

§ 431.404

42 CFR Ch. IV (10–1–12 Edition)

(b) *Purpose.* This subpart sets forth a process for application and review of Medicaid and CHIP demonstration projects that provides for transparency and public participation.

§ 431.404 Definitions.

For the purposes of this subpart:

Demonstration means any experimental, pilot, or demonstration project which the Secretary approves under the authority of section 1115 of the Act because, in the judgment of the Secretary, it is likely to assist in promoting the statutory objectives of the Medicaid or CHIP program.

Indian Health Program means a program as defined at section 4(12) of the Indian Health Care Improvement Act, (Pub. L. 94–437).

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 the provisions of § 431.408 of this subpart.

§ 431.408 State public notice process.

(a) *General.* A State must provide at least a 30-day public notice and comment period regarding applications for a demonstration project, or an extension of an existing demonstration project that the State intends to submit to CMS for review and consideration.

(1) *Public notice and comment period.* Prior to submitting an application to CMS for a new demonstration project or an extension of a previously approved demonstration project, the State must provide at least a 30-day public notice and comment period, and the public notice shall include all of the following information:

(i) A comprehensive description of the demonstration application or extension to be submitted to CMS that contains a sufficient level of detail to ensure meaningful input from the public, including:

(A) The program description, goals, and objectives to be implemented or extended under the demonstration project, including a description of the current or new beneficiaries who will be impacted by the demonstration.

(B) To the extent applicable, the proposed health care delivery system and

the eligibility requirements, benefit coverage and cost sharing (premiums, co-payments, and deductibles) required of individuals that will be impacted by the demonstration, and how such provisions vary from the State's current program features.

(C) An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable. This includes a financial analysis of any changes to the demonstration requested by the State in its extension request.

(D) The hypothesis and evaluation parameters of the demonstration.

(E) The specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

(ii) The locations and Internet address where copies of the demonstration application are available for public review and comment.

(iii) Postal and Internet email addresses where written comments may be sent and reviewed by the public, and the minimum 30-day time period in which comments will be accepted.

(iv) The location, date, and time of at least two public hearings convened by the State to seek public input on the demonstration application.

(2) *Statement of public notice and public input procedures.* (i) The State shall publish its public notice process, public input process, planned hearings, the demonstration application(s), and a link to the relevant Medicaid demonstration page(s) on the CMS Web site in a prominent location on either the main page of the public Web site of the State agency responsible for making applications for demonstrations or on a demonstration-specific Web page that is linked in a readily identifiable way to the main page of the State agency's Web site. The State must maintain and keep current the public Web site throughout the entire public comment and review process.

(ii) The State shall also publish an abbreviated public notice which must include a summary description of the demonstration, the location and times of the two or more public hearings, and an active link to the full public notice

document on the State's Web site in the State's administrative record in accordance with the State's Administrative Procedure Act, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS or in the newspapers of widest circulation in each city with a population of 100,000, or more, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS, or both.

(iii) The State must also utilize additional mechanisms, such as an electronic mailing list, to notify interested parties of the demonstration application(s).

(3) *Public hearings.* At least 20 days prior to submitting an application for a new demonstration project or extension of an existing demonstration project to CMS for review, the State must have conducted at least two public hearings, on separate dates and at separate locations, regarding the State's demonstration application at which members of the public throughout the State have an opportunity to provide comments. The State must use telephonic and/or Web conference capabilities for at least one of the two required public hearings to ensure statewide accessibility to the public hearing unless it can document it has afforded the public throughout the State the opportunity to provide comment, such as holding the two public hearings in geographically distinct areas of the State. The State must use at least two of the following public forums:

(i) The Medical Care Advisory Committee that operates in accordance with § 431.12 of this subpart; or

(ii) A commission or other similar process, where meetings are open to members of the public; or

(iii) A State legislative process, which would afford an interested party the opportunity to learn about the contents of the demonstration application, and to comment on its contents; or

(iv) Any other similar process for public input that would afford an interested party the opportunity to learn about the contents of the demonstration application, and to comment on its contents.

(b) *Tribal consultation and seeking advice from Indian health providers and urban Indian organizations.* A State with Federally-recognized Indian tribes, Indian health programs, and/or urban Indian health organizations shall include a process to consult with the Indian tribes, and seek advice from Indian Health programs and urban Indian health organizations in the State, prior to submission of an application to CMS for a new demonstration project, or an extension of a previously approved demonstration project, that has or would have a direct effect on Indians, tribes, on Indian health programs, or on urban Indian health organizations.

(1) For initial applications and applications extending existing demonstration projects that have a direct effect on Indians, tribes, Indian health programs, and urban Indian health organizations in the State, the State must demonstrate that it has conducted consultation activities with tribes and sought advice from Indian health programs and urban Indian health organizations prior to submission of such application.

(2) Consultation with Federally-recognized Indian tribes and solicitation of advice from affected Indian health providers and urban Indian organizations must be conducted in accordance with the consultation process outlined in the July 17, 2001 letter or the State's formal tribal consultation agreement or process and the process for seeking advice from Indian Health providers must be conducted as outlined in the State's approved Medicaid State Plan.

(3) Documentation of the State's consultation activities must be included in the demonstration application, which must describe the notification process, the entities involved in the consultation(s), the date(s) and location(s) of the consultation(s), issues raised, and the potential resolution for such issues.

§ 431.412 Application procedures.

(a) *Initial demonstration application content.* (1) Applications for initial approval of a demonstration will not be considered complete unless they comply with the public notice process set forth in § 431.408(a) of this subpart, and include the following: