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

On July 1, 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 proposed 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* 35156) proposes to revise user fees for Federally-Facilitated Exchanges (FFEs) and State Based Exchanges on the Federal Platform (SBE-FPs) for the 2022 benefit year, eliminate the Exchange Direct Enrollment option; and extend the Exchange open enrollment period for an additional month. It proposes 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 includes proposals to eliminate certain separate billing and segregation of funds requirements for the coverage of abortion services; and makes a number of changes related to special enrollment periods, Navigator responsibilities, among others. **Comments are due on July 28, 2021.**

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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 proposed 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.

Many of the proposals in the proposed regulation result from the Departments' examination to determine if policies and requirements are consistent with the policy goals outlined in the EOs.

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

II. Provisions of Proposed Rule

A. Requirements for Group and Individual Health Insurance Markets

1. Past Due Premiums

HHS states that it is considering revisiting a policy established in a 2017 rule (Market Stabilization final rule, 82 *FR* 18346) that permitted an insurance issuer to apply a premium payment for new coverage to any outstanding past due amount for coverage for the prior 12-month period. The policy was established to prevent individuals from withholding their end-of-year premium payments but yet maintain coverage because they qualify for a grace period; then re-enroll in new coverage once the grace period has ended. HHS will evaluate the policy to determine if it presents any unnecessary barriers to accessing health coverage and will address it in future rulemaking.

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

HHS proposes to add a paragraph to clarify that issuers offering coverage outside of Exchange would not be required to offer a proposed new special enrollment period 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 would not need to offer the SEP.

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.

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

2. Navigator Program Standards (§155.210)

HHS proposes to re-establish requirements for Navigators to assist with post-enrollment activities. Under existing rules, Exchanges *may 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 (PTC) 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 proposed rule, those activities would be required beginning with the Navigator funding for FY 2022 and are enabled by the considerably increased Navigator funding for FY 2022. The proposed changes are also consistent with EO 14009 on Strengthening Medicaid and the ACA because they are expected to improve consumers' access to health coverage information and with statutory requirements for Navigators.

The preamble of the proposed rule provides the following additional descriptions of HHS' expectations of the kinds of assistance described in §155(e)(9):

Understanding the process for filing Exchange eligibility appeals. There would be no duty for Navigators to represent a consumer in an appeal, sign an appeal or file an appeal on the consumer's behalf. Navigators would be 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 requirement would also include informing consumers about the availability of the exemption, helping fill out and submit exemption applications, obtain necessary forms, understanding how to use an exemption certificate number, and using the Exchange tool to find catastrophic plans.

Exchange-related components of the PTC reconciliation process. Helping consumers with the PTC reconciliation process would include ensuring they 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 APTC and PTC, and (4) the implications of not filing a tax return or reconciling advance premium tax credits. Navigators would be 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 a proposed 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. If the proposed changes are finalized, HHS intends to make training materials and other educational resources available to Navigators regarding the proposed expanded interpretation of this requirement.

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 proposes to eliminate the Exchange Direct Enrollment (DE) option, codified in §155.221(j). The new option was finalized in Part 1 of the 2022 Payment Notice Final Rule (86 FR 6138) and permits 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.

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

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

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 proposed rule, the Exchange DE option would be eliminated and the Exchange DE user fees rates for FFE-DE and SBE-FP-DE states for 2023 would be eliminated.

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

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

HHS proposes to extend the annual open enrollment period so that instead of ending on December 15 for a coming benefit year, it would end on January 15 of the applicable benefit year. The start of the annual open enrollment period would not be changed – it would remain November 1 for each coming benefit year. The extended open enrollment period, if finalized would begin for the 2022 coverage year and for years thereafter. It would apply to all Exchanges, including State Exchanges for the 2022 coverage year and beyond.

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 some disadvantages of a shorter period. For example, if an enrollee of the second lowest-cost silver plan has changed, consumers 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 seeks comment on the following subjects:

- **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, including impacts on resources, consumer assistance budgets, overall enrollment numbers, premiums, and market stability.**
- **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.

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

HHS proposes to establish an 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 SEP would be consistent with Section 9661 of the American Rescue Plan Act of 2021 (ARP, P.L 117-2) which decreased to zero the percentage of income required of those individuals as a contribution for the second lowest cost silver plan for tax years 2021 and 2022. State Exchanges would be permitted to choose whether to implement the SEP based on their specific market dynamics, needs and priorities while Exchanges on the federal platform would implement the SEP.

Coverage under the SEP would be required to begin on the first day of the month following plan selection and Exchanges implementing the SEP would be required to permit eligible enrollees and dependents to change to a silver metal level plan. Other plan category limitations would apply, so enrollees qualifying for the new SEP would be prevented from changing to a plan of other metal levels. HHS believes that applying plan category limitations would help to mitigate any potential adverse selection that could result from the new SEP.

