



DEPARTMENT OF THE TREASURY

31 CFR Part 33

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 155

CMS-9936-NC

State Relief and Empowerment Waivers

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

ACTION: Guidance.

SUMMARY: This guidance relates to section 1332 of the Patient Protection and Affordable Care Act (PPACA) and its implementing regulations. Section 1332 provides the Secretary of Health and Human Services and the Secretary of the Treasury (collectively, the Secretaries) with the discretion to approve a state's proposal to waive specific provisions of the PPACA (a State Innovation Waiver, now also referred to as a State Relief and Empowerment Waiver), provided the section 1332 state plan meets certain requirements. The Department of Health and Human Services and the Department of the Treasury (collectively, the Departments) finalized implementing regulations on February 27, 2012. This updated guidance provides supplementary information about the requirements that must be met for the approval of a State Innovation Waiver, the Secretaries' application review procedures, the calculation of pass-through funding, certain analytical requirements, and operational considerations. This guidance supersedes the guidance related to section 1332 of the PPACA that was previously published on December 16, 2015. Changes include increasing flexibility with respect to the manner in which a section 1332 state plan may meet section 1332 standards in order to be eligible to be approved by the

Secretaries, clarifying the adjustments the Secretaries may make to maintain federal deficit neutrality, and allowing for states to use existing legislative authority to authorize section 1332 waivers in certain scenarios. The Departments are committed to empowering states to innovate in ways that will strengthen their health insurance markets, expand choices of coverage, target public resources to those most in need, and meet the unique circumstances of each state. This guidance aims to lower barriers to innovation for states seeking to reform their health insurance markets.

DATES: Applicability date: **This guidance is applicable beginning [Insert Date of public inspection at the OFR]**

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, refer to file code CMS-9936-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this document to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address **ONLY**:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9936-NC,

P.O. Box 8010,

Baltimore, MD 21244-1810.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9936-NC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Lina Rashid, (202) 260-6098.

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SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

I. Overview

One of the Administration's priorities is to empower states by providing tools to address the serious problems that have surfaced in state individual health insurance markets with the implementation of the Patient Protection and Affordable Care Act (PPACA). After the Exchanges took full effect in 2014, individual market insurance companies began experiencing substantial losses. Industry analysts estimate aggregate losses reached \$7.2 billion (10.1 percent of premiums) in 2015.¹ In response to these losses, many issuers (some of whom entered the market as a result of the PPACA) left the market, including issuers participating on the Exchanges. The percentage of counties with one Exchange issuer grew from 7 percent in 2016 to 33 percent in 2017 and to 52 percent in 2018, representing 2 percent, 21 percent, and 26 percent of enrollees respectively.² The issuers remaining in the individual market increased premiums substantially between 2013 and 2017; average premiums for individual market health plans sold through Healthcare.gov rose by 105 percent.³ While subsidized enrollment in Exchanges remains stable, overall enrollment on and off the Exchanges dropped between 2016 and 2017 by over 10 percent, reflecting a sizable drop in unsubsidized enrollment.⁴ Kaiser Family Foundation further found that individual market enrollment dropped 12 percent between

¹ Losses in 2016 appear to be between 7% and 9% of premiums. <https://healthcare.mckinsey.com/2016-individual-market-losses-are-high-single-digits%E2%80%94slight-improvement-2015>. The insurance market is showing signs of stabilizing. <http://files.kff.org/attachment/Issue-Brief-Individual-Insurance-Market-Performance-in-Early-2018>

² <https://www.kff.org/health-reform/issue-brief/insurer-participation-on-aca-marketplaces/> and Kaiser Family Foundation analysis as of August 26, 2016

³ The data is for states using the federally-facilitated exchange. Pg 2.

<https://aspe.hhs.gov/system/files/pdf/256751/IndividualMarketPremiumChanges.pdf>. The premium increases since 2013 are partly attributable to changes in the types of policies that may be offered. For example, the Congressional Budget Office estimates that PPACA market reforms including requiring a minimum actuarial value of 60 percent, coverage of pre-existing conditions and covering more benefits likely resulted in about a 27 to 30 percent increase in premiums. See Congressional Budget Office, Private Health Insurance Premiums and Federal Policy, February 2016, p.21.

⁴ Pg 1. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-2.pdf>

the first quarter of 2017 and the first quarter of 2018.⁵ This drop represents deterioration in the individual market for people who pay the full premium. These national average premium and enrollment trends mask deeper, more serious problems occurring in certain state markets. Some states experienced premium increases in excess of 200 percent between 2013 and 2017.⁶ States with larger premium increases also tended to experience larger enrollment declines, with a few states losing more than a third of the individual market in 2017.⁷ According to Kaiser, there were 14.4 million people enrolled in the individual market as of the first quarter of 2018, compared to 10.6 million people in 2013.⁸ This gain in enrollment has come at a significant cost to the federal government as CBO estimates the premium tax credits will total about \$50 billion in 2018.⁹

This guidance intends to expand state flexibility, empowering states to address problems with their individual insurance markets and increase coverage options for their residents, while at the same time encouraging states to adopt innovative strategies to reduce future overall health care spending. Section 1332 of the PPACA permits a state to apply for a State Innovation Waiver (referred to as a section 1332 waiver or a State Relief and Empowerment Waiver) to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. The overarching goal of section 1332 waivers is to give all Americans the opportunity to gain high value and affordable health coverage regardless of income, geography, age, gender, or health status while empowering states to develop health coverage strategies that best meet the needs of their residents. Section 1332 waivers provide

⁵ <http://files.kff.org/attachment/Data-Note-Changes-in-Enrollment-in-the-Individual-Health-Insurance-Market>

⁶ Alabama, Alaska, and Oklahoma experienced premium increases in excess of 200 percent between 2013 and 2017. <https://aspe.hhs.gov/system/files/pdf/256751/IndividualMarketPremiumChanges.pdf>

⁷ Figure 4 <https://downloads.cms.gov/ccio/Summary-Report-Risk-Adjustment-2017.pdf>

⁸ <http://files.kff.org/attachment/Data-Note-Changes-in-Enrollment-in-the-Individual-Health-Insurance-Market>

⁹ <https://www.cbo.gov/system/files?file=2018-06/53826-healthinsurancecoverage.pdf>

states an opportunity to promote a stable health insurance market that offers more choice and affordability to state residents, in part through expanded competition. These waivers could potentially be used to allow states to build on additional opportunities for more flexible and affordable coverage that the Administration opened through expanded options for Association Health Plans (AHP)¹⁰ and short-term, limited-duration insurance (STLDI)¹¹.

