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U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC Web site, to the extent practicable, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2011–5757 Filed 3–11–11; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF THE TREASURY

31 CFR Part 33

RIN 1505–AC30

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 155

[CMS–9987–P]

RIN 0938–AQ75

Application, Review, and Reporting Process for Waivers for State Innovation

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

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth a procedural framework for submission and review of initial applications for a Waiver for State Innovation described in section 1332 of the Patient Protection and the Affordable Care Act including processes to ensure opportunities for public input in the development of such applications by States and in the Federal review of the applications.

DATES: Comments are due on or before May 13, 2011.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to one Department will be shared with the other Department. Please do not submit duplicates.

Department of the Treasury. Interested members of the public are invited to submit comments on this proposed rule. Comments may be submitted to Treasury by either of the following methods: Submit electronic comments through the Federal government e-rulemaking portal, *http://www.regulations.gov,* or send comments in hard copy to: Office of Benefits Tax Counsel, Attention: Waivers for State Innovation, Room 3050, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

In general, Treasury will post all comments to *http://www.regulations.gov* without change, including any business or personal information provided such as names, addresses, e-mail addresses, or telephone numbers. Treasury will also make such comments available for public inspection and copying in Treasury's Library, Room 1428, 1500 Pennsylvania Avenue, NW., Washington, DC 20220, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. Members of the public can make an appointment to inspect comments by telephoning (202) 622–0990. All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should only submit information that you wish to make available publicly.

Centers for Medicare & Medicaid Services. In commenting, please refer to file code CMS–9987–P. 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 regulation 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–9987–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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–9987–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of 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, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period 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 before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also 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.

FOR FURTHER INFORMATION CONTACT:

Department of the Treasury: Carrie Simons, (202) 622–0044.

Centers for Medicare & Medicaid Services: Ben Walker, (301) 492–4430.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1332 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148, enacted on March 23, 2010) creates a new Waiver for State Innovation and authorizes the Secretary of Health and Human Services (HHS) and the Secretary of the Treasury (the Secretaries) to waive all or any of the following requirements falling under their respective jurisdictions for health insurance coverage within a State for plan years beginning on or after January 1, 2017:

- Part I of subtitle D of Title I of the Affordable Care Act (relating to the establishment of qualified health plans);
- Part II of subtitle D of Title I of the Affordable Care Act (relating to consumer choices and insurance competition through health benefit exchanges);
- Section 1402 of the Affordable Care Act (relating to reduced cost sharing for individuals enrolling in qualified health plans); and
- Sections 36B (relating to refundable credits for coverage under a qualified health plan), 4980H (relating to shared responsibility for employers regarding health coverage), and 5000A (relating to the requirement to maintain minimum essential coverage) of the Internal Revenue Code.

Section 1332 of the Affordable Care Act provides that references in that section to "Secretary" refer to the Secretary of Health and Human Services for waivers relating to Parts I and II of subtitle D of Title I of the Affordable Care Act and section 1402 of the Affordable Care Act, and refer to the Secretary of the Treasury for waivers relating to sections 36B, 4980H, and 5000A of the Internal Revenue Code.

Section 1332(a)(4)(B) of the Affordable Care Act requires the Secretaries to issue regulations that provide the following:

- A process for public notice and comment at the State level, including public hearings, that is sufficient to ensure a meaningful level of public input (section 1332(a)(4)(B)(i) of the Affordable Care Act);
- A process for the submission of an application that ensures the disclosure of (A) the provisions of law that the State involved seeks to waive, and (B) the specific plans of the State to ensure that the waiver will be in compliance with specified statutory requirements relating to the comprehensiveness of coverage, affordability of coverage, scope of coverage, and the effect on Federal deficit (as described below) (section 1332(a)(4)(B)(ii) of the Affordable Care Act);
- A process for providing public notice and comment after the application is received by the applicable Secretary or Secretaries, that is sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedure Act (APA), or requirements that are unreasonable or unnecessarily burdensome with respect to State compliance (section 1332(a)(4)(B)(iii) of the Affordable Care Act);
- A process for the submission to the applicable Secretary or Secretaries of periodic reports by the State concerning the implementation of the program under a waiver (section 1332(a)(4)(B)(iv) of the Affordable Care Act); and
- A process for the periodic evaluation by the applicable Secretary or Secretaries of the program under a waiver (section 1332(a)(4)(B)(v) of the Affordable Care Act).

Although section 1332 of the Affordable Care Act does not authorize waivers for related programs like Medicaid (title XIX of the Social Security Act) or the Children's Health Insurance Program (title XXI of the Social Security Act), those programs have existing waiver authorities. Section 1332(a)(5) of the Affordable Care Act requires the Secretaries to develop a process for coordinating and consolidating the State waiver processes applicable under the provisions of section 1332 of the Affordable Care Act with the existing waiver processes applicable under titles XVIII (Medicare), XIX (Medicaid), and XXI (Children's Health Insurance Program, or CHIP) of the Social Security Act, and any waiver processes under other Federal laws relating to the provision of health care items or services. Section 1332(a)(5) of the Affordable Care Act further requires the process developed by the Secretaries to permit a State to submit a single application for a waiver under any or all of those provisions.

This proposed rule would implement the procedural requirements of section 1332 of the Affordable Care Act. The proposed rule is intended to provide for a waiver application process that can be coordinated and consolidated with the processes for the submission of applications for waivers under titles XVIII, XIX, and XXI of the Social Security Act.

II. Overview of the Proposed Regulations: Section 1332 of the Affordable Care Act, Waiver for State Innovation (31 CFR Part 33 and 45 CFR Part 155)

A. Introduction

To implement the provisions of section 1332 of the Affordable Care Act, the Department of the Treasury proposes to add new part 33 to 31 CFR subtitle A and the Centers for Medicare & Medicaid Services, on behalf of the Department of Health and Human Services, proposes to add new part 155 to 45 CFR Subtitle A. These new parts would address procedures for State development and submission of an application for a Waiver for State Innovation under section 1332 of the Affordable Care Act (referred to in the proposed regulations as a section 1332 waiver), a process for providing public notice and opportunity for comment at the State and Federal levels, a process for the review of applications by the Secretaries, and processes for the monitoring and evaluation of approved section 1332 waivers by the States and the Secretaries, including the periodic submission of reports by the States to the Secretaries.

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

These proposed regulations at 31 CFR 33.102 and 45 CFR 155.1302 permit, but do not require, States to submit a single application for a section 1332 waiver and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Social Security Act, or under any other Federal law relating to the provision of health care items or services, provided that the application is consistent with the procedures described in these proposed regulations, the procedures for section 1115 demonstrations, if applicable, and the procedures under any other applicable Federal law under which the State seeks a waiver.[1]

The proposed regulations require a State seeking a section 1332 waiver to submit a waiver application to the Secretary of HHS. Upon receipt, the Secretary of HHS will transmit any

[1] Although section 1332 of the Affordable Care Act does not authorize waivers for related programs like Medicaid (title XIX of the Social Security Act) or the Children's Health Insurance Program (title XXI of the Social Security Act), those programs have existing waiver authorities.

application that includes a request for a waiver of provisions under the jurisdiction of the Secretary of the Treasury (sections 36B, 4980H and 5000A of the Internal Revenue Code) to be reviewed in accordance with the provisions of these proposed regulations. The Secretaries will coordinate the review of any application that includes a request for a waiver of provisions falling under the jurisdiction of each of the Departments of Health and Human Services and the Treasury (the Departments).

C. Application Procedures (31 CFR 33.108 and 45 CFR 155.1308)

These proposed regulations establish procedures for the submission of applications for an initial section 1332 waiver.

Under 31 CFR 33.108(a) and 45 CFR 155.1308(a) of the proposed regulations, the Secretaries will subject each application for an initial section 1332 waiver to a preliminary review. The Secretaries will complete the preliminary review within 45 days after the application is submitted.

During this preliminary review period, the Secretaries will make a preliminary determination as to whether a State's application complies with the requirements set forth in 31 CFR 33.108(a)(2) and 45 CFR 155.1308(a)(2). If the Secretaries determine that an application is incomplete, the Secretary of HHS will send the State a written notice of the elements missing from the application. These proposed regulations provide that a preliminary determination that an application is complete does not preclude a finding during the 180-day Federal decision-making period that a necessary element of the application is missing or insufficient, rendering the application incomplete.

These proposed regulations provide that a submitted application will not be considered received until the Secretaries have made this preliminary determination that the application is complete. This timing protocol is necessary to ensure that the Federal public notice and comment period and the 180-day Federal decision-making period are based on applications that the Secretaries preliminarily determine to be complete, and that all relevant information is available for review during those periods.

The proposed regulations provide that, upon a preliminary determination by the Secretaries that an application they have received is complete, as defined under these proposed regulations, the Secretary of HHS will send the State a written notice informing the State that the Secretaries have made such a preliminary determination, and the date upon which they have made that preliminary determination. That date will also mark the beginning of the Federal public notice and comment period and the 180-day Federal decision-making period.

Under the proposed regulations, an application for initial approval of a section 1332 waiver will not be considered complete unless the application: (1) Complies with the application procedures of 31 CFR 33.108(a)(2)(iv) and 45 CFR 155.1308(a)(2)(iv); (2) provides written evidence of the State's compliance with the public notice requirements set forth in 31 CFR 33.112 and 45 CFR 155.1312; and (3) provides all of the following:

- A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332, as required under section 1332(a)(1)(B)(i) of the Affordable Care Act;
- A copy of the enacted State legislation authorizing such waiver request, as required under section 1332(a)(1)(C) of the Affordable Care Act;
- A list of the provisions of law that the State seeks to waive including a brief description of the reason for the specific requests; and
- The analyses, actuarial certifications, data, assumptions, targets and other information sufficient to provide the Secretaries with the necessary data to determine that the State's proposed waiver:

+ Will, as required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under Title I of the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare and Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that would be waived;

+ Will, as required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide;

+ Will, as required under section 1332(b)(1)(B)(C) of the Affordable Care Act (the scope of coverage requirement), provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide; and

+ Will not, as prohibited under section 1332(b)(1)(D) of the Affordable Care Act (the Federal deficit requirement), increase the Federal deficit.

Section 1332(a)(3) of the Affordable Care Act requires that the Secretaries provide for an alternative means by which the aggregate amount of tax credits or cost-sharing reductions that would have been paid had the State not received a waiver, be paid to the State for purposes of implementing the waiver. This amount will be determined annually by the Secretaries, on a per capita basis, taking into consideration the experience of other States for participation in an Exchange and tax credits and cost-sharing reductions provided in such other States.

To provide information necessary for the Secretaries to determine (1) that the State's proposed waiver meets the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement and (2) the annual amount, if any, of foregone tax credits and cost-sharing reductions that will be paid to the State for purposes of implementing the waiver pursuant to section 1332(a)(3) of the Affordable Care Act, the proposed regulation requires that a State's application contain:

(1) 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.

(2) Economic analyses to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

- A detailed 10-year budget plan that is deficit neutral to the Federal government, as prescribed in section 1332(a)(1)(B)(ii) of the Affordable Care Act, and includes all costs under the waiver, including administrative costs and other costs to the Federal government, if applicable; and
- A detailed analysis regarding the estimated impact of the waiver on health insurance coverage in the State.

