from those other changes occurring in the State at the same time through the use of comparison or control groups to identify the impact of significant aspects of the demonstration.

(v) A proposed date by which a final report on findings from evaluation activities conducted under the evaluation plan must be submitted to CMS.

(vi) Any other information pertinent to the State's research on the policy operations of the demonstration operations.

(d) *Evaluations for demonstration extensions.* (1) In the event that the State requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the State must submit an interim evaluation report as part of the State's request for a subsequent renewal of the demonstration.

(2) State evaluations must be published on the State's public Web site within 30 days of submission to CMS.

(e) *Approved evaluation designs.* The State must publish the CMS-approved demonstration evaluation design on the State's public Web site within 30 days of CMS approval.

(f) *Federal evaluations.* The State must comply with all requirements set forth in this subpart.

(g) *Federal public notice.* CMS will post, or provide a link to the State's public Web site, all evaluation materials, including research and data collection, on its Web site for purposes of sharing findings with the public within 30 days of receipt of materials.

§ 431.428 Reporting requirements.

(a) *Annual reports.* The State must submit an annual report to CMS documenting all of the following:

(1) Any policy or administrative difficulties in the operation of the demonstration.

(2) The status of the health care delivery system under the demonstration with respect to issues and/or complaints identified by beneficiaries.

(3) The impact of the demonstration in providing insurance coverage to beneficiaries and uninsured populations.

(4) Outcomes of care, quality of care, cost of care and access to care for demonstration populations.

(5) The results of beneficiary satisfaction surveys, if conducted during the reporting year, grievances and appeals.

(6) The existence or results of any audits, investigations or lawsuits that impact the demonstration.

(7) The financial performance of the demonstration.

(8) The status of the evaluation and information regarding progress in achieving demonstration evaluation criteria.

(9) Any State legislative developments that may impact the demonstration.

(10) The results/impact of any demonstration programmatic area defined by CMS that is unique to the demonstration design or evaluation hypothesis.

(11) A summary of the annual post-award public forum, including all public comments received regarding the progress of the demonstration project.

(b) *Submitting and publishing annual reports.* States must submit a draft annual report to CMS no later than 90 days after the end of each demonstration year, or as specified in the demonstration's STCs. The State must publish its draft annual report on its public Web site within 30 days of submission to CMS.

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

(2) The final annual report is to be published on the State's public Web site within 30 days of approval by CMS.

Authority: Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program.

Dated: March 9, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 15, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–4354 Filed 2–22–12; 11:15 am]

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DEPARTMENT OF THE TREASURY

31 CFR Part 33

RIN 1505–AC30

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 155

[CMS–9987–F]

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: Final rule.

SUMMARY: This final 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: These regulations are effective on April 27, 2012.

FOR FURTHER INFORMATION CONTACT:

Department of the Treasury: Cameron Arterton, (202) 622–0044.

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary:

A. Purpose of the Regulatory Action

Section 1332(a)(4)(B) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148, enacted on March 23, 2010), requires the Secretary of Health and Human Services (HHS) and the Secretary of the Treasury (the Secretaries) to issue regulations regarding procedures for Waivers for State Innovation under section 1332 of the Affordable Care Act. On March 14, 2011, the Secretaries published proposed rules to satisfy this requirement. This finalizes those proposed rules.

B. Summary of the Major Provisions of the Regulatory Action in Question

These final rules make a small number of changes to the proposed rules based on comments received from the public. We have removed a requirement for applications to be submitted in printed format, to reduce administrative burden. We have clarified that evidence of the State public notice and comment must include, "a description of the key issues raised * * *" during such period, to provide the Secretaries with a summary of public consultation to date. We have added a provision to specify that States must submit waiver applications sufficiently in advance of the requested effective date to ensure that an appropriate amount of time is available for implementation if the waiver is approved. We have also added a provision to specify that a complete application must include an implementation timeline, to facilitate an analysis by States and the Secretaries regarding the feasibility of the proposed implementation schedule. We have also clarified that a State does not have to enact a new law in support of a section 1332 waiver if the State already has a

law in place, to eliminate the need for redundant legislative activities.

Lastly, we have made some structural changes to one section of the rules to reduce complexity, without modifying the content.

C. Costs and Benefits

These regulations are not economically significant, under section 3(f) of Executive Order 12866.

II. Background

Section 1332 of the Affordable Care Act creates a new Waiver for State Innovation and authorizes 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 tax penalties for the failure 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 HHS 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 the 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 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 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 (the Act)) or the Children's Health Insurance Program (CHIP, title XXI of the 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 (CHIP) of the 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.

Proposed rules were issued on March 14, 2011, to implement the procedural requirements of section 1332 of the Affordable Care Act. The proposed rules were also 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 Act.

III. Summary of the Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

In the March 14, 2011 **Federal Register** (76 FR 13553), we published proposed rules addressing the procedural requirements of section 1332 of the Affordable Care Act. We received a total of 32 timely comments on the proposed rules. The modifications to the proposed regulations that are included in these final regulations reflect consideration of the comments submitted.

A. Basis and Purpose (31 CFR 33.100 and 45 CFR 155.1300)

To implement the provisions of section 1332 of the Affordable Care Act, the Department of the Treasury proposed to add new part 33 to 31 CFR Subtitle A and the CMS, on behalf of HHS, proposed to add new part 155 to 45 CFR Subtitle A. These new parts 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.

The final regulations make no change to the proposed regulations regarding these provisions.

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

The proposed regulations at 31 CFR 33.102 and 45 CFR 155.1302 permitted, but did 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 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]

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

The proposed regulations required a State seeking a section 1332 waiver to submit a waiver application to the Secretary of HHS. Upon receipt, the Secretary of HHS would transmit any 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 the regulations. The Secretaries would 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 HHS and the Treasury (the Departments).

We received the following comments concerning the proposed coordinated waiver process.

Comment: Commenters supported the proposal to permit the submission of a single, coordinated application for a section 1332 waiver and a waiver under one or more of the existing waiver processes. Several commenters asked that we provide more detail on the coordinated waiver process, and align procedures and timelines. One commenter also asked that we allow States to submit a single analysis of cost and coverage to satisfy both processes.

Response: The Departments plan to work closely with States that are considering submitting multiple waivers to craft a process that meets a State's specific circumstances. We anticipate that there may be opportunities to streamline and align the processes. We also are mindful that each of the specific waiver provisions has unique statutory requirements. We encourage any State that is considering a coordinated submission to approach the Departments as soon as is practicable to discuss how best to proceed to minimize administrative complexity while ensuring that the integrity of the review and approval processes is maintained.

Comment: One commenter requested that the Secretaries require public comment on the market impacts of a combined waiver application.

Response: We agree that public comment of this sort is useful, and we believe that 31 CFR 33.112 and 45 CFR 155.1312 of the proposed regulations, as finalized, allow stakeholders to provide such comments.