The Departments are seeking to reduce burdens that may impede a state's efforts to implement innovative changes and improvements to its health insurance market while remaining consistent with the statute. We believe that the reduction in these burdens will lead to more affordable health coverage for individuals and families. Under section 1332 of the PPACA, the Secretaries may exercise their discretion to approve a request for a section 1332 waiver¹² only if the Secretaries determine that the proposal for the section 1332 waiver meets the following four requirements (referred to as the statutory guardrails): (1) the proposal will provide coverage that is at least as comprehensive as coverage defined in PPACA's section 1302(b) and offered through Exchanges established by title I of PPACA, as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the PPACA and the provisions of the PPACA that would be waived; (2) the proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided under title I of PPACA; (3) the proposal will provide

¹⁰ <https://www.federalregister.gov/documents/2018/06/21/2018-12992/definition-of-employer-under-section-35-of-erisa-association-health-plans>

¹¹ <https://www.federalregister.gov/documents/2018/08/03/2018-16568/short-term-limited-duration-insurance>

¹² The Departments' State Innovation Waiver authority is limited to requirements described in section 1332(a)(2) of the PPACA. Further, section 1332(c) of the PPACA states that while the Secretaries have broad discretion to determine the scope of a waiver, no federal laws or requirements may be waived that are not within the Secretaries' authority. See 77 FR 11700, 11711 (February 27, 2012). Therefore, for example, section 1332 does not grant the Departments the authority to waive any provision of ERISA.

coverage to at least a comparable number of the state's residents as would be provided under title I of PPACA; and (4) the proposal will not increase the federal deficit. The Secretaries retain their discretionary authority under section 1332 to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrail requirements. The Secretaries will consider favorably section 1332 waiver applications that advance some or all of these five principles as elements of a section 1332 waiver application. The principles are:

- *Provide increased access to affordable private market coverage.* Making private health insurance coverage more accessible and affordable should be a priority for a section 1332 waiver. A section 1332 state plan should foster health coverage through competitive private coverage, including AHPs and STLDI plans, over public programs. Additionally, the Departments will look favorably upon section 1332 applications under which states increase issuer participation in state insurance markets and promote competition.

- *Encourage sustainable spending growth.* Section 1332 waivers should promote more cost-effective health coverage and be fair to the federal taxpayer by restraining growth in federal spending commitments. For example, states should consider eliminating or reducing state-level regulation that limits market choice and competition in order to reduce prices for consumers and reduce costs to the federal government, as part of their section 1332 waiver applications.

- *Foster state innovation.* States are better positioned than the federal government to assess and respond to the needs of their citizens with innovative solutions. We encourage states to craft solutions that meet the needs of their consumers and markets and innovate to the maximum extent possible under the law.

- *Support and empower those in need.* Americans should have access to affordable, high value health insurance. Some Americans, particularly those with low incomes or high expected health care costs, may require financial assistance. Policies in section 1332 waiver applications should support state residents in need in the purchase of private coverage with financial assistance that meets their specific health care situations.

- *Promote consumer-driven healthcare.* Section 1332 waivers should empower Americans to make informed choices about their health coverage and health care with incentives that encourage consumers to seek value. Instead of only offering a one-size-fits-all plan proposal, a section 1332 state plan should focus on providing people with the resources and information they need to afford and purchase the private insurance coverage that best meets their needs.

States should explain in their waiver applications how their proposals would advance some or all of these principles. Consistent with the principles laid out above, the Secretaries intend to provide states with maximum flexibility within the law to innovate, empower consumers, and expand higher value and more affordable coverage options.

As under similar waiver authorities, the Secretaries reserve the right to suspend or terminate a waiver, in whole or in part, any time before the date of expiration, if the Secretaries determine that the state materially failed to comply with the terms and conditions of the waiver. Additionally, states with approved section 1332 waivers must comply with all applicable federal laws and regulations (unless specifically waived) and must come into compliance with any changes in federal law or regulations affecting section 1332 waivers.

Final regulations at 31 CFR part 33 and 45 CFR part 155, subpart N, require a state to provide actuarial analyses and actuarial certifications, economic analyses, data and assumptions,

targets, an implementation timeline, and other necessary information to support the state's estimates that the proposed waiver will comply with section 1332 requirements.¹³

II. Changes to 2015 Guidance

In 2015, the Departments published guidance explaining how they would consider applications for waivers under section 1332 (2015 guidance)¹⁴. In light of the Departments' experience since 2015 in considering State waiver applications and communicating with states considering such applications, the Departments have reviewed the statutory guardrails to determine whether the interpretations set forth in the previous guidance could be revised to provide more flexibility to the states. As a result of this review, the Departments have determined that the analysis of comprehensiveness and affordability of coverage under a waiver should focus on the nature of coverage that is made available to state residents (access to coverage), rather than on the coverage that residents actually purchase. Adopting this more flexible interpretation of the section 1332 guardrails that focuses on coverage made available under the waiver will lower barriers to innovation and allow states to implement waiver plans that will strengthen their health insurance markets by providing a variety of coverage options.

