waivers have been impressive thus far and that CMS should allow states to rely on existing regulatory direction across administrations, particularly when the existing framework demonstrates clear, positive results.

Response: The Departments appreciate commenters' support for these proposals. The Departments agree that codifying many of the policies and interpretations outlined in the 2018 Guidance into the implementing regulations will provide stability and certainty to states as they invest significant state resources towards submission of a section 1332 waiver application and implementation of an approved section 1332 waiver, particularly waivers that require multi-year preparation. The Departments also agree that implemented section 1332 waivers are lowering premiums for consumers, and that section 1332 waivers are an important tool to lower costs and strengthen state health insurance markets by providing a variety of coverage options. The Departments note that all states that have implemented a section 1332 reinsurance waiver plan have reduced premiums compared to a scenario without these waivers in place.⁵⁶ As described in this preamble, the Departments are finalizing these policies, with modifications, to codify many of the policies and interpretations outlined in the 2018 Guidance into the section 1332 waiver implementing regulations and are not otherwise making changes to the 2018 Guidance.

Comment: A majority of commenters did not support either the 2018

⁵⁶ See CCIIO Data Brief Series, State Relief and Empowerment Waivers: State-based Reinsurance Programs (June 2020), available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Data-Brief-June2020.pdf>.

Guidance or its incorporation into the section 1332 regulations. Many of these commenters stated 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 misinterpretation of the statute. A few commenters recommended rescinding and abandoning the 2018 Guidance completely and that the Departments return to the prior interpretation of the guardrails described in now superseded guidance issued in 2015 (referred to as the 2015 Guidance).⁵⁷

Response: The Departments acknowledge commenters' concerns, but do not agree that the 2018 Guidance suffers from the purported flaws these commenters describe. The Departments note that the 2018 Guidance has been in place for more than 2 years and states have relied upon it to better understand the submission requirements for a section 1332 waiver application and how the Departments apply and interpret these requirements. The Departments are of the view that the changes finalized in this rule provide predictability and certainty for states as they decide whether to invest resources in developing and implementing innovative waiver proposals. Further, the 2018 Guidance aims to lower barriers to innovation for states seeking to reform their health insurance markets. As described more fully below, the Departments maintain that the policies announced in the 2018 Guidance are based on a sound interpretation of section 1332 of PPACA.

Comment: A majority of commenters did not support the policies outlined in the 2018 Guidance, specifically those related to how the Departments would analyze and determine whether a waiver proposal complies with the section 1332 guardrails. All of these commenters expressed concerns regarding the legality of the coverage, affordability, and comprehensiveness guardrail interpretations included in the 2018 Guidance.

Many commenters expressed concerns with the focus on the "availability of comprehensive and affordable coverage" in the 2018 Guidance and its effect on how the Departments could apply the coverage, affordability, and comprehensiveness guardrails. Some commenters raised a fundamental concern that the Department's current interpretation

conflicts with the plain language and Congressional intent of the statute, and stated that the Departments should revert to the previous approach (as outlined in the 2015 Guidance) requiring that only those actually covered in EHB-compliant plans be counted toward compliance with the guardrails. Some commenters asserted that the statute requires the Departments to consider the estimated number of state residents who would actually enroll in comprehensive, affordable coverage if the waiver were approved and implemented, not just the estimated number of residents who would have the opportunity to enroll in such coverage. The commenters were concerned that the focus on 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, and would contradict the congressional intent behind the statutory guardrails. 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.

Some commenters were concerned that the Departments' consideration of all forms of private coverage in addition to public coverage, including employer-based coverage, individual market coverage, and other forms of private health coverage would include forms of coverage that are not subject to the federal market reform requirements, including short-term, limited duration insurance (STLDI) plans and association health plans (AHPs). Other commenters were concerned that, because the 2018 Guidance would allow for STLDI to be included as a form of coverage under the analysis of whether a proposed waiver plan meets the section 1332 guardrails, there may be consumer confusion regarding what STLDI plans cover and do not cover in terms of benefits and out-of-pocket spending.

Commenters also expressed generalized concern that the 2018 Guidance could permit states to implement waiver programs that support consumer uptake of alternative plan options, including plans such as STLDI and AHPs that can be underwritten, or plans that do not meet EHB standards. In particular, commenters were concerned, in relation to the affordability guardrail, that measures taken under a state waiver program to facilitate coverage in such

alternative plan options (for example, allowing the use of subsidies for such coverage) would result in fewer comprehensive plans in the market, and that those comprehensive plans would be less affordable. Commenters asserted that this would perpetuate a tendency for comprehensive coverage to attract higher-risk consumers, while healthier, lower-risk consumers would tend to enroll in alternative plan options, with non-comprehensive coverage. This, the commenters assert, would change the risk pool, bifurcating the market into low-risk consumers enrolled in alternative plan options and high-risk consumers enrolled in comprehensive coverage and comprehensive coverage would become less affordable and less available. Commenters thus asserted concerns related to the comprehensiveness and affordability guardrails that fewer individuals would be covered by comprehensive, affordable coverage with cost-sharing protections, and any interpretation of the section 1332 guardrails that allows approval of a waiver plan that promotes less comprehensive forms of coverage such as STLDI and AHPs is inconsistent with the statute.

Commenters also expressed concern that these alternative plan options are not subject to the same limitations as comprehensive coverage in terms of consumer protections and could also impact the affordability guardrail. For instance, these alternative plan options generally lack financial limitations like out-of-pocket maximums and are not subject to the federal prohibition on annual and lifetime limits for EHB. These commenters asserted that lower-risk consumers would tend to enroll in such alternative plan options because of these plan options' lower premiums and that these consumers would bear the financial risks associated with having coverage that places no limit on enrollee out-of-pocket expenses. Furthermore, commenters asserted that these consumers could then experience an unexpected, catastrophic health event, and could therefore be forced to pay substantially more in out-of-pocket costs than if they had enrolled in comprehensive coverage. Commenters asserted that such out-of-pocket costs would far exceed any savings consumers might achieve by rejecting comprehensive coverage and choosing a cheaper alternative.

There were a variety of other comments related to potential market impacts of the interpretation of the guardrails included in the 2018 Guidance. Some commenters noted that issuers offering comprehensive coverage might be more prone to exit a market

⁵⁷ Waivers for State Innovation, 80 FR 78131, available at <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

due to instability caused by the entry of alternative plan options. These commenters raised concerns regarding the potential degradation of the risk pool due to the increased likelihood of high health care costs with healthier consumers tending to choose alternative plan options. Other commenters raised concerns that the 2018 Guidance would lead to increased uninsured and underinsured populations, which would in turn increase emergency room utilization and health care costs. Some commenters were also concerned about the impact on the risk pool that they stated could occur as a result of the inclusion of alternative plan options as a form of coverage and allowing subsidies to be used towards purchasing these plans.

Response: The Departments acknowledge commenters' concerns and agree that section 1332 waivers should be designed to improve a state's health care market while protecting those in vulnerable populations, including consumers with pre-existing conditions. However, the Departments are of the view that the 2018 Guidance is based on a sound interpretation of section 1332 of PPACA and represents a reasonable and appropriate application of the section 1332 guardrails. The Departments also are of the view that the 2018 Guidance provides states more flexibility to address problems caused by PPACA and to give Americans more options to get health coverage that better meets their needs. Under the framework outlined in the 2018 Guidance, states can pursue waivers to improve their individual insurance markets, increase affordable coverage options for their residents, and ensure that people with pre-existing conditions are protected. For all waiver requests, the Departments retain the discretion to decide whether to approve a section 1332 waiver based on the particular circumstances of each state's application, provided that the Departments determine that all of the guardrails are satisfied, and the Departments must in all cases evaluate each application for compliance with section 1332 statutory requirements.

The Departments are of the view that the framework outlined in 2018 Guidance is based upon a sound interpretation of section 1332 and its requirements for approval of a section 1332 waiver. Under section 1332, the Departments may approve a state's section 1332 waiver application when the Departments determine the waiver plan will meet the section 1332 guardrails. For example, section 1332(b)(1)(C) of PPACA, the coverage guardrail, requires that a state's plan under a waiver will provide coverage

“to at least a comparable number of its residents” as would occur without the waiver. However, the statutory text for the coverage guardrail is silent as to the type of coverage that is required or must be considered as part of this analysis. In addition, sections 1332(b)(1)(A) and (B) of PPACA state only that the state's waiver plan must “provide” coverage that is as comprehensive and affordable as would occur without a waiver, but do not require that people actually purchase and enroll in this coverage under a waiver. By its plain language, the term provide means “to supply or make available” and does not require or imply that people must use what is provided.⁵⁸ Prior to the publication of the 2018 Guidance, the interpretations and policies outlined in the 2015 Guidance focused on the number of individuals actually estimated to enroll in comprehensive and affordable coverage that meets all requirements under title I of PPACA, in effect reading the “to at least a comparable number of its residents” language from the coverage guardrail into the comprehensiveness and affordability guardrails as well.⁵⁹ However, neither the language nor structure of the statute compels that reading.