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

The proposed regulations established 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, each application for an initial section 1332 waiver will undergo a preliminary review by the Secretaries that will be completed within 45 days after the application is submitted.

During this preliminary review period, the Secretaries would 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 determined that an application is incomplete, the Secretary of HHS would send the State a written notice of the elements missing from the application. The proposed regulations provided 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.

The proposed regulations provided that a submitted application would not be considered received until the Secretaries have made this preliminary determination that the application is complete.

The proposed regulations provided that, upon a preliminary determination by the Secretaries that an application they have received is complete, as defined under the proposed regulations, the Secretary of HHS would 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 would 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 would 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 enacted 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:
  + As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), would 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 & 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;
  + As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), would 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;
  + As required under section 1332(b)(1)(B)(C) of the Affordable Care Act (the scope of coverage requirement), would 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
  + As prohibited under section 1332(b)(1)(D) of the Affordable Care Act (the Federal deficit requirement), would not 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 regulations required 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 solicited comments on whether a State should be required to submit an application at least 12 months in advance of the requested effective date, to allow for the effective implementation of approved waivers at the State level.

The requirement in the proposed regulations that a State provide certain analysis, certifications, data, assumptions, targets and other information as part of a section 1332 waiver application was 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 solicited 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 provided 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.

We received the following comments concerning application procedures.

1. Application Contents

Comment: In general, commenters supported the proposed application contents. Several commenters asked that the Secretaries require additional information to be submitted with the application, including background information on the State's insurance market; the types of health plans or other arrangements a State will utilize to provide coverage and the criteria for participation in the plan; the health benefits that will be covered and how those compare to the essential health benefits specified in section 1302(b) of the Affordable Care Act; whether and how the waiver will affect age rating and the value of financial assistance for individuals of different ages; how the waiver will affect children and youth with special health care needs and women with high-risk pregnancies; how the State will select the plans and monitor their performance; how payment rates for health plans and/or providers would be determined; how standards for provider network adequacy would be determined and met; how quality and appropriateness of care would be assessed; and how transparency in coverage and consumer choice and access to essential community providers would be monitored.

Commenters also requested that the Secretaries require a State to provide specific information for specific waiver requests. For example, one commenter asked that the Secretaries require a State seeking a waiver that would affect Federally Qualified Health Centers (FQHCs) or essential community providers (ECPs) to provide a set of detailed information about the rationale for such a proposal and the financial impact of it on FQHCs and ECPs. Another made a similar request with respect to waivers that affect essential health benefits.

Response: We recognize that additional information may be needed to determine whether a proposal meets the statutory criteria for approval. As set forth in 31 CFR 33.108(a)(2)(iv)(D)(6) and 45 CFR 155.1308(a)(2)(iv)(D)(6), a State must also submit information consistent with guidance provided by the Secretaries, in addition to the enumerated data and analyses. This provision of the regulations allows the

Secretaries to request additional information, including information suggested by commenters, which is relevant to determine whether a waiver proposal meets the statutory criteria for approval. As such, we finalized these provisions of the proposed regulations without change.

Comment: One commenter requested that States provide an implementation timeline as part of a waiver application.

Response: We agree with this comment and have added language to the final regulation in 31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv). We believe that the inclusion of an implementation timeline will help the Secretaries work with States to address the concern raised by another commenter that States implement a waiver in a manner that does not leave its residents without affordable coverage during the implementation period.

Comment: Several commenters asked the Secretaries to require States to provide a description of why the requested waivers are needed.

Response: We agree that a discussion of the reasons for requesting the waiver is important and should be more than cursory. Accordingly, the final regulation at 31 CFR 33.108(a)(2)(iv)(C) and 45 CFR 155.1308(a)(2)(iv)(C) no longer characterizes the required description as "brief."

Comment: One commenter asked that the Secretaries permit the application to use existing reports and data sources available to the Federal government.

Response: We agree that the process should be minimally burdensome for all involved entities, while still ensuring that the Secretaries are able to complete the analyses required by statute. We encourage States to utilize existing data wherever possible to facilitate the waiver approval process and we look forward to working closely with States to ensure that the proposed data sources are reliable and acceptable.

Comment: Several commenters asked that the Secretaries require applications to include a description of the key issues raised during the State public notice and comment period, along with how the State considered those comments in developing the application.

Response: The provisions of 31 CFR 33.108(a)(2)(iv)(B) and 45 CFR 155.1308(a)(2)(iv)(B) of the proposed regulations require an application to provide, "* * * written evidence of the State's compliance with the public notice requirements * * *" We agree with the commenter that this evidence should include a description of the key issues raised during the State public notice and comment period, and are adding this clarification to 31 CFR 33.108(f)(2) and 45 CFR 155.1308(f)(2) of the final rule. We believe that the substantive contents of the application will allow the Secretaries and interested parties to discern how the State considered the comments in constructing the proposal.

Comment: Commenters asked that the Secretaries clarify that in addition to providing the proposed actuarial and economic analyses, a State must also provide the underlying data and assumptions used to develop the analyses.

Response: We believe that the provisions of the proposed regulations require the State to submit the underlying data and assumption used to develop the analysis. The proposed regulations at 31 CFR 33.108(a)(2)(iv)(D)(3) and 45 CFR 155.1308(a)(2)(iv)(D)(3) specified that an application must include, "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." We are maintaining this language in the final regulations.

Comment: One commenter suggested that the Secretaries limit the amount of documentation required to be submitted if the waiver proposal does not significantly impact the stability of the insurance market.

Response: The statute requires the Secretaries to determine whether an application meets all the statutory approval criteria, regardless of its scope. Consequently, the Secretaries must receive and review the data and analyses required to be included in the application as provided in the regulations. We have no interest in requiring States to submit unnecessary information, and will work with States to ensure that the application process is appropriately tailored to the specific proposal and to the State's circumstances.

Comment: One commenter asked that the Secretaries require that all actuarial estimates of coverage and market stability be performed by independent experts.

Response: The Secretaries plan to evaluate the analyses submitted with a State's application. We expect the State analyses to adhere to generally accepted standards for quality and the regulations require the States to submit the data and assumptions underlying such analyses, which will enable the Secretaries to conduct a thoughtful review. As such, the final regulations follow the proposed regulations without change.

Comment: One commenter asked the Secretaries to clarify that there is interaction between the statutory requirements for approval of a section 1332 waiver, for example, that the affordability of coverage will affect the number of individuals who will be covered.

Response: We agree with the comment. We expect States to address such connections in the analyses supporting an application.

Comment: One commenter asked that the Secretaries require that any application that requested a waiver of the minimum coverage provision be accompanied by detailed projections demonstrating that comparable levels of coverage and affordability will be attained and maintained over at least a 10-year period in the individual market.