Section 1332(b)(1)(C) requires that a state's plan under a waiver will provide coverage "to at least a comparable number of its residents" as would occur without the waiver. By contrast, section 1332(b)(1)(A) and (B) merely state that the state's plan will provide coverage that is as comprehensive and affordable as would occur without a waiver, but do not specify to whom such coverage must be provided. The 2015 guidance focused on the number of individuals actually estimated to receive comprehensive and affordable coverage, in effect

¹³ Application, Review, and Reporting Process for Waivers for State Innovation Final Rule, February 27, 2012. Available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-02-27/pdf/2012-4395.pdf>.

¹⁴ <https://www.gpo.gov/fdsys/pkg/FR-2015-12-16/pdf/2015-31563.pdf>

reading the “to at least a comparable number of its residents” language from the coverage guardrail into the comprehensiveness and affordability guardrails as well. However, the Departments do not believe that the language or structure of the statute compels that reading.

Further, a major disadvantage of the 2015 interpretation was that it deterred states from providing innovative coverage that, while potentially less comprehensive than coverage established under the PPACA, could have been better suited to consumer needs and potentially more affordable and attractive to a broad range of its residents. For example, even if coverage similar to that made available under the PPACA remained available in a state, an offer of more attractive, but less comprehensive plans would have reduced the number of residents who elected PPACA-like coverage, and would likely have caused the state waiver plan to fail the comprehensiveness guardrail. To avoid this effect of the 2015 guidance, this guidance focuses on the *availability* of comprehensive and affordable coverage. This shift in focus ensures that state residents who wish to retain coverage similar to that provided under the PPACA can continue to do so, while permitting a state plan to also provide access to other options that may be better suited to consumer needs and more attractive to many individuals.

In order to ensure that the Departments’ revised interpretation of the comprehensiveness and affordability guardrails provides full meaning to the statute and aligns with the Administration’s principles, it is important that the two guardrails be evaluated in conjunction. In other words, it is not enough to make available some coverage that is comprehensive but not affordable, while making available other coverage that is affordable but not comprehensive. Thus, the guidance, as described in detail below, provides that a state plan will comply with the comprehensiveness and affordability guardrails, consistent with the statute, if it makes coverage

that is both comprehensive and affordable available to a comparable number of otherwise qualified residents as would have had such coverage available absent the waiver.

The 2015 guidance concerning the comprehensiveness and affordability guardrails has also been revised to focus on the aggregate effects of a waiver. The 2015 guidance largely prohibited approval of a state plan that made coverage less comprehensive or affordable for any particular group of residents. While analysis will continue to consider effects on all categories of residents, the revised guardrails will give states more flexibility to decide that improvements in comprehensiveness and affordability for state residents as a whole offset any small detrimental effects for particular residents. As discussed in this guidance and principles above, the state should also address in the application for the section 1332 waiver how the section 1332 state plan addresses the Administration's priority to support and empower those with low incomes as well as those with high expected health care costs.

The coverage guardrail requires that coverage be provided to at least a comparable number of residents as would occur absent the waiver. However, the text of the coverage guardrail provision of the statute is silent as to the type of coverage that is required.

Accordingly, to enable state flexibility and to promote choice of a wide range of coverage to ensure that consumers can enroll in coverage that is right for them, this guidance permits states to provide access to less comprehensive or less affordable coverage as an additional option for their residents to choose. This guidance on the coverage guardrail continues to consider the number of state residents who are actually receiving coverage. As long as a comparable number of residents are projected to be covered as would have been covered absent the waiver, the coverage guardrail will be met.

In addition, in another effort to provide flexibility for states and provide full meaning to the statute in this guidance, the Departments clarify that in certain circumstances, existing state legislation that provides statutory authority to enforce PPACA provisions and the state plan, combined with a duly-enacted state regulation or executive order, may satisfy the requirement that the state enact a law under section 1332(b)(2).

Finally, our analysis of the deficit neutrality guardrail has been revised to provide more specific guidance in light of the Departments' experience in evaluating waiver applications.

III. Statutory Guardrail Requirements

The following guidance explains in more detail how the Departments will evaluate each of the statutory guardrails.

A. Comprehensiveness and Affordability

The Departments may consider these guardrails met if access to coverage that is as affordable and comprehensive as coverage forecasted to have been available in the absence of the waiver is projected to be available to a comparable number of people under the waiver. The Departments will not require projections demonstrating that this coverage will actually be purchased by a comparable number of state residents; in other words, these guardrails will be met if the state plan has made other coverage options available that state residents may prefer, so long as access to affordable, comprehensive coverage is also available. Thus, the Departments will consider the affordability requirement to be met in a state plan that will provide consumers access to coverage options that are at least as affordable and 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. In evaluating whether the state plan meets the comprehensiveness and affordability guardrails, the Departments will take into account access to

affordable, comprehensive coverage to all state residents, regardless of the type of coverage they would have had access to in absence of the waiver.

Comprehensiveness

Comprehensiveness refers to the scope of benefits provided by the coverage as measured by the extent to which coverage meets essential health benefits (EHB) requirements as defined in section 1302(b) of the PPACA and offered through Exchanges established by title I of PPACA, as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services. The impact on all state residents eligible for coverage under title I of PPACA is considered, regardless of the type of coverage that they would have had access to absent the waiver.

In April 2018, CMS provided states with substantially more options in the selection of an EHB-benchmark plan.¹⁵ The Departments will evaluate comprehensiveness by comparing access to coverage under the waiver to the state's EHB benchmark (for the applicable plan year) selected by the state (or if the state does not select a benchmark, the default base-benchmark plan), any other state's benchmark plan chosen by the state for purposes of the waiver application, or any benchmark plan chosen by the state that the state could otherwise build that could potentially become their EHB-benchmark plan.