The Departments are of the view that the interpretations of the guardrails in the 2018 Guidance are reasonable and encourage states to provide, alongside coverage options that comply with PPACA market reforms, innovative coverage options that, while potentially less comprehensive than coverage established under PPACA, could be better suited to consumer needs and potentially more affordable and attractive to a broad range of a state's residents. Regarding the commenters' concerns about the focus on “availability of comprehensive and affordable coverage” as outlined in the 2018 Guidance (83 FR 53578) and its impact on how the Departments would analyze the guardrails when reviewing section 1332 waiver applications, the Departments are of the view that this focus loosens restrictions imposed by the interpretations outlined in the 2015 Guidance that were not required by PPACA and that previously limited state flexibility and consumer choice. While the 2015 Guidance focused on the number of individuals who would actually be provided comprehensive and affordable coverage under a proposed state waiver plan, the 2018 Guidance shifted focus to whether a

waiver plan would actually make available comprehensive and affordable coverage to state residents. Under the 2018 Guidance and the regulatory changes finalized in this rule, the coverage available under the proposed waiver must be both as comprehensive and affordable as coverage available without the waiver. As noted previously, this shift comports with the plain language of the statute by establishing that “provide coverage” does not mean anything more than for such coverage to be supplied or available to consumers under the waiver. This shift would allow states to provide access to health insurance coverage at different price points and benefit levels. This shift ensures that state residents who wish to retain comprehensive coverage similar to that provided under PPACA can continue to do so, while permitting a state waiver plan to also provide access to other coverage options that may be better suited to consumer needs and more attractive to many other individuals. In addition, the 2018 Guidance focuses on the aggregate effects of a waiver on all state residents, rather than requiring that the guardrails be met for specific sub-populations. This interpretation provides states more flexibility to consider the effects on all categories of residents and to decide that improvements in comprehensiveness and affordability for state residents as a whole offset any small detrimental effects for particular residents. As explained in the 2018 Guidance, the state's analysis should address in the application for the section 1332 waiver how the section 1332 state waiver plan supports and empowers those with low income as well as those with high expected health care costs.

When applying the coverage guardrail, a comparable number of residents must still be covered as would have been covered absent the waiver. The 2018 Guidance also explains that the Departments conduct an assessment that takes into account whether the section 1332 state plan sufficiently prevents gaps in or discontinuations of coverage to address any decreases in coverage for specific sub-populations.

The Departments generally have discretion to interpret the statutory guardrails, including ambiguous or undefined terms, and continue to be of the view that the interpretations and policies outlined in the 2018 Guidance are consistent with the statute. As such, the Departments are finalizing amendments to 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) to codify policies and interpretations outlined in

⁵⁸ Merriam Webster. Available at <https://www.merriam-webster.com/dictionary/provide>.

⁵⁹ See 80 FR 78132–33 (discussion of the affordability guardrail in the 2015 Guidance).

the 2018 Guidance into the section 1332 waiver implementing regulations.

In response to commenters' concerns regarding the Departments' consideration of "all forms of private coverage in addition to public coverage, including employer-based coverage, individual market coverage, and other forms of private health coverage" (85 FR 53579) for the purposes of the coverage guardrail as outlined in the 2018 Guidance, the Departments are of the view that consumers are best suited to determine what coverage best suits their individual or family's needs, whether that is a QHP, a major medical non-QHP, an STLDI plan, or another available coverage option. Section 1332 waivers should empower states to present innovative plans to provide access to coverage to every state resident, including those individuals who are not eligible for Medicaid or CHIP or who cannot afford comprehensive, major-medical coverage, but still want or need some form of coverage to protect against catastrophic expenses. In addition, regarding some commenters' concerns that fewer people may actually be covered, the Departments note that when applying the coverage guardrail, a comparable number of residents must still be covered as would have been covered absent the waiver. In response to commenters' concerns regarding the impact on the affordability guardrail due to the alternative plan options that are not subject to the same consumer protections as comprehensive coverage, the Departments previously noted that the affordability guardrail refers to state residents' ability to pay for health care expenses relative to their incomes and may generally be measured by comparing each individual's expected out-of-pocket spending for health coverage and services to his or her income. Therefore, states are required to include such analyses in waiver applications. As such, the Departments are finalizing amendments to 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) as discussed in this section of the preamble.

We generally disagree with the commenters' suggestion that the consideration of alternative plan options, including STLDI plans, in the analysis of whether a proposed waiver meets the section 1332 guardrails, may result in consumer confusion about the benefits and coverage offered by STLDI plans. If a waiver were approved that included alternative plan options, residents in the state would continue to have access under the state's waiver plan to the same metal level plans and catastrophic plans that include EHB that

are available today. Consumers would therefore have access to at least the same coverage and cost-sharing protections against excessive out-of-pocket spending as without the waiver. The availability of alternative plan options would be another option for consumers to consider as they shop for and enroll in coverage. However, recognizing the need and importance to ensure consumers are making informed choices, the Departments note that existing federal regulation requires issuers of STLDI plans to prominently display in the contract and in any application materials a consumer disclosure notice that informs consumers about the limitations of STLDI plans.⁶⁰ The Departments further note that, to the extent STLDI plans are displayed on non-Exchange direct enrollment websites approved by the FFE to assist with Exchange applications and enrollment, those websites must clearly distinguish QHPs from other available coverage options and are prohibited from displaying STLDI plans side-by-side on the same website page with QHPs.⁶¹ These display requirements ensure that consumers can easily discern which plans are QHPs eligible for APTC and which are not. In addition, many states have adopted state-specific marketing and other consumer protection laws intended to help consumers understand the differences between the different available coverage options.

The Departments are of the view that concerns related to the potential increase in the cost of comprehensive coverage are not warranted because the application of the guardrails would prevent the approval of a waiver that would reduce access to comprehensive health coverage. Under the guardrails, a waiver clearly cannot be approved if it raises the cost of the comprehensive coverage that is available to consumers. The Departments are confident that the review process applicable to section 1332 waiver applications and the Departments' discretion to reject waiver applications that would result in unreasonable harm to a state's risk pool are sufficient to mitigate commenters'

⁶⁰ See 45 CFR 144.103 (defining STLDI and providing the language of the required consumer disclosure notice).

⁶¹ See 45 CFR 155.221(b)(1) (direct enrollment entities must "[d]isplay and market QHPs and non-QHPs on separate website pages on its non-Exchange website. . . ."); 45 CFR 155.221(b)(3) (direct enrollment entities must "[l]imit marketing of non-QHPs during the Exchange eligibility application and QHP plan selection process in a manner that minimizes the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not. . . .").

concerns that the cost of comprehensive coverage will increase, in terms of premiums and out of pocket spending. Specifically, the Departments are required to evaluate each state's proposal to determine that it meets the section 1332 requirements. The Departments undertake extensive analysis and reviews of research and program information as part of these determinations. As provided in 31 CFR part 33 and 45 CFR part 155, subpart N, the waiver application must include analysis and supporting data that demonstrates that the waiver satisfies the guardrails. As such, a state is required to include an actuarial analysis and actuarial certification, economic analysis, data and assumptions and other necessary information to support the state's estimates that the proposed waiver will meet the requirements of section 1332. The actuarial and economic analysis must appropriately model the impact of the waiver plan, including impacts on enrollment and affordability for individual market single risk pool coverage, relative to a without-waiver baseline. Any net increase in premiums in the individual market risk pool in a with waiver scenario, compared to a without-waiver scenario, would likely not meet the guardrails and would not be an approvable waiver application. In addition the Departments maintain the discretion to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrail requirements. As such, the Departments can deny a proposed waiver plan that meets the guardrails, if the Departments determine the waiver would cause more harm than good to the state's residents or to a state's risk pool.

Comment: Some commenters raised concerns regarding how the interpretation of the guardrails, including the focus on the "availability of comprehensive and affordable coverage", in the 2018 Guidance would impact maintaining protections for vulnerable populations and consumers with pre-existing conditions. In particular, commenters raised concerns that alternative plan options can terminate or deny coverage based on health status, which would tend to affect high-risk individuals. Commenters asserted that coupled with the diminished affordability of comprehensive coverage, this possibility puts high-risk individuals at great risk of going without effective coverage for their health care needs. Commenters also raised concerns that the guidance

provides the flexibility to craft hypothetical EHB-benchmarks that could further diminish the quality and affordability even of comprehensive coverage under a waiver program.

Some commenters also expressed concern that the potential market effects would generally 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 waiver application, even though the impact on vulnerable population groups would be taken into account. Many vulnerable population groups were represented in the comments, including the elderly and those with pre-existing conditions like cystic fibrosis, ostomy/continent diversion, heart disease, arthritis, epilepsy, muscular dystrophy, leukemia/lymphoma, hemophilia, and others. Commenters raised the importance of ensuring compliance with specific PPACA market reforms including coverage of preventive services without cost sharing, the prohibition of pre-existing condition exclusions, the rating rules, and EHB coverage requirements, including prescription drugs and mental health and substance use disorder services. Commenters also stated concern for young adults who heavily rely on comprehensive coverage and key benefits like mental health care.

