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Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond (CMS-9906);

Summary of Final Rule

On September 27, 2021, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) and the Department of the Treasury (the Departments) published in the *Federal Register* a final rule setting certain payment parameters and making changes applicable to the 2022 plan year and beyond. The Patient Protection and Affordable Care Act (ACA); Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond (86 *FR* 53412) revises user fees for Federally-Facilitated Exchanges (FFEs) and State Based Exchanges on the Federal Platform (SBE-FPs) for the 2022 benefit year, eliminates the Exchange Direct Enrollment option; and extends the Exchange open enrollment period for an additional month. It finalizes a number of changes relating to section 1332 waivers including repeal of interpretations from 2018 Guidance[1] and provides additional guidance related to waiver applications, amendments, extensions and pass-through funding. It finalizes proposals to eliminate certain separate billing and segregation of funds requirements for the coverage of abortion services; and makes a number of changes including those related to special enrollment periods and Navigator responsibilities. The provisions become effective on November 26, 2021, although, as noted below, most of the provisions are applicable beginning for the 2022 plan year.

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[1] 83 *FR* 53575

I. Background

The Departments review the statutory and regulatory history related to the implementation of the Exchanges and relevant topics. They solicited input from states on a number of topics including the direct enrollment option for FFEs, SBE-FPs and State Exchanges. They held monthly meetings with the National Association of Insurance Commissioners; had regular contact with states, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties; and considered public input on the policies.

On January 28, 2021, the President issued Executive Order (EO) 14009, "Executive Order on Strengthening Medicaid and the Affordable Care Act", which stated the Administration's policy to protect and strengthen the ACA and to make high-quality health care accessible and affordable for every American.[2] The EO instructed the Departments to review all existing regulations, guidance, and other agency actions to determine whether they are consistent with that goal, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with it.

On January 20, 2021, the President issued EO 13985, "On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government",[3] directing that as a policy matter, the federal government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. EO 13985 also directs HHS to assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups.

The regulations in large part derive from the Departments' examination to determine if policies and requirements are consistent with the policy goals outlined in the EOs. HHS states that the final rules amend and repeal provisions and parameters, with a focus on making high-quality health care accessible and affordable and provide consumers greater access to coverage through, for example, greater education and outreach, improved affordability for consumers, reduced administrative burden for issuers and consumers, and improved program integrity.

[2] 86 FR 7793 (Feb. 2, 2021)
[3] 86 FR 7009 (Jan. 25, 2021)

HHS received a total of 390 comments from state entities, such as departments of insurance and State Exchanges, from health insurance issuers, providers and provider groups, consumer groups, industry groups, national interest groups, and other stakeholders. The comments ranged from general support for the proposed rule, to specific support of or opposition to the proposed provisions, to specific questions regarding proposed changes. A number of comments were out of scope and therefore are not addressed in the final rule.

Some commenters expressed concern that the 30-day comment period which began on the date that HHS placed the proposed rule on public display, was too short for interested parties to provide meaningful comments. HHS points out that the shortened comment period was intended to ensure that issuers had information needed to set rates for the 2022 plan year at the earliest opportunity and noted that the comments were meaningful, insightful, and were all able to be reviewed before issuing the final rules.

II. Provisions Updating Payment Parameters and Improving Health Insurance Markets

A. Requirements for Group and Individual Health Insurance Markets

1. Technical Change to Special Enrollment Period (SEP) (§147.104(b)(2))

HHS finalizes a technical change to add a paragraph to clarify that issuers offering coverage outside of Exchanges are not required to offer the new SEP for Advanced Premium Tax Credit (APTC)-eligible individuals whose income is below 150 percent of the federal poverty level (FPL) (described further below.) Because the SEP is based on APTC eligibility and APTC is not available for coverage offered outside of Exchanges, those issuers do not need to offer the SEP. Commenters generally supported the technical change.

B. Part 155 – Exchange Establishment Standards and Other Related Standards

1. Standardized Options (§155.20)

HHS briefly reviews the March 4, 2021 U.S. District Court decision[4] which considered nine policies promulgated in the 2019 Payment Notice final rule and vacated four of them. One of the policies vacated was the elimination of "standardized options" that were to be offered through FFEs.

While it is too late in the year to implement and approve new standardized options for the 2022 plan year, HHS will analyze the configurations of those options taking into account changes to the markets and will propose new standardized plan designs in the 2023 Payment Notice. HHS sought comments on its plan to undertake new standardized option configurations.

Some commenters opposed additional standardization pointing out that the existing metal level plan configurations already provide for some standardization and that going further by providing standardized plans with differential display, it will appear as if HHS were favoring certain plans

[4] City of Columbus v. Cochran, No. 18-2364, 2021 WL 825973 (D. Md. Mar. 4, 2021)

over others. Commenters recommended HHS seek to be minimally disruptive, minimize complication, and not be overly prescriptive. Some raised concerns that standardized plans could stifle innovation.

Some commenters supported HHS providing standardized options noting that they could simplify the process of choosing a plan. They noted, for example, that the considerable differences in cost sharing features among plans can make choosing the best option challenging for potential enrollees and that most plan shoppers focus on a few plan features such as the premium, which raises the likelihood of unexpected costs and financial harm. Some described the barriers that individuals face in doing detailed analysis of plan features.

Some commenters went further in recommending HHS take an even more prescriptive approach by, for example, requiring plans to offer only standardized designs, limiting the number of non-standardized plans, and preferentially or differentially displaying standardized plans. The Covered California Exchange was raised as an example. It requires any issuers offering non-standardized options to demonstrate that the plan designs are patient-centered and this has resulted in few offering non-standardized options. Other commenters offered specific plan design recommendations.

HHS notes that it will take these concerns and recommendations into account in developing standardized options.

2. Navigator Program Standards (§155.210)

HHS finalizes as proposed to re-establish requirements for Navigators to assist with post-enrollment activities. Under prior rules, Exchanges could *permit or authorize* Navigators to assist with the following post-enrollment activities described in §155.210(e)(9):

- The process for filing Exchange eligibility appeals;
- The availability of exemptions from the requirement to maintain minimum essential coverage, how to claim them, and the availability of Internal Revenue Services (IRS) resources on such exemptions;
- Exchange-related components of the premium tax credit reconciliation process and the availability of IRS resources;
- Basic concepts and rights related to health coverage and how to use it; and
- Referrals to licensed tax advisers, tax preparers, or other resources for assistance with Exchange application and enrollment, exemptions from minimum essential coverage requirements, and premium tax credit reconciliations.

Under the final rule, those activities will be required beginning with the Navigator funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance. HHS states that the finalized changes are consistent with statutory requirements for Navigators and with EO 14009 on Strengthening Medicaid and the ACA because they are expected to improve consumers' access to health coverage information.

The preamble of the final rule provides the following additional descriptions of HHS' expectations of the kinds of assistance Navigators are expected to provide under §155(e)(9):

Understanding the process for filing Exchange eligibility appeals. There is no duty for Navigators to represent a consumer in an appeal, sign an appeal or file an appeal on the consumer's behalf. Navigators are expected to assist with the process of completing and submitting appeal forms and providing fair and impartial information about enrollment through FFEs.

The availability of exemptions from the requirement to maintain minimum essential coverage. Navigators can assist consumers who are age 30 or above with filing an exemption to enroll in catastrophic coverage. This includes informing consumers about the availability of the exemption, helping to fill out and submit exemption applications, obtaining necessary forms, assisting in understanding how to use an exemption certificate number, and using the Exchange tool to find catastrophic plans.

Exchange-related components of the premium tax credit reconciliation process. Helping consumers with the premium tax credit reconciliation process includes ensuring consumers have access to IRS Forms 1095-A and 8962 and their instructions, helping consumers understand (1) how to report errors on Form 1095-A, (2) how to find silver plan premiums using the Exchange tool, (3) the difference between APTCs and premium tax credits, and (4) the implications of not filing a tax return or reconciling APTCs. Navigators are expected to familiarize themselves with the availability of materials on IRS.gov, including the Form 8962 instructions, IRS Publication 974 Premium Tax Credit, and relevant FAQs, and refer consumers with questions about tax law to those or to other resources, such as free tax return preparation assistance from the Volunteer Income Tax Assistance or Tax Counseling for the Elderly programs.

