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DEPARTMENT OF THE TREASURY

31 CFR Part 33

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 155

[CMS-9936-N]

Waivers for State Innovation

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

ACTION: Guidance.

SUMMARY: This guidance relates to Section 1332 of the Patient Protection and Affordable Care Act (ACA) and its implementing regulations. Section 1332 provides the Secretary of Health and Human Services and the Secretary of the Treasury with the discretion to approve a state's proposal to waive specific provisions of the ACA (a State Innovation Waiver), provided the proposal meets certain requirements. In particular, the Secretaries can only exercise their discretion to approve a waiver if they find that the waiver would provide coverage to a comparable number of residents of the state as would be provided coverage absent the waiver, would provide coverage that is at least as comprehensive and affordable as would be provided absent the waiver, and would not increase the Federal deficit. If the waiver is approved, the state may receive funding equal to the amount of forgone Federal financial assistance that would have been provided to its residents pursuant to specified ACA programs, known as pass-through funding. State Innovation Waivers are available for effective dates beginning on or after January 1, 2017. They may be approved for periods up to 5 years and can be renewed. The Departments promulgated implementing regulations in 2012. This document provides additional

information about the requirements that must be met, the Secretaries' application review procedures, the amount of pass-through funding, certain analytical requirements, and operational considerations.

DATES: Comment Date: Comments may be submitted at any time.

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

You may submit comments in one of four 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-N,
P.O. Box 8016,
Baltimore, MD 21244-8016.

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-N,
Mail Stop C4-26-05,
7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members. Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed.

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

FOR FURTHER INFORMATION CONTACT: Centers for Medicare & Medicaid Services: Tricia Beckmann, 301-492-4328, or Robert Yates, 301-492-5151.

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 website as soon as possible after they have been received:

<http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Comments received will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Statutory Requirements

Under Section 1332 of the Affordable Care Act (ACA), the Secretaries of Health and Human Services (HHS) and the Treasury as appropriate may exercise their discretion to approve a request for a State Innovation Waiver only if the Secretaries determine that the proposal meets the following four requirements: 1) the proposal will provide coverage to at least a comparable number of the state's residents as would be provided absent the waiver; 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 absent the waiver; 3) the

proposal will provide coverage that is at least as comprehensive for the state's residents as would be provided absent the waiver; 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 whole, including the four requirements. 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, including any of the requirements discussed in this guidance.

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 these requirements.¹

A. Coverage

To meet the coverage requirement, a comparable number of state residents must be forecast to have coverage under the waiver as would have coverage absent the waiver.

Coverage refers to minimum essential coverage (or, if the individual shared responsibility provision is waived under a State Innovation Waiver, to something that would qualify as minimum essential coverage but for the waiver). For this purpose, "comparable" means that the forecast of the number of covered individuals is no less than the forecast of the number of covered individuals absent the waiver. This condition generally must be forecast to be met in each year that the waiver would be in effect.

¹ "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>.

The impact on all state residents is considered, regardless of the type of coverage they would have absent the waiver. (For example, while a State Innovation Waiver may not change the terms of a state's Medicaid coverage or change existing Medicaid demonstration authority, changes in Medicaid enrollment that result from a State Innovation Waiver, holding the state's Medicaid policies constant, are considered in evaluating the number of residents with coverage under a waiver.)

Assessment of whether the proposal covers a comparable number of individuals also takes into account the effects across different groups of state residents, and, in particular, vulnerable residents, including low-income individuals, elderly individuals, and those with serious health issues or who have a greater risk of developing serious health issues. Reducing coverage for these types of vulnerable groups would cause a waiver application to fail this requirement, even if the waiver would provide coverage to a comparable number of residents overall. Finally, analysis under the coverage requirement takes into account whether the proposal sufficiently prevents gaps in or discontinuations of coverage.

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 this requirement, including information on the number of individuals covered by income, health status, and age groups, under current law and under the waiver, including year-by-year estimates. The application should identify any types of individuals who are less likely to be covered under the waiver than under current law.

The state should also provide a description of the model used to produce these estimates, including data sources and quality, key assumptions, and parameters. The state may be required to provide micro data and other information to inform the Secretaries' analysis.

B. Affordability

To meet the affordability requirement, health care coverage under the waiver must be forecast to be as affordable overall for state residents as coverage absent the waiver.

Affordability refers to state residents' ability to pay for health care and may generally be measured by comparing residents' net out-of-pocket spending for health coverage and services to their incomes. Out-of-pocket expenses include both premium contributions (or equivalent costs for enrolling in coverage), and any cost sharing, such as deductibles, co-pays, and co-insurance, associated with the coverage. Spending on health care services that are not covered by a plan may also be taken into account if they are affected by the waiver proposal. The impact on all state residents is considered, regardless of the type of coverage they would have absent the waiver. This condition generally must be forecast to be met in each year that the waiver would be in effect.

Waivers are evaluated not only based on how they affect affordability on average, but also on how they affect the number of individuals with large health care spending burdens relative to their incomes. Increasing the number of state residents with large health care spending burdens would cause a waiver to fail the affordability requirement, even if the waiver would increase affordability for many other state residents. Assessment of whether the proposal meets the affordability requirement also takes into account the effects across different groups of state residents, and, in particular, vulnerable residents, including low-income individuals, elderly individuals, and those with serious health issues or who have a greater risk of developing serious health issues. Reducing affordability for these types of vulnerable groups would cause a waiver to fail this requirement, even if the waiver maintained affordability in the aggregate.

In addition, a waiver would fail the affordability requirement if it would reduce the number of individuals with coverage that provides a minimal level of protection against excessive cost sharing. In particular, waivers that reduce the number of people with insurance coverage that provides both an actuarial value equal to or greater than 60 percent and an out-of-pocket maximum that complies with section 1302(c)(1) of the ACA, would fail this requirement. So too would waivers that reduce the number of people with coverage that meets the affordability requirements set forth in sections 1916 and 1916A of the Social Security Act, as codified in 42 CFR part 447, subpart A, while holding the state's Medicaid policies constant.

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 this requirement. This includes information on estimated individual out-of-pocket costs by income, health status, and age groups, absent the waiver and with the waiver. The expected changes in premium contributions and other out-of-pocket costs and the combined impact of changes in these components should be identified separately. The application should also describe any changes in employer contributions to health coverage or in wages expected under the waiver. The application should identify any types of individuals for whom affordability of coverage would be reduced by the waiver.

The state should also provide a description of the model used to produce these estimates, including data sources and quality, key assumptions, and parameters. The state may be required to provide micro data and other information to inform the Secretaries' analysis.

C. Comprehensiveness

To meet the comprehensiveness requirement, health care coverage under the waiver must be forecast to be at least as comprehensive overall for residents of the state as coverage absent the waiver.

Comprehensiveness refers to the scope of benefits provided by the coverage as measured by the extent to which coverage meets the requirements for essential health benefits (EHBs) as defined in section 1302(b) of the ACA, or, as appropriate, Medicaid and/or CHIP standards. The impact on all state residents is considered, regardless of the type of coverage they would have absent the waiver.

Comprehensiveness is evaluated by comparing coverage under the waiver to the state's EHB benchmark, selected by the state (or if the state does not select a benchmark, the default base-benchmark plan) pursuant to 45 CFR 156.100, as well as to, in certain cases, the coverage provided under the state's Medicaid and/or CHIP programs. A waiver cannot satisfy the comprehensiveness requirement if the waiver 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 and/or CHIP programs, holding the state's Medicaid and CHIP policies constant. That is, the waiver must not decrease the number of individuals with coverage that satisfies EHB requirements, the number of individuals with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services covered under the state's Medicaid and/or CHIP programs.

Assessment of whether the proposal meets the comprehensiveness requirement also takes into account the effects across different groups of state residents, and, in particular, vulnerable residents, including low-income individuals, elderly individuals, and those with serious health issues or who have a greater risk of developing serious health issues. A waiver would fail the comprehensiveness requirement if it would reduce the comprehensiveness of coverage provided to these types of vulnerable groups, even if the waiver maintained comprehensiveness in the aggregate. This condition generally must be forecast to be met in each year that the waiver would be in effect.

As provided in the final regulations at 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 this requirement. This includes an explanation of how the benefits offered under the waiver differ from the benefits provided absent the waiver (if the benefits differ at all) and how the state determined the benefits to be as comprehensive.

The state should also provide a description of the model used to produce these estimates, including data sources and quality, key assumptions, and parameters. The state may be required to provide micro data and other information to inform the Secretaries' analysis.