Response: The Departments understand commenters' concerns regarding potential impacts on vulnerable populations. The Departments are of the view that it is important that vulnerable populations have the support they need to obtain affordable and comprehensive coverage that meets their individual or family needs. As outlined in the 2018 Guidance, the Departments are committed to supporting and empowering those in need.⁶² Furthermore, as discussed in the 2018 Guidance, the state should address in the application for the section 1332 waiver how the section 1332 state plan addresses the principles outlined in the 2018 Guidance to support and empower those with low incomes as well as those with high expected health care costs as

⁶² From 2018 Guidance principles: "Support and empower those in need. Americans should have access to affordable, high value health insurance. Some Americans, particularly those with low incomes or high expected health care costs, may require financial assistance. Policies in section 1332 waiver applications should support state residents in need in the purchase of private coverage with financial assistance that meets their specific health care situations." (83 FR 53577).

it relates to the coverage, comprehensiveness, and affordability guardrails. The Departments also note that state section 1332 waiver applications are reviewed by the Departments on an individual basis, and in the 2018 Guidance, the Departments explained that state waiver applications should also identify any types of individuals for whom affordability of coverage would be reduced by the waiver and any types of individuals for whom affordability of coverage would be improved under the waiver. In addition, the Departments have encouraged and continue to encourage states to develop waiver proposals that support and empower those with low incomes as well as those with high expected health care costs. The Departments further note and emphasize that section 1332 waiver authority cannot be used to waive many of PPACA's consumer protections, including coverage of preventive services without cost sharing, the prohibition against pre-existing conditions exclusions, guaranteed issue, or the rating rules. As such, consumers will continue to have access to comprehensive coverage options that are subject to and must comply with PPACA market reforms identified by commenters.

Comment: A few commenters recommended that the Departments provide more flexibility for states to meet the requirement that a waiver will not increase the federal deficit. They recommended that instead of mandating that all waiver applications meet the deficit neutrality guardrail for each and every year of the waiver, they should instead be required to meet the deficit neutrality guardrail over a 10-year period. These commenters noted that this approach would be consistent with how CBO scores are generally analyzed for budget neutrality over a 10-year period, and would be consistent with the current requirement for states to include a 10-year budget projection in a state section 1332 waiver application.

Response: The Departments appreciate these commenters' recommendation, but the Departments are not making any changes to the Departments' interpretation or application of the federal deficit guardrail. Therefore, the Departments continue to require that a waiver 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 application.

Comment: A few commenters expressed concern that allowing states

to rely on existing general authority to enforce PPACA, in conjunction with a duly enacted regulation or Executive Order, delays stakeholder notification of a state's proposal and does not provide stakeholders adequate time to prepare comments or work with state legislatures to address concerns with proposed legislation.

Response: The Departments acknowledge these commenters' concerns, but note that the section 1332 implementing regulations include requirements for public notice at the state and federal level for new waiver applications.⁶³ In addition, states are not precluded from providing additional notice of an intent to submit a section 1332 waiver application under the section 1332 implementing regulations. The Departments therefore are not making any changes to this policy and will continue to apply the interpretation that permits states to rely on existing general authority to enforce PPACA, in conjunction with a duly enacted regulation or Executive Order.

Comment: A few commenters stated that the revisions in the 2018 Guidance constituted a significant change to prior section 1332 waiver policy and should have been proposed through rulemaking. Several commenters requested the Departments consider the comments submitted and publish a revised version of the guidance. Additional commenters stated that the 30-day comment period for the proposed 2022 Payment Notice was too short and did not provide sufficient opportunity for commenters to address the impact of these requirements to date and the potential prospective impact, including the potential negative consequences for consumers seeking affordable coverage to meet their health needs. Other commenters recommended that this rule is not an appropriate place to propose moving the 2018 Guidance into regulation and if the Departments want to pursue these policies, then the Departments must retract these provisions from this rule and repost the entire 2018 Guidance through the full APA rulemaking process with a separate notice-and-comment period.

Response: The Departments appreciate commenters' interest in policies affecting section 1332 waivers. The Departments are of the view that a

⁶³ See 31 CFR 33.112 and 45 CFR 155.1312; 31 CFR 33.116 and 45 CFR 155.1316. Also note that there is flexibility under 31 CFR 33.118 and 45 CFR 155.1318 for states to request, subject to approval by the Departments, modification from the normal public notice requirements during the COVID-19 PHE when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interest of consumers.

longer comment period would have delayed the publication of this final rule and created significant challenges in providing certainty for states developing section 1332 waiver proposals or those with existing approved waivers. Furthermore, while the Departments generally disagree that the 2018 Guidance should have been formalized in rulemaking initially or that there is a need to codify amendments to the section 1332 regulations through a separate rulemaking, stakeholders and the general public have now had two opportunities to provide feedback on the policies and interpretations outlined. The Departments have considered comments received in response to the 2018 Guidance, as well as those received in response to the section 1332 policies in the proposed rule. After consideration of these comments, for the reasons outlined earlier in this section of the preamble, the Departments are finalizing amendments to the section 1332 implementing regulations to codify many of the policies and interpretations outlined in the 2018 Guidance. The Departments, however, are not changing any of the substantive policies or interpretations in the 2018 Guidance, as the goal of this effort is to provide stability and certainty to states with existing approved waiver plans and those who may be interested in pursuing a section 1332 waiver.

Comment: Commenters requested that the Departments closely monitor waiver proposals to ensure fair and adequate access to affordable and comprehensive coverage, particularly in light of the COVID-19 PHE. A few commenters highlighted that the timing of this proposal could be particularly harmful given the current COVID-19 PHE. These commenters were concerned that this policy will have a disproportionate impact on certain populations, that have also been disproportionately impacted by COVID-19, such as certain racial and ethnic populations.

Several commenters requested that CMS closely monitor waiver proposals to ensure fair and adequate access and payment for Federally Qualified Health Centers (FQHC) services.⁶⁴ Commenters also encouraged CMS to prioritize section 1332 waiver proposals that maintain the statutory requirement for qualified health plans to include essential community providers, like FQHCs, that serve predominately low-income individuals, and that CMS

encourage states to explore section 1332 waivers that expand the vital enabling services, including outreach and enrollment assistance.

Response: The Departments note that the purpose of section 1332 waivers is for states to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. For instance, to date, reinsurance waivers have delivered measurable premium reductions. These benefits may be particularly important to address COVID-19, and the Departments have already issued regulations to provide states with flexibility to take advantage of section 1332 waivers to address the immediate issues COVID-19 presents.⁶⁵ The Departments are of the view that this rule further supports state efforts to take advantage of section 1332 waivers to address the COVID-19 PHE.

The Departments are of the view there are many areas, including those identified by commenters, in which compliance monitoring will be particularly important to ensure that approved waivers continue to meet the statutory criteria for approval, especially during the current COVID-19 PHE. Given that all policy changes can have a range of impacts due to the specifics of the state, such as the time the policy was implemented, the specific operational choices, and other market factors, the Departments may include strict safeguards and monitoring protocols in the approval letter and waiver terms and conditions to ensure that the waiver continues to meet the guardrails, including the impact on certain populations, for the duration of the waiver period. The federal government is committed to an all of government approach to providing COVID-19 relief.⁶⁶ In addition, throughout the COVID-19 PHE, CMS has worked to ensure the safety of the American public and has offered states, providers, suppliers, and group health plans and health insurance issuers flexibilities in furnishing and providing services to combat COVID-19. To the extent possible, the Departments intend to align this monitoring with each state's waiver design to effectively evaluate waiver program performance, while keeping administrative burdens to a minimum.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following ICRs.

A. ICRs Regarding State Innovation Waivers (31 CFR 33.108, 45 CFR 155.1308, 31 CFR 33.120, 45 CFR 155.1320, 31 CFR 33.128 and 45 CFR 155.1328)

The Departments are finalizing regulatory revisions codifying into section 1332 regulations policies initially announced in the 2018 Guidance governing waiver application procedures, monitoring and compliance, and periodic evaluations to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments. The Departments are not altering 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 seeking waiver approval or those states with approved waiver plans. The Departments anticipate that implementing these provisions will not significantly change the associated burden. The burden related to this information collection (Review and Approval Process for Waivers for State Innovation (CMS-10383)) is currently under review by OMB. CMS did not receive comments on these ICRs.

⁶⁴ Specifically, the FQHC protections in section 1311(c)(1)(C) of PPACA and section 10104(b)(2) of PPACA (adding (g) to section 1311 of PPACA)) should not be compromised in any waiver granted to a state under section 1332.

⁶⁵ See 85 FR 71142 (Nov. 6, 2020) (adopting flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers during the COVID-19 PHE).

⁶⁶ See <https://www.usa.gov/coronavirus>.

B. ICRs Regarding Exchange Direct Enrollment (DE) Option (§ 155.221)

Current SBEs that elect to implement the Exchange DE option will need to revise their Exchange Blueprint (Blueprint) under § 155.221(j)(1) to describe precisely how the state proposes to implement the Exchange DE option in compliance with related requirements. We believe that any costs of revising the Blueprint will be nominal, as this process involves logging into a CMS web interface that serves as the repository for all states' Exchange Blueprints to input additional information on the updated processes and controls the state will implement to manage its new Exchange DE program. The burden related to completing the Blueprint is currently approved under OMB Control Number 0938–1172 (Blueprint for Approval of Affordable State-based and State Partnership Insurance Exchanges (CMS–10416)). We sought comment on the burden associated with this activity, but did not receive any.

Prospective DE entities must contract with an independent third-party auditor to complete a security and privacy controls assessment, which must be submitted to HHS for review. Once approved, a DE entity must submit quarterly plans of action and milestones (POA&Ms) to HHS to document the identification and resolution of any new or existing security or privacy risks. We will prepare an ICR submission for review and approval by OMB through the normal PRA notice-and-comment process.

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule, please visit the CMS website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410–786–1326.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule includes provisions related to FFE and SBE–FP user fees for the 2022 benefit year. It also includes changes related to acceptance of payments by issuers of individual market QHPs. It clarifies the regulation imposing network adequacy standards with regard to QHPs that do not

differentiate benefits based on whether an enrollee receives services from an in-network or out-of-network provider. It also creates a new direct enrollment (DE) option for states served by State Exchanges, FFEs, and SBE–FPs. In addition, relating to State Innovation Waivers, this rule finalizes regulatory revisions codifying into section 1332 regulations policies initially announced in the section 1332 2018 Guidance, governing waiver application procedures, monitoring and compliance, and periodic evaluations to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver.

