

credit agencies from continuing to disburse funds to subawardees after December 31, 2010 provided:

(1) A subaward has been made to the subawardee on or before December 31, 2010;

(2) The subawardee has, by the close of 2010, paid or incurred at least 30 percent of the subawardee's total adjusted basis in land and depreciable property that is reasonably expected to be part of the low-income housing project; and

(3) Any funds not disbursed to the subawardee by December 31, 2011, must be returned to the Treasury by January 1, 2012.

[74 FR 44752, Aug. 31, 2009]

PART 33—WAIVERS FOR STATE INNOVATION

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§ 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

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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

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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

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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.

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(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

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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.

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(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.