Basic concepts and rights related to health coverage and how to use it. HHS notes that these activities could be supported through the use of existing resources including CMS' "From Coverage to Care" initiative, which Navigators are encouraged to review.[5] That resource describes the expanded interpretation of the required activities including helping consumers understand (1) key terms used in health coverage materials, such as "deductible" and "coinsurance," and how they relate to the consumer's health plan; (2) the cost and care differences between a visit to the emergency department and to a primary care provider; (3) how to evaluate health care options and make cost-conscious decisions, including using information required under "Transparency in Coverage Final Rules" (85 *FR* 72158); (4) how to identify in-network providers and how to use tools and resources available through the No Surprises Act to make informed decisions about needed care; (5) how the consumer's coverage addresses steps that often are taken after an appointment with a provider, such as making a follow-up appointment and filling a prescription; and (6) the right to coverage of certain preventive health services without cost sharing under qualified health plans (QHPs)—including information and resources related to accessing viral testing and vaccination options supported by Exchange coverage. HHS intends to make training materials and other educational resources available to Navigators regarding the expanded interpretation of this requirement.

[5] https://marketplace.cms.gov/c2c

HHS notes that certified application counselors (CACs) do not receive grants from federal Exchanges. Because they have more limited resources, HHS is not requiring any expansion of their duties.

Commenters overwhelmingly supported the provisions noting the importance of the assistance of Navigators for particular populations including those with limited English proficiency. Some commenters raised the concern that the duties are duplicative of those provided by agents or brokers. HHS responds that it is important for consumers to have access to Navigators who are impartial, required to receive training, and to meet other certification and licensing requirements.

Some commenters recommended that CMS restore the requirements: (1) to have at least two in-person Navigator organizations in each state and to ensure that at least one of those organizations was a community and consumer-focused nonprofit group; and (2) that Navigators receiving grants maintain a physical presence in the Exchange service area. HHS declines to make the changes. It raises concerns about the first requirement unnecessarily limiting an Exchange's ability to award grants to the strongest applicants especially where the strongest applicant is not a community and consumer-focused nonprofit group. With respect to the second, HHS points out that the majority of 2021 grantees will be maintaining a physical presence in the state they are serving, and there will be at least one physically present Navigator organization in every FFE state. HHS further notes that nothing in the final rule prevents an Exchange from selecting grantees that are physically present.

HHS does not expect the changes to Navigator duties to increase collection burden. It notes that the added consumer assistance and information requirements do not increase the number of reports that Navigator grantees are required to submit. Navigators who were awarded grant funding in FY 2021 and are already not performing these duties could revise their project plans to incorporate the duties for FY 2022. HHS expects, however, that most FFE Navigators have continued to provide this information and assistance. In addition, if approved, all costs associated with the requirements would be considered covered by Navigator grants for those consumers in FFEs.

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

HHS finalizes its proposal to eliminate the Exchange Direct Enrollment (DE) option which had been codified in §155.221(j). The option, which was finalized in Part 1 of the 2022 Payment Notice Final Rule (86 FR 6138), permitted a process for states to work directly with private sector entities (including insurance issuers, web-brokers, and agents and brokers) to operate enrollment websites through which consumers can apply for coverage, receive an eligibility determination, and purchase an individual market QHP with APTC and cost-sharing reductions if eligible. States would have been able to use the Exchange DE option instead of operating a centralized eligibility and enrollment system operated by an Exchange.

In the final rule, HHS clarifies that states may continue to choose other DE programs—including classic direct enrollment and enhanced direct enrollment—both of which provide a broad availability of non-Exchange websites to assist consumers in applying for, or enrolling in QHPs.

HHS now finds that the Exchange DE option is inconsistent with recent EOs and would divert resources from new higher priority requirements such as legislative initiatives and COVID-related special enrollment periods. Further, no state has expressed interest in implementing the Exchange DE option. HHS also now agrees with many commenters who provided input on the Exchange DE option when proposed that it would harm consumers by fracturing enrollment processes, foster consumer confusion, and disrupt coordination of coverage with other insurance affordability programs, Medicaid and CHIP.

Under the final rule, the Exchange DE option as well as the Exchange DE user fees rates for FFE-DE and SBE-FP-DE states for 2023 are eliminated.

HHS expects that repealing the Exchange DE option will have minimal impact on stakeholders since no resources have been expended by states or HHS toward implementing it.

Commenters overwhelmingly supported eliminating the Exchange DE option. They noted the absence of empirical data to support this option; and raised concerns about consumer confusion, misaligned incentives steering consumers toward less comprehensive coverage options, the cost and burden of increased oversight, and the impact on disadvantaged communities.

In response to a request to clarify the continuing availability of the existing FFE DE pathways, HHS confirms that those pathways will continue to be available and that states with State Exchanges will continue to have the option to leverage DE based on the needs of their markets, and health care priorities.

Commenters opposed to eliminating the Exchange DE option pointed out that it is premature to repeal it on the grounds of lack of state interest, since it has only been an option for a short time. Others supported the state flexibility that it offered, and asserted that DE entities are better able than Navigators to innovate and meet consumer needs. Some asserted that the Departments' concerns about steering consumers to non-comprehensive plans or being unable to coordinate with Medicaid and CHIP were exaggerated since other protections are in place to prevent those outcomes. HHS responds that while some of the functionality of the Exchange DE option could be useful, states will continue to be able to incorporate that functionality through the existing DE pathways; it disagrees that the Exchange DE option would be superior to Navigators and Exchanges in innovating or meeting consumer needs; and reiterates its concerns about the impact of the option on enrollments, including those among underserved or historically marginalized consumers.

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

HHS finalizes its proposal to extend the annual open enrollment period with one important change. The rule finalizes the proposal to end the open enrollment period for FFEs and SBE-FPs on January 15 of the applicable benefit year instead of on December 15. The change from the proposed rule is that it would codify the flexibility for State Exchanges that operate their own eligibility and enrollment platforms to offer extended periods of annual open enrollment and to choose the closing date so long as it is no earlier than December 15. The start of the annual open enrollment period is unchanged (November 1 for each coming benefit year.) The extended open

enrollment period, for FFEs and SBE-FPs will begin for the 2022 coverage year and apply for years thereafter.

In prior rules, HHS indicated a preference for shorter open enrollment periods to simplify operational processes, and to be more consistent with the end of open enrollment periods for other types of public and private coverage. Recently, however, HHS has identified the disadvantages of a shorter period. For example, if an enrollee in the second lowest-cost silver plan finds that it is no longer the second lowest-cost silver plan, they often do not have enough time to change plans after finding out about their increased cost of coverage. In addition, Navigators and other enrollment assisters have provided feedback that they need additional time to help applicants with their plan choices.

HHS sought comment on the following:

- Whether a January 15th end date would provide a balance between providing consumers with additional time to make informed plan choices and increasing access to health coverage, while mitigating risks of adverse selection, consumer confusion, and issuer and Exchange operational burden.
- The benefits or adverse effects that stakeholders would experience because of a January 15th end date.
- Whether the extension would incent consumers who need coverage to begin on January 1st to still make a choice and enroll by December 15th, while also preserving sufficient time in the remainder of the plan year for issuers and Exchanges to perform other obligations such as QHP certification.
- Alternative approaches to extending open enrollment to address coverage gaps or enrollment challenges.
- Whether HHS should explore the possibility of a new SEP, such as for current enrollees who are automatically re-enrolled and experienced a significant cost increase, to address concerns for specific consumer challenges as an alternative to extending the annual open enrollment period.
- Whether a notice or a special, targeted outreach would address the needs of consumers who are automatically re-enrolled in areas where the second lowest-cost silver plan drops in value, thereby reducing APTC amounts.
- Ways to improve communication and consumer engagement around potential cost changes for consumers who do not actively re-enroll in coverage.
- If improved education and outreach during the coverage year would raise awareness of existing special enrollment period opportunities, such as those for loss of coverage or becoming newly eligible or ineligible for financial assistance.
- Whether outreach approaches could be a viable alternative to extending the open enrollment end date.
- Whether flexibility on the closing date should be permitted for State Exchanges and operational challenges that such Exchanges could experience if the extended open enrollment period is finalized.

HHS does not expect the extended open enrollment period to introduce a significant change in the Exchange risk pool. Increased enrollments could lead to higher Exchange costs but could

reduce outreach costs on Exchanges and enrollment assisters by spreading out enrollments over a longer period of time.