Response: We appreciate this comment. The Secretaries intend to work with States to ensure that the required analyses are consistent with one another. For future guidance, we will consider requiring an analysis for applications requesting a waiver of specific provisions to be provided over a specific time frame.

Comment: One commenter objected to proposed questions regarding the impact of a proposed waiver on unwaived provisions and how the State will provide the Federal government with information necessary to administer the waiver at the Federal level.

Response: We believe that these questions are important to assess whether the proposal complies with the statutory criteria for approval. In particular, we believe that the question about Federal administration is important to understand the impact of the proposal on the Federal deficit.

Comment: One commenter suggested that the Secretaries require States to provide analysis to ensure that proposed innovations do not have the unintended effect of increasing the cost of insurance for the remaining market and decreasing enrollment.

Response: The analyses in 31 CFR 33.108(a)(2)(iv)(C)(4) and 45 CFR 155.1308(a)(2)(iv)(C)(4) of the proposed rules were based on the statutory criteria for waiver approval, as specified in section 1332(b)(1) of the Affordable Care Act. In describing the scope of coverage and affordability requirements, the statute specifies that comparisons are to be made with respect to the provisions of title I of the Affordable Care Act, which contains the market reform provisions that affect the individual and small group markets—

inside and outside the Exchange. Consequently, we believe that the provisions of the proposed regulations specified that a State must provide the type of analysis that is requested by the commenter. We maintain this language in the final regulations.

2. Timing of Applications

Comment: We received a number of comments regarding whether the Secretaries should require a State to submit an application for a section 1332 waiver 12 months (or some other amount of time) in advance of the requested effective date, to allow for the careful implementation of what may be complex waivers. In general, commenters supported a timing requirement of either 12 or 24 months in advance. However, some commenters opposed any timing requirement. In addition, one commenter asked that the Secretaries require at least 18 months between approval and implementation.

Response: In recognition of the range of time standards recommended by commenters, along with the likelihood that the scope of section 1332 waivers will vary widely based on the provisions a State proposes to waive and other related factors, we are amending the proposed language to specify that applications must be submitted sufficiently in advance of the requested effective date to allow for an appropriate implementation timeline. In addition, as discussed previously, the final regulations adopt a recommendation to include an implementation timeline as part of the waiver application. We believe this new timeline requirement will help ensure applications are submitted sufficiently in advance of the effective date. We further encourage States to contact the Secretaries during the conceptual phase of a section 1332 waiver to establish a reasonable timeframe for the submission of an application and the effective date of an approved proposal.

Comment: One commenter asked the Secretaries to clarify that there can only be one 45-day preliminary review period per application.

Response: We agree with the commenter's clarification. We note that to the extent that a State's application is denied and the State resubmits the application, the Secretaries will treat the application as a new application that is subject to a 45-day preliminary review period.

3. Approval Standards

We received a number of comments regarding standards a section 1332 waiver proposal must meet to be approved by the Secretaries. The proposed regulations covered only the procedural standards for section 1332 waivers, and did not address the substantive standards for approval beyond restating the statutory criteria.

Comment: Several commenters asked that the Secretaries define the comprehensive-coverage, affordability, and scope of coverage requirements specified in sections 1332(b)(1)(A), (B), and (C) of the Affordable Care Act. One commenter proposed a specific framework for the comprehensive-coverage standard based on the service categories specified in section 1302(b) of the Affordable Care Act, along with other analyses. Another commenter asked that the Secretaries clarify that affordability benchmarks will take into account the income of eligible individuals and the premium and cost-sharing subsidies they would receive. Another commenter asked that affordability analyses include consideration of services that are excluded from the proposed waiver. Lastly, one commenter asked that the Secretaries provide benchmarks for the scope of coverage analysis and allow public comment on such benchmarks.

Commenters suggested that the Secretaries should expand the criteria for approval to include providing a sufficient choice of health plans. One commenter specified that the Secretaries should require the State to ensure a selection of health plans that meet the needs of low-income individuals. Another commenter asked that States be required to demonstrate the adequacy of provider networks as a condition of approval.

Commenters also suggested that the Secretaries condition waiver approval on the inclusion of specific services and categories of services in the benefit package; the coordination of private and public delivery systems; the integration of enrollment and renewal processes; and the ability of delivery systems to measure acuity and severity and adjust cost structures appropriately.

One commenter asked the Secretaries to specify that if any waiver alters Medicaid and CHIP, a State must maintain Medicaid and CHIP protections and "enabling services" (such as transportation and translation) for the Medicaid and CHIP population. Another commenter asked the Secretaries to require States to demonstrate adequate protections for Medicaid beneficiaries who are included in a section 1332 waiver. Another commenter asked the Secretaries to require that States provide children who are currently covered by CHIP with coverage, cost-sharing protections, and benefits comparable to CHIP.

A commenter asked that the Secretaries require States seeking a waiver to provide for a similar age rating rule to the rule in section 1334 of the Affordable Care Act.

Commenters also asked that the Secretaries require States to comply with other provisions of the Affordable Care Act as a condition of waiver approval. These included the nondiscrimination provisions of section 1557 of the Affordable Care Act and the market reform rules that take effect in 2014.

One commenter said that States and the Secretaries must consider whether a proposal meets the statutory requirements for approval for both the overall population and specifically for American Indians and Alaska Natives.

Lastly, one commenter asked the Secretaries to require the CMS actuary to certify whether a State's proposal would provide coverage to a comparable number of residents purchasing individual insurance policies.

Response: We appreciate the comments submitted on standards for approval and will consider them as we develop the substantive component of the waiver approval process. Further, we clarify that section 1332(a)(2) of the Affordable Care Act clearly defines the scope of authority under section 1332, and does not extend to subtitle A of title I of the Affordable Care Act, which includes the market reform provisions, or section 1557 of the Affordable Care Act, which includes the nondiscrimination provisions.

4. General

Comment: Commenters asked the Secretaries to clarify that a State does not have to enact a new law and establish new programs if a sufficient law or program already exists.

Response: We agree with this comment. The final regulations at 31 CFR 33.108(f)(3)(ii) and 45 CFR 155.1308(f)(3)(ii) were modified to make clear that States with an existing law or program that addresses the waiver process and requirements are not required to enact a new law.

Comment: One commenter suggested that the Secretaries consider not requiring applications to be submitted in printed format.

Response: We agree with the commenter's suggestion, and are removing this requirement from the final rules.

Comment: One commenter asked the Secretaries to specify that they will process all submitted applications.

Response: We agree with the comment and believe that the proposed regulations address it. As set forth in 31 CFR 33.108(a)(2) and 45 CFR 155.1308(a)(2), the Secretaries will make a determination as to whether each submitted application is complete, and 31 CFR 33.116(c) and 45 CFR 155.1316(c) of the proposed rules specified that the Secretaries will make a final decision regarding all applications that are found to be complete. We are maintaining these provisions in the final regulations.