Affordability

Affordability refers to state residents' ability to pay for health care expenses relative to their incomes and may generally be measured by comparing each individual's expected out-of-pocket spending for health coverage and services to their income. Out-of-pocket spending for

¹⁵ As finalized in the HHS Notice of Benefit and Payment Parameters for 2019, starting in plan year 2020 CMS is providing states with additional flexibility in how they select their EHB-benchmark plan. The final rule provides states with substantially more options in what they can select as an EHB-benchmark plan. Instead of being limited to 10 options, states will now be able to choose from the 50 EHB-benchmark plans used for the 2017 plan year in other states or select specific EHB categories, such as drug coverage or hospitalization, from among the categories used for the 2017 plan year in other states. States will also now be able to build their own set of benefits that could potentially become their EHB-benchmark plan, subject to certain scope of benefits requirements.

health care includes premiums (or equivalent costs for enrolling in coverage) and spending such as deductibles, co-pays, and co-insurance associated with the coverage, or direct payments for healthcare. In evaluating affordability, the Departments will take into account access to affordable, comprehensive coverage available to all state residents, regardless of the type of coverage they would have had access to in the absence of the waiver. In addition to considering the number of state residents for whom comprehensive coverage has become more or less affordable, the Departments will take into account the magnitude of such changes. For example, a waiver that makes coverage slightly more affordable for some people but much less affordable for a comparable number of people would be less likely to be granted than a waiver that makes coverage substantially more affordable for some people without making others substantially worse off. In addition, a waiver that makes coverage much more affordable for some people and only slightly more costly for a larger number of people would likely meet this guardrail. The Departments will consider the changes in affordability for all groups, including low-income residents and those with high expected health care costs.

As provided in 31 CFR part 33 and 45 CFR part 155, subpart N, the waiver application must include analysis and supporting data that establishes that the waiver satisfies the comprehensiveness and affordability guardrails. This includes an explanation of how the coverage available under the waiver differ from the coverage chosen absent the waiver (if the coverage differs at all) and how the state determined the coverage to be as comprehensive. It also includes information on estimated individual out-of-pocket costs (premium and out-of-pocket expenses for deductibles, co-payments, co-insurance, co-payments and plan differences) by income, health expenses, health insurance status, and age groups, absent the waiver and for available coverage under the waiver. The application should identify any types of individuals

(including, but not limited to, those individuals who are low income or have high expected health care costs) for whom affordability of coverage would be reduced by the waiver and also identify any types of individuals for whom affordability of coverage would be improved by the waiver. The state should also address in its section 1332 waiver application how it would address the Administration's priority to support and empower consumers, including those with high expected health care costs and those with low incomes.

B. Number of State Residents Covered (Coverage)

To meet the coverage requirement, the section 1332 state plan must provide meaningful health care coverage to a comparable number of its residents as title I of PPACA would provide. The Departments will assess the coverage guardrail by requiring the state to forecast, for each year the section 1332 state plan will be in effect, the number of individuals that will have health care coverage under the section 1332 state plan, and compare that to the number of individuals that would have had health care coverage absent the waiver. A section 1332 state plan will be considered to comply with this coverage guardrail if, for each year the waiver is in effect, the state can demonstrate that a comparable number of state residents eligible for coverage under title I of PPACA will have health care coverage under the section 1332 state plan as would have had coverage absent the waiver. For purposes of meeting this guardrail, in line with the Administration's priority favoring private coverage, including AHPs and STLDI plans, the Departments will consider all forms of private coverage in addition to public coverage, including employer-based coverage, individual market coverage, and other forms of private health

coverage. Coverage refers to minimum essential coverage as defined in 26 USC 5000A(f) and 26 CFR 1.5000A-2, and health insurance coverage as defined in 45 CFR 144.103¹⁶.

Under this guardrail, the impact on all state residents eligible for coverage under title I of PPACA will be considered, regardless of the type of coverage they would have had absent the waiver. For example, while a section 1332 waiver alone may not change the terms of a state's Medicaid coverage or change existing Medicaid demonstration authority, changes in Medicaid enrollment – whether increases or decreases – that result from a section 1332 waiver, holding the state's Medicaid policies constant, will be considered in evaluating the number of residents with coverage under a waiver. The Departments will consider the effects the section 1332 state plan will have on coverage in the aggregate across all state residents. However, as noted in this guidance, an application for a section 1332 waiver should address the Administration's priority to support and empower consumers, including those with high expected health care costs and those with low incomes. The assessment under the coverage requirement will take into account whether the section 1332 state plan sufficiently prevents gaps in or discontinuations of coverage. The section 1332 guardrails generally should be forecast to be met in each year that a waiver would be in effect. However, the Departments will consider the longer-term impacts of a state's proposal, and may approve a waiver even where a state expects a temporary reduction in coverage but can demonstrate that the reduction is reasonable under the circumstances, and that the innovations will produce longer-term increases in the number of state residents who have coverage such that, in the aggregate, the coverage guardrail will be met or exceeded over the course of the waiver term. For example, the Departments may approve a 1332 waiver plan that

¹⁶ *Health insurance coverage* means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer. Health insurance coverage includes group health insurance coverage, individual health insurance coverage, and short-term, limited-duration insurance.

is not forecast to meet the coverage guardrail on Day 1 of the waiver, if the state's plan is forecast to meet or exceed pre-waiver coverage levels within a reasonable amount of time, and any coverage reductions are offset by coverage gains. The reasonableness of a proposed transition period will be considered, taking into account the following: the reasons it is infeasible under the state's plan to fully maintain pre-waiver coverage levels at the outset; the degree of the departure from the pre-waiver levels during the transition period; the state's ability to demonstrate the long-term gains in coverage as compared to pre-waiver levels; other features of the plan that mitigate the impact of the departure, if any; and any other relevant factors.