Many commenters supported the extended open enrollment period and supported the flexibility for states to extend their open enrollment periods. They identified populations that would benefit from it including those experiencing coverage terminations or loss of Medicaid. Commenters offered recommendations to extend the period further by changing either the start or ending date but HHS believes the finalized provision sufficiently balances its priorities of allowing additional time for enrollment while still promoting full coverage year enrollment.

Those opposed to the provision raised concerns about increasing adverse selection and offered alternatives including a new special enrollment period for enrollees who are automatically re-enrolled with a significant cost increase, or improved renewal notices to address where customers may be caught unaware with increasing costs. HHS notes that in cases where states have extended open enrollment periods, no significant increases in adverse selection have been identified; states that the extended open enrollment is the preferred approach because it is more streamlined than establishing a new SEP; and welcomed suggestions for improving renewal notices but disagrees that such notices may be a sufficient alternative for ensuring additional enrollment time.

5. Monthly SEP for Low-Income Individuals (§155.420(d)(16))

HHS finalizes a new optional monthly SEP for qualified individuals, enrollees, or their dependents who are eligible for APTC and whose household income is no greater that 150% of the FPL. The final rule includes several changes to the policy including:

- The finalized SEP is available only while enhanced subsidies for APTC are available under Section 9661 of the American Rescue Plan Act of 2021 (ARP, P.L 117-2) and for those whose required contribution is decreased, under that provision, to zero for the second lowest-cost silver plan.
- Clarifications to the enrollment options for dependents to make clear that *newly-enrolling* qualified individuals and dependents are not subject to plan category limitations; while other enrollees are subject to certain plan category limitations. The final rule makes clear that an enrollee who is adding a qualified individual or dependent through the SEP may add the newly-enrolling household member to their current QHP; change to a silver-level QHP and add the newly-enrolling household member to the silver-level QHP; or, change to a silver-level QHP and enroll the newly-enrolling qualified individual or dependent in a separate QHP. All eligible enrollees and dependents may be permitted to change to a silver metal level plan. Changing to a plan of other metal levels, however, is not permitted. HHS believes that applying plan category limitations will help to mitigate any potential adverse selection that could result from the new SEP.
- Technical amendments are finalized in several places that are consistent with the plan category choices and limitations in the finalized policy.

As proposed, State Exchanges may choose whether to implement the SEP based on their specific market dynamics, needs and priorities while Exchanges on the federal platform will implement the SEP beginning with plan year 2022.

Coverage under the SEP begins on the first day of the month following plan selection.

As noted above, a proposed amendment to §147.104(b)(2)(i)(G) clarifies that issuers will not be required to provide this SEP for enrollees of coverage offered outside of Exchanges since eligibility for it is dependent on qualifying for APTC.

HHS indicates that it plans to undertake extensive outreach to promote enrollment for 2022 coverage and indicates that it expects the SEP to help consumers who lose Medicaid coverage especially after the COVID-19 PHE ends since state Medicaid programs will no longer be required to suspend Medicaid disenrollment.

Exchanges electing the SEP will have the option to require individuals to confirm their eligibility in accordance with existing pre- and post- enrollment verification programs. HHS will rely on consumers' attested household income for this purpose and states its view that requiring documentation for pre-enrollment verification would result in needless delays in coverage.

HHS sought comment on:

- Whether plan category limitations should or should not apply;
- The risk of adverse selection;
- Is post-enrollment verification of income sufficient for Exchanges or should other measures be put in place to protect program integrity;
- Implementation burdens for Exchanges electing the SEP;
- Should the proposed special enrollment period be available indefinitely (as proposed), or be time-limited?

HHS estimated that the adverse selection risk could result in issuers increasing premiums by between 0.5 to 2 percent, and a corresponding increase in APTC outlays and decrease in income tax revenues of $250 million to $1 billion, when the enhanced APTC provisions of the ARP are in effect. It believes, however, that the risk of adverse selection is outweighed by the benefit of providing an opportunity to enroll in a different plan.

Many commenters supported the proposal, pointing out that it would improve health equity. Some encouraged additional outreach and education to increase awareness of the SEP as well as other potentially available SEPs that are underutilized. Some identified outreach strategies for HHS to consider.

Some commenters provided evidence from existing state programs that suggest that the risk of adverse selection is minimal. Others believe that HHS underestimated the increase in premium rates due to adverse selection, that the higher rates would disproportionately impact unsubsidized consumers, and that the HHS risk-adjustment methodology would not adequately compensate issuers for those enrolling through the SEP for only a part-year. In response to concerns about adverse selection and in particular the likelihood that it will vary significantly in different

markets, HHS finalizes the proposal but limits its availability to only those whose enhanced APTC reduce their required contribution to zero. HHS believes the time-limited nature of the finalized provision and its limited availability will reduce the risk of adverse selection. HHS will also monitor the markets to track potential adverse impacts.

Some raised the concern that issuers do not have adequate time to build the increases to premiums into their rates for the 2022 plan years and request delaying its implementation to 2023. HHS responds that because of the unusual nature of the COVID-19 pandemic, rapid responses are necessary. HHS declines to apply additional plan category or other limitations. In response to commenters requesting additional limitations be applied – for example by permitting changes to only a single plan, or only permitting the SEP one time per year – HHS states that it believes such restrictions are unnecessary; that individuals will be motivated to retain their existing plans to preserve progress toward their cost-sharing limitations; and such restrictions would raise complexity for Exchanges.

Commenters recommended alternatives to the proposed SEP for improving the transition of individuals between Medicaid coverage and Exchange coverage including: (1) A SEP for those losing expanded Medicaid under COVID-19-related coverage; (2) Allowing Medicaid managed care organizations to assist customers with re-enrollment; (3) Automatically enrolling all qualifying individual into coverage with an opt-out option; and (4) HHS establish an "automatic retention" program. HHS will consider the recommendations in the future.

6. SEP for Enrollees Newly Eligible or Ineligible for Premium Tax Credit (§155.420 (f))

HHS finalizes without change a new paragraph at the end of §155.420 stating that for the purposes of this section (a section describing the various SEPs that must or may be made available), references to being eligible for APTC refers to being eligible for an amount greater than zero dollars per month; references to ineligibility for APTC refers *both to being ineligible for such payments and to being eligible for zero dollars per month of such payments*.

The purpose of the amendment is to clarify that an individual is considered to be APTC ineligible if they qualify for a maximum APTC of zero. It is intended to be consistent with the objective of permitting an individual whose financial condition changes during the coverage year to be able to change their QHP status as a result. The preamble describes the SEPs for which the clarification would be helpful (those specified in (d)(6)(i) through (v)) and those for which the clarification would have no impact. The SEPs that may be impacted are those that are based on gaining or losing eligibility for financial assistance towards premiums that would affect an individual's decision about the type of coverage they can afford.

The Departments sought comment in the following areas:

- Whether State Exchanges currently define APTC eligibility consistent with this interpretation.
- Should Exchanges be provided with flexibility in terms of when they are required to ensure that their operations reflect this definition, or should Exchanges be permitted to adopt a more inclusive definition?

- Should the clarification that an individual is considered to be APTC ineligible if they qualify for a maximum APTC of zero be applied to all SEP qualifying events or limited to only apply to some of them?

Multiple commenters supported the provision and one confirmed that it is consistent with its State Exchange interpretation. One commenter recommended it not apply to the SEP for individuals losing employer sponsored coverage and newly eligible for APTC to ensure those individuals can obtain Exchange coverage. HHS disagrees that the exemption is necessary because another SEP specifically applies to individuals losing employment-based coverage.

C. Health Insurance Issuer Standards Including Standards Related to Exchanges

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

HHS initially finalized user fee rates for 2022 in part 1 of the 2022 Payment Notice Final Rule for all participating FFE issuers at 2.25 percent of monthly premiums and for issuers offering QHPs through SBE-FPs at 1.75 percent of monthly premiums.

In accordance with EO 14009, however, HHS considerably expanded Navigator Funding for 2022 and consumer outreach and education.[6] Taking into account the additional costs of expanded consumer outreach and education in the FFE and SBE-FPs and expanded Navigator funding for 2022, HHS proposed raising QHP issuer user fee rates for the 2022 plan year. It finalizes the increased rates as proposed: for FFE issuers at 2.75 percent of monthly premiums, and for SBE-FP issuers, 2.25 percent of monthly premiums.

Consistent with years past, the FFE user fee reflects the costs of certifying plans as QHPs, and selling coverage through the FFE for those determined eligible to enroll in a QHP. Other benefits that issuers receive via federal Exchanges are consumer assistance tools, consumer outreach and education, the Navigator program, regulation of agents and brokers, eligibility determinations, and enrollment processes.