B. Overall Impact

The Departments have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA), Public Law 96–354 (September 19, 1980), section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (March 22, 1995), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act, 5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. An RIA must be prepared for rules with economically significant effects (\$100 million or more in any one year).

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary

impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and a “significant” regulatory action is subject to review by OMB. The Departments have concluded that this rule is likely to have economic impacts of \$100 million or more in at least one year, and therefore, meets the definition of “significant rule” under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

The provisions in this final rule aim to ensure that consumers continue to have access to affordable coverage and health care, and that states have flexibility and control over their insurance markets. The changes related to the Exchange DE option and section 1332 waivers will reduce regulatory burdens for states. Through the reduction in financial uncertainty for states and issuers and increased affordability for consumers, these provisions are expected to promote greater market stability and to increase access to affordable health coverage. In states that implement the Exchange DE option, there will be start-up costs for states, DE entities (including web-brokers, agents and brokers, and issuers), and the federal government related to start-up, approval, implementation, and oversight. However, consumers in such states will likely have more options to shop for coverage and an improved shopping experience. Some issuers may incur minimal costs to make operational changes in order to accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA.

Comment: A few commenters stated that the RIA in the proposed rule was inadequate.

Response: As explained in the proposed rule, the Departments are unable to quantify all the effects of the provisions of this rule. There are uncertainties regarding the impact of several provisions. For example, it is not certain how many states will implement the Exchange DE option or how many states will submit section 1332 waiver applications. Therefore, the Departments have included qualitative

discussions of costs and benefits related to the provisions in this final rule.

C. Impact Estimates of the Payment Notice Provisions and Accounting Statement

In accordance with OMB Circular A-4, Table 1 depicts an accounting statement summarizing the Departments' 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 and in an Exchange. Although we are 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 some of the provisions of this rule.

For 2022, we are finalizing a reduction in the FFE user fee rate from 3.0 percent of total premiums charged to 2.25 percent of total premiums charged, and a reduction in the SBE-FP user fee rate from 2.5 percent of total premiums charged to 1.75 percent of total premiums charged. For the 2023 benefit year, we are finalizing the FFE-DE and SBE-FP-DE user fee rate of 1.5 percent of total premiums charged. While our

current budget estimates may change in the future, we believe that it is important to keep the user fee in all markets at the lowest level possible to cover the costs of the Exchanges and keep premiums low for consumers and issuers. We expect transfers from the issuers to federal government to be reduced by approximately \$270 million in 2022 and by approximately \$60 million in 2023 due to changes in user fee rates and state transitions; transitions from FFE or SBE-FP to State Exchange, SBE-FP in 2022, or to FFE-DE in 2023 are included in the reduction in user fee transfers from issuers to federal government.

TABLE 1: Accounting Statement

Benefits:				
Qualitative:				
<ul style="list-style-type: none"> ● Continued access to coverage and health care for consumers. ● Potential reduction in operational costs for the federal government if FFE or SBE-FP states elect to implement the FFE-DE or SBE-FP-DE option. ● Potential improved shopping experience for consumers in states with Exchanges that implement the Exchange DE option. This may result in a potential increase in enrollments in a state that implements this option. ● Potential improvements to the individual market risk pool through increased incentives for DE entities to enroll people who would otherwise not enroll—a potentially healthier group—in states that implement the Exchange DE option. ● Increased certainty for states to pursue section 1332 waivers, which could, in turn, help increase the number of states that apply for waivers to improve their individual insurance markets and increase affordable coverage options for their residents. ● Ease of administration of individual coverage HRAs and QSEHRAs when issuers accept payments made on behalf of enrollees. 				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$ 0.03 million	2020	7 percent	2021-2023
	\$ 0.03 million	2020	3 percent	2021-2023
Quantitative:				
<ul style="list-style-type: none"> ● Regulatory familiarization costs of approximately \$80,000 in 2021. 				
Qualitative:				
<ul style="list-style-type: none"> ● Increased costs due to increases in providing medical services (if health insurance enrollment increases). ● Start-up costs for states seeking to transition to an SBE for future plan years in order to utilize the new Exchange DE option. These costs may potentially be higher as compared to start-up costs for states seeking to transition to an SBE without implementing the Exchange DE option, due to the additional interfaces to DE entities that must be implemented and managed. ● Increased operational costs for existing SBEs electing to implement the Exchange DE option for ongoing monitoring and oversight of the DE entities, as well as for maintaining and managing the individual interfaces and transactions with each DE entity. ● Costs incurred by prospective DE entities (including web-brokers, agents and brokers, and issuers) and the federal government related to startup, approval, and implementation of the Exchange DE Option. ● Increase in administrative costs for issuers that need to make operational adjustments in order to accept premium payments from individual coverage HRAs or QSEHRAs made on behalf of enrollees. ● Potential increase in consumer confusion associated with a transition to an Exchange that implements the DE option. This may result in a potential reduction in enrollments through an Exchange that implements this option. 				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	- \$108.5 million	2020	7 percent	2021-2023
	- \$109.4 million	2020	3 percent	2021-2023
Quantitative:				
<ul style="list-style-type: none"> ● Reduction in transfers from the issuers to the federal government by approximately \$270 million in 2022 due to changes in user fee rates, and approximately \$60 million in 2023, due to the availability of the DE option to FFE and SBE-FP states beginning with the 2023 benefit year. 				
Qualitative:				
<ul style="list-style-type: none"> ● Pass-through funding amounts paid to states would increase if the number of states that apply for and receive 1332 waivers increases. Under a section 1332 waiver, a state may receive pass-through funding associated with the resulting elimination or reductions in federal spending on Exchange financial assistance (that is, PTC, CSR, or small business health insurance tax credits (SBTC) under section 45R of the Code), provided pursuant to PPACA that would have been paid on behalf of participants in the Exchange in the state in the calendar year in the absence of the waiver, but will not be paid as a result of the waiver. 				

1. Exchange Direct Enrollment (DE) Option (§ 155.221)

We are finalizing the proposal to add § 155.221(j) to establish a new Exchange direct enrollment (DE) option by which states can 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. State Exchanges, as well as SBE-FP and FFE states can elect, subject to HHS approval, to implement the Exchange DE option. The impact of the new Exchange DE option will depend on the specific Exchange model and the number of states that take advantage of the new option. There are various stakeholders in states that elect to implement the Exchange DE option that could be impacted, including consumers, State Exchanges, web-brokers, issuers, and agents and brokers, as well as the federal government. However, we note that the FFEs' current direct enrollment pathways (Classic DE and EDE) generally reduce operational costs to the federal government while alleviating certain burdens on consumers.

The Exchange DE option may have varied impacts on consumers, and we solicited public comments to help us to understand how implementation of the Exchange DE option and a corresponding increase in the number of potential websites through which consumers could shop for QHP coverage might impact consumers and consumer behavior with respect to QHP enrollment.

At this time, we do not anticipate that any of the 15 current SBEs will implement the Exchange DE option in plan year 2022 because these states have not implemented direct enrollment interfaces with web-brokers or other direct enrollment entities similar to those implemented by the FFE. However, current SBEs that elect to implement the Exchange DE option will be responsible for meeting certain requirements for approval, in particular revising their Exchange Blueprint (Blueprint) under new § 155.221(j)(1) to describe precisely how the state proposes to implement the Exchange DE option. We believe that any costs of revising the Blueprint will be nominal, as this process involves logging into a CMS web interface that serves as the repository for all states' Exchange Blueprints to input additional information on the updated processes and controls the state will implement to manage its new Exchange DE program.

However, we sought comment on the burden associated with this activity, noting that the Blueprint is currently approved under the PRA under OMB Control Number 0938-1172.

For states seeking to transition to an SBE in future plan years and implement the SBE-DE option, we anticipate that start-up costs may potentially be higher than the start-up costs for states seeking to transition to an SBE without implementing the Exchange DE option, due to the additional interfaces that must be implemented between the Exchange's eligibility platform and each approved DE entity and managed on an ongoing basis by the Exchange. States transitioning to an SBE-DE will be required to complete the Exchange Blueprint in the same manner as required prior to this final rule and will be required to meet all required minimum functions of an Exchange. In terms of implementation costs, these states can realize savings by virtue of not having to maintain and operate a consumer-facing enrollment website capable of handling all Exchange-related internet traffic for all state residents, instead relying on DE entities and their websites to provide the majority of the Exchange's consumer-facing enrollment functionality.

The costs associated with consumer-facing enrollment functionality may be relatively lower than those associated with building the back-end Exchange eligibility platform, interfaces with DE entities to accept Exchange applications and complete eligibility determinations, the connections required from an Exchange's back-end eligibility platform to the Federal Data Services Hub for eligibility verifications, connections from the Exchange's back-end eligibility platform to the respective state Medicaid agency for coordinating Medicaid and CHIP eligibility determinations, and the Exchange's data management and reporting functionality necessary to submit required eligibility and enrollment data regarding all Exchange enrollees to HHS and the IRS. Based on recent state transitions to the SBE model, the design, development, and implementation costs for an Exchange depend on a number of factors. Recent design, development, and implementation costs have ranged from \$4 million for a smaller state, to almost \$24 million for a larger state. As no SBE to date has implemented direct enrollment, however, we are not able to provide accurate cost estimates in this regard. States may be able to partner with existing federal DE partners who are already fully-compliant with federal operational requirements to achieve administrative savings related to the

approval process for DE entities seeking to operate in their state. Any operational cost increases or savings may, in turn, affect an SBE's user fee and premium costs.