As noted above, a proposed amendment to §147.104(b)(2)(i)(G) would clarify that issuers would 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 seeks comment on:

- **Whether plan category limitations should or should not apply. For example, does requiring plan category limitations increase implementation burden for Exchanges? Are limitations unnecessary because eligible enrollees are unlikely to change to a plan category other than a silver metal-level plan?**
- **The risk of adverse selection. Does it increase because some qualifying individuals will not have access to a silver plan with a zero-dollar premium prompting some to enroll in coverage due to a health care need and end coverage once the need has been met? Would the risk of adverse selection be mitigated by the availability of free or very low-cost coverage with a 94 percent actuarial value and the application of plan limitations? Whether the adverse selection risk created by the proposed SEP cannot be sufficiently mitigated such that its creation may result in significant rate increases. Would it cause adverse selection among higher income individuals with variable hours and income?**
- **Is it sufficient for Exchanges to verify applicants' projected annual household income post-enrollment, 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 estimates that this adverse selection risk may result in issuers increasing premiums by approximately 0.5 to 2 percent, and a corresponding increase in APTC outlays and decrease in income tax revenues of approximately $250 million to $1 billion, when the enhanced APTC provisions of the ARP are in effect. It believes, however, that the risk of adverse selection is outweighed by the benefit of providing an opportunity to enroll in a different plan.

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

HHS proposes a new paragraph at the end of §155.420 stating that for the purposes of this section (a section describing the various special enrollment periods 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 and 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 seek comment in the following areas:

- **Whether State Exchanges currently define APTC eligibility consistent with this interpretation. If not, whether there are policy concerns about the interpretation including increasing burden.**
- **Should Exchanges be provided with flexibility in terms of when they are required to ensure that their operations reflect this definition, and whether Exchanges should be permitted to adopt a more inclusive definition, for example, to consider an individual to be newly eligible or ineligible for APTC for purposes of the SEP at §155.420(d)(6) based on a change from a zero-dollar maximum APTC amount to APTC ineligibility for another reason.**
- **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 at or limited to only apply to some of them.**

C. Health Insurance Issuer Standards Including Standards Related to Exchanges

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

HHS 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% of monthly premiums.

In accordance with EO 14009, HHS, HHS considerably expanded Navigator Funding for 2022 and consumer outreach and education. 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 proposes raising QHP issuer user fee rates for the 2022 plan year. The proposed rates for the FFE issuers are 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.

As noted above, the 2023 Exchange DE option user fee rate which was published in Part 1 of the 2022 Payment Notice Final Rule is proposed to be repealed along with the Exchange DE option.

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

A technical amendment is proposed 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 is proposing replacing 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.

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 requests recommendations on how the federal government should approach network adequacy reviews.**

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 PTC or cost-sharing reduction funds are used to pay for abortion services for which public funding is prohibited. Existing regulations at §156.280(e)(2)(ii) require 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 is proposing 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[6] finding that the separate billing regulation was arbitrary and capricious and setting it aside nationwide. After reassessing the policy, HHS no longer believes it is justified in light of the high burden it imposes on issuers, states, State Exchanges and consumers.

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

In addition to the change described above, HHS proposes renaming section §156.280. Instead of "Separate billing and segregation of funds for abortion services" the section would be "Segregation of funds for abortion services." In addition, HHS would discontinue its non-enforcement policies that it had adopted in the 2019 Program Integrity Rule. The non-enforcement policies were intended to mitigate potential coverage losses resulting from enrollee confusion.

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 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 $546.1 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.

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

Part I of the 2022 Payment Notice finalized in Treasury regulations (in 31 CFR Part 33) and in HHS regulations (in 45 CFR Part 155) contained certain provisions that incorporated by reference 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).

Upon review and consistent with EO 14009 and EO 13985, HHS has determined that the 2018 Guidance as incorporated in regulations are 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.

Under section 1332 of the ACA, the Secretaries of HHS the Treasury may exercise their discretion to approve a request for a section 1332 waiver only if the Secretaries determine that the proposal for the section 1332 waiver meets the following four requirements, referred to as the statutory guardrails: (1) The proposal will provide coverage that is at least as comprehensive as coverage defined in section 1302(b) of the ACA and offered through Exchanges established under title I of the ACA, as certified by the Office of the Actuary of CMS, based on sufficient data from the state and from comparable states about their experience with programs created by the ACA and the provisions of the ACA that would be waived; (2) the proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided under title I of the ACA; (3) the

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

Language incorporating the 2018 Guidance interpreting the statutory guardrails is proposed to be removed and replaced by new interpretations of those guardrails generally consistent with guidance provided to states in 2015 (the 2015 waiver guidance).[7] The proposed changes include additional guidance in the preamble providing instruction regarding the processes and procedures the Departments would 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 do not propose any regulatory changes to those sections, they reiterate and clarify the coordinated waiver process. They note that this process continues to be in line with both the 2018 and 2015 waiver guidance.