(3) The data and assumptions used to demonstrate that the State's proposal is in compliance with the comprehensive coverage requirement, the affordability requirement, the scope of coverage

requirement and the Federal deficit requirement, including:

• Information on the age, income, health expenses and current health insurance status of the relevant State population; the number of employers, categorized by number of employees and by whether the employer offers health insurance; cross-tabulations of these variables; and an explanation of data sources and quality; and

• An explanation of the key assumptions and methodology used to develop the estimates of the effect of the waiver on health insurance coverage in the State and on the Federal budget, such as individual and employer participation rates, behavioral changes, premium and price effects, and other relevant factors.

(4) Additional information supporting the State's proposed waiver, including:

• An explanation as to whether the waiver increases or decreases the administrative burden on individuals, insurers, and employers, and if so, how and why;

• An explanation of whether and how the waiver will affect the implementation of the provisions of the Affordable Care Act which the State is not requesting to waive in the State and at the Federal level;

• An explanation of how the waiver will affect residents who need to obtain health care services out-of-State, as well as the States in which such residents may seek such services;

• If applicable, an explanation of how the State will provide the Federal government with all information necessary to administer the waiver at the Federal level; and

• An explanation of how the State's proposal will address potential individual, employer, insurer, or provider compliance, waste, fraud and abuse within the State or in other States.

(5) For purposes of post-award monitoring, suggested quarterly, annual, and cumulative targets for the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement of section 1332(b) of the Affordable Care Act.

(6) Other information consistent with guidance provided by the Secretaries.

Under the proposed regulations, there is no minimum time specified between the submission of an application and start date of the waiver. However, we solicit comments on whether a State should be required to submit an application at least 12 months in advance of the requested effective date, in order to allow for the effective implementation of approved waivers at the State level.

The requirement in the proposed regulation that a State provide certain analysis, certifications, data, assumptions, targets and other information as part of a section 1332 waiver application is designed to ensure that a State's development of a waiver proposal addresses major relevant issues for the State and provides the Secretaries with sufficient information to fully assess the projected impact of section 1332 waiver proposals for the statutory requirements and to accurately determine the amount to be paid to the State for purposes of implementing the waiver under section 1332(a)(3) of the Affordable Care Act. The Secretaries also solicit comments regarding these proposed requirements, as well as what other types of analysis, certifications, data, assumptions, targets and information States would consider useful in supporting an application for a section 1332 waiver and whether these regulations should specifically require such additional analyses, certifications, data, assumptions, targets and information to be included as part of a section 1332 waiver application.

Lastly, during the Federal review process, the proposed regulation provides that the Secretaries may request additional supporting information from the State as needed to address public comments or to address issues that arise in reviewing the application.

D. State Public Notice Requirements (31 CFR 33.112 and 45 CFR 155.1312)

Consistent with the provisions of section 1332 of the Affordable Care Act, to facilitate public involvement in the review and approval of section 1332 waiver applications, 31 CFR 33.112(a)(1) and 45 CFR 155.1312(a)(1) of the proposed regulations require a State to provide a public notice and comment period sufficient to ensure a meaningful level of public input for a section 1332 waiver application prior to the submission of that application to the Secretary of HHS for review and consideration. In addition, the proposed regulations require a State with one or more Federally-recognized Indian tribes within its borders to consult with those Indian tribes in accordance with Executive Order 13175.

Because meaningful input requires notice of the nature of the section 1332 waiver application, as part of the State notice and comment period, the proposed regulations require a State to provide the public with the following prior to the submission of an application:

• A comprehensive description of the section 1332 waiver application to be submitted to the Secretary of HHS, including information and assurances related to all statutory requirements and other information consistent with guidance provided by the Secretaries;

• Where copies of the section 1332 waiver application are available for public review and comment;

• How and where written comments may be submitted and reviewed by the public, and the timeframe during which public comments may be submitted; and

• The location, date and time of public hearings that will be convened by the State to seek public input on the section 1332 waiver application.

31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2) of the proposed regulations require States to conduct public hearings that provide interested parties with the opportunity to learn about and comment on the contents of the section 1332 waiver application.

The State public notice and comment process must comply with applicable civil rights rules for accessibility, which require, for example—

• The provision of auxiliary aids and services such as interpreters for persons with disabilities where necessary for effective communication;

• The use of accessible meeting places for the hosting of public forums provided for in the Rule;

• Reasonable steps to provide meaningful access for limited English proficient (LEP) persons, such as the inclusion of "tag lines" on State web sites containing phone numbers for LEP persons to call to reach "language line" interpreters for assistance; and

• Other civil rights requirements applicable to the States under the Americans with Disabilities Act, section 504 of the Rehabilitation Act of 1973 and Title VI of the Civil Rights Act of 1964, among others.

E. Federal Public Notice and Approval Process (31 CFR 33.116 and 45 CFR 155.1316)

Consistent with section 1332 of the Affordable Care Act and the Secretaries' desire to implement a State waiver application process that promotes transparency, facilitates public involvement and input, and encourages sound decision-making at all levels of government, 31 CFR 33.116 and 45 CFR 155.1316 of the proposed regulations provide for a Federal public notice and comment period following a preliminary determination by the Secretaries that a State's application for a section 1332 waiver is complete. As required by section 1332 of the Affordable Care Act, the Federal notice and comment period is designed to ensure a meaningful level of public

input, while avoiding the imposition of requirements that are in addition to, or duplicative of, those imposed under the APA or that are unreasonable or unnecessarily burdensome for State compliance.

To facilitate public participation in the section 1332 waiver application process, the proposed regulations require the Secretary of HHS to provide the public with notice of a section 1332 waiver application that has been preliminarily determined to be complete, including any supplemental materials received from a State during the Federal public notice and comment period, as well as regular updates for the status of a State's section 1332 waiver application. In addition, the Secretary of HHS will provide the public with information relating to (A) where copies of the section 1332 waiver application are available for public review and comment; (B) how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments may be submitted; and (C) any public comments received during the Federal public notice and comment period.

Following the conclusion of the Federal notice and comment period, but in no event later than 180 days following the preliminary determination by the Secretaries that a State's application for a section 1332 waiver is complete, the final decision of the Secretaries on a State's section 1332 waiver application will be issued by the Secretary of HHS.

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

As section 1332 waivers are likely to a have a significant impact on individuals, States and the Federal government, the proposed regulations establish processes and methodologies to ensure that the Secretaries receive adequate and appropriate information regarding the effectiveness of section 1332 waivers (consistent with section 1332(a)(4)(B)(iv) of the Affordable Care Act).

Under 31 CFR 33.120(a) and 45 CFR 155.1320(a) of the proposed regulations, a State is required to comply with all applicable Federal laws, regulations, policy statements and Departmental guidance unless a law or regulation has specifically been waived. Further, the proposed regulations require a State to come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers within the timeframes specified in law, regulation, interpretive policy, or guidance, unless the provision being changed is expressly waived, and to comply with the terms and conditions of the agreement entered into between the Secretaries and the State to implement a section 1332 waiver, or the section 1332 waiver will be suspended or terminated in whole or in part by the Secretaries.

Under 31 CFR 33.120(b) and 45 CFR 155.1320(b) of the proposed regulations, as part of the terms and conditions of any section 1332 waiver, a State must conduct periodic reviews related to the implementation of the waiver. The Secretaries will review, and when appropriate investigate, documented complaints that a State is failing to materially comply with requirements specified in the terms and conditions of the section 1332 waiver. In addition, the Secretaries will share with the State any complaint that has been received, and notify the State of any applicable monitoring and compliance issues.

Under 31 CFR 33.120(c) and 45 CFR 155.1320(c) of the proposed regulations, to ensure continued public input after the initial 6 months of the waiver's implementation, and annually thereafter, States are required to hold a public forum at which members of the public have an opportunity to provide comments on the progress of the section 1332 waiver. The proposed regulation further requires States to include a summary of this forum to the Secretary of HHS as part of the quarterly and annual reporting requirements under 31 CFR 33.124 and 45 CFR 155.1324.

Under 31 CFR 33.120(c)(1) and 45 CFR 155.1320(c)(1) of the proposed regulations, States are required to publish the date, time, and location of the public forum in a prominent location on the State's public Web site at least 30 days prior to the date of the planned public forum.

Under 31 CFR 33.120(d) and 45 CFR 155.1320(d) of the proposed regulations, the Secretaries reserve the right to suspend or terminate a section 1332 waiver, in whole or in part, any time before the date of expiration, if the Secretaries determine that the State has materially failed to comply with the terms and conditions of the section 1332 waiver. In the event that all or a portion section 1332 waiver is terminated or suspended by the Secretaries, or if all or a portion of the section 1332 waiver is withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination of the section 1332 waiver, as described in 31 CFR 33.120(e) and 45 CFR 155.1320(e).

Under 31 CFR 33.120(f) and 45 CFR 155.1320(f) of the proposed regulations, in the event that the Secretaries undertake an independent evaluation of any component of the section 1332 waiver, the State must cooperate fully with the Secretaries or the independent evaluator selected by the Secretaries. This cooperation includes, but is not limited to, the submission of all necessary data and information to the Secretaries or the independent evaluator.

G. State Reporting Requirements (31 CFR 33.124 and 45 CFR 155.1324)

Section 1332 of the Affordable Care Act requires that the Secretaries provide for a procedure for the periodic submission of reports by a State concerning the implementation of the program under a section 1332 waiver.

In order for the Secretaries to effectively monitor the implementation of a waiver, the proposed regulations require a State to submit a quarterly progress report in accordance with the terms and conditions of the State's section 1332 waiver. States are also required to submit an annual report, as described in 31 CFR 33.124(b) and 45 CFR 155.1324(b), documenting the following:

- The progress of the section 1332 waiver;
- Data on compliance with section 1332(b)(1)(A) through (D) of the Affordable Care Act;
- A summary of the annual post-award public forum, including all public comments received regarding the progress of the section 1332 waiver and action taken in response to such concerns or comments; and
- Other information consistent with the State's approved terms and conditions.

Under 31 CFR 33.124(c) and 45 CFR 155.1324(c) of the proposed regulations, States are required to submit a draft annual report to the Secretary of Health and Human Services no later than 90 days after the end of each waiver year. Within 60 days of receipt of comments from the Secretary of Health and Human Services, a State is required to submit a final annual report for the waiver year to the Secretary of Health and Human Services. Finally, a State is required to publish the draft and final annual reports on the State's public Web site.

The Secretaries intend to issue future guidance under section 1332 regarding periodic reports.

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

Section 1332 of the Affordable Care Act requires that the Secretaries provide for a procedure for the periodic evaluation of section 1332 waivers by the Secretary or Secretaries with jurisdiction over the provisions for which the waiver was granted. These

proposed regulations require that each periodic evaluation shall include a review of all annual reports submitted by the State in accordance with 45 CFR 155.1324 and 31 CFR 33.124 that relate to the period of time covered by the evaluation.

As part of this proposed regulation, the Secretaries are soliciting public comments regarding specific components of the periodic evaluation of a section 1332 waiver. Potential components of a periodic evaluation could include, but not be limited to, the impact of the waiver on the following:

- Choice of health plans for individuals and employers;
- Stability of coverage for individuals and employers;
- Small businesses, individuals with pre-existing conditions, and the low-income population;
- The overall health care system in the State; and
- Other States and the Federal government.