For issuers offering coverage through state Exchanges using the Federal Platform for Exchange functions (in which a state chooses use the federal information technology platform for certain Exchange functions), the user fee amount reflects the proportion of FFE costs associated with FFE information technology infrastructure, the consumer call center, and eligibility and enrollment services.

The 2023 Exchange DE option user fee rate which was published in Part 1 of the 2022 Payment Notice Final Rule is repealed as proposed consistent with the finalized provision to repeal the Exchange DE option.

Most commenters supported the increased fee. In response to a commenter recommending bigger increases, HHS responds that the finalized amounts are sufficient for the full functioning of the

[6] On August 27, 2021, CMS awarded $80 million in grant funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year. See Biden-Harris Administration Quadruples the Number of Health Care Navigators Ahead of HealthCare.gov Open Enrollment Period | CMS.

Federal platform. In response to concern about those costs being passed onto consumers in their premiums, HHS notes that while true, it believes that the benefits of the action justify the costs and points out that the rates are lower than those in effect for the 2021 plan year. In response to a request for additional transparency on the costs associated with the user fees, HHS directs those interested to the detailed information on Federal Exchange Activities and the agency's budget request. For 2022, that information is available at https://www.hhs.gov/sites/default/files/fy-2022-budget-in-brief.pdf.

2. Provision of Essential Health Benefits (EHB) (§156.115)

A technical amendment is finalized to §156.115 to clarify a cross reference to the requirements of the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) in defining the mental health and substance use disorder services that must be incorporated as part of EHB. The existing cross-reference is to the MHPAEA regulations. HHS finalizes its proposal to replace the cross reference with the statutory section reference, stating that this change makes it clear that health plans must comply with all of the requirements of MHPAEA including any amendments to MHPAEA. Several commenters supported the technical change.

3. Network Adequacy (§156.230)

Another policy vacated by City of Columbus v. Cochran was the 2019 Payment Rule's elimination of federal network adequacy reviews. HHS states that it intends to implement the court's decision through rulemaking but is unable to address the issues—including setting a new network adequacy review process, and providing sufficient time for issuers to assess whether their networks meet the new regulatory standard, submit any required information or contract with additional providers to meet such standards—in time for plan year 2022. It will instead address the issues in time for plan year 2023. HHS requested recommendations on how the federal government should approach network adequacy reviews.

Commenters made a large number of recommendations for network adequacy standards including that they:

- Support equitable access;
- Are enforced using strategies that include direct testing, examination of out-of-network claims submission and denial rates, compliance reports, consumer survey, etc.;
- Utilize National Committee for Quality Assurance standards;
- Are consistent across states or alternately permit flexibility for states;
- Support telehealth services;
- Prevent discrimination against providers, for example mid-level practitioners;
- Utilize metrics – examples include time and distance standards, provider-to-enrollee minimums; available of providers accepting new patients, among others.

HHS summarizes the following approach that it is currently considering:

- Time and distance standards calculated at the county level based on the numbers and types of providers that enrollees most generally use and/or that have historically been the subject of network adequacy concerns (for example, behavioral health providers); geographic location; and other factors yet to be determined. Issuers that are unable to

meet the standards would be able to submit a justification to account for variances, and the FFEs would review the justification to determine whether the variances are reasonable;
- Using standards informed by Medicare Advantage;
- Implementing methodologies that account for local geographical and topographical features and varied travel modes;
- In light of the expanded use of, and reimbursement for, telehealth services during the COVID-19 PHE, time and distance standards that account for the availability of telehealth services; and
- Other network adequacy standards, including appointment wait times and standards that promote health equity.

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

Under existing statute, if a QHP issuer elects to cover abortion services, the issuer must take certain steps to ensure that no premium tax credit or cost-sharing reduction funds are used to pay for abortion services for which public funding is prohibited. Prior regulations at §156.280(e)(2)(ii) required individual market QHP issuers to send a separate bill for the portion of a policy holder's premium that is attributable to coverage for abortion services for which federal funds are prohibited and to instruct such policy holders to pay for the separate bill in a separate transaction.

In light of a recent federal district court decision invalidating the policy, HHS finalizes its proposal to repeal the separate billing regulation and to replace it with prior rules which permitted QHP issuers to satisfy the statutory requirement in one of several ways, including by sending the enrollee a single monthly invoice or bill that separately itemizes the premium amount for coverage of abortion services for which federal funds are prohibited; sending the enrollee a separate monthly bill for these services; or sending the enrollee a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge.

HHS reviews the legal challenges and outcomes including the July 20, 2020 U.S District Court decision[7] finding that the separate billing regulation was arbitrary and capricious and setting it aside nationwide. After reassessing the prior policy, HHS no longer believes it was justified in light of the high burden it imposed on issuers, states, State Exchanges and consumers.

In addition to the change described above, HHS finalizes its proposal to rename section §156.280. Instead of "Separate billing and segregation of funds for abortion services" the section is "Segregation of funds for abortion services." In addition, HHS discontinues its non-enforcement policies that it had adopted in the 2019 Program Integrity Rule.

HHS reviews the burden that was estimated in 2019 as a result of the separate billing regulations. The burdens included one-time costs for issuers and State Exchanges performing premium billing and payment processing for operational changes such as implementation of the technical

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

build to implement the necessary system changes to support separate billing and receipt of separate payments; the ongoing annual costs for sending a separate bill to impacted enrollees, and its associated record keeping, customer service, and compliance, materials costs of printing and sending separate bills; the burden on State Exchange operations for one-time technical changes to update online payment portals to accept separate payments and update enrollment materials, as well as ongoing annual costs associated with increased customer service, outreach, and compliance; and increased call volumes and additional customer services efforts. Altogether, HHS estimated the projected burden to all issuers, states, State Exchanges, FFEs, and consumers would have totaled almost $550 million in 2020, and about $230 million in each subsequent year.

In its reevaluation, HHS expects the policy would have resulted in additional burden in the form of consumer confusion, especially for communities who already face barriers to care.

The majority of commenters supported the proposed changes adding to HHS' concerns by noting that the separate billing requirements contradicted well-established industry billing practices, that the need for such practices were unsupported by evidence, they violated certain states' laws, and that the inadvertent effects of the practice were likely to disproportionately fall on disadvantaged populations. In response to commenters recommending that HHS prohibit altogether issuers sending separate bills, HHS states its belief that most issuers will decline to do so. It encourages those issuers that do send separate bills to ensure they minimize consumer confusion and promote continuity of coverage.

In response to those objecting to the changes, HHS reminds them that because the prior rules were invalidated by the Federal district courts, HHS is prohibited from enforcing the requirements. HHS disagrees with commenters who state that the statute unambiguously requires separate billing and reviews its prior burden estimates and methodology in response to those who asserted that HHS over-estimated its burden.

III. Section 1332 Waivers – Departments of HHS and the Treasury

Part I of the 2022 Payment Notice codified guidance published in October of 2018 relating to the granting of waivers under section 1332 of the Affordable Care Act (State Relief and Empowerment Waivers, 83 *FR* 53575). This guidance was incorporated into Treasury regulations (31 CFR Part 33) and HHS regulations (45 CFR Part 155).

Upon review and consistent with EO 14009 and EO 13985, HHS determined that the 2018 guidance incorporated in regulations is not consistent with current policy objectives. The Departments are concerned that in states with waivers approved under that guidance, fewer people would have access to comprehensive and affordable coverage and that the 2018 guidance is not consistent with the congressional intent behind the statutory guardrails.

As a result, the Departments proposed that the Secretaries of HHS and the Treasury may exercise their discretion to approve a request for a section 1332 waiver only if the following four requirements, referred to as the statutory guardrails, are met: (1) The proposal will provide coverage that is at least as comprehensive as provisions of the of title I of the ACA that would be

waived (as certified by the CMS Office of the Actuary); (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 the ACA; (3) the proposal will provide coverage to at least a comparable number of the state's residents as would be provided under title I of the ACA; and (4) the proposal will not increase the federal deficit. The Secretaries proposed to 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. These policies were finalized and the guardrails are described in greater detail below.

The Departments finalize proposals to remove language incorporating the 2018 Guidance with respect to the statutory guardrails and replace it with interpretations of those guardrails that are generally consistent with guidance provided to states in 2015 (the 2015 waiver guidance[8]). The final rule includes additional guidance in the preamble providing instruction regarding the processes and procedures the Departments will apply in reviewing new waiver applications, waiver amendments, extension requests, and pass-through funding determinations. The Departments state that their aim is to assist states in developing markets that expand coverage, lower costs, and make high-quality health care more accessible.