As provided in 31 CFR part 33 and 45 CFR part 155, subpart N, the waiver application must include analysis and supporting data that establishes that the waiver satisfies the scope of coverage requirement, including information on the number of individuals covered by income, health expenses, health insurance status, and age group, under title I of PPACA and under the waiver, including year-by-year estimates. The application should identify any types of individuals who are more or less likely to be covered under the waiver than under current law.

C. Deficit Neutrality

Under the deficit neutrality requirement, the projected federal spending net of federal revenues under the section 1332 waiver must be equal to or lower than projected federal spending net of federal revenues in the absence of the section 1332 waiver.

The estimated effect on federal revenue includes all changes in income, payroll, or excise tax revenue, as well as any other forms of revenue (including but not limited to user fees), that would result from the proposed waiver. Estimated effects would include, for example, changes in amounts the federal government pays in premium tax credits (PTC) and small business tax credits; changes in the amount of employer shared responsibility payments and excise taxes on

high-cost employer-sponsored plans collected by the federal government; and changes in income and payroll taxes resulting from changes in tax exclusions for employer-sponsored insurance and in deductions for medical expenses.

The effect on federal spending includes all changes in Exchange financial assistance and any other spending that result from the section 1332 waiver. Projected federal spending under the waiver proposal also includes all administrative costs of the federal government, including any changes in Internal Revenue Service administrative costs, federal Exchange administrative costs, or other administrative costs associated with the waiver or alleviated by the waiver.

Waivers must not increase the federal deficit over the period of the waiver (which may not exceed 5 years unless renewed) or in total over the 10-year budget plan submitted by the state as part of the application. We have revised the 2015 guidance to clarify that the ten-year budget plan should describe the changes in projected federal spending and changes in federal revenues attributed to the waiver for each of the ten years.

The 10-year budget plan should assume the waiver would continue permanently, unless such an assumption would be inconsistent with the nature and intent of the state plan. However, the budget plan should not include federal spending or savings attributable to any period outside of the 10-year budget window. A variety of factors, including the likelihood and accuracy of projected spending and revenue effects and the timing of those effects, will be considered when evaluating the effect of the waiver on the federal deficit.

IV. Federal Pass-Through Funding

Section 1332 directs the Secretaries to pay pass-through funding for the purpose of implementing the state plan under the waiver. The amount of federal pass-through funding equals the Secretaries' annual estimate of the federal financial assistance, including PTC, small

business tax credits, or cost-sharing reductions, provided pursuant to the PPACA that would have been paid on behalf of participants in the Exchange in the state in the calendar year in the absence of the waiver, but will not be paid as a result of the waiver. This includes any amount of federal financial assistance pursuant to the PPACA not paid due to an individual not qualifying for financial assistance or qualifying for a reduced level of financial assistance resulting from a waived provision as a direct result of the waiver plan. The pass-through amount does not include any savings other than the reduction in PPACA financial assistance. The pass-through amount will be reduced by any other increase in spending or decrease in revenue if necessary to ensure deficit neutrality. The estimates take into account experience in the relevant state and similar states. This amount is calculated annually by the Departments. The annual amount may be updated at any time to reflect changes in state or federal law (including regulation and sub-regulatory guidance).

The waiver application, consistent with the Departments' regulations, must provide analysis and supporting data to inform the estimate of the pass-through funding amount. For states that do not utilize a Federally-facilitated Exchange, this includes information about enrollment, premiums, and Exchange financial assistance in the state's Exchange by age, income, and type of policy, and other information as may be required by the Secretaries. For further information on the demographic and economic assumptions to be used in determining the pass-through amount, see Section V of this guidance.

As part of the state's waiver application, the state should include a description of the provisions for which the state seeks a waiver and how the waiver is necessary to facilitate the state's waiver plan. Further, as part of the state's waiver plan if the state is seeking pass-through funding, the state waiver application should include an explanation of how, due to the structure

of the section 1332 state plan and the statutory provisions waived, the state anticipates that individuals would no longer qualify for financial assistance (PTC, small business tax credits, or cost-sharing reductions) or would qualify for reduced financial assistance for which they would not be eligible absent the section 1332 waiver. The state should also explain how the state intends to use that funding for the purposes of implementing its section 1332 state plan. Pass-through funding may only be used to implement the approved section 1332 state plan. States have a wide range of flexibility in designing their section 1332 waiver application and section 1332 state plan.

V. Economic Assumptions and Methodological Guidelines

The determination of whether a waiver meets the requirements under section 1332 and the calculation of the pass-through funding amount are made using generally accepted actuarial and economic analytic methods, such as micro-simulation. The analysis relies on assumptions and methodologies that are similar to those used to produce the baseline and policy projections included in the most recent President's Budget (or Mid-Session Review)¹⁷, but adapted as appropriate to reflect state-specific conditions. As provided in 31 CFR 33.108(f)(4)(i) and 45 CFR 155.1308(f)(4)(i), the state must include actuarial analyses and actuarial certifications to support the state's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, and the scope of coverage requirement. In this guidance, we clarify that this actuarial analysis and certification should be conducted by a member of the American Academy of Actuaries.

The Departments' analysis is based on state-specific estimates of the current level and distribution of population by the relevant economic and demographic characteristics, including

¹⁷ <https://www.whitehouse.gov/omb/budget/>

income and source of health coverage. It generally uses federal estimates of population growth, economic growth as published in the Analytical Perspectives volume released as part of the President's Budget (https://www.whitehouse.gov/omb/budget/Analytical_Perspectives) and health care cost growth (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/NationalHealthExpendData/>) to project the initial state variables through the 10-year Budget plan window. However, in limited circumstances where it is expected that a state will experience substantially different trends than the nation as a whole in the absence of a waiver, the Secretaries may determine that state-specific assumptions will be used.