The Secretaries intend to issue future guidance under section 1332 regarding periodic evaluations.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, the Departments are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is approved by the Office of Management and Budget (OMB). To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that the Departments solicit comment on the following issues:

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

The Departments have no way to accurately quantify the burden until the provisions that section 1332 authorizes the Secretaries to waive pursuant to an application by a State take effect in 2014. The Departments are soliciting public comments on the annual number of waiver applications that the Departments may receive, and will reevaluate this issue in future guidance. With that said, the Departments have developed estimates of the burden associated with information collection requirements in this proposed regulation.

The Departments are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Application Procedures (31 CFR 33.108 and 45 CFR 155.1308)

31 CFR 33.108 and 45 CFR 155.1308 of the proposed regulations establish the application process for section 1332 waivers. A State's application for approval of a section 1332 waiver must be submitted to CMS as both printed and electronic documents. Paragraph (a)(2)(iv) of 31 CFR 33.108 and 45 CFR 155.1308 specify that applications for a section 1332 waiver will not be considered complete if they do not contain written evidence of compliance with the State public notice and comment process described in 31 CFR 33.112 and 45 CFR 155.1312, as well as the information specified in paragraph (a)(2)(iv)(C) and (D) of 31 CFR 33.108 and 45 CFR 155.1308.

The burden associated with the requirements in 31 CFR 33.108 and 45 CFR 155.1308 is the time and effort necessary for a State to develop and submit a complete application for a section 1332 waiver. The Departments estimate that it will take 200 hours for a State to develop and submit a complete section 1332 waiver application, at a total cost of $4,134.

B. ICRs Regarding State Public Notice Requirements (31 CFR 33.112 and 45 CFR 155.1312)

Paragraph (a)(1) of 31 CFR 33.112 and 45 CFR 155.1312 of the proposed regulations require a State to provide a public notice and comment period regarding applications for section 1332 waivers. 31 CFR 33.112 and 45 CFR 155.1312 specify that prior to submitting an application to HHS and Treasury for a section 1332 waiver, the State must provide a public notice and comment period sufficient to ensure a meaningful level of public input. The public notice must address the information requirements listed in paragraphs (b)(1) through (4) of 31 CFR 33.112 and 45 CFR 155.1312.

The burden estimate associated with this requirement is the time and effort necessary to develop and publish a public notice that complies with the aforementioned information requirements. The Departments estimate that each State submitting an application for a section 1332 waiver will require 40 hours to comply with the requirements in this section, at a total cost of $827 per State.

Paragraph (c) of 31 CFR 33.112 and 45 CFR 155.1312 specify that after issuing the public notice and prior to submitting an application for a section 1332 waiver, a State must conduct public hearings regarding the State's waiver application. The minimum burden associated with this requirement is the time and effort necessary for a State to conduct public hearings prior to submitting an application for a section 1332 waiver. While this requirement is subject to the PRA, the Departments believe the associated burden is exempt under 5 CFR 1320.3(h)(4). Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment are not subject to the PRA.

Paragraph (a)(2) of 31 CFR 33.112 and 45 CFR 155.1312 require States with one or more federally-recognized Indian tribes to consult with such tribes before submitting a section 1332 waiver application. Paragraph (a)(2)(iv)(B) of 31 CFR 33.108 and 45 CFR 155.1308 explain that documentation of the State's public notice, which incorporates this consultation, must be included in the waiver application.

The burden associated with these requirements is both the time and effort necessary for a State to conduct its tribal consultations and the time and effort necessary to notify CMS of the State's compliance with paragraph (a)(2)(iv)(B) of 31 CFR 33.108 and 45 CFR 155.1308. The Departments estimate that each State submitting an application for a section 1332 waiver will require 40 hours to both conduct its tribal consultations and to submit the aforementioned evidence to CMS, at a total cost of $827.

C. ICRs Regarding Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320)

31 CFR 33.120 and 45 CFR 155.1320 of the proposed regulations require States to periodically perform reviews of the implementation of the section 1332 waiver. The Departments estimate that it will take a State 40 hours annually to periodically review the waiver's implementation, at a total cost of $827.

Paragraph (c) of 31 CFR 33.120 and 45 CFR 155.1320 of the proposed

regulations further specifies that at least 6 months after the implementation date of the waiver and annually thereafter, the State must hold a public forum to solicit comments on the progress of a section 1332 waiver. As proposed in paragraph (c)(1) of 31 CFR 33.120 and 45 CFR 155.1320, the State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

The burden associated with these provisions includes the time and effort necessary to conduct the public meeting and the time and effort necessary for a State to publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum. While these requirements are subject to the PRA, the Departments believe the associated burden is exempt from the PRA. As discussed previously in this collection, facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment are not subject to the PRA. Therefore, the burden associated with the annual public hearing requirement is exempt. Similarly, the Departments believe the time and effort necessary for a State to publish the date, time, and location of the public forum in a prominent location on the State's public Web site is a burden that would be incurred in the course of usual and customary State business practices and is therefore exempt from the PRA under 5 CFR 1320.3(b)(3).

D. ICRs Regarding State Reporting Requirements (31 CFR 33.124 and 45 CFR 155.1324)

Paragraph (a) of 31 CFR 33.124 and 45 CFR 155.1324 of the proposed regulations requires States to submit quarterly reports to CMS in accordance with the terms and conditions of a State's approved section 1332 waiver. The burden associated with this reporting requirement is the time and effort necessary to submit quarterly reports to CMS. The Departments estimate that it will take 10 hours per quarter for each State to comply with this reporting requirement, for a total of 40 hours per year, at a total annual cost of $827.

Paragraph (b) of 31 CFR 33.124 and 45 CFR 155.1324 of the proposed regulations requires States to submit annual reports to CMS documenting the information listed in paragraph (b)(1) through (4) of 31 CFR 33.124 and 45 CFR 155.1324. As part of the submission process, paragraph (c) of 31 CFR 33.124 and 45 CFR 155.1324 requires States to submit draft annual reports to CMS no later than 90 days after the end of each waiver year, or as specified in the State's terms and conditions. The burden associated with this reporting requirement is the time and effort necessary to submit draft annual reports to CMS. The Departments estimate that it will take 24 hours for each State to comply with this reporting requirement, at a total cost of $496.

Paragraph (c)(1) of 31 CFR 33.124 and 45 CFR 155.1324 of the proposed regulations specifies that within 60 days of receipt of comments from CMS, the State must submit to CMS the final annual report for the waiver year. While this requirement is subject to the PRA, the Departments believe the associated burden is exempt under 5 CFR 1320.3(h)(9). Facts or opinions obtained or solicited through non-standardized follow-up questions designed to clarify responses to approved collections of information are not subject to the PRA.

Paragraph (c)(2) of 31 CFR 33.124 and 45 CFR 155.1324 of the proposed regulations specify that the draft and final annual reports must be published on the State's public Web site. The burden associated with this is the time and effort required for a State to post the aforementioned information on the State's public Web site. The Departments estimate that it will take 2 hours for each State to comply with this requirement, at a total cost of $42.

E. ICRs Regarding Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

31 CFR 33.128 and 45 CFR 155.1328 of the proposed regulations specify that the Secretary of Health and Human Services and the Secretary of the Treasury shall periodically evaluate the implementation of section 1332 waivers. One potential option for satisfying this requirement is for a State to design and conduct an evaluation, with Federal approval of the evaluation design and interim and final reports. The burden associated with this approach is the time and effort necessary to design and execute an evaluation for a section 1332 waiver. The Departments estimate that it will take a State 80 hours to develop an evaluation design, 80 hours to develop and submit an interim evaluation report, and 36 hours to publish CMS-approved evaluations on a State's public Web site. The Departments estimate that it will take a State 196 hours over the course of a 5-year waiver term to complete these activities at a total cost of $4,051.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING AND REPORTING BURDEN

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
31 CFR 33.108 and 45 CFR 155.1308	0938–New	X	1	200	n/a	20.67	n/a	0	n/a
Paragraph (a)(1) of 31 CFR 33.112 and 45 CFR 155.1312.	0938–New	X	1	40	n/a	20.67	n/a	0	n/a
Paragraph (a)(2) of 31 CFR 33.112 and 45 CFR 155.1312.	0938–New	X	1	40	n/a	20.67	n/a	0	n/a
Paragraph (b)(1) of 31 CFR 33.120 and 45 CFR 155.1320.	0938–New	X	1	40	n/a	20.67	n/a	0	n/a
Paragraph (a) of 31 CFR 33.124 and 45 CFR 155.1324.	0938–New	X	4	10	n/a	20.67	n/a	0	n/a
Paragraph (b) of 31 CFR 33.124 and 45 CFR 155.1324.	0938–New	X	1	24	n/a	20.67	n/a	0	n/a
Paragraph (c)(2) of 31 CFR 33.124 and 45 CFR 155.1324.	0938–New	X	1	2	n/a	20.67	n/a	0	n/a
31 CFR 33.128 and 45 CFR 155.1328	0938–New	X	1	196	n/a	20.67	n/a	0	n/a
Total		X	10		n/a		n/a	0	n/a

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer [CMS–9987–P]; Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a control number assigned by OMB.

IV. Response to Comments

Because of the large number of public comments the Departments normally receive on **Federal Register** documents, the Departments are not able to acknowledge or respond to them individually. The Departments will consider all comments the Departments receive by the date and time specified in the **DATES** section of this preamble, and, when the Departments proceed with a subsequent document, the Departments will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

The Departments have examined the impacts of this proposed rule as required by Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This rule has been designated a "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business and having revenues of less than $7 million to $34.5 million in any 1 year. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432, November 17, 2000.) Individuals and States are not included in the definition of a small entity. The Departments are not preparing an analysis for the RFA because the Departments have determined, and the Secretaries certify, that this proposed rule will not have a significant impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. Because this rule does not mandate State participation in section 1332 waivers, there is no obligation for the State to make any change to their existing programs. As a result, there is no mandate for the State. Therefore, the Departments estimate this rule will not mandate expenditures in the threshold amount of $136 million in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation would not impose costs on State or local governments, the requirements of Executive Order 13132 are not applicable. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 155

Health care, Health insurance, Reporting and recordkeeping requirements.

Department of the Treasury

31 CFR Subtitle A

For the reasons set forth in the preamble, the Department of the Treasury proposes to amend 31 CFR subtitle A to add new part 33 to read as follows:

PART 33—WAIVERS FOR STATE INNOVATION

Sec.
33.100 Basis and purpose.
33.102 Coordinated waiver process.
33.104 Definitions.
33.108 Application procedures.
33.112 State public notice requirements.
33.116 Federal public notice and approval process.
33.120 Monitoring and compliance.
33.124 State reporting requirements.
33.128 Periodic evaluation requirements.

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

§ 33.100 Basis and purpose.

(a) *Statutory basis.* This part implements provisions of section 1332 of the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148, relating to Waivers for State Innovation, which the Secretary may authorize for plan years beginning on or after January 1, 2017. Section 1332 of the Affordable Care Act requires the Secretary to issue regulations that provide for all of the following:

(1) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input.

(2) A process for the submission of an application that ensures the disclosure of all of the following:

(i) The provisions of law that the State involved seeks to waive.

(ii) The specific plans of the State to ensure that the waiver will meet all requirements specified in section 1332 of the Affordable Care Act.

(3) A process for the provision of public notice and comment after a waiver application is received by the Secretary of Health and Human Services, that is sufficient to ensure a meaningful level of public input and that does 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.

(4) A process for the submission of reports to the Secretary by a State

relating to the implementation of a waiver.

(5) A process for the periodic evaluation by the Secretary of programs under waivers.

(b) *Purpose.* This part sets forth certain procedural requirements for Waivers for State Innovation under section 1332 of the Affordable Care Act.

§ 33.102 Coordinated waiver process.

(a) *Coordination with applications for waivers under other Federal laws.* A State may submit a single application to the Secretary of Health and Human Services for a waiver under section 1332 of the Affordable Care Act and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Social Security Act, or under any other Federal law relating to the provision of health care items or services, provided that such application is consistent with the procedures described in this part, the procedures for section 1115 demonstrations, if applicable, and the procedures under any other applicable Federal law under which the State seeks a waiver.

(b) *Coordinated process for section 1332 waivers.* A State seeking a section 1332 waiver must submit a waiver application to the Secretary of Health and Human Services. Any application submitted to the Secretary of Health and Human Services that requests to waive sections 36B, 4980H, and 5000A of the Internal Revenue Code, in accordance with section 1332(a)(2)(D) of the Affordable Care Act, shall upon receipt be transmitted by the Secretary of Health and Human Services to the Secretary to be reviewed in accordance with 31 CFR part 33.

§ 33.104 Definitions.

For the purposes of this part:

Complete application means an application that has been submitted and for which the Secretary and the Secretary of Health and Human Services have made a preliminary determination that it includes all required information and satisfies all requirements that are described in § 33.108(a)(2)(iv).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action consistent with § 33.112.

Section 1332 waiver means a Waiver for State Innovation under section 1332 of the Affordable Care Act.

§ 33.108 Application procedures.

(a) *Initial waiver applications*—(1) *Acceptable formats for applications.* (i) Applications for initial approval of a section 1332 waiver shall be submitted in both printed and electronic formats to the Secretary of Health and Human Services.

(ii) [Reserved]

(2) *Guidelines for applications.* (i) Each application for a section 1332 waiver will be subject to a preliminary review by the Secretary and the Secretary of Health and Human Services, who will make a preliminary determination that the application is complete. A submitted application will not be deemed received until the Secretary and the Secretary of Health and Human Services have made the preliminary determination that the application is complete.

(A) The Secretary and the Secretary of Health and Human Services will complete the preliminary review of the application within 45 days after it is submitted.

(B) If the Secretary and the Secretary of Health and Human Services determine that the application is not complete, the Secretary of Health and Human Services will send the State a written notice of the elements missing from the application.

(C) The preliminary determination that an application is complete does not preclude a finding during the 180-day Federal decision-making period that a necessary element of the application is missing or insufficient.

(ii) Upon making the preliminary determination that an application is complete, as defined in this part, the Secretary of Health and Human Services will send the State a written notice informing the State that the Secretary and the Secretary of Health and Human Services have made such a preliminary determination. That date will also mark the beginning of the Federal public notice process and the 180-day Federal decision-making period.

(iii) Upon receipt of a complete application for an initial section 1332 waiver, the Secretary of Health and Human Services will—

(A) Make available to the public the application, and all related State submissions, including all supplemental information received from the State following the receipt of a complete application for a section 1332 waiver.

(B) Indicate the status of the application.

(iv) An application for initial approval of a section 1332 waiver will not be considered complete unless the application meets all of the following conditions:

(A) Complies with paragraph (a) of this section.

(B) Provides written evidence of the State's compliance with the public notice requirements set forth in § 33.112.

(C) Provides all of the following:

(*1*) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332;

(*2*) A copy of the enacted State legislation authorizing such waiver request, as required under section 1332(a)(1)(C) of the Affordable Care Act;

(*3*) A list of the provisions of law that the State seeks to waive, including a brief description of the reason for the specific requests; and

(*4*) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information set forth in paragraph (a)(2)(iv)(D) of this section sufficient to provide the Secretary and the Secretary of Health and Human Services with the necessary data to determine that the State's proposed waiver:

(*i*) Will, as required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare and Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive;

(*ii*) Will, as required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide;

(*iii*) Will, as required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide; and

(*iv*) Will not, as prohibited under section 1332(b)(1)(D) of the Affordable Care Act (the Federal deficit requirement), increase the Federal deficit.

(D) Contains the following supporting information:

(*1*) *Actuarial analyses and actuarial certifications.* 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.

(*2*) *Economic analyses.* Economic analyses to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(*i*) A detailed 10-year budget plan that is deficit neutral to the Federal government, as prescribed by section 1332(a)(1)(B)(ii) of the Affordable Care Act, and includes all costs under the waiver, including administrative costs and other costs to the Federal government, if applicable; and

(*ii*) A detailed analysis regarding the estimated impact of the waiver on health insurance coverage in the State.

(*3*) *Data and assumptions.* The data and assumptions used to demonstrate that the State's proposed waiver is in compliance with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(*i*) Information on the age, income, health expenses and current health insurance status of the relevant State population; the number of employers by number of employees and whether the employer offers insurance; cross-tabulations of these variables; and an explanation of data sources and quality; and

(*ii*) An explanation of the key assumptions used to develop the estimates of the effect of the waiver on coverage and the Federal budget, such as individual and employer participation rates, behavioral changes, premium and price effects, and other relevant factors.

(*4*) *Additional information.* Additional information supporting the State's proposed waiver, including:

(*i*) An explanation as to whether the waiver increases or decreases the administrative burden on individuals, insurers, and employers, and if so, how and why;

(*ii*) An explanation of how the waiver will affect the implementation of the provisions of the Affordable Care Act which the State is not requesting to waive in the State and at the Federal level;

(*iii*) An explanation of how the waiver will affect residents who need to obtain health care services out-of-State, as well as the States in which such residents may seek such services;

(*iv*) If applicable, an explanation as to how the State will provide the Federal government with all information necessary to administer the waiver at the Federal level; and

(*v*) An explanation of how the State's proposal will address potential individual, employer, insurer, or provider compliance, waste, fraud and abuse within the State or in other States.

(*5*) *Reporting targets.* Quarterly, annual, and cumulative targets for the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement, and the Federal deficit requirement.

(*6*) *Other information.* Other information consistent with guidance provided by the Secretary and the Secretary of Health and Human Services.

(b) *Additional supporting information.* (1) During the Federal review process, the Secretary may request additional supporting information from the State as needed to address public comments or to address issues that arise in reviewing the application.

(2) Requests for additional information, and responses to such requests, will be made available to the public in the same manner as information described in § 33.116(b).

§ 33.112 State public notice requirements.

(a) *General.* (1) Prior to submitting an application for a new section 1332 waiver to the Secretary of Health and Human Services for review and consideration, a State must provide a public notice and comment period sufficient to ensure a meaningful level of public input for the application for a section 1332 waiver.

(2) Such public notice and comment period shall include, for a State with one or more federally-recognized Indian tribes within its borders, a separate process for meaningful consultation with such tribes.

(b) *Public notice and comment period.* The State shall make available at the beginning of the public notice and comment period, through its Web site or other effective means of communication, and shall update as appropriate, a public notice that includes all of the following:

(1) A comprehensive description of the application for a section 1332 waiver to be submitted to the Secretary of Health and Human Services including information and assurances related to all statutory requirements and other information consistent with guidance provided by the Secretary and the Secretary of Health and Human Services.

(2) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(3) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(4) The location, date, and time of public hearings that will be convened by the State to seek public input on the application for a section 1332 waiver.

(c) *Public hearings.* (1) After issuing the public notice and prior to submitting an application for a new section 1332 waiver, a State must conduct public hearings regarding the State's application.

(2) Such public hearings shall provide an interested party the opportunity to learn about and comment on the contents of the application for a section 1332 waiver.

(d) *Submission of initial application.* After the State public notice and comment period has concluded, the State may submit an application to the Secretary of Health and Human Services for an initial waiver in accordance with the requirements set forth in § 33.108.

§ 33.116 Federal public notice and approval process.

(a) *General.* The Federal public notice and approval process begins on the first business day after the Secretary and the Secretary of Health and Human Services determine that all elements for a complete application were documented and submitted to the Secretary of Health and Human Services.

(b) *Public notice and comment period.* (1) Following a determination that a State's application for a section 1332 waiver is complete, the Secretary and the Secretary of Health and Human Services will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input and that does 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.

(2) At the beginning of the Federal notice and comment period, the Secretary of Health and Human Services will make available through its Web site and otherwise, and shall update as appropriate, public notice that includes all of the following:

(i) The complete application for a section 1332 waiver, updates for the status of the State's application, and any supplemental materials received from the State prior to and during the Federal public notice and comment period.

(ii) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(iii) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(iv) Any public comments received during the Federal public notice and comment period.

(c) *Approval of a section 1332 waiver application.* The final decision of the Secretary and the Secretary of Health and Human Services on a State application for a section 1332 waiver will be issued by the Secretary of Health and Human Services no later than 180 days after the determination by the Secretary and the Secretary of Health and Human Services that a complete application was received in accordance with § 33.108.

§ 33.120 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of Health and Human Services, a State must comply with all applicable Federal laws, regulations, interpretive policy statements and interpretive guidance unless expressly waived. A State must, within the timeframes specified in law, regulation, policy, or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) A State must comply with the terms and conditions of the agreement between the Secretary, the Secretary of Health and Human Services, and the State to implement a section 1332 waiver.

(b) *Implementation reviews.* (1) The terms and conditions of an approved section 1332 waiver will provide that the State will perform periodic reviews of the implementation of the section 1332 waiver.

(2) The Secretary and the Secretary of Health and Human Services will review documented complaints that a State is failing to comply with requirements specified in the terms and conditions of any approved section 1332 waiver.

(3) The Secretary and the Secretary of Health and Human Services will promptly share with a State any complaint that the Secretary and the Secretary of Health and Human Services has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within 6 months after the implementation date of a section 1332 waiver and annually thereafter, a State must hold a public forum to solicit comments on the progress of a section 1332 waiver. The State must hold the public forum at which members of the public have an opportunity to provide comments and must provide a summary of the forum to the Secretary of Health and Human Services as part of the quarterly report specified in § 33.124(a) that is associated with the quarter in which the forum was held, as well as in the annual report specified in § 33.124(b) that is associated with the year in which the forum was held.

(1) The State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

(2) [Reserved]

(d) *Terminations and suspensions.* The Secretary and the Secretary of Health and Human Services reserve the right to suspend or terminate a section 1332 waiver in whole or in part, at any time before the date of expiration, whenever the Secretaries determine that a State has materially failed to comply with the terms of a section 1332 waiver.

(e) *Closeout costs.* If all or part of a section 1332 waiver is terminated or suspended, or if a portion of a section 1332 waiver is withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination, suspension, or withdrawal, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) A State must fully cooperate with the Secretary, the Secretary of Health and Human Services, or an independent evaluator selected by the Secretary or the Secretary of Health and Human Services to undertake an independent evaluation of any component of a section 1332 waiver.

(2) As part of this required cooperation, a State must submit all requested data and information to the Secretary, the Secretary of Health and Human Services, or the independent evaluator.

§ 33.124 State reporting requirements.

(a) *Quarterly reports.* A State must submit quarterly reports to the Secretary of Health and Human Services in accordance with the terms and conditions of the State's section 1332 waiver. These quarterly reports must include, but are not limited to, reports of any ongoing operational challenges and plans for and results of associated corrective actions.

(b) *Annual reports.* A State must submit an annual report to the Secretary of Health and Human Services documenting all of the following:

(1) The progress of the section 1332 waiver.

(2) Data on compliance with section 1332(b)(1)(A) through (D) of the Affordable Care Act.

(3) A summary of the annual post-award public forum, held in accordance with § 33.120(c), including all public comments received at such forum regarding the progress of the section 1332 waiver and action taken in response to such concerns or comments.

(4) Other information consistent the State's approved terms and conditions.

(c) *Submitting and publishing annual reports.* A State must submit a draft annual report to the Secretary of Health and Human Services no later than 90 days after the end of each waiver year, or as specified in the waiver's terms and conditions.

(1) Within 60 days of receipt of comments from the Secretary of Health and Human Services, a State must submit to the Secretary of Health and Human Services a final annual report for the waiver year.

(2) The draft and final annual reports are to be published on a State's public Web site within 30 days of submission and approval to the Secretary of Health and Human Services, respectively.

§ 33.128 Periodic evaluation requirements.

(a) *General.* (1) The Secretary and the Secretary of Health and Human Services shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of Health and Human Services and any terms and conditions governing the section 1332 waiver.

(2) Each periodic evaluation must include a review of the annual report or reports submitted by the State in accordance with § 33.124 that relate to the period of time covered by the evaluation.

Department of Health and Human Services

45 CFR Subtitle A

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B to add new Part 155 to read as follows:

PART 155—WAIVERS FOR STATE INNOVATION

Subparts A Through M [Reserved]

Subpart N—State Flexibility

Sec.

155.1300 Basis and purpose.
155.1302 Coordinated waiver process.
155.1304 Definitions.
155.1308 Application procedures.
155.1312 State public notice requirements.
155.1316 Federal public notice and approval process.
155.1320 Monitoring and compliance.
155.1324 State reporting requirements.
155.1328 Periodic evaluation requirements.

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

Subparts A Through M [Reserved]

Subpart N—State Flexibility

§ 155.1300 Basis and purpose.

(a) *Statutory basis.* This subpart implements provisions of section 1332 of the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148, relating to Waivers for State Innovation, which the Secretary may authorize for plan years beginning on or after January 1, 2017. Section 1332 of the Affordable Care Act requires the Secretary to issue regulations that provide for all of the following:

(1) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input.

(2) A process for the submission of an application that ensures the disclosure of all of the following:

(i) The provisions of law that the State involved seeks to waive.

(ii) The specific plans of the State to ensure that the waiver will meet all requirements specified in section 1332.

(3) A process for the provision of public notice and comment after a waiver application is received by the Secretary, that is sufficient to ensure a meaningful level of public input and that does 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.

(4) A process for the submission of reports to the Secretary by a State relating to the implementation of a waiver.

(5) A process for the periodic evaluation by the Secretary of programs under waivers.

(b) *Purpose.* This subpart sets forth certain procedural requirements for Waivers for State Innovation under section 1332 of the Affordable Care Act.

§ 155.1302 Coordinated waiver process.

(a) *Coordination with applications for waivers under other Federal laws.* A State may submit a single application to the Secretary for a waiver under section 1332 of the Affordable Care Act and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Social Security Act, or under any other Federal law relating to the provision of health care items or services, provided that such application is consistent with the procedures described in this part, the procedures for section 1115 demonstrations, if applicable, and the procedures under any other applicable Federal law under which the State seeks a waiver.

(b) *Coordinated process for section 1332 waivers.* A State seeking a section 1332 waiver must submit a waiver application to the Secretary. Any application submitted to the Secretary that requests to waive sections 36B, 4980H, and 5000A of the Internal Revenue Code, in accordance with section 1332(a)(2)(D) of the Affordable Care Act, shall upon receipt be transmitted by the Secretary to the Secretary of the Treasury to be reviewed in accordance with 31 CFR part 33.

§ 155.1304 Definitions.

For the purposes of this subpart:

Complete application means an application that has been submitted and for which the Secretary and the Secretary of the Treasury have made a preliminary determination that it includes all required information and satisfies all requirements that are described in § 155.1308(a)(2)(iv).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action consistent with § 155.1312.

Section 1332 waiver means a Waiver for State Innovation under section 1332 of the Affordable Care Act.

§ 155.1308 Application procedures.

(a) *Initial waiver applications*—(1) *Acceptable formats for applications.* (i) Applications for initial approval of a section 1332 waiver shall be submitted in both printed and electronic formats to the Secretary.

(ii) [Reserved]

(2) *Guidelines for applications.* (i) Each application for a section 1332 waiver will be subject to a preliminary review by the Secretary and the Secretary of the Treasury will make a preliminary determination that the application is complete. A submitted application will not be deemed received until the Secretary and the Secretary of the Treasury have made the preliminary determination that the application is complete.

(A) The Secretary and the Secretary of the Treasury will complete the preliminary review of the application within 45 days after it is submitted.

(B) If the Secretary and the Secretary of the Treasury determine that the application is not complete, the Secretary will send the State a written notice of the elements missing from the application.

(C) The preliminary determination that an application is complete does not preclude a finding during the 180-day Federal decision-making period that a necessary element of the application is missing or insufficient.

(ii) Upon making the preliminary determination that an application is complete, as defined in this part, the Secretary will send the State a written notice informing the State that the Secretary and the Secretary of the Treasury have made such a preliminary determination. That date will also mark the beginning of the Federal public notice process and the 180-day Federal decision-making period.

(iii) Upon receipt of a complete application for an initial section 1332 waiver, the Secretary will—

(A) Make available to the public the application, and all related State submissions, including all supplemental information received from the State following the receipt of a complete application for a section 1332 waiver.

(B) Indicate the status of the application.

(iv) An application for initial approval of a section 1332 waiver will not be considered complete unless the application meets all of the following conditions:

(A) Complies with paragraph (a) of this section.

(B) Provides written evidence of the State's compliance with the public notice requirements set forth in § 155.1312.

(C) Provides all of the following:

(*1*) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332;

(*2*) A copy of the enacted State legislation authorizing such waiver request, as required under section 1332(a)(1)(C) of the Affordable Care Act;

(*3*) A list of the provisions of law that the State seeks to waive including a brief description of the reason for the specific requests; and

(*4*) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information

set forth in paragraph (a)(2)(iv)(D) of this section sufficient to provide the Secretary and the Secretary of the Treasury with the necessary data to determine that the State's proposed waiver:

(*i*) Will, as required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare and Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive;

(*ii*) Will, as required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide;

(*iii*) Will, as required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide; and

(*iv*) Will not, as prohibited under section 1332(b)(1)(D) of the Affordable Care Act (the Federal deficit requirement), increase the Federal deficit.

(D) Contains the following supporting information:

(*1*) *Actuarial analyses and actuarial certifications.* 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;

(*2*) *Economic analyses.* Economic analyses to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(*i*) A detailed 10-year budget plan that is deficit neutral to the Federal government, as prescribed by section 1332(a)(1)(B)(ii) of the Affordable Care Act, and includes all costs under the waiver, including administrative costs and other costs to the Federal government, if applicable; and

(*ii*) A detailed analysis regarding the estimated impact of the waiver on health insurance coverage in the State.

(*3*) *Data and assumptions.* The data and assumptions used to demonstrate that the State's proposed waiver is in compliance with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(*i*) Information on the age, income, health expenses and current health insurance status of the relevant State population; the number of employers by number of employees and whether the employer offers insurance; cross-tabulations of these variables; and an explanation of data sources and quality; and

(*ii*) An explanation of the key assumptions used to develop the estimates of the effect of the waiver on coverage and the Federal budget, such as individual and employer participation rates, behavioral changes, premium and price effects, and other relevant factors.

(*4*) *Additional information.* Additional information supporting the State's proposed waiver, including:

(*i*) An explanation as to whether the waiver increases or decreases the administrative burden on individuals, insurers, and employers, and if so, how and why;

(*ii*) An explanation of how the waiver will affect the implementation of the provisions of the Affordable Care Act which the State is not requesting to waive in the State and at the Federal level;

(*iii*) An explanation of how the waiver will affect residents who need to obtain health care services out-of-State, as well as the States in which such residents may seek such services;

(*iv*) If applicable, an explanation as to how the State will provide the Federal government with all information necessary to administer the waiver at the Federal level; and

(*v*) An explanation of how the State's proposal will address potential individual, employer, insurer, or provider compliance, waste, fraud and abuse within the State or in other States.

(*5*) *Reporting targets.* Quarterly, annual, and cumulative targets for the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement.

(*6*) *Other information.* Other information consistent with guidance provided by the Secretary and the Secretary of the Treasury.

(b) *Additional supporting information.* (1) During the Federal review process, the Secretary may request additional supporting information from the State as needed to address public comments or to address issues that arise in reviewing the application.

(2) Requests for additional information, and responses to such requests, will be made available to the public in the same manner as information described in § 155.1316(b).

§ 155.1312 State public notice requirements.

(a) *General.* (1) Prior to submitting an application for a new section 1332 waiver to the Secretary for review and consideration, a State must provide a public notice and comment period sufficient to ensure a meaningful level of public input for the application for a section 1332 waiver.

(2) Such public notice and comment period shall include, for a State with one or more Federally-recognized Indian tribes within its borders, a separate process for meaningful consultation with such tribes.

(b) *Public notice and comment period.* The State shall make available at the beginning of the public notice and comment period, through its Web site or other effective means of communication, and shall update as appropriate, a public notice that includes all of the following:

(1) A comprehensive description of the application for a section 1332 waiver to be submitted to the Secretary including information and assurances related to all statutory requirements and other information consistent with guidance provided by the Secretary and the Secretary of the Treasury.

(2) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(3) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(4) The location, date, and time of public hearings that will be convened by the State to seek public input on the application for a section 1332 waiver.

(c) *Public hearings.* (1) After issuing the public notice and prior to submitting an application for a new section 1332 waiver, a State must conduct public hearings regarding the State's application.

(2) Such public hearings shall provide an interested party the opportunity to learn about and comment on the contents of the application for a section 1332 waiver.

(d) *Submission of initial application.* After the State public notice and comment period has concluded, the State may submit an application to the Secretary for an initial waiver in accordance with the requirements set forth in § 155.1308.

§ 155.1316 Federal public notice and approval process.

(a) *General.* The Federal public notice and approval process begins on the first business day after the Secretary and the Secretary of the Treasury determine that all elements for a complete application were documented and submitted to the Secretary.

(b) *Public notice and comment period.* (1) Following a determination that a State's application for a section 1332 waiver is complete, the Secretary and the Secretary of the Treasury will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input and that does 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.

(2) At the beginning of the Federal notice and comment period, the Secretary will make available through its Web site and otherwise, and shall update as appropriate, public notice that includes all of the following:

(i) The complete application for a section 1332 waiver, updates for the status of the State's application, and any supplemental materials received from the State prior to and during the Federal public notice and comment period.

(ii) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(iii) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(iv) Any public comments received during the Federal public notice and comment period.

(c) *Approval of a section 1332 waiver application.* The final decision of the Secretary and the Secretary of the Treasury on a State application for a section 1332 waiver will be issued by the Secretary no later than 180 days after the determination by the Secretary and the Secretary of the Treasury that a complete application was received in accordance with § 155.1308.

§ 155.1320 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, a State must comply with all applicable Federal laws, regulations, interpretive policy statements and interpretive guidance unless expressly waived. A State must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) A State must comply with the terms and conditions of the agreement between the Secretary, the Secretary of the Treasury, and the State to implement a section 1332 waiver.

(b) *Implementation reviews.* (1) The terms and conditions of an approved section 1332 waiver will provide that the State will perform periodic reviews of the implementation of the section 1332 waiver.

(2) The Secretary and the Secretary of the Treasury will review documented complaints that a State is failing to comply with requirements specified in the terms and conditions of any approved section 1332 waiver.

(3) The Secretary and the Secretary of the Treasury will promptly share with a State any complaint that the Secretary and the Secretary of the Treasury has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within at least 6 months after the implementation date of a section 1332 waiver and annually thereafter, a State must hold a public forum to solicit comments on the progress of a section 1332 waiver. The State must hold the public forum at which members of the public have an opportunity to provide comments and must provide a summary of the forum to the Secretary as part of the quarterly report specified in § 155.1324(a) that is associated with the quarter in which the forum was held, as well as in the annual report specified in § 155.1324(b) that is associated with the year in which the forum was held.

(1) The State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

(2) [Reserved]

(d) *Terminations and suspensions.* The Secretary and the Secretary of the Treasury reserve the right to suspend or terminate a section 1332 waiver in whole or in part, at any time before the date of expiration, whenever the Secretaries determine that a State has materially failed to comply with the terms of a section 1332 waiver.

(e) *Closeout costs.* If all or part of a section 1332 waiver is terminated or suspended, or if a portion of a section 1332 waiver is withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination, suspension, or withdrawal, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) A State must fully cooperate with the Secretary, the Secretary of the Treasury, or an independent evaluator selected by the Secretary or the Secretary of the Treasury to undertake an independent evaluation of any component of a section 1332 waiver.

(2) As part of this required cooperation, a State must submit all requested data and information to the Secretary, the Secretary of the Treasury, or the independent evaluator.

§ 155.1324 State reporting requirements.

(a) *Quarterly reports.* A State must submit quarterly reports to the Secretary in accordance with the terms and conditions of the State's section 1332 waiver. These quarterly reports must include, but are not limited to, reports of any ongoing operational challenges and plans for and results of associated corrective actions.

(b) *Annual reports.* A State must submit an annual report to the Secretary documenting all of the following:

(1) The progress of the section 1332 waiver.

(2) Data on compliance with section 1332(b)(1)(A) through (D) of the Affordable Care Act.

(3) A summary of the annual post-award public forum, held in accordance with § 155.1320(c), including all public comments received at such forum regarding the progress of the section 1332 waiver and action taken in response to such concerns or comments.

(4) Other information consistent the State's approved terms and conditions.

(c) *Submitting and publishing annual reports.* A State must submit a draft annual report to the Secretary no later than 90 days after the end of each waiver year, or as specified in the waiver's terms and conditions.

(1) Within 60 days of receipt of comments from the Secretary, a State must submit to the Secretary the final annual report for the waiver year.

(2) The draft and final annual reports are to be published on a State's public Web site within 30 days of submission

and approval to the Secretary, respectively.

§ 155.1328 Periodic evaluation requirements.

(a) *General.* (1) The Secretary and the Secretary of the Treasury shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of the Treasury and any terms and conditions governing the section 1332 waiver.

(2) Each periodic evaluation must include a review of the annual report or reports submitted by the State in accordance with § 155.1324 that relate to the period of time covered by the evaluation.

Authority: Sec. 1332 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

Approved: February 22, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: March 4, 2011.

Kathleen Sebelius,

Secretary of Health and Human Services.

Approved: March 7, 2011.

Michael F. Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–5583 Filed 3–10–11; 11:15 am]

BILLING CODE 4510–29–P, 4120–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2011–0099; FRL–9280–2]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Adoption of Control Techniques Guidelines for Flat Wood Paneling Surface Coating Processes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania (Pennsylvania). This SIP revision includes amendments to Chapter 121—General Provisions and Chapter 129—Standards for Sources of Title 25 of the Pennsylvania Code. Pennsylvania's SIP revision meets the requirement to adopt Reasonably Available Control Technology (RACT) for sources covered by EPA's Control Techniques Guidelines (CTG) standards for flat wood paneling surface coating processes and will help Pennsylvania attain and maintain the National Ambient Air Quality Standard (NAAQS) for ozone. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before April 13, 2011.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2011–0099 by one of the following methods:

A. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *E-mail: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2011–0099, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2011–0099. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Irene Shandruk, (215) 814–2166, or by e-mail at *shandruk.irene@epa.gov.*

SUPPLEMENTARY INFORMATION: On January 4, 2011, the Pennsylvania Department of Environmental Protection (PADEP) submitted to EPA a SIP revision concerning the adoption of the CTG for flat wood paneling surface coating processes.

I. Background

Section 172(c)(1) of the CAA provides that SIPs for nonattainment areas must include reasonably available control measures (RACM), including RACT for sources of emissions. Section 182(b)(2)(A) provides that for certain nonattainment areas, States must revise their SIPs to include RACT for sources of volatile organic compounds (VOC) emissions covered by a CTG document issued after November 15, 1990 and prior to the area's date of attainment.

CTGs are intended to provide state and local air pollution control authorities information that should assist them in determining RACT for VOCs from various sources, including flat wood paneling surface coatings. In developing these CTGs, EPA, among other things, evaluated the sources of VOC emissions from this industry and the available control approaches for addressing these emissions, including the costs of such approaches. Based on available information and data, EPA provided recommendations for RACT for VOCs from flat wood paneling.

In June 1978, EPA published a CTG for flat wood paneling coatings (EPA–

in the definition of a small entity. The Departments are not preparing an analysis for the RFA because the Departments have determined, and the Secretaries certify, that these final rules will not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million or more in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. Because these rules do not mandate State participation in section 1332 waivers, there is no obligation for the State to make any change to their existing programs. As a result, there is no mandate for the State. Therefore, the Departments estimate these rules will not mandate expenditures in the threshold amount of $136 million in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since these regulations would not impose costs on State or local governments, the requirements of Executive Order 13132 are not applicable. In accordance with the provisions of Executive Order 12866, these regulations were reviewed by the Office of Management and Budget.

List of Subjects

31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 155

Health care, Health insurance, Reporting and recordkeeping requirements.

Department of the Treasury

31 CFR Subtitle A

For the reasons set forth in the preamble, the Department of the Treasury amends 31 CFR subtitle A by adding part 33 to read as follows:

PART 33—WAIVERS FOR STATE INNOVATION

Sec.

33.100 Basis and purpose.
33.102 Coordinated waiver process.
33.104 Definitions.
33.108 Application procedures.
33.112 State public notice requirements.
33.116 Federal public notice and approval process.
33.120 Monitoring and compliance.
33.124 State reporting requirements.
33.128 Periodic evaluation requirements.

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

§ 33.100 Basis and purpose.

(a) *Statutory basis.* This part implements provisions of section 1332 of the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148, relating to Waivers for State Innovation, which the Secretary may authorize for plan years beginning on or after January 1, 2017. Section 1332 of the Affordable Care Act requires the Secretary to issue regulations that provide for all of the following:

(1) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input.

(2) A process for the submission of an application that ensures the disclosure of all of the following:

(i) The provisions of law that the State involved seeks to waive.

(ii) The specific plans of the State to ensure that the waiver will meet all requirements specified in section 1332 of the Affordable Care Act.

(3) A process for the provision of public notice and comment after a waiver application is received by the Secretary of Health and Human Services, that is sufficient to ensure a meaningful level of public input and that does 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.

(4) A process for the submission of reports to the Secretary by a State relating to the implementation of a waiver.

(5) A process for the periodic evaluation by the Secretary of programs under waivers.

(b) *Purpose.* This part sets forth certain procedural requirements for Waivers for State Innovation under section 1332 of the Affordable Care Act.

§ 33.102 Coordinated waiver process.

(a) *Coordination with applications for waivers under other Federal laws.* A State may submit a single application to the Secretary of Health and Human Services for a waiver under section 1332 of the Affordable Care Act and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Social Security Act, or under any other Federal law relating to the provision of health care items or services, provided that such application is consistent with the procedures described in this part, the procedures for demonstrations under section 1115 of the Social Security Act, if applicable, and the procedures under any other applicable Federal law under which the State seeks a waiver.

(b) *Coordinated process for section 1332 waivers.* A State seeking a section 1332 waiver must submit a waiver application to the Secretary of Health and Human Services. Any application submitted to the Secretary of Health and Human Services that requests to waive sections 36B, 4980H, or 5000A of the Internal Revenue Code, in accordance with section 1332(a)(2)(D) of the Affordable Care Act, shall upon receipt be transmitted by the Secretary of Health and Human Services to the Secretary to be reviewed in accordance with this part.

§ 33.104 Definitions.

For the purposes of this part:

Complete application means an application that has been submitted and for which the Secretary and the Secretary of Health and Human Services have made a preliminary determination that it includes all required information and satisfies all requirements that are described in § 33.108(f).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action consistent with § 33.112.

Section 1332 waiver means a Waiver for State Innovation under section 1332 of the Affordable Care Act.

§ 33.108 Application procedures.

(a) *Acceptable formats for applications.* Applications for initial approval of a section 1332 waiver shall be submitted in electronic format to the Secretary of Health and Human Services.

(b) *Application timing.* Applications for initial approval of a section 1332 waiver must be submitted sufficiently in advance of the requested effective date to allow for an appropriate implementation timeline.

(c) *Preliminary review.* Each application for a section 1332 waiver will be subject to a preliminary review by the Secretary and the Secretary of Health and Human Services, who will make a preliminary determination that the application is complete. A submitted application will not be deemed received until the Secretary and the Secretary of Health and Human Services have made the preliminary

determination that the application is complete.

(1) The Secretary and the Secretary of Health and Human Services will complete the preliminary review of the application within 45 days after it is submitted.

(2) If the Secretary and the Secretary of Health and Human Services determine that the application is not complete, the Secretary of Health and Human Services will send the State a written notice of the elements missing from the application.

(3) The preliminary determination that an application is complete does not preclude a finding during the 180-day Federal decision-making period that a necessary element of the application is missing or insufficient.

(d) *Notification of preliminary determination.* Upon making the preliminary determination that an application is complete, as defined in this part, the Secretary of Health and Human Services will send the State a written notice informing the State that the Secretary and the Secretary of Health and Human Services have made such a preliminary determination. That date will also mark the beginning of the Federal public notice process and the 180-day Federal decision-making period.

(e) *Public notice of completed application.* Upon receipt of a complete application for an initial section 1332 waiver, the Secretary of Health and Human Services will—

(1) Make available to the public the application, and all related State submissions, including all supplemental information received from the State following the receipt of a complete application for a section 1332 waiver.

(2) Indicate the status of the application.

(f) *Criteria for a complete application.* An application for initial approval of a section 1332 waiver will not be considered complete unless the application meets all of the following conditions:

(1) Complies with paragraphs (a) through (f) of this section.

(2) Provides written evidence of the State's compliance with the public notice requirements set forth in § 33.112, including a description of the key issues raised during the State public notice and comment period.

(3) Provides all of the following:

(i) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332;

(ii) 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 Affordable Care Act;

(iii) A list of the provisions of law that the State seeks to waive, including a description of the reason for the specific requests; and

(iv) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of Health and Human Services with the necessary data to determine that the State's proposed waiver:

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide; and

(D) As prohibited under section 1332(b)(1)(D) of the Affordable Care Act (the Federal deficit requirement), will not increase the Federal deficit.

(4) Contains the following supporting information:

(i) *Actuarial analyses and actuarial certifications.* 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.

(ii) *Economic analyses.* Economic analyses to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) A detailed 10-year budget plan that is deficit neutral to the Federal government, as prescribed by section 1332(a)(1)(B)(ii) of the Affordable Care Act, and includes all costs under the waiver, including administrative costs and other costs to the Federal government, if applicable; and

(B) A detailed analysis regarding the estimated impact of the waiver on health insurance coverage in the State.

(iii) *Data and assumptions.* The data and assumptions used to demonstrate that the State's proposed waiver is in compliance with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) Information on the age, income, health expenses and current health insurance status of the relevant State population; the number of employers by number of employees and whether the employer offers insurance; cross-tabulations of these variables; and an explanation of data sources and quality; and

(B) An explanation of the key assumptions used to develop the estimates of the effect of the waiver on coverage and the Federal budget, such as individual and employer participation rates, behavioral changes, premium and price effects, and other relevant factors.

(iv) *Implementation timeline.* A detailed draft timeline for the State's implementation of the proposed waiver.

(v) *Additional information.* Additional information supporting the State's proposed waiver, including:

(A) An explanation as to whether the waiver increases or decreases the administrative burden on individuals, insurers, and employers, and if so, how and why;

(B) An explanation of how the waiver will affect the implementation of the provisions of the Affordable Care Act which the State is not requesting to waive in the State and at the Federal level;

(C) An explanation of how the waiver will affect residents who need to obtain health care services out-of-State, as well as the States in which such residents may seek such services;

(D) If applicable, an explanation as to how the State will provide the Federal government with all information necessary to administer the waiver at the Federal level; and

(E) An explanation of how the State's proposal will address potential individual, employer, insurer, or

provider compliance, waste, fraud and abuse within the State or in other States.

(vi) *Reporting targets.* Quarterly, annual, and cumulative targets for the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement, and the Federal deficit requirement.

(vii) *Other information.* Other information consistent with guidance provided by the Secretary and the Secretary of Health and Human Services.

(g) *Additional supporting information.* (1) During the Federal review process, the Secretary may request additional supporting information from the State via the Secretary of Health and Human Services as needed to address public comments or to address issues that arise in reviewing the application.

(2) Requests for additional information, and responses to such requests, will be made available to the public in the same manner as information described in § 33.116(b).

§ 33.112 State public notice requirements.

(a) *General.* (1) Prior to submitting an application for a new section 1332 waiver to the Secretary of Health and Human Services for review and consideration, a State must provide a public notice and comment period sufficient to ensure a meaningful level of public input for the application for a section 1332 waiver.

(2) Such public notice and comment period shall include, for a State with one or more Federally-recognized Indian tribes within its borders, a separate process for meaningful consultation with such tribes.

(b) *Public notice and comment period.* The State shall make available at the beginning of the public notice and comment period, through its Web site or other effective means of communication, and shall update as appropriate, a public notice that includes all of the following:

(1) A comprehensive description of the application for a section 1332 waiver to be submitted to the Secretary of Health and Human Services including information and assurances related to all statutory requirements and other information consistent with guidance provided by the Secretary and the Secretary of Health and Human Services.

(2) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(3) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(4) The location, date, and time of public hearings that will be convened by the State to seek public input on the application for a section 1332 waiver.

(c) *Public hearings.* (1) After issuing the public notice and prior to submitting an application for a new section 1332 waiver, a State must conduct public hearings regarding the State's application.

(2) Such public hearings shall provide an interested party the opportunity to learn about and comment on the contents of the application for a section 1332 waiver.

(d) *Submission of initial application.* After the State public notice and comment period has concluded, the State may submit an application to the Secretary of Health and Human Services for an initial waiver in accordance with the requirements set forth in § 33.108.

§ 33.116 Federal public notice and approval process.

(a) *General.* The Federal public notice and approval process begins on the first business day after the Secretary and the Secretary of Health and Human Services determine that all elements for a complete application were documented and submitted to the Secretary of Health and Human Services.

(b) *Public notice and comment period.* (1) Following a determination that a State's application for a section 1332 waiver is complete, the Secretary and the Secretary of Health and Human Services will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input and that does 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.

(2) At the beginning of the Federal notice and comment period, the Secretary of Health and Human Services will make available through its Web site and otherwise, and shall update as appropriate, public notice that includes all of the following:

(i) The complete application for a section 1332 waiver, updates for the status of the State's application, and any supplemental materials received from the State prior to and during the Federal public notice and comment period.

(ii) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(iii) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(iv) Any public comments received during the Federal public notice and comment period.

(c) *Approval of a section 1332 waiver application.* The final decision of the Secretary and the Secretary of Health and Human Services on a State application for a section 1332 waiver will be issued by the Secretary of Health and Human Services no later than 180 days after the determination by the Secretary and the Secretary of Health and Human Services that a complete application was received in accordance with § 33.108.

§ 33.120 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of Health and Human Services, a State must comply with all applicable Federal laws, regulations, interpretive policy statements and interpretive guidance unless expressly waived. A State must, within the timeframes specified in law, regulation, policy, or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision changed is expressly waived.

(2) A State must comply with the terms and conditions of the agreement between the Secretary, the Secretary of Health and Human Services, and the State to implement a section 1332 waiver.

(b) *Implementation reviews.* (1) The terms and conditions of an approved section 1332 waiver will provide that the State will perform periodic reviews of the implementation of the section 1332 waiver.

(2) The Secretary and the Secretary of Health and Human Services will review documented complaints that a State is failing to comply with requirements specified in the terms and conditions of any approved section 1332 waiver.

(3) The Secretary and the Secretary of Health and Human Services will promptly share with a State any complaint that the Secretary and the Secretary of Health and Human Services has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within 6 months after the implementation date of a section 1332 waiver and annually thereafter, a State must hold a public forum to solicit comments on the progress of a section 1332 waiver. The State must hold the

public forum at which members of the public have an opportunity to provide comments and must provide a summary of the forum to the Secretary of Health and Human Services as part of the quarterly report specified in § 33.124(a) that is associated with the quarter in which the forum was held, as well as in the annual report specified in § 33.124(b) that is associated with the year in which the forum was held.

(1) The State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

(2) [Reserved]

(d) *Terminations and suspensions.* The Secretary and the Secretary of Health and Human Services reserve the right to suspend or terminate a section 1332 waiver in whole or in part, at any time before the date of expiration, whenever the Secretaries determine that a State has materially failed to comply with the terms of a section 1332 waiver.

(e) *Closeout costs.* If all or part of a section 1332 waiver is terminated or suspended, or if a portion of a section 1332 waiver is withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination, suspension, or withdrawal, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) A State must fully cooperate with the Secretary, the Secretary of Health and Human Services, or an independent evaluator selected by the Secretary or the Secretary of Health and Human Services to undertake an independent evaluation of any component of a section 1332 waiver.

(2) As part of this required cooperation, a State must submit all requested data and information to the Secretary, the Secretary of Health and Human Services, or the independent evaluator.

§ 33.124 State reporting requirements.

(a) *Quarterly reports.* A State must submit quarterly reports to the Secretary of Health and Human Services in accordance with the terms and conditions of the State's section 1332 waiver. These quarterly reports must include, but are not limited to, reports of any ongoing operational challenges and plans for and results of associated corrective actions.

(b) *Annual reports.* A State must submit an annual report to the Secretary of Health and Human Services documenting all of the following:

(1) The progress of the section 1332 waiver.

(2) Data on compliance with section 1332(b)(1)(A) through (D) of the Affordable Care Act.

(3) A summary of the annual post-award public forum, held in accordance with § 33.120(c), including all public comments received at such forum regarding the progress of the section 1332 waiver and action taken in response to such concerns or comments.

(4) Other information consistent with the State's approved terms and conditions.

(c) *Submitting and publishing annual reports.* A State must submit a draft annual report to the Secretary of Health and Human Services no later than 90 days after the end of each waiver year, or as specified in the waiver's terms and conditions.

(1) Within 60 days of receipt of comments from the Secretary of Health and Human Services, a State must submit to the Secretary of Health and Human Services a final annual report for the waiver year.

(2) The draft and final annual reports are to be published on a State's public Web site within 30 days of submission to and approval by the Secretary of Health and Human Services, respectively.

§ 33.128 Periodic evaluation requirements.

(a) The Secretary and the Secretary of Health and Human Services shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of Health and Human Services and any terms and conditions governing the section 1332 waiver.

(b) Each periodic evaluation must include a review of the annual report or reports submitted by the State in accordance with § 33.124 that relate to the period of time covered by the evaluation.

Department of Health and Human Services

45 CFR Subtitle A

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B by adding part 155 to read as follows:

PART 155—WAIVERS FOR STATE INNOVATION

Subparts A Through M [Reserved]

Subpart N—State Flexibility

Sec.

155.1300 Basis and purpose.
155.1302 Coordinated waiver process.
155.1304 Definitions.
155.1308 Application procedures.
155.1312 State public notice requirements.
155.1316 Federal public notice and approval process.
155.1320 Monitoring and compliance.
155.1324 State reporting requirements.
155.1328 Periodic evaluation requirements.

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

Subparts A Through M [Reserved]

Subpart N—State Flexibility

§ 155.1300 Basis and purpose.

(a) *Statutory basis.* This subpart implements provisions of section 1332 of the Affordable Care Act, relating to Waivers for State Innovation, which the Secretary may authorize for plan years beginning on or after January 1, 2017. Section 1332 of the Affordable Care Act requires the Secretary to issue regulations that provide for all of the following:

(1) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input.

(2) A process for the submission of an application that ensures the disclosure of all of the following:

(i) The provisions of law that the State involved seeks to waive.

(ii) The specific plans of the State to ensure that the waiver will meet all requirements specified in section 1332.

(3) A process for the provision of public notice and comment after a waiver application is received by the Secretary, that is sufficient to ensure a meaningful level of public input and that does 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.

(4) A process for the submission of reports to the Secretary by a State relating to the implementation of a waiver.

(5) A process for the periodic evaluation by the Secretary of programs under waivers.

(b) *Purpose.* This subpart sets forth certain procedural requirements for Waivers for State Innovation under section 1332 of the Affordable Care Act.

§ 155.1302 Coordinated waiver process.

(a) *Coordination with applications for waivers under other Federal laws.* A State may submit a single application to the Secretary for a waiver under section 1332 of the Affordable Care Act and a waiver under one or more of the existing waiver processes applicable under titles

XVIII, XIX, and XXI of the Act, or under any other Federal law relating to the provision of health care items or services, provided that such application is consistent with the procedures described in this part, the procedures for demonstrations under section 1115 of the Act, if applicable, and the procedures under any other applicable Federal law under which the State seeks a waiver.

(b) *Coordinated process for section 1332 waivers.* A State seeking a section 1332 waiver must submit a waiver application to the Secretary. Any application submitted to the Secretary that requests to waive sections 36B, 4980H, or 5000A of the Code, in accordance with section 1332(a)(2)(D) of the Affordable Care Act, shall upon receipt be transmitted by the Secretary to the Secretary of the Treasury to be reviewed in accordance with 31 CFR Part 33.

§ 155.1304 Definitions.

For the purposes of this subpart:

Complete application means an application that has been submitted and for which the Secretary and the Secretary of the Treasury, as applicable, have made a preliminary determination that it includes all required information and satisfies all requirements that are described in § 155.1308(f).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action consistent with § 155.1312.