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

Regulations at (31 CFR 33.102 and 45 CFR 155.1302) permit states to submit a single application for a section 1332 waiver and a waiver under other waiver processes including under Medicaid, Medicare, or CHIP. While the Departments did not propose any regulatory changes to those sections, they reiterated and clarified the coordinated waiver process. They noted that this process continues to be in line with both the 2018 and 2015 waiver guidance.

The final rule provides additional guidance with respect to coordinated waivers. In reviewing or approving a coordinated waiver, the Departments will not consider (1) The potential impact of policy changes that are contingent on further state action, such as state legislation that is proposed but not yet enacted; and (2) The impact of changes contingent on other federal determinations, including approval of federal waivers under other federal laws other than section 1332 of the ACA regardless of whether the waiver is sought as part of the coordinated application. For example, the Departments will not consider proposed changes to Medicaid or CHIP state plans that require separate federal approval, such as changes in coverage or federal Medicaid or CHIP spending that would result from a proposed section 1115 demonstration, regardless of whether the section 1115 demonstration proposal is submitted as part of a coordinated waiver application with a section 1332 waiver. The Departments' determination also will not take into account any proposed changes to the Medicaid or CHIP state plan that are subject to federal approval.

Savings accrued under either proposed or current Medicaid or CHIP demonstrations are not counted when determining if a section 1332 waiver meets the deficit neutrality requirement.

[8] Waivers for State Innovation (80 FR 78131)

The Departments take into account changes in Medicaid or CHIP coverage or in federal spending for Medicaid or CHIP that result directly from the proposed waiver provisions. For example, if a state section 1332 waiver results in more or less Medicaid spending, this impact would be considered in the assessing the section 1332 waiver for deficit neutrality.

The waiver applications included in a coordinated waiver application will each be reviewed by the applicable agency independently and according to the federal laws and regulations that apply to each waiver application.

The Departments received a few comments in support of the clarifications. Commenters also encourage the Departments to consider additional flexibilities, for example, allowing states to consider deficit neutrality across coordinated waivers and to demonstrate savings across programs for consumers or enrollees. HHS responds that there are differences in the budget neutrality provisions that require different considerations. The Departments remind stakeholders that they are committed to providing technical assistance to states and encourage innovative waiver proposals.

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

Existing HHS and Treasury rules in 31 CFR 33.108 and 45 CFR 155.1308 describe application procedures for states seeking waivers under section 1332 including public notice requirements, enactment of state legislation, and an implementation plan.

The Departments did not propose any changes to the application provisions but described certain timing objectives intended to help states to understand if the application is being submitted sufficiently in advance of the waiver effective date to allow for federal review and to ensure smooth Exchange operations. The Departments reiterate those points in the final rule.

States are strongly encouraged to engage with the Departments when formulating their section 1332 waiver approach. The Departments state that they will work with states to take into account state legislative sessions and rate filing deadlines in formulating workable timelines. An initial waiver application should be submitted early enough to allow for public comment, review by the Department and implementation of the state plan. For a waiver impacting the individual market, for example, the Departments provide that there would be sufficient review time if it were submitted in the first quarter of the year prior to the year that the plan would take effect.

One commenter expressed general support for this guidance.

3. Statutory Guardrails (31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv))

The Departments finalize their proposal to change the interpretations of the guardrails that had previously been finalized in Part 1 of the 2022 Payment Notice final rule. The amended guardrail interpretations largely align with the guardrail interpretations described in the 2015 guidance.

The guardrail interpretations previously finalized for 2022 were consistent with the 2018 guidance and with the goals of increasing consumer choice and promoting market competition. The Administration at that time sought to provide states with the maximum flexibility under the law to innovate, empower consumers, and expand more affordable coverage choices.

Under those principles, the rules provided that the comprehensive coverage guardrail is considered to be met if the waiver plan provides consumers *access* to coverage options that are at least as comprehensive as the coverage options provided without the waiver, to at least a comparable number of people as would have had *access* to such coverage absent the waiver. The affordability requirement is considered to be met if the plan would provide consumers access to coverage options that are at least as affordable as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. Further, the comprehensiveness and affordability guardrails may be 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, *as opposed to the actual number of people enrolled in comprehensive and affordable coverage*.

Commenters on Part 1 of the 2022 Payment Notice proposed rule raised concerns that the 2018 guidance as codified in regulatory text would result in fewer consumers having comprehensive and affordable coverage. Upon further consideration, the Departments agree with those concerns. They now conclude that those previously finalized guardrail interpretations were not consistent with the goal of EO 14009 – to reduce barriers for expanding comprehensive affordable coverage, and EO 13989 – to advance health equity. In addition, the guardrails previously finalized for 2022 are inconsistent with the current Administration's focus, given the COVID-19 PHE, to increase enrollment in comprehensive affordable coverage.

The changes implemented in this final rule reflect the Departments' view that the comprehensiveness and affordability guardrails should focus on the types of coverage residents actually purchase, rather than the types of coverage residents have access to. The Departments expect that states will be minimally impacted by the changes.

The Departments sought input on innovative policies that meet the statutory guardrails and focus on equity and expand access to comprehensive coverage; and on the impact of the changes on affected parties and stakeholders.

The majority of commenters were generally supportive of the amended guardrail interpretations (which are each described in greater detail below) and are consistent with preventing states from using 1332 waivers to remove coverage or advocate plans that would adversely affect vulnerable and underserved populations. A few commenters were concerned that the changes would be overly restrictive and inconsistent with Congressional intent to give states a meaningful level of flexibility. The Departments disagree that the finalized policies are overly restrictive and note that the changes are only intended to limit states' ability to promote non-comprehensive coverage at the expense of comprehensive coverage. The reiterate that they are committed to working with states to develop innovative waiver plans.

a. Comprehensive Coverage ((31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 55.1308(f)(3)(iv)(A))

The Departments finalize their proposal to modify the comprehensive coverage guardrail. Under the existing comprehensive coverage requirement, the Secretaries must determine that the state plan would provide "consumers *access to* coverage options that are at least as comprehensive as the coverage options provided without the waiver. Under the new requirement, at least a comparable number of people must have "*coverage* under the state plan forecasted to be at least as comprehensive overall for residents of the state as coverage absent the waiver."

The Departments provide additional guidance in the preamble that comprehensiveness refers to the scope of benefits provided by the coverage and would be measured based on the extent to which it covers EHBs.[9] The impact on all state residents must be considered.

The Departments will evaluate comprehensiveness of a waiver by comparing coverage under the waiver to the states' EHB benchmark. A waiver does not satisfy the comprehensiveness requirement if it decreases: (1) the number of residents with coverage that is at least as comprehensive as the benchmark in all ten EHB categories; (2) for any of the ten EHB categories, the number of residents with coverage that is at least as comprehensive as the benchmark in that category; or (3) the number of residents whose coverage includes the full set of services that would be covered under the state's Medicaid or CHIP programs, holding the state's Medicaid and CHIP policies constant.

The comprehensiveness assessment will take into account the impact among different groups of state residents, and in particular the impact on vulnerable and underserved residents including low-income individuals, older adults, those with serious health conditions or are at risk of developing serious health conditions, and those who have been historically underserved or adversely impact by poverty and inequality.

Analysis and supporting data are required to accompany a waiver application including an explanation of how the benefits under the waiver would differ from benefits absent the waiver and how the state determines the benefits to be as "comprehensive."

The Departments clarify, in response to comment, that the interpretations and policies related to the comprehensiveness guardrail will be evaluated in each year that the section 1332 waiver would be in effect. The Departments disagree with a commenter who believes the finalized interpretation would stifle a state's ability to innovate through plan design. In response, they review existing provisions in §45 CFR 156.111 that provide states with the flexibility to change their EHB benchmark plan without the need to pursue a waiver. States are encouraged to consider increasing the generosity of their EHB-benchmark plan's benefits to address health equity.

[9] Defined in section 1302(a) of the ACA.

b. Affordability

The Departments finalize their proposal to make changes to the affordability guardrail. Under the existing requirement, the Secretaries must determine that the state plan would "provide *access to coverage options* that are at least as affordable as the coverage options provided without the waiver. Under the new requirement, the state plan must be "forecasted to be as affordable for state residents as coverage absent the waiver" for a comparable number of people.

