

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

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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 of PPACA. In analyzing whether the State has satisfied the requirement under section 1332(b)(2)(A) of PPACA that the State enact a law authorizing a waiver under section 1332 of PPACA, the Secretary and the Secretary of Health and Human Services, as applicable, may consider existing State legislation combined with duly-enacted State regulation or an executive order so long as the State legislation provides statutory authority to enforce PPACA provisions or the State plan;

(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, 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, as applicable, with the necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with the provisions of this paragraph (f)(3)(iv):

(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 Afford-

able 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. To satisfy the comprehensive coverage requirement, the Secretary and the Secretary of Health and Human Services, as applicable, must determine that the coverage under the State plan is forecasted to be at least as comprehensive overall for residents of the State as coverage absent the waiver;

(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. To satisfy the affordability requirement, the Secretary and the Secretary of Health and Human Services, as applicable, must determine that the coverage under the State plan is forecasted to be as affordable overall for State residents as coverage absent the waiver;

(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. To satisfy the scope of coverage requirement, the Secretary and the Secretary of the Health and Human Services, as applicable, must determine that the State plan will provide coverage to a comparable number of State residents under the waiver as would have coverage absent the waiver; 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

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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).

[77 FR 11715, Feb. 27, 2012, as amended at 86 FR 6176, Jan. 19, 2021; 86 FR 53501, Sept. 27, 2021]

### § 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