



Center for Medicaid and CHIP Services

SHO# 12-001

Re: Revised Review and
Approval Process for Section 1115 Demonstrations

April 27, 2012

Dear State Medicaid Director:

Dear State Health Official:

The Centers for Medicare & Medicaid Services (CMS) is issuing this letter to provide further guidance to State Medicaid and Children's Health Insurance Program (CHIP) agencies on the implementation of the revised review and approval process for section 1115 demonstrations in accordance with section 10201(i) of the Patient Protection and Affordable Care Act, P.L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010; P.L. 111-152 (the Affordable Care Act). On February 27, 2012, CMS issued a final regulation, as described below, to implement the Affordable Care Act requirements. This letter reviews the key provisions of the regulation and provides additional guidance on how these provisions will be operationalized, in particular with respect to amendments to ongoing demonstration projects.

Background

Section 1115 demonstrations can have a significant impact on beneficiaries, providers, States, Tribes and local governments. They can also influence policy-making at the State, Tribal and Federal level by introducing new approaches that can be models for other States and lead to programmatic changes nationwide. In light of the potential impact demonstration projects can have, the Affordable Care Act made changes to the process by which States apply for demonstrations, and the Federal government reviews such applications, to ensure public input.

The Affordable Care Act required the Secretary to set forth transparency and public notice procedures for experimental, pilot, and demonstration projects approved under section 1115 of the Social Security Act in order to increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects is publicly available, as well as to promote public input as States develop and the Federal government reviews these demonstrations. CMS issued a final regulation on February 27, 2012, outlining the new regulatory requirements for initial section 1115 demonstration applications and extension requests, public notice procedures, and reporting and evaluation requirements. The rule can be found at <http://www.gpo.gov/fdsys/pkg/FR-2012-02-27/pdf/2012-4354.pdf>. The rule is effective April 27, 2012.

Provisions of the Final Regulation

The final rule outlines the series of steps that States will need to complete during the course of submitting a demonstration application for review to CMS and the steps that will be taken once an application has been submitted to CMS.

Standardized Application Elements

To assure meaningful public input at the Federal level, and to facilitate the demonstration application process for States, the final rule standardizes demonstration application requirements so that the public and CMS can meaningfully assess States' applications. CMS is developing a standardized application template that will be available on Medicaid.gov and that States may use in developing their applications. The template is designed to assist States in ensuring that their application includes all of the elements that CMS needs to review the application; however, if a State elects to not utilize the template, the State is responsible for ensuring that its application is complete and contains all of the required elements as described in section 431.412(a). As always, CMS is available to provide technical assistance to States as they develop their applications, including the review of a pre-application concept paper as further described in section 431.412(a)(3).

For new demonstration applications, the required elements are outlined in section 431.412(a)(1) and include:

- A comprehensive program description of the application;
- A description of the proposed health care delivery system, eligibility requirements, benefit coverage and cost sharing that will apply to individuals who will be impacted by the demonstration;
- An estimate of expected annual enrollment and expenditures;
- Current enrollment data and enrollment projections;
- Other expected modifications to Medicaid or CHIP;
- Requested waiver and expenditure authorities;
- A description of the research hypotheses that the demonstration will test and a plan for evaluating the hypotheses; and
- Written documentation of the State's compliance with the public notice requirements.

In addition, States must submit information related to the populations affected by and the financing of the demonstration, as well as budget neutrality information.

For demonstration extension requests, similar elements are required, along with information outlined in section 431.412(a)(1) to enable CMS to assess the impact of the demonstration and to evaluate any changes that are proposed for the extension period.