Estimates of the effect of the waiver assume, in accordance with standard estimating conventions, that macroeconomic variables like population, output, and labor supply are not affected by the waiver. However, estimates take into account, as appropriate, other changes in the behavior of individuals, employers, and other relevant entities induced by the waiver where applicable, including employer decisions regarding what coverage (and other compensation) they offer and individual decisions regarding whether to take up coverage. The same state-specific and federal data, assumptions, and model are used to calculate comprehensiveness, affordability, and coverage, and relevant state components of federal taxes and spending under the waiver and under current law.

The analysis and information submitted by the state as part of the application should conform to these standards as outlined in this guidance. The application should describe all modeling assumptions used, sources of state-specific data, and the rationale for any deviation from federal forecasts. A state may be required under 31 CFR 33.108(f)(4)(vii) and 45 CFR

155.1308(f)(4)(vii) to provide to the Secretaries copies of any data used for their waiver analyses that are not publicly available so that the Secretaries can independently verify the analysis produced by the state.

For each of the guardrails, the state should clearly explain its estimates with and without the waiver. The actuarial and economic analyses must compare comprehensiveness, affordability, coverage, and net federal spending and revenues under the waiver to those measures absent the waiver (the baseline) for each year of the waiver. If the state is submitting a waiver application for less than a 5-year period, the actuarial analysis can be submitted for the period of the waiver. The Departments, in accordance with their regulations, may request additional information or data in order to conduct their assessments.

The state should also provide a description of the models used to produce these estimates, including data sources and quality of the data, key assumptions, and parameters for the section 1332 state plan. The Departments are not prescribing any particular method of actuarial analysis to estimate the potential impact of a section 1332 waiver. However, the state should explain its modeling in sufficient detail to allow the Secretaries to evaluate the accuracy of the state's modeling and the comprehensiveness and affordability of the coverage available under the state's waiver proposal. As permitted under 45 CFR 155.1308(g) and 31 CFR 33.108(g), the state may be required to provide data or other information that it used to make its estimates to inform the Secretaries' assessment, including an explanation of the assumptions used in the actuarial analysis.

VI. Operational Considerations

A. Federally-facilitated Exchanges

CMS operates the Exchange information technology platform (the federal platform) utilized by the Federally-facilitated Exchanges (FFE) and some state Exchanges. Previously, CMS stated that the federal platform could not accommodate different eligibility and enrollment rules for different states. Since then, the federal platform has undergone technical enhancements necessary for the FFE's operations that will enable it to support increased variation and flexibility for states that may want to leverage components of the federal platform to implement new models through section 1332 waivers. These improvements will include functionality that will enable states to work with private industry partners to create their own Web sites that could replace the consumer-facing aspects of HealthCare.gov for their state, while allowing the state to utilize aspects of the back-end technology that supports the FFE. Using this enhanced direct enrollment functionality¹⁸ as well as other CMS technology, states and private partners could customize the display of plan data and the information provided to consumers, or access specific eligibility verifications for use in state-specific eligibility determinations. Further, for states that opt to waive the requirement to establish an Exchange under section 1311(b)(1) of the PPACA and transition their Exchange-eligible populations to a state-based 1332 program, in compliance with applicable privacy law and standards and with the consent of the relevant enrollees, the new FFE data-sharing functionality could make information on current enrollees accessible to states outside of the Exchange context. The new FFE data-sharing functionality potentially could provide data on the status of data matching issues and special enrollment period verification

¹⁸ Enhanced direct enrollment is a program in which CMS will provide direct enrollment entities with the ability to provide an account creation, application, enrollment and coverage maintenance experience for consumers and agents/brokers working with consumers.

issues, account creation, and document uploading which would ease transition periods to a potential new non-Exchange program and mitigate risk pool deterioration. HHS is continuing to evaluate what types of flexibilities related to plan management, financial assistance, and consumer assistance are feasible, and seeks to engage with states to determine interest in potential models. States should engage with HHS early in the section 1332 waiver application process to determine whether the federal platform could accommodate state needs. During this time, HHS will work to estimate potential funding costs to implement the requested flexibilities. States will be responsible for funding all customized technical builds, in addition to funding of year-round customized operational support.

CMS may provide services in support of the state's section 1332 waiver plan including but not limited to eligibility determinations or data verification services to support eligibility determinations for participation in State waiver programs under the Intergovernmental Cooperation Act (ICA). Under the ICA, a federal agency generally may provide certain technical and specialized services to state governments, so long as the state covers the full costs of those services. Accordingly, where a state intends to rely on CMS for services, the state must cover CMS's costs. For this reason, the Departments will not consider costs for CMS services covered under the ICA as an increase in federal spending resulting from the state's waiver plan for purposes of the deficit neutrality analysis.

As noted in Section III.C of this guidance, costs associated with changes to federal administrative processes are taken into account in determining whether a waiver application satisfies the deficit neutrality requirement. Regulations at 31 CFR part 33 and 45 CFR part 155, subpart N, require that such costs be included in the 10-year budget plan submitted by the state.

B. Internal Revenue Service

Certain changes that affect Internal Revenue Service (IRS) administrative processes may make a section 1332 waiver proposal infeasible for the Departments to accommodate. At this time, the IRS generally is not able to administer different sets of tax rules for different states. As a result, while a state may propose to entirely waive the application of one or more of the tax provisions listed in section 1332 to taxpayers in the state, it is generally not feasible to design a waiver that would require the IRS to administer an alteration to these provisions for taxpayers in the state.