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 required 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 required 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 public notice and comment period, the proposed regulations required a State to provide the public with the following information 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 required 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.

We received the following comments concerning the proposed State public notice and comment process.

1. Timing

Comment: In general, commenters expressed support for a robust State public notice and comment process. Several commenters suggested that the Secretaries should specify a minimum amount of time for the State public notice and comment process, ranging from 45 to 90 days.

Response: We agree with commenters that the State public notice and comment period is an important element of a transparent approach. The proposed regulations require that the State public notice period be, "sufficient to ensure a meaningful level of public input". Because section 1332 waiver applications may take on a wide range of proposals, we believe that this approach better suits section 1332 waivers. To the extent that a proposal is particularly wide-ranging, the proposed regulations will support a longer State public notice and comment period, and if the proposal is minor, it can support a shorter period. As such, we are maintaining the language of the proposed regulations in the final rules. We further encourage States to contact the Secretaries during the conceptual phase of a section 1332 waiver to establish a reasonable timeframe for the State public notice and comment period.

2. Tribal Consultation

Comment: One commenter suggested that the Secretaries encourage States to use Medicaid tribal consultation procedures in the section 1332 waiver process.

Response: As set forth in 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2), a State with one or more Federally-recognized tribes within its borders must conduct a separate process for meaningful consultation with such tribes as part of the State public notice and comment process. In the preamble associated with this section, the Secretaries noted that such process is in accordance with Executive Order 13175, which mandated the establishment of regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have "tribal implications," which are defined as policies or actions "with substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." As this executive order also applies to Medicaid, a State could use a Medicaid consultation process to satisfy the consultation needed for a section 1332 waiver. We agree with the commenter and encourage States to consider whether the use of such a process would be appropriate for section 1332 proposals.

3. Public Hearings

Comment: Commenters supported the requirement for public hearings. Commenters suggested allowing States to determine the appropriate number of public hearings, with a minimum of one or two. One commenter asked the Secretaries to specify that hearings must happen in multiple geographic locations.

Response: As set forth in 31 CFR 33.112(c)(1) and 45 CFR 155.1312(c)(1), "* * * a State must conduct public hearings regarding the State's application." We believe that the proposed regulation permits a State to determine the appropriate number of hearings, but, by definition, "hearings" means no less than two. As such, the final regulations were not changed.

31 CFR 33.112(c)(2) and 45 CFR 155.1312(c)(2) provides that "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." We interpret this to mean that a State must provide the opportunity for parties throughout a State to comment, either through multiple hearings in different locations, or through the use of phone or videoconferencing. We will maintain this provision in the final regulations.

Comment: Commenters supported the provisions in 31 CFR 33.112(c)(2) and

45 CFR 155.1312(c)(2) that specify that public hearings must provide an opportunity for an interested party to comment on the contents of an application for a section 1332 waiver. One commenter recommended that the Secretaries specify that legislative hearings can substitute for the State public notice and comment process. Other commenters opposed this recommendation, noting that legislative hearings may provide only limited opportunities for members of the public to comment.

Response: While the proposed rules do not specifically address whether legislative hearings may satisfy the public hearing requirement, 31 CFR 33.112(c)(2) and 45 CFR 155.1312(c)(2) of the proposed regulation provide that, "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." If a legislative hearing provides an opportunity for interested parties to comment on the contents of a waiver application, then it meets the public hearing requirement; if, however, a legislative hearing does not allow the public to contribute, it does not meet the requirement. Specifically, we believe that to use a legislative hearing towards meeting this requirement, a State would need to provide a concrete proposal for comment well in advance of the hearing, as well as an opportunity for the public to speak at the hearing. We are maintaining this approach in the final regulations to provide States with flexibility but at the same time ensure that the public has a meaningful opportunity to comment.

4. General

Comment: One commenter recommended that the Secretaries require consumers to be full participants as waivers are designed, implemented, and monitored, and that such participation should include serving on an advisory board and a governing board.

Response: We agree with the commenter that States should involve consumers in the development, implementation, and monitoring of section 1332 waivers. We believe that the proposed State and Federal public notice and comment processes, along with the post-award public forum provision, ensure formal opportunities for participation. To ensure that consumers can participate, we clarify that the State public notice and comment process, the post-award public forum, and the draft and final annual reports published on a State's public Web site must comply with applicable civil rights requirements for accessibility, which are discussed in the preamble to this section. We also note that we expect that States will inform consumers and other interested parties regarding the availability of auxiliary aids and services for public forums.

We encourage States to consider where other opportunities for consumer involvement exist. Given that section 1332 waivers may be broad or narrow in scope, we have not modified the proposed regulation to add a provision requiring the establishment of advisory or governing boards. We believe that such a requirement would be overly burdensome for a State seeking a waiver that is limited in scope. We will work closely with States to ensure that the State public notice and comment process is sufficient to ensure a meaningful level of public input, as proposed in 31 CFR 33.112(a)(1) and 45 CFR 155.1312(a)(1).

Comment: A commenter asked that the Secretaries require that a State send a copy of any waiver proposal affecting FQHCs or ECPs directly to each FQHC in the State as well as to the State primary care association, and that the State allow the primary care association and at least two FQHCs time to speak at the public hearing.

Response: We acknowledge the critical role that FQHCs and ECPs have in providing services to low-income and other vulnerable populations. Given the potentially broad scope of section 1332 waivers, the Secretaries opted to take a broad approach to describing the State public notice and comment process in the proposed rules, to ensure that it would remain flexible to accommodate comments from all key stakeholders. The provisions of 31 CFR 33.112(a)(1) and 45 CFR 155.1312(a)(1) specify that, "a State must provide public notice and comment period sufficient to ensure a meaningful level of public input * * *" This will give FQHCs, ECPs, and other interested or affected stakeholders an opportunity for engagement.

Comment: A few commenters asked the Secretaries to clarify that the description of the proposal that is shared with the public must include specific details of the proposal, including analyses of financing and enrollment.

Response: We agree with the commenters that this information is important to ensuring that stakeholders have an opportunity to provide meaningful input. As set forth in 31 CFR 33.112(b)(1) and 45 CFR 155.1312(b)(1), the public notice must include the following: "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." We believe that this provision addresses the commenters' recommendations by ensuring that the public will have access to in-depth information needed to assess the impact of the proposal. We also retain the flexibility to clarify this provision in future guidance to address any areas in which additional information is needed to ensure that the State public notice and comment period is sufficient to ensure a meaningful level of public input.

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 provided 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.

To facilitate public participation in the section 1332 waiver application process, the proposed regulations required 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 would 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 would be issued by the Secretary of HHS.