We do anticipate that an SBE electing the Exchange DE option will have increased operational costs for ongoing monitoring and oversight of the approved DE entities, as well as for maintaining and managing the individual interfaces and transactions with each DE entity. However, any savings achieved through a decrease in call center volume or other consumer supports due to DE partners assisting consumers with enrollment would offset any increased operational costs. Any operational cost increases or savings stemming from implementation of the Exchange DE option could, in turn, affect an SBE's user fee and consumer premium costs.

We also anticipate that the Exchange DE option can have significant impacts on prospective DE entities (including web-brokers, agents and brokers, and issuers) and the federal government as a result of start-up, approval, and implementation costs. Such costs may be incurred by entities who enter a state's market as a new DE entity for the first time, or by existing DE entities that expand into new markets. We presume that DE entities will act rationally and enter a state's market or expand into new markets if the benefits exceed the costs. For the SBE-FP-DE and FFE-DE option, prospective federal DE entities pursuing approval to host their own DE platforms will incur a number of costs associated with startup and implementation activities, including costs to implement the appropriate privacy and security infrastructure, business controls, and with meeting eligibility application technical requirements related to ensuring the proper coordination with state Medicaid and CHIP programs.

In terms of privacy/security approval and startup costs, prospective DE entities operating through the SBE-FP-DE and FFE-DE option will be required to implement almost 300 security and privacy controls consistent with a system security and privacy plan provided by CMS. After control implementation, prospective DE entities must contract with an independent third-party auditor to complete a security and privacy controls assessment test plan, which must be submitted to CMS for review. Once approved, a DE entity must submit quarterly POA&Ms to CMS to document the identification and resolution of any new or existing security or privacy risks. DE entities must also incur costs to

contract with a third-party auditor to perform an annual assessment of their security and privacy posture consistent with continuous monitoring requirements published by CMS, and feedback provided on their quarterly POA&Ms.

In terms of approval and startup costs of implementing appropriate business controls, prospective DE entities that wish to serve an SBE-FP-DE or FFE-DE option state and host an eligibility application also will be required to implement a dynamic user interface (UI) that adapts to consumer scenarios based on complex business rules and integration with a range of application programming interfaces (APIs). They must also implement post-enrollment support functionality. After development, integration, and testing are complete, a prospective DE entity serving an SBE-FP-DE or FFE-DE option state must contract with a third-party auditor to evaluate its implementation consistent with business audit report toolkits provided by CMS. The audit consists of evaluation of the UI to ensure its consistency with program requirements, as well as completion of functional and integration testing. Once approved, a DE entity is required to implement CMS-initiated change requests to update its DE implementation as needed. In addition, DE entities are subject to periodic application audits to confirm their platforms continue to meet program requirements and remain functional.

There are additional technical startup and approval costs related to the eligibility application functionality that DE entities serving SBE-FP-DE or FFE-DE option states are required to implement. They must have the ability to provide the Exchange with all the information necessary for it to determine eligibility to enroll in QHPs, as well as to determine eligibility for APTC, CSRs, Medicaid, and CHIP. Consumers who complete an eligibility application on a DE entity's website must be provided with an eligibility determination notice (EDN) from the Exchange, and related information must display within the DE entity's website UI about consumers' eligibility. Therefore, if a consumer is determined eligible for Medicaid or CHIP after completing an eligibility application through a DE entity's website, they will receive the same information in their EDN about that eligibility and next steps as if they completed the application on *HealthCare.gov*.

We also anticipate that there will be costs specific to web-brokers and issuers that choose to enter into fee-based

arrangements with other agents, brokers, or issuers, or that choose to enter new economic or legal arrangements with states, that help to offset the costs of the DE services provided. In terms of costs to issuers, generally any changes in issuer costs associated with the Exchange DE option could have downstream effects on premium rates. Issuers will be impacted by adjustments in Exchange user fees, and may have an incentive to promote direct enrollment if user fees are lower under the Exchange DE option, and the savings achieved through those lower user fees exceed the new costs of arrangements with web-brokers. Issuers may also be impacted if the Exchange DE option leads to shifts in consumer enrollment patterns, such as movement from a QHP offered by one issuer to another QHP. If issuers choose to build out standalone consumer-facing applications to enroll in coverage under the Exchange DE option, this would be another cost to consider that could impact them directly and have downstream impacts.

There are a number of additional anticipated costs to the federal government associated with the Exchange DE option beyond startup and approval. Under the FFE-DE and SBE-FP-DE option, for instance, we will continue to provide back-end eligibility services, notice and tax form generation, the processing of data matching and special enrollment verification issues, eligibility appeals, casework, advanced customer service, enrollment reconciliation, IRS reporting, and an alternate/back-up consumer-facing eligibility and enrollment platform (as we do today). In addition, the *HealthCare.gov* website will continue to provide standardized comparative information for QHPs offered through an SBE-FP or FFE and will remain available for enrollment, as well to ensure there is an avenue to handle eligibility applications that approved DE partners are unable to process. Assuming an FFE-DE state chooses existing DE entities with whom HHS has partnered for the FFE's DE and EDE programs, we anticipate that there will be minimal increases in federal administrative costs associated with implementing the FFE-DE option since we have already implemented these programs. Any changes in payment amounts of the federal user fee for these services or any changes in issuer costs associated with the DE option may have downstream impacts on premiums, and therefore, federal tax expenditures on PTCs, which are benchmarked to premiums. We anticipate that any HHS costs associated with supporting the

additional monitoring and oversight in states that elect to implement the SBE-DE option will be nominal given that SBEs will retain primary responsibility for overseeing their approved DE entities and HHS can leverage its existing SBE oversight mechanism⁶⁷ and associated processes to ensure that this is occurring.

We sought comment on this proposal, including any additional consumer, state, SBE, HHS, issuer, web-broker, or other costs, benefits or transfers that should be considered. We also sought data and information that would help us to quantify the potential impacts associated with this proposal. Comment summaries and our responses are included earlier in the preamble.

2. FFE and SBE-FP User Fees (§ 156.50)

We are finalizing an FFE user fee rate of 2.25 percent for the 2022 benefit year, which is lower than the 3.0 percent FFE user fee rate finalized for 2021 benefit year. We are also finalizing an SBE-FP user fee rate of 1.75 percent for the 2022 benefit year, which is lower than the 2.5 percent SBE-FP user fee rate we finalized for the 2021 benefit year. We are finalizing an FFE-DE and SBE-FP-DE user fee rate of 1.5 percent for the 2023 benefit year. Subject to HHS approval, SBE-FP or FFE states may implement the Exchange DE option starting in 2023. Based on our estimated costs, enrollment (including anticipated transitions of states from the FFE and SBE-FP models to either the SBE-FP or State Exchange models), premiums for the 2021 and 2022 benefit years, and the finalized user fee rates, we are estimating FFE and SBE-FP user fee transfers from issuers to the federal government will be lower by \$270 million in 2022 compared to those estimated for the prior benefit year. Costs may be shifted to approved DE entities (including QHP issuers) that states elect to use, so there may not actually be any cost savings on the part of issuers in SBE or FFE states that elect the Exchange DE option. As such, there may not be an incentive for issuers in FFE-DE or SBE-FP-DE states to adopt these models solely as a result of the lower user fee rate. While there will be reduced transfers to the federal government in FFE-DE or SBE-FP-DE states, we expect that available user fee collections from current and prior years will be sufficient to fund Exchange operations. Based on our finalization of the FFE-DE and SBE-FP-DE user fee rates, transfers to the federal

⁶⁷ https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/smart_2018_9.pdf.

government will be reduced by \$60 million in 2023.

Comment: While some commenters supported the reduced user fee rates stating that these rates could lead to lower premiums, many other commenters expressed concern regarding the reduced user fee rates and the potential impact on Exchange operations, specifically how these rates could impact enrollment. However, two commenters specifically criticized the information provided in the RIA section of the proposed rule. Both commenters expressed concern that HHS had not sufficiently analyzed the financial and health impacts of the proposed user fee rate reductions, as HHS had not investigated how reduced Exchange operations, Navigator services, marketing and outreach, health plan oversight, call center and consumer appeals services, among others may translate into reduced enrollment, and the health costs associated. The second commenter further suggested that the proposed user fee rate would not be sufficient to enable the Exchange to reduce premiums.

Response: We are finalizing 2022 benefit year user fee rates at 2.25 percent for FFE issuers and 1.75 percent for SBE-FP issuers as proposed. We have addressed the general concern for reductions in user fees in the earlier preamble response sections. With respect to the specific comment of the RIA, we have sufficiently analyzed the financial and health impacts of the proposed user fee rate reductions and our internal analysis suggests that user fees will provide the necessary funding for the full functioning of Exchange operations including Navigator services, oversight functions, call center, and appeals services, among others for the 2022 benefit year. Based on prior years' additional collections and future projected changes in costs, enrollment, and premiums, we project that HHS can fully fund Federal platform costs associated with providing special benefits to these issuers.