Section 1332 waiver means a Waiver for State Innovation under section 1332 of the Affordable Care Act.

§ 155.1308 Application procedures.

(a) *Acceptable formats for applications.* Applications for initial approval of a section 1332 waiver shall be submitted in electronic format to the Secretary.

(b) *Application timing.* Applications for initial approval of a section 1332 waiver must be submitted sufficiently in advance of the requested effective date to allow for an appropriate implementation timeline.

(c) *Preliminary review.* Each application for a section 1332 waiver will be subject to a preliminary review by the Secretary and the Secretary of the Treasury, as applicable, who will make a preliminary determination that the application is complete. A submitted application will not be deemed received until the Secretary and the Secretary of the Treasury, as applicable, have made the preliminary determination that the application is complete.

(1) The Secretary and the Secretary of the Treasury, as applicable, will complete the preliminary review of the application within 45 days after it is submitted.

(2) If the Secretary and the Secretary of the Treasury, as applicable, determine that the application is not complete, the Secretary will send the State a written notice of the elements missing from the application.

(3) The preliminary determination that an application is complete does not preclude a finding during the 180-day Federal decision-making period that a necessary element of the application is missing or insufficient.

(d) *Notification of preliminary determination.* Upon making the preliminary determination that an application is complete, as defined in this part, the Secretary will send the State a written notice informing the State that the Secretary and the Secretary of the Treasury, as applicable, have made such a preliminary determination. That date will also mark the beginning of the Federal public notice process and the 180-day Federal decision-making period.

(e) *Public notice of completed application.* Upon receipt of a complete application for an initial section 1332 waiver, the Secretary will—

(1) Make available to the public the application, and all related State submissions, including all supplemental information received from the State following the receipt of a complete application for a section 1332 waiver.

(2) Indicate the status of the application.

(f) *Criteria for a complete application.* An application for initial approval of a section 1332 waiver will not be considered complete unless the application meets all of the following conditions:

(1) Complies with paragraphs (a) through (f) of this section.

(2) Provides written evidence of the State's compliance with the public notice requirements set forth in § 155.1312, including a description of the key issues raised during the State public notice and comment period.

(3) Provides all of the following:

(i) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332;

(ii) 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 Affordable Care Act;

(iii) A list of the provisions of law that the State seeks to waive including a description of the reason for the specific requests; and

(iv) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of the Treasury, as applicable, with the necessary data to determine that the State's proposed waiver:

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive;

(B) As required under section 1332(b)(1)(B) of the Affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide; and

(D) As prohibited under section 1332(b)(1)(D) of the Affordable Care Act (the Federal deficit requirement), will not increase the Federal deficit.

(4) Contains the following supporting information:

(i) *Actuarial analyses and actuarial certifications.* 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;

(ii) *Economic analyses.* Economic analyses to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) A detailed 10-year budget plan that is deficit neutral to the Federal government, as prescribed by section 1332(a)(1)(B)(ii) of the Affordable Care

Act, and includes all costs under the waiver, including administrative costs and other costs to the Federal government, if applicable; and

(B) A detailed analysis regarding the estimated impact of the waiver on health insurance coverage in the State.

(iii) *Data and assumptions.* The data and assumptions used to demonstrate that the State's proposed waiver is in compliance with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) Information on the age, income, health expenses and current health insurance status of the relevant State population; the number of employers by number of employees and whether the employer offers insurance; cross-tabulations of these variables; and an explanation of data sources and quality; and

(B) An explanation of the key assumptions used to develop the estimates of the effect of the waiver on coverage and the Federal budget, such as individual and employer participation rates, behavioral changes, premium and price effects, and other relevant factors.

(iv) *Implementation timeline.* A detailed draft timeline for the State's implementation of the proposed waiver.

(v) *Additional information.* Additional information supporting the State's proposed waiver, including:

(A) An explanation as to whether the waiver increases or decreases the administrative burden on individuals, insurers, and employers, and if so, how and why;

(B) An explanation of how the waiver will affect the implementation of the provisions of the Affordable Care Act which the State is not requesting to waive in the State and at the Federal level;

(C) An explanation of how the waiver will affect residents who need to obtain health care services out-of-State, as well as the States in which such residents may seek such services;

(D) If applicable, an explanation as to how the State will provide the Federal government with all information necessary to administer the waiver at the Federal level; and

(E) An explanation of how the State's proposal will address potential individual, employer, insurer, or provider compliance, waste, fraud and abuse within the State or in other States.

(vi) *Reporting targets.* Quarterly, annual, and cumulative targets for the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement.

(vii) *Other information.* Other information consistent with guidance provided by the Secretary and the Secretary of the Treasury, as applicable.

(g) *Additional supporting information.* (1) During the Federal review process, the Secretary may request additional supporting information from the State as needed to address public comments or to address issues that arise in reviewing the application.

(2) Requests for additional information, and responses to such requests, will be made available to the public in the same manner as information described in § 155.1316(b).

§ 155.1312 State public notice requirements.

(a) *General.* (1) Prior to submitting an application for a new section 1332 waiver to the Secretary for review and consideration, a State must provide a public notice and comment period sufficient to ensure a meaningful level of public input for the application for a section 1332 waiver.

(2) Such public notice and comment period shall include, for a State with one or more Federally-recognized Indian tribes within its borders, a separate process for meaningful consultation with such tribes.

(b) *Public notice and comment period.* The State shall make available at the beginning of the public notice and comment period, through its Web site or other effective means of communication, and shall update as appropriate, a public notice that includes all of the following:

(1) A comprehensive description of the application for a section 1332 waiver to be submitted to the Secretary including information and assurances related to all statutory requirements and other information consistent with guidance provided by the Secretary and the Secretary of the Treasury, as applicable.

(2) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(3) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(4) The location, date, and time of public hearings that will be convened by the State to seek public input on the application for a section 1332 waiver.

(c) *Public hearings.* (1) After issuing the public notice and prior to submitting an application for a new section 1332 waiver, a State must conduct public hearings regarding the State's application.

(2) Such public hearings shall provide an interested party the opportunity to learn about and comment on the contents of the application for a section 1332 waiver.

(d) *Submission of initial application.* After the State public notice and comment period has concluded, the State may submit an application to the Secretary for an initial waiver in accordance with the requirements set forth in § 155.1308.

§ 155.1316 Federal public notice and approval process.

(a) *General.* The Federal public notice and approval process begins on the first business day after the Secretary and the Secretary of the Treasury, as applicable, determine that all elements for a complete application were documented and submitted to the Secretary.

(b) *Public notice and comment period.* (1) Following a determination that a State's application for a section 1332 waiver is complete, the Secretary and the Secretary of the Treasury, as applicable, will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input and that does 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.

(2) At the beginning of the Federal notice and comment period, the Secretary will make available through its Web site and otherwise, and shall update as appropriate, public notice that includes all of the following:

(i) The complete application for a section 1332 waiver, updates for the status of the State's application, and any supplemental materials received from the State prior to and during the Federal public notice and comment period.

(ii) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(iii) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(iv) Any public comments received during the Federal public notice and comment period.

(c) *Approval of a section 1332 waiver application.* The final decision of the Secretary and the Secretary of the Treasury, as applicable, on a State

application for a section 1332 waiver will be issued by the Secretary no later than 180 days after the determination by the Secretary and the Secretary of the Treasury, as applicable, that a complete application was received in accordance with § 155.1308.

§ 155.1320 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, as applicable, a State must comply with all applicable Federal laws, regulations, interpretive policy statements and interpretive guidance unless expressly waived. A State must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) A State must comply with the terms and conditions of the agreement between the Secretary, the Secretary of the Treasury, as applicable, and the State to implement a section 1332 waiver.

(b) *Implementation reviews.* (1) The terms and conditions of an approved section 1332 waiver will provide that the State will perform periodic reviews of the implementation of the section 1332 waiver.

(2) The Secretary and the Secretary of the Treasury, as applicable, will review documented complaints that a State is failing to comply with requirements specified in the terms and conditions of any approved section 1332 waiver.

(3) The Secretary and the Secretary of the Treasury, as applicable, will promptly share with a State any complaint that the Secretary and the Secretary of the Treasury has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within at least 6 months after the implementation date of a section 1332 waiver and annually thereafter, a State must hold a public forum to solicit comments on the progress of a section 1332 waiver. The State must hold the public forum at which members of the public have an opportunity to provide comments and must provide a summary of the forum to the Secretary as part of the quarterly report specified in § 155.1324(a) that is associated with the quarter in which the forum was held, as well as in the annual report specified in § 155.1324(b) that is associated with the year in which the forum was held.

(1) The State must publish the date, time, and location of the public forum in a prominent location on the State's public web site, at least 30 days prior to the date of the planned public forum.

(2) [Reserved]

(d) *Terminations and suspensions.* The Secretary and the Secretary of the Treasury, as applicable, reserve the right to suspend or terminate a section 1332 waiver in whole or in part, at any time before the date of expiration, whenever the Secretary or the Secretary of the Treasury, as applicable, determines that a State has materially failed to comply with the terms of a section 1332 waiver.

(e) *Closeout costs.* If all or part of a section 1332 waiver is terminated or suspended, or if a portion of a section 1332 waiver is withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination, suspension, or withdrawal, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) A State must fully cooperate with the Secretary, the Secretary of the Treasury, as applicable, or an independent evaluator selected by the Secretary or the Secretary of the Treasury, as applicable, to undertake an independent evaluation of any component of a section 1332 waiver.

(2) As part of this required cooperation, a State must submit all requested data and information to the Secretary, the Secretary of the Treasury, as applicable, or the independent evaluator.

§ 155.1324 State reporting requirements.

(a) *Quarterly reports.* A State must submit quarterly reports to the Secretary in accordance with the terms and conditions of the State's section 1332 waiver. These quarterly reports must include, but are not limited to, reports of any ongoing operational challenges and plans for and results of associated corrective actions.

(b) *Annual reports.* A State must submit an annual report to the Secretary documenting all of the following:

(1) The progress of the section 1332 waiver.

(2) Data on compliance with section 1332(b)(1)(A) through (D) of the Affordable Care Act.

(3) A summary of the annual post-award public forum, held in accordance with § 155.1320(c), including all public comments received at such forum regarding the progress of the section 1332 waiver and action taken in response to such concerns or comments.

(4) Other information consistent with the State's approved terms and conditions.

(c) *Submitting and publishing annual reports.* A State must submit a draft annual report to the Secretary no later than 90 days after the end of each waiver year, or as specified in the waiver's terms and conditions.

(1) Within 60 days of receipt of comments from the Secretary, a State must submit to the Secretary the final annual report for the waiver year.

(2) The draft and final annual reports are to be published on a State's public web site within 30 days of submission to and approval by the Secretary, respectively.

§ 155.1328 Periodic evaluation requirements.

(a) The Secretary and the Secretary of the Treasury, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of the Treasury, as applicable, and any terms and conditions governing the section 1332 waiver.

(b) Each periodic evaluation must include a review of the annual report or reports submitted by the State in accordance with § 155.1324 that relate to the period of time covered by the evaluation.

Authority: Sec. 1332 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

Approved: January 26, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: January 30, 2012.

Kathleen Sebelius,

Secretary of Health and Human Services.

Emily S. McMahon,

Acting Assistant Secretary (Tax Policy), Department of the Treasury.

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