We received the following comments concerning the proposed Federal public notice and approval process.

1. Federal Public Notice Process

Comment: Commenters suggested that the Secretaries post applications and supporting materials on a dedicated Web site.

Response: As set forth in 31 CFR 33.116(b)(2) and 45 CFR 155.1316(b)(2), the Secretary of HHS, " * * * will make available through its Web site and otherwise, and shall update as appropriate, public notice * * *." The proposed rules list the contents of this public notice, which include applications and supporting materials. We will consider whether to implement this requirement through a dedicated Web site, or through a page on the main HHS or CMS Web site.

Comment: Several commenters asked that the Secretaries require a specific length for the Federal public notice and comment period. One commenter suggested 45 days.

Response: We agree with commenters that the Federal public notice and comment period is an important element of a transparent approach. The proposed regulations require that the Federal public notice period be, "sufficient to ensure a meaningful level of public input." Because the waiver applications may cover a wide range of proposals, we believe that this approach better suits section 1332 waivers. To the extent that a proposal is particularly wide-ranging, the proposed regulation will support a longer Federal public notice and comment period, and if the proposal is minor, it can support a shorter period. As such, we are maintaining the language of the proposed regulations in the final rules.

Comment: Commenters suggested that the Secretaries create an electronic mailing list to notify interested parties of the submission of an application and other actions taken.

Response: We will consider this suggestion as we develop the details of the Federal public notice and comment process.

Comment: Commenters asked that the Secretaries specify that the Secretaries will electronically publish all comments received during the Federal public notice and comment process.

Response: We agree with the commenter's suggestion. This provision was included in 31 CFR 33.116(b)(2)(iv) and 45 CFR 155.1316(b)(2)(iv) of the proposed regulations, and we will maintain this in the final regulations.

Comment: One commenter suggested that the Secretaries modify the proposed process to incorporate a notification of the State primary care association in any State that is requesting to waive provisions related to FQHCs, and to require the Secretaries to provide written responses related to comments on this topic, as well as explanations and supporting information related to the approval of any proposal that contains such provisions.

Response: We acknowledge the critical role that FQHCs have in providing services to low-income and other vulnerable populations. Given the potentially broad scope of section 1332 waivers, the Secretaries opted to take a broad approach to describing the Federal public notice and comment process in the proposed rules, to ensure that it would remain flexible to accommodate comments from all key stakeholders. 31 CFR 33.116(b)(1) and 45 CFR 155.1316(b)(1) specified that, "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 * * *" This will give FQHCs, ECPs, and other interested or affected stakeholders an opportunity for engagement.

Comment: One commenter expressed concerns as to whether comments from entities outside a State requesting a waiver would be applicable to the State's proposal.

Response: We recognize that entities within a State requesting a waiver are well positioned to contribute meaningful comments; we also recognize that there are entities throughout the country that will have an interest in and expertise in the topics of waiver proposals, particularly to the extent that a State's waiver proposal could affect other States. In the interests of creating a transparent process, the Secretaries will consider all comments submitted during the Federal public notice and comment period, and make decisions in accordance with the statutory criteria for approval.

2. Approval Process

Comment: One commenter suggested that the Secretaries establish a waiver review panel that consists of consumers, providers, and federal and nongovernmental technical experts to review testimony and comments and make recommendations regarding the approval of a waiver.

Response: We will consider this suggestion, along with other approaches to creating an efficient and transparent process, as we move closer to the point at which States will begin to develop section 1332 proposals.

Comment: Commenters asked for clarification on how the Secretaries would implement the 180-day Federal decision-making period. One commenter suggested that the Secretaries should allow reasonable adjustments to an application without affecting timeframes, when the adjustments are the result of State-Federal negotiations. Another commenter asked the Secretaries to clarify whether the provision allowing the Secretaries to determine an application incomplete after first determining it complete was purposeful, and asked for the Secretaries to revise this provision such that it would not affect the 180-day Federal decision-making period.

Response: The Secretaries intend to develop protocols related to the Federal decision-making process that are responsive to the needs of each State and promote efficiency and transparency. These protocols may vary from proposal to proposal, and will certainly evolve as States and the Secretaries gain additional expertise in navigating the process. We will strive to ensure clear and open lines of communication between a State and the Secretaries throughout the Federal decision-making process.

We agree with the comment regarding the allowance to modify an application without affecting the timeframe as a result of negotiation. We anticipate that this will be a regular occurrence during the Federal decision-making period, and that making agreed-upon changes as the process moves forward will facilitate an efficient process for all involved parties.

We clarify that the provision in 31 CFR 33.108(a)(2)(i)(C) and 45 CFR 155.1308(a)(2)(i)(C) of the proposed regulations was indeed purposeful in specifying that a preliminary finding that an application is complete does not preclude the Secretaries from later finding that an application is not complete. We anticipate that conversations between a State and the Secretaries may reveal additional information that is needed to evaluate whether an application meets the statutory requirements for approval. When such a situation occurs without sufficient time for the State to respond before the end of the 180-day Federal decision-making period, the Secretaries can either deny the application or find the application incomplete; we believe that the latter option provides greater flexibility to States, and reduces duplicate burden that would be placed on States and on the Federal government if an application must be

resubmitted. As such, we are maintaining this provision in the final regulations. As noted above, we intend to work closely with States to create an efficient process for waiver approval, and preserve timeframes wherever possible.

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 established processes and methodologies to ensure that the Secretaries receive adequate and appropriate information regarding 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 required 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 would 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 would 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 would 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 six months of the waiver's implementation, and annually thereafter, States were 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 required 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 were 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 reserved 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 determined that the State materially failed to comply with the terms and conditions of the section 1332 waiver. In the event that all or a portion of a section 1332 waiver is terminated or suspended by the Secretaries, or if all or a portion of a section 1332 waiver is withdrawn, Federal funding would be 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 undertook 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 would include, but is not limited to, the submission of all necessary data and information to the Secretaries or the independent evaluator.

We received the following comments concerning the proposed provisions regarding monitoring and compliance.

1. Post-Award Public Forum

Comment: In general, commenters supported the proposal for an annual public forum. Some commenters requested that the Secretaries provide additional detail on the post-award public forum requirement, including requiring the development of a formal advisory body similar to the Medical Care Advisory Committee (MCAC). Commenters also asked the Secretaries to clarify that the public must have an opportunity to comment at a post-award public forum, and that the Secretaries should require States to publish the date, time, and location of public forums in the State equivalent of the **Federal Register**.

Response: We believe that it is appropriate to provide a State with flexibility to determine the appropriate public forums. Consequently, we have not added a provision requiring a State to establish an advisory board. Further, given the possibility for section 1332 waivers to be broad or narrow in scope, we want to avoid requiring the creation of burdensome structures.