Public Input at the State Level Prior to Submission to CMS

The final rule directs States to solicit meaningful public input in the development of a section 1115 demonstration application or extension request. The public will have a minimum of 30 days prior to a demonstration application being submitted to CMS to provide comments, and the rule outlines several ways in which States will notify the public about their intent to submit a

demonstration application for CMS consideration, and how the public will be afforded the opportunity to provide comments:

- **Electronic Mailing List:** The State must use mechanisms in addition to published notices, such as an electronic mailing list, in order to notify the public of the State's intent to submit an application to CMS.
- **Notices:** The State must publish a notice in either the State's administrative record or in newspapers with the widest circulation informing the public that it is seeking public comment on its proposed demonstration application or extension request. This notice can be an abbreviated notice, but must contain a summary description of the proposed demonstration project, the location and times of two or more public hearings, even if the public hearing has already occurred, and a link to the State's Web site where the application and the full public notice can be viewed. The requirements for the full public notice are outlined further in section 431.408(a)(1). At the State's request, CMS will review a draft notice to ensure that these standards are met.
- **State Web site:** The State must post its full public notice on its Web site along with a demonstration application that has a sufficient level of detail to provide the public with an opportunity to review and provide meaningful input. The State also must post information on public hearings to solicit feedback on the application.
- **Public Hearings:** The State must hold at least two public hearings, which must be held at least 20 days prior to the State's submission to CMS. These hearings can include already existing forums for public input that would allow an interested party to learn about and comment on the demonstration application, as well as forums that may have occurred during the State legislative process.

The State will compile a report of the issues raised through the public comment period and describe how the State considered those comments when developing its application for submission to CMS. A State with Federally-recognized Indian tribes, Indian health programs, and/or urban Indian health organizations must consult with these entities as outlined in section 431.408(b) and consistent with other tribal consultation policies in effect.

Public Input at the Federal Level

The final rule outlines steps that CMS will follow to facilitate public comment, as well as its own review of State proposals. Once a State submits an application for a new demonstration or an extension, the following steps will occur:

- **Electronic Mailing List:** CMS will maintain its own electronic mailing list to notify interested parties when a State's section 1115 demonstration application or extension request is available. The public will be able to register for CMS' electronic mailing list on the Medicaid.gov Web site.
- **Completeness Review:** Upon submission of a State's application, CMS will, within 15 days, formally notify the State whether its application is complete. CMS will determine

if the application is complete by applying the criteria outlined in section 431.412(a)(1) of the final rule, including a review of the public notice process conducted by the State. CMS will send the State a written notification once it has determined that the application is in fact complete. In cases where the application is not complete, CMS will notify the State in writing and will work with the State in an expeditious manner to resolve the outstanding items needed to complete the application. Significant changes or additions to the application may necessitate a new public notice process at the State level.

Many existing demonstrations have a requirement in the Special Terms and Conditions (STCs) that States submit an extension request 12 months prior to the demonstration's expiration. We recognize that in some cases the State may not be able to submit a complete application in this timeframe. In the event that the State meets this requirement, but the extension request requires further information and/or development, CMS will send the State a written notification confirming receipt of the extension request and will hold the request for publication on Medicaid.gov until a revised request is submitted. Once an updated request has been received and determined to be complete, which will include compliance with the State public notice requirements outlined in §431.408, CMS will initiate the 30-day Federal public comment period. CMS encourages States to submit a complete demonstration extension request in a timely fashion in order for CMS to have sufficient time to review the extension request prior to a demonstration's expiration. Please note that CMS cannot render a decision until 45 days after an extension request has been determined complete.

- **Posting on Medicaid.Gov for 30-Day Public Comment Period:** Once CMS determines that an application is complete, CMS will post the State's application on the Medicaid.gov Web site as well as any comments CMS receives. While CMS will publish, review, and consider all comments, it will not provide written responses to them.
- **CMS Consideration of Public Comments:** In order to provide time for CMS to receive and consider all written public comments, CMS will not render a final decision on a demonstration application until 45 days, at a minimum, after the State's application is complete.
- **Post-Consideration Public Record:** CMS will also maintain and publish on its Web site an administrative record that will include the demonstration application, public comments sent to CMS, formal questions that are sent to the State, as well as the State's responses, and, if the application is approved, the final special terms and conditions, and the State's acceptance letter.

Post Approval Requirements

If CMS approves the demonstration or extension request, the State must convene a post-award implementation forum at least six months after approval in order to solicit public comment on implementation.