3. State Innovation Waivers

The Departments are finalizing the policies, with modifications, to codify many of the policies and interpretations outlined in the 2018 Guidance into the section 1332 waiver implementing regulations governing waiver application procedures, monitoring and compliance, and periodic evaluations to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments. As such, the Departments are finalizing changes to 31 CFR 33.108, 31 CFR 33.120, 31 CFR 33.128, 45 CFR

155.1308, 45 CFR 155.1320, and 45 CFR 155.1328. This final rule does not alter any of the requirements related to state innovation waiver applications, compliance and monitoring, nor evaluation in a way that would create any additional costs or burdens for states seeking waiver approval or those states with approved waiver plans. The Departments are of the view that the increased certainty regarding the application requirements will allow states to have greater confidence that the significant time and monetary investments necessary to plan for and submit a section 1332 waiver application will not result in wasted resources and taxpayer dollars. This increased certainty could help increase the number of states that apply for waivers and 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.

Comment: The Departments received many comments on the proposal and the potential impacts of the 2018 Guidance. Some commenters were concerned that finalization of the policy would increase health care costs, though the commenters did not define these costs further, and could potentially lead to increased premiums. A commenter stated that the Departments failed to analyze the distributional effects of the proposal, including its impact across the population and economy. The commenters asserted that the Departments failed to adequately identify and analyze the effects of codifying the policies in the 2018 Guidance in regulation.

Response: The Departments acknowledge that federal agencies, where appropriate, should analyze and consider the distributional effects of regulatory actions, which are the impacts of a regulatory action across the population and economy, divided up in various ways (for example, by income groups, race, sex, industrial sector, geography).⁶⁸ The Departments must analyze and determine whether each state waiver proposal complies with the section 1332 guardrails, which include comprehensiveness, affordability, coverage, and Federal deficit neutrality.

As explained earlier in section IV. of this final rule, a state's application and accompanying actuarial and economic analysis must appropriately model the impact of the waiver plan, including impacts on enrollment and affordability for individual market single risk pool

⁶⁸ OMB Circular A-4, Regulatory Analysis (Sept. 17, 2003).

coverage. Any increase in premiums in the individual market risk pool with the waiver, compared to a without-waiver scenario, would likely not meet the guardrails and would not be an approvable waiver application. To date, waivers have reduced premiums in comparison to premiums anticipated in the absence of the waivers.⁶⁹ In addition, the Departments maintain the discretion to reject any proposed waiver plan that meets the guardrails, such as if the Departments determine would cause more harm than good to the state's residents, or for example to a state's risk pool.⁷⁰ The Departments' approval letters for state waivers include information regarding the Departments' determination of whether a state's analysis and waiver plan satisfies the requirements of the section 1332 guardrails, as well as information on the projected impacts of waiver proposals.⁷¹

The Departments also acknowledge commenters' interest in the distributive impacts of incorporating the policies described in the 2018 Guidance into regulation text. As noted by commenters, OMB Circular A-4 is guidance issued by OMB and instructs that agencies should analyze the "distributional effect" of regulatory actions, which refers to the impact of a regulatory action across the population and economy, divided up in various ways (for example, income groups, race, sex, industrial sector, geography). However, the policies announced in the 2018 Guidance, specifically those that explain how the Departments will analyze compliance with the section 1332 guardrails, are not determinative of the specific waiver plans states may propose. Section 1332 waivers allow states to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. The Departments have encouraged states to propose innovative approaches to meet the unique needs of their population through the flexibilities

⁶⁹ Information about the pass-through amounts states received is available on HHS's CCIIO 1332 website, and information on the methodology and key components of the pass-through calculation is available under the "pass-through funding tools and resources" section and data brief on state relief and Empowerment Waivers, available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-.

⁷⁰ 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 guardrail requirements.

⁷¹ All section 1332 waiver approval letters available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-#Section_1332_State_Application_Waiver_Applications.

Congress made available to states under section 1332 of PPACA. As such, the Departments are unable to predict or analyze the impact of various state waiver plans that have not yet been submitted, including the distributional effects on various segments of the population. Based on previous waiver applications, the Departments know that the impact of waivers vary widely based on the state's specific waiver plan. For example, the actual impact of the waiver on statewide average premiums compared to the estimated impact on statewide average premiums (that is, as estimated in the original state waiver application) for each waiver year varies based on the state's specific waiver program. In plan year 2020, states that implemented reinsurance waivers have lowered premiums ranging from 3.8 percent in Rhode Island to 37.1 percent in Alaska when comparing with and without the waivers, depending on a variety of factors of the states' plans and the composition of the state's population.⁷²

A potential distributional impact for certain section 1332 waivers includes the substitution of pass-through funds from the federal government to the state in lieu of PTC, SBTC, or CSR, if a state waiver plan eliminates or reduces the amount of PTC, SBTC, or CSR that individuals and employers in the state receive ("pass-through funding").⁷³ Pass-through funding amounts are adjusted to ensure that waivers remain deficit neutral, as required by statute. As discussed in the 2018 Guidance and consistent with the Departments' regulations, when applying for a section 1332 waiver, the state should include in the waiver application sufficient analysis and supporting data to inform the estimate of any pass-through funding amount; states with approved waivers must report additional data and information to support the annual estimate of pass-through funding. Furthermore, pass-through funding may be for the amount of federal financial assistance pursuant to the PPACA not paid due to an individual not qualifying for financial assistance or qualifying for a reduced level of financial assistance resulting from a waived provision as a

direct result of the waiver plan.⁷⁴ Although pass-through funding payments would be operationalized by the federal government, the transfers, as categorized for purposes of this regulatory impact analysis, would flow from the individuals and employers who would otherwise receive PTC, SBTC, or CSR (not from the federal government) to the relevant states for the purposes of implementing the waiver plan.

The Departments are unable to estimate or determine how many or which states will apply for a section 1332 waiver once the policies described in the 2018 Guidance are codified in regulation. Based on our interactions with states that previously proposed or considered proposing section 1332 waiver plans, the Departments anticipate that more states will be able to take advantage of section 1332 waivers if approval standards are reasonable, appropriate, and sufficiently flexible to allow states to design waiver plans that are capable of addressing the specific needs and circumstances of their residents. The Departments are also of the view that, despite the significant investment of tax dollars and other state resources necessary to consider, design, and submit a section 1332 waiver proposal, more states will consider a waiver as a viable option to improve or address specific problems in their health care markets if they do not have to be concerned that the Departments' standards will change without notice or an opportunity to comment. For these reasons, the Departments are of the view that codifying the policies announced in the 2018 Guidance in rulemaking, as a general matter, will likely provide greater opportunities for states to lower premiums, provide greater health care support for state residents at a greater variety of income levels, and develop innovative strategies to address the needs of vulnerable populations.

The Departments note that the distributive impact of a state's particular waiver plan would be analyzed as part of the waiver application and review process. Specifically, as part of a state waiver application, final regulations at 31 CFR part 33 and 45 CFR part 155, subpart N, require a state to provide actuarial analyses and actuarial certifications, economic analyses, data and assumptions, targets, an implementation timeline, and other necessary information to support the

state's estimates that the proposed waiver will comply with section 1332 requirements to satisfy the section 1332 waiver guardrails. The 2012 regulation also specified that data and assumptions used should include information on the age, income, health expenses, and current health insurance status of the relevant state population; the number of employers by number of employees and whether the employer offers insurance; cross tabulations of these variables; and an explanation of data sources and quality that the Departments would use to evaluate any waiver application and address regulatory impact across the population and economy. For example, state waiver applications' actuarial and economic analysis showed that enrollment increased when comparing the with and without-waiver scenarios over different age ranges and income levels for states that are implementing a reinsurance program.⁷⁵ Furthermore, the Departments complete a preliminary review of any waiver application received in accordance with 45 CFR 155.1308(c) and 31 CFR 33.108(c), and if an application does not have the aforementioned information the Secretaries can make a preliminary determination that the application is not complete. In that case, the waiver application would not be reviewed further unless additional information is provided.

Furthermore, section 1332(a)(4)(B) of PPACA provides that the Secretary of HHS and the Secretary of the Treasury 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 after the 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 waiver requests, and 31 CFR 33.116(b) and 45 CFR 155.1316(b) specify the accompanying public notice and comment period requirements under the Federal public notice and approval process.⁷⁶ Under the current regulations

⁷² <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Data-Brief-June2020.pdf>.

⁷³ Information about the pass-through amounts states received is available on the CCIIO 1332 website and information on the methodology and key components of the pass-through calculation is available, under the "pass-through funding tools and resources" section and data brief on state relief and Empowerment Waivers "here: https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-

⁷⁴ The guidance on State Relief and Empowerment Waivers is available online at <https://www.federalregister.gov/documents/2018/10/24/2018-23182/state-reliefand-empowerment-waivers>.

⁷⁵ An example of information showing the distributional impact of a waiver on the population by age can be found in Table 3C. See <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Delaware-1332-Waiver-Application-July-10-2019.pdf>.

⁷⁶ Also note that there is flexibility under 31 CFR 33.118 and 45 CFR 155.1318 for states to request, subject to approval by the Departments, modification from the normal public notice requirements during the COVID-19 PHE when a delay would undermine or compromise the purpose

at 31 CFR 33.112 and 45 CFR 155.1312, states are required to provide a public notice and comment period prior to submitting an application for a new section 1332 waiver. In addition, under section 1332(a)(4)(B)(iii) of PPACA and the existing implementing regulations at 31 CFR 33.116(b) and 45 CFR 155.1316(b), the Secretary of HHS and the Secretary of the Treasury are required to provide a Federal public notice and comment period following their preliminary determination that a state's section 1332 waiver application is complete. As such, the Departments are of the view that the public has a meaningful opportunity to provide comments on waiver proposals and to understand the distributional effects on various segments of the population prior to waiver approval.