In reviewing or approving a coordinated waiver, the Departments would 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 would 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 would 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 would not be counted when determining if a section 1332 waiver meets the deficit neutrality requirement.

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

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

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

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 do not propose any changes to the application provisions but describe 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.

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, 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.

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

The Departments propose to change the interpretations of the guardrails that were finalized in Part 1 of the 2022 Payment Notice final rule. The proposed changes largely align with the guardrail interpretations described in the 2015 guidance.

The guardrail interpretations that were 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 provide 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 the existing guardrail interpretations are 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 proposed changes 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 would be minimally impacted by the proposed changes.

The Departments seek 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 proposed changes on affected parties and stakeholders.

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

The Departments propose to modify the comprehensive coverage guardrail to replace the existing requirement that to satisfy the comprehensive coverage requirements, 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, to at least a comparable number of people as would have had access to such coverage absent the waiver" with "*coverage* under the state plan forecasted to be at least as comprehensive overall for residents of the state a coverage absent the waiver."

The preamble further describes the guardrail. The Departments propose 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.[8] 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 would 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.

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

The comprehensiveness assessment would 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 would be 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."

b. Affordability

The Departments propose to modify the affordability guardrail to replace the existing requirement that to satisfy the 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, to at least a comparable number of people as would have had access to such coverage absent the waiver." with the requirement that the state plan is "forecasted to be as affordable for state residents as coverage absent the waiver."

The preamble further proposes that affordability would 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 would 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 would not likely be approved.

The waiver application would be 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.

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

The Departments propose non-substantive changes to the coverage guardrail but include additional guidance in the preamble regarding this guardrail which is generally consistent with the 2015 Guidance.

To meet the coverage guardrails, the Departments propose 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 would refer to "minimum essential coverage"[9] and "comparable" would mean that the forecast of the number of covered individuals is no lower than that number absent the waiver. The impact on all state residents would 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 would not likely be approved. Analysis under the coverage requirement would also need to take into account how the waiver impacts gaps or discontinuations of coverage.

The waiver application would be required to 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.

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

The Departments do not propose changes to the deficit neutrality guardrail but include additional guidance in the preamble regarding how it would 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 would be required to include all changes in income, payroll, or excise tax revenue, as well as any other forms of revenue (including user fees), that would result from the proposed waiver.
- The effect on federal spending would include all changes in federal financial assistance (PTC, 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 would also need to include all administrative costs to the federal government

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 waivers compliance with the guardrails. The Departments do not propose any regulatory changes to the provisions but propose 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:

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

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

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

The application would be required to 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.

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

The Departments do not propose changes to the requirement that states include an implementation timeline in their section 1332 waiver application but propose 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 PTCs, 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 PTC eligibility or

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

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.

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

The Departments do not propose regulatory changes to public input requirements but review existing requirements and propose 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 propose 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 propose that the length of the period will generally be no less than 30 days.

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 Department proposes to extend certain flexibilities that were adopted during the COVID-19 PHE with respect public notice and public participation requirements. Under the proposed rule, similar flexibilities would be allowed 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 amendments would make the flexibilities available in state or local emergent situations or state designated emergencies and would be similar to those available under Medicaid section 1115 Demonstration Waivers.

The Departments propose to broaden the Secretaries' authority to modify, in part, the otherwise applicable public notice procedures to expedite a decision on a proposed section 1332 waiver request that is submitted or would otherwise become due during emergent situations, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. The proposed 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)

Under the proposal, the Secretaries would be permitted to modify state public notice requirements and federal public notice requirements to expedite a decision on a proposed section 1332 waiver during an emergent situation as described above. The Secretaries clarify that the proposed rule would not permit the separate tribal consultation to be waived nor could a state eliminate public notice and participation procedures.

Examples of the public notice and participation procedures that a state could seek to waive or change during a future emergent situation include the requirement that states notify the public and hold hearings prior to applying, that the state hold more than one public hearing in more than one location, and that the Departments provide for public notice and comment after an application is determined to be complete. States 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 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 public notice procedures;
- Provide a justification for the alternative procedures.

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

The Departments would 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 propose to extend the COVID-19 post-award public notice requirement to be available for other future emergent situations.

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

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

The Departments propose 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.

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 Secretary 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. In the proposed rule, the Departments codify in new regulatory text details regarding the determination of pass-through funding for an approved section 1332 waiver.