Public Notice Requirements for Section 1115 Demonstration Applications and Extension Requests Submitted Prior to April 27, 2012

The final rule does not address public notice requirements for section 1115 demonstration applications and extension requests that were submitted to CMS prior to the final rule's April 27, 2012, effective date. For States that submitted applications for a new demonstration or a request to extend an existing demonstration prior to the effective date of the final rule, CMS will not require the State to comply with the requirements as outlined under the final rule; however, States must continue to meet the public notice requirements outlined in the September 27, 1994 Federal Register notice (59 FR 49249) on the 1115 process. When such applications are received prior to the effective date of the final rule, CMS will solicit public input on the application by posting the State's application on the Medicaid.gov Web site in order to initiate the 30-day Federal comment period so long as it will not delay the processing of the request. For State applications that are currently under review, CMS will post the State's application for public comment on the Medicaid.gov Web site with the caveat that CMS cannot assure that all comments received during the review process will be considered.

Public Notice Requirements for Section 1115 Demonstration Amendments

The final rule left open the question of public notice requirements for proposed amendments to existing demonstrations. In order to ensure time to develop an appropriate policy related to amendments that would affect State processes, States do not need to comply at this time with the State public notice and comment process, as outlined in the final rule, with respect to amendment requests. We encourage States to do so, however, particularly with respect to amendments that seek to modify benefits, cost sharing, or eligibility, or to make delivery system changes, such as mandatory managed care.

We are committed to ensuring that the public is afforded the opportunity to provide comments on proposed amendment requests, and as such, beginning on the effective date of the final regulation (April 27, 2012), CMS will post and accept public comments on all amendments. In collaboration with States and other stakeholders, CMS will evaluate the types of demonstration amendments that are submitted and issue further guidance in the future on how the notice and comment provisions would best be applied at the State and Federal levels to amendments that have a significant impact.

Role of Medicaid.gov

The Medicaid.gov Web site will be the mechanism that CMS uses to manage the Federal transparency requirements. States' applications will be included on the section 1115 demonstration list as pending requests and they will be searchable, allowing CMS to create filters to list out only pending items for easier use by the public. The Medicaid.gov Web site will also enable the public to filter those applications that are currently in the 30-day Federal public comment period and open to receive comments. Amendment requests will also be posted to the Medicaid.gov Web site under the circumstances described above. The Medicaid.gov Web site

will also allow the public to register for the CMS electronic mailing list, e.g., “Gov Delivery.” Members of the public and stakeholders will be notified of incoming demonstration applications through the Gov Delivery notification system. Members of the public and stakeholders will be able to submit their comments through a web-enabled application on Medicaid.gov that will allow the public to submit individual comments or, if they prefer, to add their voice to an existing comment to indicate agreement or disagreement. The public will also be able to submit unique comments in response to comments that have previously been posted.

The Web site will also be used to maintain the administrative record for the demonstration, as required by the final rule. The final rule specifies that final approval documents, as well as quarterly and annual reports will be included in the administrative record; however, CMS will also post on the Medicaid.gov Web site all formal correspondence regarding the demonstration. Formal correspondence will include formal letters received by CMS from the State, Members of Congress and stakeholders, as well as CMS’ response. In addition, CMS recognizes that during the negotiation process programmatic changes can occur resulting in significant differences between the State’s application and the final STCs. As such, CMS will also post all formal questions that are sent to the State, the State’s responses, and any amendments to the pending application submitted by the State.

Section 1115 Demonstration Application and Extension Templates

CMS is currently working to make available in early 2013 a web-based system that will enable States to submit section 1115 demonstration applications (as well as certain types of Medicaid and CHIP State Plan Amendments) electronically. This system, entitled the Medicaid and CHIP Program System (MACPro) will streamline CMS review and adjudication of pending actions.

As CMS progresses with the development and implementation of MACPro, an interim electronic (downloadable) section 1115 demonstration application will soon be available to States to use at their option. States will be able to download the interim application template in an electronic format, complete the application and submit the application electronically to CMS. This template will be located at www.medicaid.gov. Until the template is finalized, information on application requirements can be found at <http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/application.html> to assist States as they develop their applications.

I hope you will find this information helpful. Please contact Allison Orris, Acting Director, Division of State Demonstrations and Waivers at 410-786-1597 or via email at allison.orris@cms.hhs.gov with any questions.

Sincerely,

/s/

Cindy Mann
Director

cc:

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