4. Network Adequacy Standards (§ 156.230)

We are finalizing the proposal to revise § 156.230 to reflect the longstanding interpretation that plans that do not utilize a provider network are not required to comply with network adequacy standards to obtain QHP certification. We make no other changes to QHP certification requirements or requirements under the market reform provisions under title I of PPACA; plans that do not utilize a provider network must still comply with all other applicable QHP certification requirements to obtain QHP certification. Because the codified interpretation is the status quo, we do not anticipate any burden to result from finalization of this policy. We disagree with some commenters' assertions that finalization of this policy will create increased costs for consumers or a proliferation of plans that do not differentiate benefits based on whether enrollees receive covered services from in-network providers, which may not be advantageous for certain consumers. As we explain earlier in the preamble, the changes to the QHP network adequacy standard we are finalizing make no changes to QHP certification requirements. There have only been 12 such plans that did not utilize a provider network approved as QHPs, which were approved for sale in Wisconsin for plan year 2016. In the last five plan years, there have been no such plans approved for QHP certification. Accordingly, we do not expect this policy to result in increased consumer costs or any proliferation appreciable increases to such plans seeking QHP certification.

of the proposed waiver request and be contrary to the interest of consumers.

5. Enrollment Process for Qualified Individuals (§ 156.1240)

We are finalizing this policy with some minor modifications to the regulatory text and the adoption of additional language specifying that QHP issuers must also accept premium payments using a payment method described in § 156.1240(a)(2) that are made directly by enrollees who are enrolled in an individual coverage HRA or QSEHRA. We expect this approach will ease administration of individual coverage HRAs and QSEHRAs by altering the behavior of QHP issuers who do not yet accept premium payments using such payment methods. It will also make the individual coverage HRA and QSEHRA experience more seamless for employers and employees by ensuring that individual coverage HRAs and QSEHRAs may pay premiums for employees through direct payments to the issuer, rather than through reimbursements of premium payments to employees.

We received several comments asserting that finalizing these changes would place cost burdens on issuers and have addressed them earlier in the preamble. As discussed, we did not propose and are not finalizing a requirement for QHP issuers to accept payments from individual coverage HRAs or QSEHRAs when such payments are made using a form of payment that is not described in § 156.1240(a)(2) or to accept aggregate payments from an individual coverage HRA or QSEHRA made on behalf of multiple enrollees.⁷⁷ While it may be possible that some issuers may incur administrative costs to implement operational changes necessary to comply with this requirement, such issuer costs should be minimal because QHP issuers, as a general matter, are already required to accept premium payments that are made using the forms of payment described in § 156.1240(a)(2). Accordingly, the rule we finalize here does not require issuers to incur additional costs to invest in information technology infrastructure that can generally accommodate roster, or list, billing.

6. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, the Departments 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, the Departments assume that the this rule will be reviewed by all affected issuers, states, and some individuals and other entities that commented on the proposed rule. The Departments acknowledge 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, the Departments consider the number of affected entities and commenters to be a fair estimate of the number of reviewers of this rule.

HHS is required to issue a portion of this rule each year under their regulations and the Departments estimate that approximately half of the remaining provisions would cause additional regulatory review burden that stakeholders do not already anticipate. The Departments also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for purposes of our estimate, the Departments assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that HHS is required to issue each year.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), the Departments estimate that the cost of reviewing this rule is \$110.74 per hour, including overhead and fringe benefits.⁷⁸ Assuming an average reading speed, the Departments estimate that it will take approximately 1 hour for staff to review the relevant portions of this final rule that causes unanticipated burden. The Departments assume that approximately 725 entities will review this final rule. For each entity that reviews the rule, the estimated cost is approximately \$110.74. Therefore, the Departments estimate that the total cost of reviewing this regulation is approximately \$80,287 (\$110.74 × 725 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, the Departments considered numerous alternatives. Below the Departments discuss the key regulatory alternatives that were considered.

As an alternative to the proposed reduction in user fee rates, we considered maintaining the FFE and SBE-FP user fee rates at their current 2021 levels. However, our analysis supported reducing the user fee rate. In

⁷⁷ 85 FR 78572, 78644.

⁷⁸ https://www.bls.gov/oes/current/oes_nat.htm.

light of the projected premium and enrollment increases, HHS believed that a reduction in FFE and SBE-FP user fees was warranted for 2022.

We considered including a requirement for states to submit and be approved for a State Innovation Waiver under section 1332 of PPACA as part of the proposed Exchange DE option described at new § 155.221(j). However, nothing under the plain terms of section 1311(d)(4) PPACA governing the functions of an Exchange requires an Exchange to host a single, consumer-facing enrollment website to receive applications or support plan shopping and selection.⁷⁹ Thus we concluded that there is no requirement in PPACA that must be waived to allow a state to implement the Exchange DE option, and requiring states to expend taxpayer dollars to file a waiver application would be unnecessary and unduly burdensome. We also considered aligning the implementation timeframe for all Exchange models interested in the Exchange DE option to plan year 2023; however, because we believe that this option could improve health insurance markets and that State Exchanges could implement the option by plan year 2022, we chose not to do so.

Regarding the section 1332 waiver policies in this rule, the Departments considered not proposing to codify the 2018 Guidance. Additionally, the Departments considered proposing the 2018 Guidance through separate notice and comment rulemaking. The Departments did not take either of these options because it would be contrary to the interest of states. Specifically, the Departments concluded that not proposing codifying the 2018 Guidance would lead to uncertainty for states considering section 1332 waiver applications, and the Departments concluded that separate notice and comment rulemaking was unnecessary because this rulemaking provided a public notice and comment period.

In this final rule, the Departments seek to provide certainty to states that the requirements and expectations of the section 1332 waiver program will not change abruptly during a period in which states are doing the work to prepare a waiver proposal. The Departments considered alternatives to the interpretations set forth in the 2018 Guidance, including interpretations that could further increase flexibility.

⁷⁹ Section 1311(d)(4)(C) of PPACA requires only that “[a]n Exchange shall, at a minimum . . . maintain an Internet website through which enrollees and prospective enrollees of qualified health plans may obtain standardized comparative information on such plans . . .”

However, the Departments determined that changing guidance and the criteria required for approval would increase regulatory uncertainty and make states less likely to submit section 1332 waivers. The Departments are of the view that finalizing these policies with modifications will help states that are interested in undertaking the complicated and potentially expensive work to design a waiver program that meets the four guardrails, as described in the 2018 Guidance. Codification of many of the policies described in the 2018 Guidance could also encourage more states to apply for section 1332 waivers. As discussed section IV.A. of this the preamble, this consideration is especially important because the process of developing and submitting a proposal may take significant time and taxpayer resources at the state level, and states do not want to undertake these efforts if the probability of success is low and the probability of the Departments changing requirements is high. As part of this rulemaking, the Departments substantively considered comments and determined that changes to 2018 Guidance were not warranted based on comments received.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the 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 uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

The provisions in this rule will affect health insurance issuers in the individual and small group markets. The Departments are of the view 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 are 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.⁸⁰ The Departments are of the view that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report⁸¹ 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 companies that may be affected, since over 67 percent of 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. Therefore, the Departments do not expect the provisions of this rule to affect a substantial number of small entities.

The changes related to section 1332 waivers may have an impact on small businesses. Section 1332 allows a state to waive Part I of Subtitle D of Title I of the ACA (relating to establishing QHPs); Part II of Subtitle D of Title I of the ACA (relating to consumer choices and insurance competition through Exchanges); sections 36B of the Code and 1402 of the ACA (relating to premium tax credits and cost-sharing reductions for plans offered through Exchanges); section 4980H of the Code (relating to employer shared responsibility); and section 5000A of the Code (relating to individual shared responsibility). To date, the Departments have approved one waiver that impacts small businesses. Hawaii’s waiver waived the small business health options program (SHOP) and related provisions in order to allow Hawaii to operate its own state program consistent with its state law. The state program, the Prepaid Health Care Act, requires virtually all employers to offer coverage to their employees and provides small employers premium assistance. As part of its the waiver, Hawaii waived the SBTC under section 45R of the Code. As such, the SBTC amounts that would otherwise be paid to small employers in Hawaii has been provided as a pass-through payment to the state, which it

⁸⁰ <https://www.sba.gov/document/support-table-size-standards>.

⁸¹ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

used to support a state fund that helps small businesses cover their health care-related costs.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule under title XVIII, title XIX, or part B of title 42 of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, the Departments define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, the Departments have determined that this rule will not affect small rural hospitals. Therefore, the Secretaries have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any federal mandate that may result in expenditures in any one year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$156 million. Although the Departments have not been able to quantify all costs, the Departments expect 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 issues a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. In the Departments' view, while this final rule will not impose substantial direct requirement costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets.

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, the Departments have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the NAIC, and consulting with state insurance officials on an individual basis.

While developing this rule, the Departments attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, the Departments complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange. 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.

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. Under the Congressional Review Act, the Office of Information and Regulatory Affairs designated this final rule as 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.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least

two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

This final rule primarily results in transfers and is thus not a regulatory or deregulatory action for the purposes of E.O. 13771.

List of Subjects

31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements, Waivers for State Innovation.

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 subtitle A as set forth below:

PART 33—WAIVERS FOR STATE INNOVATION

■ 1. The authority citation for part 33 continues to read as follows:

Authority: Sec. 1332, Pub. L. 111–148, 124 Stat. 119.

