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November 15, 2010

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2325-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

**Re: File Code CMS-2325-P, Medicaid Program; Review and Approval  
Process for Section 1115 Demonstrations, 75 Federal Register, September 17,  
2010**

Dear Sir or Madam:

The American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL) represents nearly 11,000 non-profit and for-profit providers dedicated to continuous improvement in the delivery of professional and compassionate care for our nation's citizens who are frail, elderly and have disabilities who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

AHCA/NCAL appreciates the opportunity to comment on this proposed rule, which will implement provisions of section 10201(i) of the Patient Protection and Affordable Care Act of 2010 (ACA) and set forth transparency and public notice procedures for demonstration projects under section 1115 waivers.

Section 1115 of the Social Security Act allows the Secretary of the Department of Health and Human Services to waive selected provisions of the Act for experimental, pilot, or demonstration projects. States have used Section 1115 demonstrations for different reasons including constraining eligibility or benefits in ways not otherwise permitted by law. Clearly, these waivers can significantly impact access to health care for our vulnerable citizens who are in need of long term care services and supports. We are delighted that the legislation and proposed rule will make the section 1115 waiver process more transparent and allow for public participation.

AHCA/NCAL commends the Centers for Medicare & Medicaid Services (CMS) for drafting a proposed rule that balances opportunities for meaningful input by consumers and health care providers with avoiding onerous administrative burdens for state officials.

We offer the following recommendations to strengthen and clarify the proposed rule:

**§431.408 State Public Notice Process:**

CMS asks for suggestions that would give the public opportunities to provide meaningful input into the development of state demonstration applications while ensuring that the demonstration process moves forward in a timely and efficient manner. We believe that our three suggestions below would strengthen the public input process without hindering a demonstration from moving forward in a timely fashion.

- Paragraph (a) establishes a 30-day comment period prior to submission of an application for a demonstration project or for an extension of an existing demonstration project. We recommend that the public comment period be extended to 60 days to allow concerned individuals adequate time to develop comments.
- Paragraph (a) (1) describes the information that must be provided to the public. We recommend adding sub-paragraph (E) that would require that the information provided to the public include: “The type of waivers and expenditure authorities that the state believes to be necessary to authorize the demonstration.” The proposed rule requires that this information be included in the application. Therefore, making it available to the public during the comment period should not burden states.
- Paragraph (a) (3) requires that the state hold at least two public hearings before submission of the application for a demonstration. We suggest that the rule clarify that members of the public are given an opportunity to speak at the hearings and suggest the following language: “. . .the State must have conducted at least two public hearings regarding the State’s demonstration application *at which members of the public have an opportunity to provide comments*, using at least two of the following public forums.”

**§431.412 Application Procedures:**

We support the requirement at (a)(1)(viii) and (c)(2), that states must submit, with their applications, a report of the key issues raised during the public comment period and how the state considered them. However, we suggest removing the word “key” since it is subjective and could lead to important issues not being included.

**§431.416 Federal Public Notice and Approval Process:**

CMS asks for comments on how to balance the need for transparency and the need for an expeditious review process. We believe that this section, which establishes the federal process for notice and comment, does a good job of balancing transparency with an expeditious review process. We offer the following suggestions to strengthen the approval process while not impeding the review process:

- Paragraph (d) requires CMS to publish the public comments received and states that CMS must review and consider all comments, but need not provide written responses. While we agree that CMS should not have to provide an individualized written response to every comment, we strongly urge that CMS provide a summary report of public comments received and CMS’ response. This would mirror the process used in responding to public comments on proposed rules, which should be the standard CMS response to comments.

- Paragraph (g) establishes an exception to the normal public notice process in the case of a proposed demonstration or demonstration renewal that “addresses a natural, social, economic or similar disaster.” We agree with the need to establish such an exception, but believe that it should be limited to natural or man-made disasters such as earthquakes, floods, or terrorist attacks or a public health disaster and not extend beyond these events. The language at paragraph (g) is overly broad in this regard, and we recommend that the word “economic” be deleted.
- In addition, to ensure that the emergency/disaster exception is not too broad and/or used inappropriately, we recommend that the criteria described at (g)(3)(iv) be revised to add a new paragraph (v) which reads: “ Waiver requests which restrict eligibility and/or reduce benefits or increase cost-sharing for beneficiaries would not normally be eligible for the exception to the public process requirements.”

**§431.420 Monitoring and Compliance:**

We support the requirement for a post-decision public forum six months after implementation and annually thereafter. As noted earlier in our comment on the initial public hearings, the requirement for a public forum should be clarified to make it clear that members of the public have a meaningful opportunity to comment at the forum.

**§431.424 Evaluation Requirements:**

Paragraph (c) establishes an evaluation design plan that includes a number of specific components. This section could be strengthened by incorporating some of the components referenced in the following section that governs the annual reports that states must submit. In particular, evaluation designs should ensure evaluation of how the demonstration will impact the outcomes of care, quality of care, cost of care, and access to care for demonstration populations where appropriate.

**§431.428 Reporting Requirements:**

We agree that the specifics detailed in the proposed rule are necessary components in state annual reports. We recommend that these annual reports be posted on the CMS website as well as the state’s public website.

Thank you again for the opportunity to comment. If you have any questions, feel free to contact me or Janice Zalen of my staff at 202-898-2831 or [jzalen@ahca.org](mailto:jzalen@ahca.org).

Sincerely,



Bruce Yarwood  
President and CEO  
American Health Care Association