The preamble further provides that affordability will be measured by comparing each individual's expected out-of-pocket spending for health coverage and services to their incomes. Out-of-pocket spending includes payment for premiums, deductibles, co-pays, and co-insurance as well as health spending on services not covered by the plan. The impact on all state residents must be considered. These considerations must be forecast for each year that the waiver would be in place.

Waivers will be evaluated both on how they impact affordability on average and on how they impact the number of people with large health care spending burdens relative to their income. The Departments will assess the impact of the waiver across different groups of state residents, and in particular, on vulnerable or underserved residents. A waiver that reduces affordability among those groups is not likely to be approved.

Under the final rules, the waiver application is required to include analysis and supporting data to satisfy these assessments including information on out-of-pocket costs by income, health expenses, health insurance status, age, and with or without the waiver. It should also describe changes to employer contributions for health coverage or wages expected as a result of the waiver.

Commenters were generally supportive of the proposed changes; one commenter recommended the Departments codify a rule stating that the waiver analysis must include an examination of the effect on vulnerable groups and those eligible for the largest premium credits and cost sharing reductions. The Departments point out that evaluations of the impact of the waiver must address not only affordability on average but also on the number of individuals with large health spending burden relative to their incomes. It does not agree that additional specification in regulations is necessary.

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

The Departments finalize their proposals to make non-substantive changes to the coverage guardrail and include additional guidance in the preamble which is generally consistent with the 2015 Guidance.

To meet the coverage guardrails, the Departments finalize that a comparable number of state residents would be required to be forecast to have coverage in each year under the waiver as absent the waiver. Coverage refers to "minimum essential coverage"[10] and "comparable" means that the forecast of the number of covered individuals is no lower than that number absent the

[10] As defined in 26 USC 5000A(f).

waiver. The impact on all state residents must be considered – including Medicaid program enrollment (holding Medicaid policies constant.)

The Departments will assess the impact of the waiver across different groups of state residents, and in particular, on vulnerable or underserved residents. A waiver that reduces coverage among those groups is not likely to be approved. Analysis under the coverage requirement must also take into account how the waiver impacts gaps or discontinuations of coverage.

The waiver application must include analysis and supporting data to satisfy these assessments including the number of individuals covered by income, health expenses, health insurance status, age, and with and without the waiver for each year of the waiver.

Commenters were generally supportive; one recommended clarifying language to further specify the meaning of comprehensive coverage. The Departments decline to add additional specificity stating that it is unnecessary.

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

The Departments did not propose changes to the deficit neutrality guardrail but include additional guidance in the preamble regarding how it will evaluate waiver proposals against the guardrail.

Under the deficit neutrality guardrail, projected federal spending net of federal revenues under the waiver is required to be equal to or lower than projected federal spending net of federal revenues absent the waiver.

- The estimated effect on federal revenue must include all changes in income, payroll, or excise tax revenue, as well as any other forms of revenue (including user fees), that would result from the proposed waiver.
- The effect on federal spending must include all changes in federal financial assistance (premium tax credits, small business tax credits, or cost-sharing reductions) and other direct spending, such as changes in Medicaid spending (while holding the state's Medicaid policies constant) that would result from the waiver. Projected federal spending must also include all administrative costs to the federal government.

In response to a recommendation that deficit neutrality should be calculated over a 10-year period instead of year by year, the Departments clarify that the evaluation of whether a section 1332 waiver increases the deficit will consider the impact of the waiver on costs over the period of the waiver (which is generally 5 years) and over the 10-year budget plan. They note, however, that a waiver that increases the Federal deficit in any given year is less likely to meet the guardrail than one that does not.

Commenters made other suggestions for deficit neutrality calculations – asserting that the Departments' approach is overly strict, could prevent states from pursuing innovative models, and is contrary to the goals of the ACA and EOs 14009 and 13985. The recommendations included that the Departments take into account those who are currently eligible for coverage but not enrolled; and that they compute pass-through funding on a per capita basis. The Departments

decline to make changes to its deficit neutrality approach but reaffirm their aim to promote health equity and increase coverage through waivers.

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

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

Existing rules require a state applying for a section 1332 waiver to provide actuarial analyses and certifications, economic analyses and the data and assumption used to demonstrate the waiver's compliance with the guardrails. The Departments did not propose any regulatory changes to the provisions but provided additional guidance relating to those requirements to ensure the Departments have the information needed for review.

To determine if a waiver meets guardrail requirements and to calculate pass-through funding – or the amount of federal funds that would otherwise be paid on a state's behalf through provisions of the ACA for which a waiver is being requested – calculations must:

- Be made using generally accepted actuarial and economic analytic methods;
- Rely on assumptions and methodologies similar to those used to produce the baseline or policy projections included in the most recent President's Budget (or Mid-Session Review) adapted for state-specific circumstances;
- Include actuarial analyses and actuarial certification as provided by a member of the American Academy of Actuaries.

The Departments' analysis is based on state-specific population estimates and generally uses federal estimates of population growth and economic growth published in the Analytical Perspectives volume released as part of the President's Budget[11] and healthcare cost growth projected as part of the National Health Expenditure Data[12] to project the 10-year budget plan. The Secretary may, however, determine that state-specific assumptions apply.

Estimates must assume that certain macroeconomic variables are not affected, such as population, output, or labor supply. Estimates are required, however, to take into account behavioral change of individuals and employers and other relevant entities where applicable.

The application must describe all models, modeling assumptions, data sources, and any rationale for deviation from federal forecasts. Copies of the data may be requested by the Secretary. Estimates must be clearly explained and estimates of the four guardrails must be provided assuming the waiver and without the waiver.

The Departments received no comments on this guidance.

[11] https://www.whitehouse.gov/omb/budget/Analytical_Perspectives
[12] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/NationalHealthExpendData/

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

The Departments did not propose changes to the requirement that states include an implementation timeline in their section 1332 waiver application but provide the following additional considerations for states developing waiver proposals.

The federal platform used by FFEs and by some Exchanges generally supports uniform administration across states but HHS notes that it would be open to inquiries and further discussion with states that are interested in potential technical collaboration. If interested, states are encouraged to involve HHS early in the process. Further, under the Intergovernmental Cooperation Act, if a federal agency provides certain or specialized services to a state government, the costs of those services must be fully covered by the state. HHS notes that those state-covered costs would not be considered to be an increase in federal costs in the state's deficit neutrality analysis.

To the extent that a waiver plan incorporates changes to premium tax credits, or employer responsibility payments, or any other changes that would affect IRS administrative processes, some of those changes may not be able to be approved. The IRS is generally not able to administer different federal tax rules in different states. In limited circumstances, the IRS can accommodate small adjustments to existing systems but it cannot administer a different set of premium tax credit eligibility or computation rules for individuals in different states, for example. The Departments suggest that if a state were considering modifying a federal tax provision, they should consider waiving the provision entirely.

In addition, if a waiver proposal increases administrative costs for the IRS, those amounts must be taken into account in the deficit neutrality analysis.

The Departments received no comments on this guidance.

5. Public Input on Waiver Proposals (31 CFR 33.112 and 45 CFR 155.1312)

The Departments did not propose regulatory changes to public input requirements but review existing requirements and provide additional guidance on the process. Under current rules, states must provide a public notice and comment period sufficient to ensure a meaningful level of public input before submitting a waiver application. They must conduct a separate process for meaningful consultation with federally-recognized tribes in a state with one or more such tribes.

While states have the flexibility to determine the length of the comment period to allow for meaningful and robust public engagement, the Departments state that a state comment period should be no shorter than 30 days and a longer period may be appropriate for complex waiver plans.

Likewise, with respect to the federal comment period required by section 1332(a)(4)((iii) of the ACA, the Departments provide that the length of the period will generally be no less than 30 days.

The Departments received no comments on this guidance.

6. Modification from normal public notice requirements (31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320)

The Departments finalize as proposed to extend certain flexibilities that were adopted during the COVID-19 PHE with respect public notice and public participation requirements for section 1332 waivers. Under prior rules, the Secretaries and states have additional flexibility around public notice and public participation requirements in the event of future natural disasters; PHEs or other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life. The final rule extends those flexibilities so that they are available in state or local emergent situations or state designated emergencies. This policy is similar to the flexibilities applicable to Medicaid section 1115 Demonstration Waivers.