In some cases, the IRS may be able to accommodate small adjustments to the existing system for administering federal tax provisions. For example, a state that has not expanded its Medicaid program may wish to expand eligibility for APTC and PTC to individuals under 100 percent of the Federal Poverty Level (FPL). It may be feasible for IRS to implement this change because it currently administers a special rule that allows certain individuals to claim PTC if they are under 100 percent FPL and get APTC. However, it is generally not feasible to have the IRS administer a different set of PTC eligibility rules for individuals over 100 percent FPL in a particular state. Thus, states contemplating a waiver proposal that includes a modified version of a federal tax provision might consider waiving the provision entirely and creating a subsidy program administered by the state as part of its section 1332 waiver plan.

In addition, a waiver proposal that partly or completely waives one or more tax provisions in a state may create administrative costs for the IRS. As noted in Section III.C of this guidance, costs associated with changes to federal administrative processes are taken into account in determining whether a waiver application satisfies the deficit neutrality requirement. Regulations at 31 CFR part 33 and 45 CFR part 155, subpart N, require that such costs be

included in the 10-year budget plan submitted by the state. States contemplating to waive any part of a federal tax provision should engage with the Departments early in the section 1332 application process to assess whether the waiver proposal is feasible for the IRS to implement, and to assess the administrative costs to the IRS of implementing the waiver proposal.

VII. Application Timing

Consistent with the regulations at 31 CFR 33.108(b) and 45 CFR 155.1308(b), states are required to submit initial section 1332 waiver applications sufficiently in advance of the requested waiver effective date to allow for an appropriate implementation timeline. We strongly encourage states interested in applying for any section 1332 waivers, including coordinated section 1115 and section 1332 waivers, to engage with the Departments promptly for assistance in formulating an approach that meets the requirements of section 1332.

In order to help ensure timely approval, states should plan to submit their initial waiver applications with enough time to allow for public comment, review by the Departments, and implementation of the section 1332 state plan as outlined in the waiver application. In general, submission during the first quarter of the year prior to the year health plans affected by the waiver would take effect would permit sufficient time for review and implementation of both the waiver application and affected plans. It is important to note that the Departments cannot guarantee a state's request for expedited review or approval under a regular waiver submission and will continue to review applications consistent with the timeline requirements outlined in the regulations and statute.¹⁹ We encourage states to work with the Departments on timeframes that take into account the state's legislative sessions and timing of rate filings if the section 1332 waiver is projected to have any impact on premiums. If a state's waiver application includes

¹⁹ 45 CFR 155.1308(c)(1), Sections 1332 (d), 1332 (e) of P.L. 111-148

potential operational changes or accommodations to the federal information technology platform or its operations, additional time may be needed. States should engage with the Departments early in the process to determine whether federal infrastructure can accommodate technical changes that support their requested flexibilities.

VIII. Enacted State Legislation

States are required under the statute to enact or amend state laws to apply for and implement state actions under a section 1332 waiver. Under 31 CFR 33.108(f)(3)(i) and 45 CFR 155.1308(f)(3)(i), as part of the state's waiver application, the state must include a comprehensive description of the state legislation and program to implement a plan meeting the requirements for a waiver under section 1332. In addition, under 31 CFR 33.108(f)(3)(ii) and 45 CFR 155.1308(f)(3)(ii), the state must include a copy of the enacted state legislation that provides the state with authority to implement the proposed waiver, as required under section 1332(a)(1)(C) of the PPACA.

Generally, a state must enact legislation establishing authority to pursue a section 1332 waiver and for the program to implement a section 1332 state plan, but the Departments also recognize that administrative regulations and executive orders generally carry the force of the law. In implementing this guidance, the Departments clarify that in certain circumstances, states may use existing legislation if it provides statutory authority to enforce PPACA provisions and/or the state plan, combined with a duly-enacted state regulation or executive order, may satisfy the requirement that the state enact a law under section 1332(b)(2).

As one example, a state might have a statute that grants to a state official or agency authority to implement and enforce PPACA and to promulgate regulations to implement PPACA programs in the state. The state also has in place an executive order directing the appropriate

state official or agency to pursue a State Innovation Waiver, as well as regulations that further authorize specific actions to be taken under a waiver. The Departments may consider these legislative, administrative, and executive actions together and determine that section 1332(b)(2) is satisfied.

It is not possible to describe every combination of legislative, administrative and/or executive action that may satisfy the section 1332(b)(2) requirement. But so long as the state has enacted through its legislative branch a statute that authorizes the pursuit of a State Innovation Waiver, even broadly, the Departments will consider additional state administrative and executive branch actions in determining whether the section 1332(b)(2) requirement is satisfied. If a state is using an Executive Order or regulation to meet the requirement to enact a law for purposes of a 1332 waiver the state must include a letter from the state executive or Governor outlining that the state authority is sufficient to implement the state plan. The Departments generally will look favorably upon a state's interpretation of its own state law.

As a result, the Departments may determine that section 1332(b)(2) is satisfied, to enact a law where existing legislation, coupled with an administrative regulation or executive order provides the authority to pursue a section 1332 waiver. This reflects the Departments' intention to allow states increased flexibility to pursue a section 1332 waiver despite timing or other constraints, such as state legislative calendars that result in short or infrequent legislative sessions, provided that the state law at issue provides a sufficient foundation for an administrative regulation or executive order.

IX. Public Input on Waiver Proposals

Section 1332, and regulations at 31 CFR 33.112 and 45 CFR 155.1312 require states to provide a public notice and comment period for a waiver application sufficient to ensure a

meaningful level of public input prior to submitting an application. As part of the public notice and comment period, a state with one or more Federally-recognized tribes must conduct a separate process for meaningful consultation with such tribes. Because State Innovation Waiver applications may vary significantly in their complexity and breadth, the regulations provide states with flexibility in determining the length of the comment period required to allow for meaningful and robust public engagement. The comment period should in no case be less than 30 days.