■ 2. Section 33.108 is amended by revising paragraphs (f)(3)(i), (f)(3)(iv) introductory text, and (f)(3)(iv)(A) through (C) to read as follows:

§ 33.108 Application procedures.

* * * * *

(f) * * *

(3) * * *

(i) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332 of PPACA. In analyzing whether the State has satisfied the requirement under section 1332(b)(2)(A) of PPACA that the State enact a law authorizing a waiver under section 1332 of PPACA, the Secretary and the Secretary of Health and Human Services, as applicable, may consider existing State legislation combined with duly-enacted State regulation or an executive order so long as the State legislation provides statutory authority to enforce PPACA provisions or the State plan;

* * * * *

(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) and interpretive guidance published by the Secretary and the Secretary of Health and Human Services:

(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 State plan will 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. These coverage options must also satisfy the affordability requirement in paragraph (f)(3)(iv)(B) of this section;

(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 State plan will 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 coverage options must also satisfy the comprehensive coverage requirement in paragraph (f)(3)(iv)(A) of this section;

(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. Coverage refers to 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; and

* * * * *

■ 3. Section 33.120 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 33.120 Monitoring and compliance.

(a) * * *

(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, regulations, and interpretive policy statements, as well as interpretive guidance published by the Secretary and the Secretary of Health and Human Services, unless expressly

waived. A State must, within the timeframes specified in law, regulation, interpretive policy or guidance, come into compliance with any changes in Federal law, regulation, or policy 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 § 33.108(f)(3)(iv) and interpretive guidance published by the Secretary and the Secretary of Health and Human Services when conducting implementation reviews under paragraph (b) of this section.

* * * * *

■ 4. Section 33.128 is amended 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 interpretive guidance published by the Secretary and the Secretary of Health and Human Services, as applicable, and any terms and conditions governing the section 1332 waiver.

* * * * *

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 155 and 156 as set forth below.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 5. 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.

■ 6. Section 155.221 is amended by—
■ a. Redesignating paragraphs (c) through (h) as paragraphs (d) through (i), respectively.

■ b. Adding a reserved paragraph (c);
■ c. In newly redesignated paragraphs (g) introductory text, (g)(6) and (7), and (h) by removing the reference to “paragraph (e)” and adding in its place a reference to “paragraph (f)”; and
■ d. Adding paragraph (j).

The additions and revisions read as follows:

§ 155.221 Standards for direct enrollment entities and for third parties to perform audits of direct enrollment entities.

* * * * *

(c) [Reserved]

* * * * *

(j) *Process for States to elect the Exchange direct enrollment option.* Subject to HHS approval, and in addition to or in lieu of the Exchange operating its own consumer-facing eligibility application and enrollment website, a State may elect for the State Exchange, State Exchange on the Federal platform, or federally-facilitated Exchange in the State to approve one or more enrollment entities described in paragraph (a) of this section to make available a non-Exchange online website to enroll qualified individuals in a QHP offered through the Exchange in the State in a manner that constitutes enrollment through the Exchange, as specified in paragraph (j)(1) or (2) of this section. Through the websites of these approved entities, consumers in the State apply for and enroll in coverage using an eligibility application as described in § 155.405, and receive eligibility determinations from the Exchange for QHP enrollment, advance payments of the premium tax credit and cost-sharing reductions, as well as receive assessments or determinations from the Exchange for Medicaid and CHIP eligibility in accordance with §§ 155.302 and 155.405.

(1) *Direct enrollment option for a State Exchange.* A State may receive approval, under §§ 155.105(b) and 155.106(a), to operate a State Exchange using the direct enrollment option described in this paragraph (j). The State Exchange must meet all Federal statutory and regulatory requirements for the operation of an Exchange. An approved State Exchange that wishes to implement this option must submit a revised Exchange Blueprint in accordance with § 155.105(e). In order to obtain approval for the State Exchange to implement this option, the State must:

(i) Demonstrate to HHS operational readiness for the State Exchange to enroll qualified individuals in a QHP through approved direct enrollment entity websites in a manner that constitutes enrollment through the Exchange, including enabling individuals to apply for, and receive eligibility determinations from the Exchange for QHP enrollment and advance payments of the premium tax credit and cost-sharing reductions, as well as receive assessments or determinations of Medicaid and CHIP eligibility from the Exchange as described in § 155.302, using the eligibility application described in § 155.405;

(ii) Provide HHS an implementation plan and timeline that details the key activities, milestones, and communication and outreach strategy to support the transition of enrollment operations to direct enrollment entities; and

(iii) Ensure that a minimum of one direct enrollment entity approved by the State meets minimum Federal requirements for HHS approval to participate in the federally-facilitated Exchange direct enrollment program, including requirements at § 155.220 and this section, particularly § 155.220(c)(3)(i)(A) and (D) so that at least one approved web-broker in the state displays detailed information for all available QHPs and meets accessibility requirements under § 155.205(c) and is capable of enrolling all consumers in the State, including those who present complex eligibility scenarios. Where no direct enrollment entity approved by the State meets such minimum Federal requirements or possesses the capability to enroll all consumers in the State, the State must offer a consumer-facing website that meets such requirements and possesses such capability.

(2) *Direct enrollment option for a State with a federally-facilitated Exchange or State Exchange on the Federal platform.* Pursuant to a request from a State, the federally-facilitated Exchange or a State Exchange on the Federal platform may partner with the requesting State to implement the direct enrollment option described in this paragraph (j). The federally-facilitated Exchange or State-based Exchange on the Federal platform must meet all Federal statutory and regulatory requirements for the operation of an Exchange. In order to obtain approval for the federally-facilitated Exchange or State Exchange on the Federal platform in a State to implement this option, a State must:

(i) Coordinate with HHS on an implementation plan and timeline that allows for a transition period, developed at the discretion of HHS in consultation with the State, necessary for the federally-facilitated Exchange to operationalize the necessary changes to implement this option;

(ii) Execute a Federal agreement with HHS that includes the terms and conditions for the arrangement and which defines the division of responsibilities between HHS and the State;

(iii) Agree to procedures developed by HHS for the collection and remittance of the monthly user fee described in § 156.50(c) of this subchapter; and

(iv) Perform and cooperate with activities established by HHS related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act, including complying with reporting and compliance activities required by HHS and described in the Federal agreement.

■ 7. Section 155.1308 is amended by revising paragraphs (f)(3)(i), (f)(3)(iv) introductory text, and (f)(3)(iv)(A) through (C) to read as follows:

§ 155.1308 Application procedures.

* * * * *

(f) * * *

(3) * * *

(i) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332 of PPACA. In analyzing whether the State has satisfied the requirement under section 1332(b)(2)(A) of PPACA that the State enact a law authorizing a waiver under section 1332 of PPACA, the Secretary and the Secretary of the Treasury, as applicable, may consider existing State legislation combined with duly-enacted State regulation or an executive order so long as the State legislation provides statutory authority to enforce PPACA provisions or the State plan;

* * * * *

(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 (f)(3)(iv) and interpretive guidance published by the Secretary and the Secretary of the Treasury;

(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 State plan will 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. These coverage options must also satisfy the affordability requirement in paragraph (f)(3)(iv)(B) of this section;

(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 State plan will 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 coverage options must also satisfy the comprehensive coverage requirement in paragraph (f)(3)(iv)(A) of this section;

(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. Coverage refers to 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; and

* * * * *

■ 8. Section 155.1320 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 155.1320 Monitoring and compliance.

(a) * * *

(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, regulations, and interpretive policy statements, as well as interpretive guidance published by the Secretary and the Secretary of the Treasury, unless expressly waived. A State must, within the timeframes specified in law, regulation, interpretive policy or guidance, come into compliance with any changes in Federal law, regulation, or policy 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) and interpretive guidance published by the Secretary and the Secretary of the Treasury when conducting implementation reviews under paragraph (b) of this section.

* * * * *

■ 9. Section 155.1328 is amended 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 interpretive guidance published by the Secretary and the Secretary of the Treasury, as applicable, and any terms and conditions governing the section 1332 waiver.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 10. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, and 26 U.S.C. 36B.

■ 11. Section 156.230 is amended by adding paragraph (f) to read as follows:

§ 156.230 Network adequacy standards.

* * * * *

(f) *Exception.* Paragraphs (a) through (e) of this section do not apply to a plan for which an issuer seeks QHP certification or to any certified QHP that does not use a provider network, meaning that the plan or QHP does not condition or differentiate benefits based on whether the issuer has a network participation agreement with the provider that furnishes covered services.

■ 12. Section 156.1240 is amended by adding paragraph (a)(3) to read as follows:

§ 156.1240 Enrollment process for qualified individuals.

(a) * * *

(3) For payments in the individual market made using a payment method described in paragraph (a)(2) of this section, accept premium payments made by or on behalf of an enrollee in connection with an individual coverage HRA (as described in § 146.123(b) of this subchapter) or qualified small employer health reimbursement arrangement (as described in section 9831(d)(2) of the Internal Revenue Code of 1986, as amended) in which the enrollee is enrolled.

* * * * *

Dated: January 8, 2021.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

Dated: January 12, 2021.

Alex M. Azar II,
Secretary, Department of Health and Human Services.

Dated: January 13, 2021.

David J. Kautter,
Assistant Secretary (Tax Policy), Department of the Treasury.

[FR Doc. 2021–01175 Filed 1–14–21; 4:15 pm]

BILLING CODE 4120–01–P