D. Deficit Neutrality

Under the deficit neutrality requirement, the projected Federal spending net of Federal revenues under the State Innovation Waiver must be equal to or lower than projected Federal spending net of Federal revenues in the absence of the waiver.

The estimated effect on Federal revenue includes 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. Estimated effects would include, for example, changes in: the

premium tax credit and health coverage tax credit, individual shared responsibility payments, employer shared responsibility payments, the excise tax on high-cost employer-sponsored plans, the credit for small businesses offering health insurance, 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 other direct spending, such as changes in Medicaid spending (while holding the state's Medicaid policies constant) that result from the changes made through the State Innovation Waiver.

Projected Federal spending under the waiver proposal also includes all administrative costs to the Federal government, including any changes in Internal Revenue Service administrative costs, Federal Exchange administrative costs, or other administrative costs associated with 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 ten-year budget plan submitted by the state as part of the State Innovation Waiver application. The ten-year budget plan must describe for both the period of the waiver and for the ten-year budget the projected Federal spending net of Federal revenues under the State Innovation Waiver and the projected Federal spending net of Federal revenues in the absence of the waiver.

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

The state should also provide a description of the model used to produce these estimates, including data sources and quality, key assumptions, and parameters. The state may be required to provide micro data and other information to inform the Secretaries' analysis.

As provided in 31 CFR part 33 and 45 CFR part 155, subpart N, a state must submit evidence to demonstrate deficit neutrality, including a description of the analysis used to produce its estimate of the impact of the waiver on the Federal deficit. The description must include detailed information about the model, data sources and quality, key assumptions, and parameters. The state may be required to provide micro data and other information to support actuarial and economic analyses, so that the Secretaries can independently verify that the waiver meets the deficit neutrality requirement.

II. 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 ACA 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 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.

III. Federal Pass-Through Funding

The amount of Federal pass-through funding equals the Secretaries' annual estimate of the Federal cost (including outlays and forgone revenue) for Exchange financial assistance provided pursuant to the ACA that would be claimed by participants in the Exchange in the state

in the calendar year in the absence of the waiver, but will not be claimed as a result of the waiver. The calculation of the amount of pass-through funding does not account for any other changes in Federal spending or revenues as a result of the waiver, including Federal administrative expenses for making the payments (note, however that changes to Federal spending on administrative expenses is considered in determining whether a waiver proposal meets the deficit neutrality requirement). The estimates take into account experience in the relevant state and similar states. The amount is calculated annually.

The waiver application 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 or state Partnership 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 IV below.

IV. 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), but adapted as appropriate to reflect state-specific conditions.

The analysis is based on state-specific estimates of the current level and distribution of population by the relevant economic and demographic characteristics, including 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 ten-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, 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 must conform to these standards. The application must describe all modeling assumptions used, sources of state-specific data, and the rationale for any deviation from Federal forecasts. A state may be required 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.

V. Operational Considerations

A. Federally-Facilitated Exchanges

The Centers for Medicare & Medicaid Services (CMS) operates the Federally-facilitated Exchange (FFE) platform. Certain changes that affect FFE processes may make a waiver proposal not feasible to implement at this time. Until further guidance is issued, the Federal platform cannot accommodate different rules for different states. For example, waivers that would require changes to the calculation of Exchange financial assistance, non-standard enrollment period determinations, customized plan management review options, or changes to the design used to display plan options are generally not feasible at this time due to operational limitations. In addition, the Federal platform cannot accommodate changes to its plan management templates in the near term. States contemplating a waiver that requires such changes may consider establishing their own platform administered by the state.

As noted in Section I.D. 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 waiver proposal not feasible to implement. At this time, the IRS is not generally able to administer different sets of rules in 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. For example, it is generally not feasible to have the IRS administer a different set of eligibility rules for the premium tax credit for residents of a particular state. States contemplating a waiver proposal that includes a modified version of a Federal tax provision may consider waiving the provision entirely and relying on a tax program administered by the state.

In addition, a waiver proposal that completely waives one or more tax provisions in a state may create administrative costs for the IRS. As noted in Section I.D. above, 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.

VI. Public Input on Waiver Proposals

Consistent with the statutory provisions of Section 1332, 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 must be sufficient to ensure a meaningful level of public input and in no case can 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. 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 Procedures 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.

Dated: December 8, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: December 11, 2015.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

Approved: December 10, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

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