Consistent with HHS regulations, waiver applications must be posted online in a manner that meets national standards to assure access to individuals with disabilities. Such standards are issued by the Architectural and Transportation Barriers Compliance Board, and are referred to as “section 508” standards. Alternatively, the World Wide Web Consortium’s Web Content Accessibility Guidelines (WCAG) 2.0 Level AA standards would also be considered as acceptable national standard for Web site accessibility. For more information, see the WCAG Web site at <http://www.w3.org/TR/WCAG20/>.

Section 1332 and its implementing regulations also require the Federal Government to provide a public notice and comment period, once the Secretaries receive an application. A submitted application will not be deemed received until the Secretaries have made the preliminary determination that the application is complete. The period must be sufficient to ensure a meaningful level of public input and must not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedure Act, or requirements that are unreasonable or unnecessarily burdensome with respect to state compliance. As with the comment period described above, the length of the comment period should reflect the complexity of the proposal and in no case can be less than 30 days.

X. Impact of Other Program Changes on Assessment of a Waiver Proposal

The assessment of whether a State Innovation Waiver proposal satisfies the statutory criteria set forth in Section 1332 takes into consideration the impact of changes to PPACA provisions made pursuant to the State Innovation Waiver. The assessment also considers related changes to the state's health care system that, under state law, are contingent only on the approval of the State Innovation Waiver. For example, the assessment would take into account the impact of a new state-run health benefits program that, under legislation enacted by the state, would be implemented only if the State Innovation Waiver were approved.

The assessment does not consider the impact of policy changes that are contingent on further state action, such as state legislation that is proposed but not yet enacted. It also does not include the impact of changes contingent on other Federal determinations, including approval of Federal waivers pursuant to statutory provisions other than Section 1332. Therefore, the assessment would not take into account changes to Medicaid or CHIP 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 State Innovation Waiver. Savings accrued under either proposed or current Section 1115 Medicaid or CHIP demonstrations are not factored into the assessment of whether a proposed State Innovation Waiver meets the deficit neutrality requirement. The assessment also does not take into account any changes to the Medicaid or CHIP state plan that are subject to Federal approval.

The assessment does take into account changes in Medicaid and/or CHIP coverage or in Federal spending on Medicaid and/or CHIP that would result directly from the proposed waiver of provisions pursuant to Section 1332, holding state Medicaid and CHIP policies constant.

As the Departments receive and review waiver proposals, we will continue to examine the types of changes that will be considered in assessing State Innovation Waivers.

Nothing in this guidance alters a state's authority to make changes to its Medicaid and CHIP policies consistent with applicable law. This guidance does not alter the Secretary of Health and Human Services' authority or CMS' policy regarding review and approval of Section 1115 demonstrations, and states should continue to work with CMS' Center for Medicaid and CHIP Services on issues relating to Section 1115 demonstrations. A state may submit a coordinated waiver application as provided in 31 CFR 33.102 and 45 CFR 155.1302; in such a case, each waiver will be evaluated independently according to applicable Federal laws.

XI. Applicability

This guidance supersedes the 2015 guidance, published on December 16, 2015 (80 FR 78131), which provided additional information about the requirements that must be met, the Secretaries' application review procedures, the amount of pass-through funding, certain analytical requirements, operational considerations and public comment. This guidance will be in effect on the date of publication and will be applicable for section 1332 waivers submitted after the publication date of this guidance (including section 1332 waivers submitted, but not yet approved). Applications for waivers approved under section 1332 before the publication date of this guidance will not require reconsideration of whether such applications meet these updated requirements of section 1332.

On January 20, 2017, the President issued an Executive Order (EO)²⁰, which stated that “to the maximum extent permitted by law, the Secretary of HHS and heads of all other executive departments and agencies with authorities and responsibilities under the PPACA

²⁰ <https://www.federalregister.gov/documents/2017/01/24/2017-01799/minimizing-the-economic-burden-of-the-patient-protection-and-affordable-care-act-pending-repeal>

(Pub. L. 111-148) shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the PPACA that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health issuers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications.” Furthermore, the EO stated that “To the maximum extent permitted by law, the Secretary and the heads of all other executive departments and agencies with authorities and responsibilities under the Act, shall exercise all authority and discretion available to them to provide greater flexibility to states and cooperate with them in implementing healthcare programs.” In the spirit of this EO, the Departments are seeking to reduce burdens that may impede a state’s efforts to implement innovative changes and improvements to their health care market while remaining consistent with the statute. We believe that the reduction in these burdens will lead to more affordable health coverage for individuals and families.

Final regulations at 31 CFR part 33 and 45 CFR part 155 Subpart N remain in effect and require a state to provide actuarial analyses and actuarial certifications, economic analyses, data and assumptions, targets, an implementation timeline, and other necessary information to support the state’s estimates that the proposed waiver will comply with these requirements.²¹ The May 11, 2017, Checklist for Section 1332 State Innovation Waiver Applications, including specific items applicable to High-Risk Pool/State-Operated Reinsurance Program Applications, remains available to assist states in assembling an application for a section 1332 waiver. The Departments will apply the regulations and statutory requirements when reviewing state

²¹ “Application, Review, and Reporting Process for Waivers for State Innovation Final Rule.” February 27, 2012. Available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-02-27/pdf/2012-4395.pdf>.

applications for section 1332 waivers and will work to provide states with the flexibility they need to be innovative and respond to the needs in their state.

XII. Collection of Information Requirements

This document does not impose new information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Dated: October 9, 2018.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 12, 2018.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

Dated: October 10, 2018.

David J. Kautter,

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