Under the final rule, the Secretaries are provided with the flexibility to modify pre-approval and post-approval state public notice requirements and federal public notice requirements to expedite a decision on a proposed section 1332 waiver during an emergent situation when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. The flexibilities would be available in future natural disasters; PHEs; and other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life, rather than being limited to only the duration of the COVID-19 PHE.

a. Public Notice Procedures and Approval (31 CFR 33.118 and 45 CFR 155.1318)

The Departments finalize new flexibilities for pre-approval public notice during emergent situations. Examples of the public notice and participation procedures that could be waived or modified during a future emergent situation include the requirement that a state notify the public and hold hearings prior to submitting a waiver application, that a state hold more than one public hearing in more than one location, and that the Departments provide for public notice and comment after an application is determined to be complete. States could also request to modify the state and/or federal comment periods to be less than 30 days and to host public hearings virtually rather than in-person.

For the Secretaries to approve a modification request, the state is required to:

- Request a modification in the form and manner as specified by the Secretaries;
- Act in good faith in the preparation of the request;
- Detail the requested modification and the alternative public notice procedures;
- Provide a justification for the alternative procedures.

The Secretaries make clear that the added flexibility does not permit the separate tribal consultation to be waived nor permit a state to *eliminate* public notice and participation procedures. A state may only waive certain features or modify their public notice procedures as described above.

The state must amend the application request to reflect public comments or other relevant feedback received during the alternative state-level public notice procedures. The Departments will evaluate a state's request for a modification of the public participation requirements and issue their modification determination within approximately 15 calendar days after the request is received.

The Departments will evaluate whether the relevant circumstances are sufficiently emergent and will consider circumstances to be emergent when they could not have been reasonably foreseen.

The Departments remind states that any public participation processes must continue to comply with applicable federal civil rights laws, including taking reasonable steps to provide meaningful access for individuals with limited English proficiency and taking appropriate steps to ensure effective communication with individuals with disabilities.

b. Monitoring and Compliance ((31 CFR 33.120 and 45 CFR 155.1320)

As part of the Secretaries' monitoring and oversight of approved waivers, existing rules provide for a process of continued public input beginning within 6 months after the implementation and annually thereafter. In the November 2020 Interim Final Rule with Comment Period, the Departments provided the Secretaries with the ability to waive, in part, post-award public notice requirements during the COVID-19 PHE.

Consistent with the proposed flexibilities for pre-approval public notice during emergent situations, the Departments proposed to extend the COVID-19 post-award public notice requirement to be available for other future emergent situations.

Under the final rule, the Secretaries have the ability to approve a state request to modify the post-award public notice procedures when they would be contrary to the interest of consumers during future emergency situations.

For the Secretaries to approve a modification request, a state would be required to:

- Request a modification in the form and manner as specified by the Secretaries;
- Act in good faith in the preparation of the request;
- Detail the requested modification and the alternative post award public notice procedures;
- Provide a justification for the alternative procedures.

The Departments will evaluate a state's request and issue their determination within approximately 15 days of receiving the request. The state is required to publish on its website any modification requests and determinations by the Departments within 15 calendar days of receipt of the determination, as well as information on the approved revised timeline for the state's post award public notice procedures. Since the state is already required to post materials as part of post-award annual reporting requirements, such as the notice for the public forum and annual report, states will be responsible for ensuring that the public is aware of the determination to modify the public notice procedures and must include this information along with the other information in a prominent location on the state's public website.

States are reminded that they are still required to comply with all applicable federal civil rights requirements including those related to accessibility – so if virtual hearing were to be requested, the state would need to ensure that the hearings are accessible to individuals with disabilities or with limited English proficiency.

Commenters recommended additional specificity for certain definitions including emergencies and health insurance coverage, and that the flexibilities be available for non-emergent situations. HHS declines to adopt more specific definitions, nor extend the flexibilities for non-emergent situations. They do, however, provide examples of the kinds of situations that would be accommodated by the amended rules. For example, a state that experiences a hurricane, which often happens quickly, could impact the state's ability to hold an in-person hearing; a state could experience a new emergent situation that could lead to limited or no Exchange plan options in a geographic area—perhaps from a very recent and sudden economic downturn, issuer insolvency, or other reasons—that could threaten consumers' access to health insurance coverage or care. The Departments would not consider an ongoing recession, by itself, to be an emergent situation. Existing threats to consumers' access to health coverage or care— such as in geographic areas in which issuer participation has been historically low—would not be considered emergent situations for purposes of applying the flexibilities finalized in the rule.

The Departments will consider providing additional examples of emergencies that may or may not be reasonably foreseeable in the future and encourages states interested in using the flexibilities to reach out to the Departments as soon as practicable.

The Departments reply to concerns that the flexibilities would permit states to avoid providing the public with a meaningful opportunity to provide input and that the risk of unintended negative consequences would be increased. They note that the flexibilities do not permit a state to completely waive the public notice and participation procedures. The flexibilities only permit certain types of procedures to be waived or modified.

7. Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320)

The Departments finalize the proposal to eliminate the reference to "interpretive guidance" from the list of laws, regulations and guidance that states must ensure their waiver programs comply with. This would leave states and the Departments to rely and statutes and regulations and other guidance as outlined in applicable notice and comment rulemaking. Commenters generally expressed support for this proposal.

8. Pass-through Funding (31 CFR 33.122 and 45 CFR 155.1322)

Under an approved Section 1332 waiver, a state may qualify for pass-through funding. The funding amount is determined by the Secretaries and reflects the amounts that individuals and small employers in the state would otherwise be eligible for had the state not received approval to waive certain ACA provisions. The Departments finalize, as proposed, codifying in new regulatory text details regarding the determination of pass-through funding for an approved section 1332 waiver.

Under the final rule, if a state has an approved section 1332 waiver and under that waiver, individuals and small employers in the state do not qualify for (or qualify for a reduced amount of) premium tax credit, a small business tax credit, or for cost-sharing reductions for which they would otherwise be eligible, pass-through funding is available in the aggregate amount of such credits (or reductions in credits) to the state for implementing the waiver plan. The Departments clarify that the pass-through amount is be reduced by any net increase in federal spending or any net decrease in federal revenue if necessary to ensure deficit neutrality.

The Secretaries will determine that amount annually taking into consideration the experience of other states with respect to Exchange participation and tax credits provided under those provisions to their residents. The pass-through amounts may be updated to take into account any applicable changes in federal or state law.

Consistent with existing waiver application requirements, the Departments reiterate that state waiver applications are required to provide analysis and supporting data to inform the Department's estimate of pass-through funding and the impact of the waiver on deficit neutrality. For states that don't use the FFE, this includes enrollment, premiums, federal financial assistance provided via the Exchange by age, income, type of policy and other information required by the Secretaries. In addition, the waiver application should include an explanation of how the states anticipate that individuals would no longer qualify for the federal financial assistance (or reduced assistance) and how the state intends to use the pass-through funding.

9. Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

Consistent with other provisions in the proposed rule, the Departments finalize removing a reference to "interpretive guidance" from the regulatory text requiring the Secretaries to periodically evaluate the implementation of a waiver program to ensure it is consistent with laws and regulations and conditions governing the waiver. It received no comments on the change.

10. Waiver Amendment (31 CFR 33.130 and 45 CFR 155.1330)

The Departments finalized its proposal to add regulatory text to describe a waiver amendment and explicitly permit amendments to be approved as the statute does not specifically mention amendments. Under the final rule a state could seek an amendment to an approved waiver. A section 1332 waiver amendment is described as a change to an approved waiver plan that is not otherwise allowable under the terms and conditions of the approved waiver, a change that could impact any of the statutory guardrails, or a change to the program design. A state is not authorized to implement any aspect of the proposed amendment without prior approval by the Secretaries.

Additional guidance is provided regarding the waiver amendment content requirements and approval process. The Departments require a waiver amendment to be submitted with a letter of intent in electronic format. The letter must include a detailed description of the intended change or changes and timeline for implementation. States are encouraged to provide the letter of intent at least 15 months prior the proposed implementation date. The Departments will respond within 30 days of receipt to identify the information it needs to review the request.

The waiver amendment itself should be submitted no later than 9 months prior to its intended implementation. If it is complex, a state may want to submit it earlier. The state must maintain uninterrupted operations of the Exchange and provide adequate notice to any impacted stakeholders or issuers.

The Departments' amendment review process is similar to the original section 1332 review process. The amendment request must meet the statutory guardrails; if approved, it would qualify for pass-through funding; and the public must be provided with a meaningful opportunity to provide input. The final rule provides for the same state-level public notice and comment requirements to apply to amendments and will apply the same federal-level public notice and comment processes.