We agree with commenters that the public should have an opportunity to comment at a post-award public forum, which was reflected in 31 CFR 33.120(c) and 45 CFR 155.1320(c) of the proposed regulations. We are maintaining this provision in the final regulations.

We also agree that the public should have notice of a public forum. As set forth in 31 CFR 33.120(c)(1) and 45 CFR 155.1320(c)(1), a State must publish the date, time, and location of a post-award public forum in a prominent location on the State's public Web site at least 30 days prior to the forum. We believe that a State's public web site is a more effective means of communication to the public than a State's equivalent of the **Federal Register**, and as such, will maintain this provision in the final regulation. With that said, we encourage States to publish the notice of a post-award forum in other locations that will ensure appropriate public notice.

Comment: One commenter asked that the Secretaries consider delaying the initial post-award public forum and removing the requirement after 2 to 3 years of operation, with the potential to trigger forums when changes occur.

Response: We support the commenter's desire to reduce burden on States. However, we believe that post-award forums will be critical to ensuring that public has a regular opportunity to learn about and comment on the progress of a waiver. As such, we are maintaining this provision in the final regulations.

2. General

Comment: One commenter suggested that 31 CFR 33.120(a) be modified to remove the term "interpretive guidance." The commenter stated that States should be subject only to "laws, regulations, and interpretive policy that have been published and are of general applicability.

Response: We believe that the authority available to States under section 1332 demands that the Federal government have a broad set of tools for ensuring ongoing compliance with the statutory criteria for the approval of waivers and providing needed clarifications to States, including interpretive guidance. With that noted, we will work closely with States to provide as much advance notice as possible of upcoming guidance that

affects waivers, as well as to incorporate State input in crafting such guidance where possible.

Comment: A commenter asked the Secretaries to reduce Federal discretionary authority to discontinue waivers.

Response: As set forth in 31 CFR 33.120(d) and 45 CFR 155.1320(d), the Secretaries' authority to terminate or suspend a waiver is limited to situations in which the Secretaries find, "* * * that a State has materially failed to comply with the terms of a section 1332 waiver." We believe that this provision is sufficiently limited and is critical to ensuring that Federal dollars are spent in accordance with applicable rules. As such, we will maintain this provision in the final regulations.

Comment: One commenter asked that the Secretaries require States to develop a transition plan that would allow the public to continue to have access to quality, affordable health care should a State's waiver be terminated or suspended.

Response: We agree that it would be useful for States to develop a transition plan, depending on the scope of the approved section 1332 waiver. We will consider including this as a standard component of the terms and conditions of an approved waiver.

Comment: One commenter asked the Secretaries to closely monitor approved waivers to ensure fair and adequate access to and payment for FQHC services.

Response: We believe that there are many areas in which monitoring will be particularly important to ensure that approved waivers continue to meet the statutory criteria for approval. To the extent possible, we will align this monitoring with each State's waiver design to reduce administrative burden.

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 process for the periodic submission of reports by a State concerning the implementation of the program under a section 1332 waiver.

For the Secretaries to effectively monitor the implementation of a waiver, the proposed regulations required a State to submit a quarterly progress report in accordance with the terms and conditions of the State's section 1332 waiver. States were 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 were 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 would be required to submit a final annual report for the waiver year to the Secretary of Health and Human Services. Finally, a State would be required to publish the draft and final annual reports on the State's public web site.

The Secretaries noted that they intended to issue future guidance under section 1332 regarding periodic reports.

We received the following comments concerning the proposed process for State reporting on approved waivers.

Comment: Several commenters requested that the Secretaries require States and the Federal government to publish quarterly and annual reports on State and Federal web sites in a timely fashion.

Response: The provisions of 31 CFR 33.124(c)(2) and 45 CFR 155.1324(c)(2) specify that a State must publish both draft and final annual reports on its public web site. We are maintaining this provision in the final regulations. We will consider the other elements of this comment in developing future guidance on reporting.

Comment: In general, commenters supported the proposed quarterly and annual reporting provisions. Some commenters requested that the Secretaries add specific reporting topics and analyses in regulation, as opposed to addressing this in future guidance.

Response: We appreciate the commenters' detailed suggestions. We are not including additional specificity in the final regulations at this time, given that the rules regarding the underlying provisions are not yet final. We will consider the specific suggestions in developing future guidance on reporting, as well as in crafting the reporting provisions that may be specific to an approved waiver.

Comment: One commenter recommended that the frequency of reporting be reduced from quarterly to semi-annual for the first 2 to 3 years of a waiver period, with annual reporting after that. The commenter also suggested that annual reports be replaced with high-level summaries after the first 2 to 3 years of a waiver period.

Response: We support the commenter's desire to reduce burden on States. However, we believe that given the potentially broad scope of section 1332 waivers, quarterly and annual reporting will be critical to ensuring that the Secretaries can exercise appropriate oversight of approved waivers, and States can formally communicate areas in which best practices have emerged or technical assistance may be needed. We also believe that such reporting is important to enable the Secretaries to calibrate future budgetary estimates. Within this construct, we intend to work with States to ensure that quarterly and annual reporting do not include duplicative or unnecessary information, and are closely aligned to the design of a State's waiver.

Comment: One commenter objected to the provision that allows the Secretaries to review a draft version of the annual report prior to its release to the public.

Response: Consistent with the practice that we are adopting for section 1115 waivers, which is specified in a concurrently issued final rule in 42 CFR 431.428(b), the provisions of 31 CFR 33.124(c)(2) and 45 CFR 155.1324(c)(2) specify that a State must publish the draft annual report on a public Web site within 30 days of submission to the Secretary of HHS. We believe that this is appropriate to allow the State to complete any internal process it has for preparing the document for publication (for example, ensuring that the document meets electronic accessibility standards) and posting it electronically. We are maintaining this provision in the final rules.

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 process for the periodic evaluation of section 1332 waivers by the Secretary or Secretaries with jurisdiction over the provisions for which the waiver was granted. The proposed regulations required that each periodic evaluation 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 solicited public comments regarding specific components of the periodic evaluation

of a section 1332 waiver. The Secretaries noted that 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 noted that they intended to issue future guidance under section 1332 regarding periodic evaluations.

We received the following comments concerning the proposals regarding the evaluation of approved waivers.

Comment: Several commenters asked the Secretaries to include additional specific evaluation criteria in regulation, including, the use of Healthcare Effectiveness Data and Information Set (HEDIS) and the Consumer Assessment of Healthcare Providers and Systems (CAHPS); system-wide, audited quality outcome measures; and metrics on accessibility, cost, health and wellness, administrative expenses, evidence-based practices, and the impact of the waiver on individuals with pre-existing conditions and low-income populations.

Commenters also offered additional suggestions for the evaluation process, including requiring comparisons with States without waivers; requiring that evaluations be conducted by objective, independent, peer-reviewed evaluators at least every 3 years; and allowing States flexibility in constructing evaluations.