Under the proposed rule, if a state has an approved section 1332 waiver and under that waiver, individuals and small employers in the state would not qualify for or would qualify for a reduced amount of PTC, a small business tax credit, or for cost-sharing reductions for which they would otherwise be eligible, pass-through funding would be available in the aggregate amount of such credits to the state for implementing the waiver plan. The Departments clarify that the pass-through amount would 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 would remove 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.

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

The Departments propose new regulatory text to describe a waiver amendment and explicitly permit amendments to be approved as the statute does not specifically mention amendments. Under the proposed rule a state could seek an amendment to an approved waiver. A section 1332 waiver amendment would be 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 proposed regarding the waiver amendment content requirements and approval process. The Departments would require a waiver amendment to be submitted with a letter of intent in electronic format. The letter would 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

would respond within 30 days of receipt to identify the information it would need 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 Departments propose that the state must maintain uninterrupted operations of the Exchange and provide adequate notice to any impacted stakeholders or issuers.

The Departments' amendment review process would be 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 Departments propose the same state-level public notice and comment requirements would apply to amendments and will apply the same federal-level public notice and comment processes.

A state pursuing an amendment would be required to submit similar information and analysis as for new waiver applications. Amendment requests would be required to 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.

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

The Departments propose to codify 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 propose additional guidance on submitting an extension request and the process for reviewing and approving such requests.

Under the proposed rule, states would be 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 would 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 pursing 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.

IV. Collection of Information Requirements

HHS addresses the potential for information collection burden for three provisions as required by the Paperwork Reduction Act of 1995.

- The Departments do not expect the proposal to require Navigators to provide consumers with information and assistance on post-enrollment topics to increase the number of reports that Navigator grantees are required to submit and therefore the proposal would not increase collection burden.
- As described above, estimates of the burden associated with separate billing requirements for QHPs that offer coverage of abortion services are reviewed. The proposal to eliminate those requirements would be expected to remove the associated information collection requirements under the separate billing regulation and reduce burden on QHP issuers, Exchanges, and consumers.
- Provisions eliminating references to the 2018 Guidance for section 1332 waivers, to replace with regulations largely in line with the 2015 Guidance, and to provide additional information on the processes for applying for and approving waiver applications, amendments, and extensions are not expected to significantly change the associated burden.

V. Regulatory Impact Analysis (RIA)

OMB has determined that this proposed 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 proposed rule's estimated costs and benefits. Comments are invited on the estimates and qualitative impacts included in the RIA.

Table 1 of the proposed rule summarizes the estimated qualitative and quantitative impacts and estimated direct monetary costs and transfers that would result from the proposals. The Departments note that they are unable to quantify all of the benefits and costs of the proposed rule.

In addition to the impacts of provisions described above, HHS describes the potential regulatory impact of the proposed monthly SEP for individuals in households with income below 150 percent of FPL. It reviews its premium estimates, described above, and the ways by which it expects the adverse selection impact would be mitigated. It estimates a 0.5 to 2 percent increase in premiums in states where the special enrollment period is implemented, which could result in an estimated $250 million to $1 billion increase in APTC/PTC outlays and decrease in income tax revenues nationwide. **HHS seeks comment on the estimate. In addition, HHS also seeks comment on:**

- **Practices, including education and outreach, including to help ensure that consumers who are eligible for the SEP enroll in the zero-dollar premium silver plan that is available to them;**
- **The potential for adverse risk for issuers including whether issuers would account for this risk through premium increases;**
- **The impact on premiums of this policy and potential regulatory tools to mitigate the adverse selection risks; and**
- **Whether Exchanges would be able to implement the SEP in time to make it available for the 2022 plan year.**

HHS provides some data points in its consideration of the impact of the provision to clarify that, for the purposes of certain SEPs a person who qualifies for an APTC of zero would also be considered to not be APTC eligible. There were 36,000 of those individuals enrolled through the Exchanges on the federal platform in March of 2021 and 42,000 in May of 2021, indicating that those numbers are rising and are expected to continue to do so since the passage of ARP which permits people with income above 400 percent of FPL to qualify for APTCs. HHS expects that policy to draw additional individuals to Exchanges who may qualify for an APTC amount equal to zero dollars. **HHS seeks comments on policy concerns as well as concerns about burden for state Exchange operations, and whether individuals would qualify for a SEP could be harmed by such a clarification.**

Other quantitative estimates provided include:

- Increased FFE and SBE-FP user fees are estimated to increase transfers from issuers to the federal government by approximately $200 million in plan year 2022.
- As noted above, HHS expects that the increased flexibility provided by the proposal to eliminate the separate billing regulation would remove a significant financial burden for issuers, states, state Exchanges, and consumers. The total projected burden of the separate billing policy was estimated to be $546 million in 2020, and about $230 million annually thereafter.