A state pursuing an amendment is required to submit similar information and analysis as for new waiver applications. Amendment requests must include:

- A detailed description of the requested amendment, its impact on the guardrails, and supporting documentation;
- An explanation and evidence of the public input process;
- Evidence of sufficient authority under state law to pursue the amendment (as required under ACA section 1332(b)(2)(A);
- Analysis demonstrating how the amended waiver will meet the guardrails;
- An explanation of the estimated impact on pass-through funding; and
- Any further requested information and/or analysis determined necessary by the Departments to evaluate the section 1332 waiver amendment.

Commenters were generally supportive and appreciative of the clarifications. Some commenters requested additional clarification about whether two waiver amendments may be considered at the same time; whether an extension and an amendment may be considered in a single submission, and whether a proposal from a state with an approved waiver is always considered to be a waiver amendment rather than a separate waiver request. The Departments state that it is difficult to state in advance whether a proposal is a waiver amendment, a technical change to an existing waiver, or a new waiver application request until the information and analysis are reviewed. For that reason, they encourage states to contacts the Departments early in their process. The Departments agree with commenters that the process should minimize the burden on states.

11. Waiver Extension (31 CFR 33.132 and 45 CFR 155.1332)

The Departments finalize their proposal to codify in regulations section 1332(e) of the ACA which provides that an approved waiver may be granted for no more than 5 years and that states may request a continuation of a waiver. The continuation is deemed granted unless the Secretaries either deny in writing or request additional information within 90 days. In addition to codifying those requirements, the Departments provide additional guidance on submitting an extension request and the process for reviewing and approving such requests.

Under the final rule, states are required to inform the Departments that they plan to pursue a waiver extension at least one year prior to the waiver's end date with a letter of intent in electronic format. The Departments will respond within 30 days of receipt to identify if any changes would require the waiver amendment process rather than the waiver extension process.

The Departments' may request updated economic or actuarial analysis although a full new analysis may not be necessary as they will have information that has been provided under periodic reporting requirements for approved waivers. A state may use its annual public forum required under 31 CFR 33.120(c) and 45 CFR 155.1320(c) to solicit input on a proposed waiver extension. The federal government will, however, undertake a similar federal public notice and review process for extension requests as for new applications.

A state pursuing a waiver extension may be required to submit:

- Updated economic or actuarial analysis;
- Preliminary evaluation data and analysis from the existing section 1332 waiver program;
- Evidence of sufficient authority under state law to pursue the extension (as required under ACA section 1332(b)(2)(A));
- Explanation of the state's public input process; and
- Any further information requested by the Departments to decide on the extension request.

Commenters generally supported the provision and additional guidance. Several raised the question as to whether a waiver extension could be submitted with other amendments in a single submission. The Departments clarify that an extension proposal may only incorporate technical changes such as revisions to a state's reinsurance program parameters or a state's authorized funding source. Other changes would be considered an amendment.

IV. Collection of Information Requirements

Taking into account comments received, HHS finalizes estimates of information collection burden as required by the Paperwork Reduction Act of 1995 for three provisions.

- The Departments do not project burden to increase due to the finalized requirement that Navigators provide consumers with information and assistance on post-enrollment topics, as the number of reports that Navigator grantees are required to submit is expected to be unchanged and changes to the data elements for reported are expected to be insignificant.
- The Departments project burden to decrease for QHP issuers and State Exchanges that perform premium billing and payment processing as a result of the finalized repeal of separate billing regulations regarding coverage of abortion services for which federal funds are prohibited. Elimination of separate billing regulations will remove the associated information collection requirements and reduce burden on QHP issuers, Exchanges, and consumers. QHP issuers will have flexibility in selecting a method to comply with the separate payment requirements of section 1303 of the ACA. While HHS acknowledges some uncertainty in its burden estimation, it believes that an established ICR adequately captures the burden of issuer compliance (OMB control number: 0938-1156, Establishment of Exchanges and Qualified Health Plans (CMS-10400)).

- The Departments project that finalized changes to the section 1332 waiver implementing regulations do not impose additional costs or burdens for states seeking waiver approvals or states with approved waiver plans for which burden was not captured in prior estimates.

V. Regulatory Impact Analysis (RIA)

OMB has determined that this final rule is "economically significant" within the meaning of Executive Order 12866, because it is likely to have an annual effect of $100 million or more in any one year. Accordingly, the Departments have prepared an RIA that discusses the final rule's estimated costs and benefits while taking into account comments received.

HHS states that the final rule will expand consumer access to affordable health care, decrease regulatory burden of states, and lower administrative costs for Exchanges and issuers. Table 9 of the final rule summarizes HHS' assessment of the qualitative impacts and estimated direct monetary costs and transfers that result from the changes in the final rule. HHS states that the numerous effects of this final rule's changes prevent HHS from quantifying all of the benefits and costs of the rule.

HHS highlights some impacts of specific provisions of this final rule as described below.

- Costs associated with requiring Navigators to resume providing consumers in FFEs with information and assistance regarding certain post-enrollment topics will be covered by FFE Navigator grants.
- Removing the Exchange Direct Enrollment Option will have minimal stakeholder impact, as no resources have yet been expended by states or HHS for implementation.
- HHS believes that extending the individual market annual open enrollment period will not significantly impact the Exchange risk pool though may increase technical infrastructure costs for the enrollment period by $8.3 million.
- HHS acknowledges a potential risk for adverse selection by adding a monthly SEP for APTC-eligible qualified individuals in households with income below 150 percent of FPL whose applicable taxpayer has an applicable percentage of zero, and estimates an associated premium increase of 0.5 to 2 percent. HHS agrees with commenters that the adverse selection and premium increases could vary significantly by state market-level factors (e.g., Medicaid expansion status). However, HHS concludes that the benefit of gains in coverage will clearly outweigh the adverse selection risk.
- HHS states that clarifying SEP availability for enrollees who are newly eligible or newly ineligible for APTCs will help ensure that the SEPs are available to the intended target population: enrollees who are determined to be newly eligible for an APTC amount greater than zero dollars.
- HHS estimates that increased FFE and SBE-FP user fees will increase transfers from issuers to the federal government by approximately $200 million in plan year 2022.
- Repealing separate billing regulations for coverage of abortion services for which federal funds are prohibited will negate the previously projected associated burden increase (about $550 million in 2020 and about $230 million in each subsequent year). HHS notes

that in states where coverage of abortion services is required, consumers will not have access to a silver plan with a zero-dollar premium.
- The Departments state that the modified section 1332 waiver implementation regulations will not create any additional costs for states seeking waiver approvals or states with approved waiver plans for which impact estimates were not previously made.

HHS provides a regulatory review cost estimate for this final rule of $114.24 per reviewing entity and a total aggregate cost estimate of $74,588.80 for 652 entities.

HHS notes key regulatory alternatives that were considered for inclusion in this final rule.
- Not providing a monthly SEP for APTC-eligible qualified individuals in households with income below 150 percent of FPL; HHS instead chose to limit the availability of the SEP to periods when the applicable taxpayer has an applicable percentage of zero to mitigate adverse selection concerns expressed by commenters.
- Not providing clarification of SEP availability for enrollees who are newly eligible or newly ineligible for APTCs; in keeping with public comments received, HHS chose to clarify in order to maximize transparency about the SEP.
- Restoring FFE and SBE-FE user fees rates to their 2021 levels (3 percent and 2.5 percent, respectively); HHS instead raised rates to 2.75 percent and 2.25 percent, respectively, that HHS calculated will provide sufficient funding of essential Exchange functions.
- Finalizing new policies and interpretations of section 1332 waiver implementation provisions was chosen over rescinding the relevant 2018 Guidance and over codifying the relevant 2015 Guidance. The approach chosen is viewed as providing maximal clarity about the requirements for submission and approval of section 1332 waivers.

HHS states that the changes made in this final rule do not create effects that meet the threshold for preparation of an impact analysis for small entities, small rural hospitals, or unfunded mandates. HHS views this final rule as having federalism implications due to its potential direct effects on the distribution of power and responsibilities among the state and federal governments related to determining standards for health insurance offered in the individual and small group markets. Therefore, to comply with Executive Order 13132, HHS engaged with stakeholders through conference calls, national conferences, and individual consultations with state insurance officials. Finally, HHS notes that this rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996.