Response: We have carefully reviewed the submitted comments and will consider them as we develop guidance on this topic. We intend to work closely with States and stakeholders to ensure that evaluations are aligned with the design and goals of a State's waiver and section 1332.

Comment: Commenters asked that evaluation criteria not necessarily include choice of health plans, to allow evaluation criteria to accommodate different approaches that States may take in section 1332 waivers.

Response: The potential evaluation criteria offered in the preamble to the proposed regulations represents a starting point for the development of guidance on the evaluation of approved section 1332 waivers. We anticipate that the primary focus of the evaluation will be the four statutory criteria for approval specified in section 1332(b)(1) of the Affordable Care Act. As noted above, we intend to work closely with States to ensure that evaluations are aligned with the design and goals of a State's waiver and section 1332.

Comment: Commenters asked that the Secretaries, and not the States, conduct evaluations.

Response: We are maintaining the language in 31 CFR 33.128(a)(1) and 45 CFR 155.1328(a)(1), as the law requires periodic evaluations by the Secretaries. We will consider how best to carry out this responsibility as we develop future guidance related to the evaluation process.

I. Other Comments

We received the following comments, which were not related to a specific section of the proposed regulation.

1. Scope of Waivers

Comment: We received a number of comments that requested that the Secretaries clarify or restrict waiver authority in various ways, including prohibiting States from: imposing more stringent coverage requirements on employers; waiving the minimum coverage provision; waiving provisions related to essential community providers; granting exceptions from the medical loss ratio requirement; or affecting employer-sponsored insurance. One commenter also asked that the Secretaries emphasize the importance of preserving employer-based coverage.

In particular, a number of commenters asked the Secretaries to clarify the interaction between section 1332 waivers and the Employee Retirement Income Security Act (ERISA).

In addition, one commenter asked whether States will be permitted to use redirected premium tax credits and cost-sharing reductions to fund Health Savings Accounts (HSAs).

Response: Section 1332(a)(2) of the Affordable Care Act specifies that waiver authority is limited to parts I and II of subtitle D of the Affordable Care Act; section 1402 of the Affordable Care Act; and sections 36B, 4980H, and 5000A of the Internal Revenue Code. Further, section 1332(c) of the Affordable Care Act states while the Secretaries have broad discretion to determine the scope of a waiver, no Federal laws or requirements may be waived that are not within the Secretaries' authority. As previously noted, we encourage States to contact the Secretaries to discuss specific waiver proposals, particularly after the substantive rules subject to section 1332 waivers are finalized.

2. General

Comment: One commenter asked that the Secretaries include provisions for waiver amendments and renewals, and clarify which requirements apply in these situations. Another commenter recommended that the renewal process include a thorough reevaluation.

Response: We acknowledge that information regarding waiver amendments and renewals will be needed as we move closer to the date on which section 1332 waivers could be effective. However, amendments and renewals are beyond the purview of the proposed rules, which were limited in accordance with section 1332(a)(4)(B) of the Affordable Care Act.

Comment: A commenter asked that the Secretaries clarify that waivers are approved for a fixed timeframe.

Response: We note that section 1332(e) of the Affordable Care Act specifies that the initial term of a section 1332 waiver may not extend longer than five years.

Comment: One commenter asked how HHS will determine the total amount of Federal funding under an approved waiver.

Response: We will provide additional information on this issue as we move closer to the date on which section 1332 waivers could be effective and regulations regarding the underlying provisions are promulgated.

IV. Provisions of the Final Regulations

For the most part, these final rules incorporate the provisions of the proposed rules. Those provisions of these final rules that differ from the proposed rules are as follows:

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

We have clarified that "section 1115 demonstration" in 31 CFR 33.102(a) and 45 CFR 155.1302(a) refers to a demonstration under section 1115 of the Act.

We have replaced the word "and" with the word "or" in 31 CFR 33.102(b) and 45 CFR 155.1302(b) to clarify that the Secretary of Health and Human Services will transmit any proposal that requests to waive one or more of the provisions under the authority of the Secretary of the Treasury to the Secretary of the Treasury.

B. Definitions (31 CFR 33.104 and 45 CFR 155.1304)

We have revised the definition of "Complete application" to reflect structural changes in 31 CFR 33.108 and 45 CFR 155.1308.

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

We have revised 31 CFR 33.108 and 45 CFR 155.1308 substantially to adopt a simpler structural layout. We have revised and added headings and sections for (a), (b), (c), (d), (e), and (f), now titled, "Acceptable formats for applications"; "Application timing"; "Preliminary review"; "Notification of preliminary determination"; "Public notice of completed application"; and, "Criteria for a complete application", respectively. We also made changes to cross-references to reflect the new layout. With the exception of the new headings, revised cross-references, and the below modifications, all content is the same.

We have modified 31 CFR 33.108(a) and 45 CFR 155.1308(a) to remove the requirement that a State submit applications in printed format.

We have added a provision at 31 CFR 33.108(b) and 45 CFR 155.1308(b) to specify that States must submit waiver applications sufficiently in advance of the requested effective date to allow for an appropriate implementation timeline.

We have modified 31 CFR 33.108(f)(2) and 45 CFR 155.1308(f)(2) to clarify that written evidence of the State's compliance with the public notice and comment process includes, "a description of the key issues raised during the State public notice and comment period."

We have amended 31 CFR 33.108(f)(3)(ii) and 45 CFR 155.1308(f)(3)(ii) to clarify that the requirement to provide a copy of a law that provides the State with authority to implement the proposed waiver can be satisfied through the submission of an existing law, if such a law exists.

We have amended 31 CFR 33.108(f)(3)(iii) and 45 CFR 155.1308(f)(3)(iii) to remove the word "brief" from the provision describing information that States must provide regarding the rationale for a State's specific waiver requests.

We have made minor wording changes to 31 CFR 33.108(f)(3)(v)(A)–(D) and 45 CFR 155.1308(f)(3)(v)(A–D) to improve clarity.

We have added a provision at 31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv) to specify that States must submit an implementation timeline as part of the supporting information required for a complete initial application.

We have modified 31 CFR 33.108(g)(1) and 45 CFR 155.1308(g)(1) to clarify that requests for additional information from the Secretary of the Treasury will be transmitted to a State through the Secretary of Health and Human Services, which follows the process used elsewhere in the rules.

D. General

Throughout 45 CFR 155 subpart N, we have added, "as applicable" after references to the Secretary of the Treasury, to clarify that the specified requirements only involve the Secretary of the Treasury to the extent that a waiver proposal or approved waiver includes a waiver of a provision under the authority of the Secretary of the Treasury.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 PRA 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 will be able to more accurately estimate 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 solicited public comments on the annual number of waiver applications that the Departments may receive, but did not receive any responses. With that said, the Departments developed estimates of the burden associated with information collection requirements in the proposed regulations, and has modified them based on the below comments. Further, the burden estimates provided are estimated averages, and the actual burden will vary based on the scope of the waiver and the State's existing infrastructure for these activities.

We received the following comments on information collection requirements.

Comment: One commenter asked that we estimate the number of States that will seek waivers.

Response: We solicited comment on this in the proposed rules, and did not receive any responses. Given the lack of response and length of time before the earliest possible effective date for section 1332 waivers, the Secretaries have no way to accurately quantify the number of States that will seek waivers. With that said, we believe that the per-State burden estimates provided in the proposed rule provide adequate information regarding the collections related to these rules. As such, for the purpose of this estimate, we use one State.

Comment: One commenter asked that we explain the average wage used in the burden analyses. Another suggested that the calculated burden estimates were too low.

Response: We have revisited the average wage used and agree with the commenter that it was too low. We have also revisited some of the estimates of the number of hours and adjusted them. The combined impact of these changes is to increase the overall burden estimate, both in terms of hours and dollars. We have recomputed the average wage based on a 75 percent/25 percent blend for a Management Analyst (Occupation No. 13–1111 in the Bureau of Labor Statistics' May 2010 National Occupational Employment and Wage Estimate; Industry: State Government; Category: Business and Financial Operations Occupations) and a General and Operations Manager (Occupation No. 11–1021 in the May 2010 Bureau of Labor Statistics' National Occupational Employment and Wage Estimate; Industry: State Government; Category: Management Occupations). We believe that this better reflects wages for these activities by using actual average wages for State government employees at an expected staff/management mix. In addition, we have incorporated a factor of 31.2 percent to account for additional employer costs (paid leave, supplemental pay, insurance, retirement and savings, and legally-required benefits) by using the State and local government rate for such costs for management, professional, and related workers from the Bureau of Labor Statistics' September 2011 Employer Costs for Employee Compensation survey. By using this methodology, we have revised the average wage from $20.67 per hour to $46.67 per hour, which results in commensurate increases to all of the burden estimates.

The Departments solicited public comment on each of these issues for the following sections of this document that

contain information collection requirements (ICRs):

A. ICRs Regarding the Coordinated Waiver Process (31 CFR 33.102 and 45 CFR 155.1302) and Application Procedures (31 CFR 33.108 and 45 CFR 155.1308)

Under certain conditions, 31 CFR 33.102 and 45 CFR 155.1302(a) and (b) provide that a State may submit a single application 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. 31 CFR 33.108 and 45 CFR 155.1308 establish the application process for section 1332 waivers. Under 31 CFR 33.108(a) and 45 CFR 155.1308(a), a State's application for approval of a section 1332 waiver must be submitted to the Secretary as an electronic document. Paragraph (f) of 31 CFR 33.108 and 45 CFR 155.1308 specifies that an application for a section 1332 waiver will not be considered complete unless the application meets all of the conditions set out those sections.

The burden associated with the requirements in 31 CFR 33.102 and 33.108 and 45 CFR 155.1302 and 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 400 hours for a State to develop and submit a complete section 1332 waiver application, at a cost of $18,668.

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

Paragraph (a) of 31 CFR 33.112 and 45 CFR 155.1312 require a State to provide a public notice and comment period prior to submitting an application for a section 1332 waiver.

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 the requirements in paragraph (a)(1) and (b) of this section is the time and effort necessary to develop and provide public notice and obtain and consider public comments. The Departments estimate that each State submitting an application for a section 1332 waiver will require 80 hours to comply with the requirements in this section, at a total cost of $3,734 per State.

Paragraph (a)(2) of 31 CFR 33.112 and 45 CFR 155.1312 require States with 1 or more Federally-recognized Indian tribes to consult with such tribes before submitting a section 1332 waiver application. Paragraph (f)(2) 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 (f)(2) of 31 CFR 33.108 and 45 CFR 155.1308. The Departments estimate that each State with federally recognized tribes that submits 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 $1,867.

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. 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.

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

31 CFR 33.120(b) and 45 CFR 155.1320(b) require States to periodically perform reviews of the implementation of the section 1332 waiver. The Departments estimate that it will take a State 80 hours annually to periodically review the waiver's implementation, at a total cost of $3,734.

Paragraph (c) of 31 CFR 33.120 and 45 CFR 155.1320 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 specified 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 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 develop and 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 $3,734.

Paragraph (b) of 31 CFR 33.124 and 45 CFR 155.1324 requires States to submit annual reports to CMS documenting the information listed in paragraphs (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 develop and submit draft annual reports to CMS. The Departments estimate that it will take 40 hours for each State to comply with this reporting requirement, at a total cost of $1,867.

Paragraph (c)(1) of 31 CFR 33.124 and 45 CFR 155.1324 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 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 4 hours for each State to comply with this requirement, at a total cost of $187.

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

31 CFR 33.128 and 45 CFR 155.1328 specify that the Secretary of Health and Human Services and the Secretary of the Treasury shall periodically evaluate the implementation of section 1332 waivers. The Departments recognize that evaluation will likely involve information collections, but are not seeking OMB approval for collections related to this provision at this time. The Departments will seek OMB approval, as needed, once it develops guidance for States regarding this evaluation requirement. Such approval will be requested following the 60- and 30-day comment periods required by the PRA.

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 ..	1	1	400	400	46.67	$18,668	0	$18,668
Paragraph (a)(1) of 31 CFR 33.112 and 45 CFR 155.1312.	0938–New ..	1	1	80	80	46.67	3,734	0	3,734
Paragraph (a)(2) of 31 CFR 33.112 and 45 CFR 155.1312.	0938–New ..	1	1	40	40	46.67	1,867	0	1,867
Paragraph (b)(1) of 31 CFR 33.120 and 45 CFR 155.1320.	0938–New ..	1	1	80	80	46.67	3,734	0	3,734
Paragraph (a) of 31 CFR 33.124 and 45 CFR 155.1324.	0938–New ..	1	4	10	40	46.67	1,867	0	1,867
Paragraph (b) of 31 CFR 33.124 and 45 CFR 155.1324.	0938–New ..	1	1	40	40	46.67	1,867	0	1,867
Paragraph (c)(2) of 31 CFR 33.124 and 45 CFR 155.1324.	0938–New ..	1	1	4	4	46.67	187	0	187
Total	.....	1	10	.....	684	.....	31,922	0	31,922

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Officer, [CMS–9987–F], *Fax:* (202) 395–6974; or *Email: 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 obtains a control number assigned by OMB.

VI. Regulatory Impact Statement

The Departments have examined the impacts of these final rules 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). These rules have been designated "significant regulatory actions" although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, these rules have 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 economic 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 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 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 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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