

FILE CODE: CMS-2325-P RE: Medicaid Program; Review and Approval Process for Section 1115 Demonstrations

November 16, 2010

Dear Sir or Madam:

The undersigned organizations appreciate the opportunity to comment on the proposed rule on the review and approval process for section 1115 demonstration projects that was published on September 17, 2010.

The Affordable Care Act (ACA) requires these regulations to improve the process for approving section 1115 demonstration projects for both Medicaid and the Children's Health Insurance Program (CHIP). As noted in the preamble to the proposed rule, section 1115 demonstrations often result in noteworthy substantive and fiscal changes to state health programs. Demonstrations often significantly affect access to vital health care services for millions of our most vulnerable Americans – including children, pregnant women, people with disabilities, seniors and others.

State experience with section 1115 demonstrations underscores that these projects often have enormous programmatic and budgetary consequences. Despite the significance of these changes, negotiations are often conducted largely behind closed doors. Multiple reports by the Government Accountability Office have documented the need for improved public participation in the process, and we are pleased that the ACA directed the Department of Health and Human Services to promulgate regulations to reinvigorate the process of public participation in the development of section 1115 demonstration projects.

The proposed rule is a welcome and important contribution to efforts to develop transparency and accountability in government at both the state and federal level. In general, the proposed rule does a thorough and clear job in establishing workable processes that strike the right balance in improving the ability of consumers and health care providers affected by the proposed changes to have a voice in the process, and at the same time avoiding undue burdens for state and federal officials. We applaud the agency's efforts to develop clear guidance in a timely fashion.

We do want to note, however, that in the period prior to these regulations being finalized, it would be helpful for the Centers for Medicare and Medicaid Services to provide the public with more information on its website about Section 1115 demonstrations that are currently being considered for extensions and new Section 1115 demonstrations that have been submitted. At the moment it is difficult to obtain consistent and reliable information on the status of pending Section 1115 demonstrations.

In light of these ongoing challenges, we believe that the proposed regulations are an essential step forward in this area especially in light of full implementation of the ACA in 2014 and the subsequent companion process for waivers of ACA

requirements as outlined in Section 1332 of the law that becomes effective in 2017. To the extent possible, we recommend that the Department of Health and Human Services align procedures for public notice and comment as required by ACA's Section 1332 (a)(4)(B) with public notice and comment procedures required for Section 1115 demonstrations.

The implementation of ACA may precipitate an upturn in the number of states applying for approval of section 1115 demonstrations. Because the stakes for a vital public process are likely to grow, we recommend strengthening and clarifying the proposed regulations in the following ways:

§431.408 State public notice process:

- The proposed regulation at 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. Because of the far-reaching changes to state Medicaid and CHIP programs that demonstrations often allow, we recommend that the state public comment period be extended to 60 or at least 45 days to allow the public adequate time to develop comments.
- Paragraph (a)(1) describes the information that must be provided to the public to ensure a meaningful opportunity for public comment. This section is very important as in the past the public has often been unable to provide meaningful input, because few details of proposals for demonstration projects were shared. To ensure that adequate information is provided to the public, we recommend that an additional sub-paragraph (E) be added that explicitly requires that the information provided to the public include: "The types of waivers and expenditure authorities that the State believes is necessary to authorize the demonstration." The proposed rule requires that this information be included in the application when it is submitted to CMS. 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 at least 20 days before submission of the application for a demonstration and lists the types of hearings that would satisfy the requirement including meetings of the Medical Care Advisory Committee, a state commission, or legislative process. While we support the public hearing requirement, we suggest that the proposed rule be strengthened by making it clear that members of the public would actually have meaningful opportunity to speak at the hearings. As currently drafted, the rule appears to allow an open commission meeting to satisfy the public hearing requirement. Members of the public may have limited opportunities to speak at legislative hearings or at the meetings of the Medical Care Advisory Committee. We suggest that the language of this section be strengthened to read " . . .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:

- At (a)(1)(viii) we strongly support the requirement 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.
- At (b)(3), which states the CMS will publish on its website the status of all State submissions, we assume that this includes the publication of all materials that the state has submitted as part of the application process.

§431.416 Federal public notice and approval process: This section, which establishes the federal process for notice and comment, could be strengthened in the following ways:

- Paragraph (d), which requires CMS to publish the public comments received, states that CMS must review and consider all comments but need not provide written responses. The preceding paragraph (c)(2) notes that CMS will provide on its website a “listing of the issues raised through the public notice process.” While we do not believe that CMS should have to provide an individualized written response to every comment, we do believe that CMS should provide a summary report of public comments received and how they have been addressed. This would be similar to the process used in responding to public comments on proposed regulations and would also establish an analogous requirement to that created for States at §431.412 (a)(1)(viii).
- We support the establishment at (e) of a 45-day period for CMS to consider public comments before rendering a final decision on a demonstration application.
- 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 understand 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 you delete the word “economic”.
- In addition, to ensure that this 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 strongly support the requirement for a post-decision public forum six months after implementation and annually thereafter. As noted 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: We applaud the inclusion of a robust evaluation requirement in the proposed rule, as many far-reaching section 1115 demonstration projects have not been thoroughly evaluated.

- To ensure that the privacy of beneficiaries is protected we recommend that the following language be added to (a)(2): “The evaluation process must minimize burden on beneficiaries *and protect their privacy* in terms of implementing and operating the policy approach ...”
- 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 very much support the specifics detailed as necessary in state annual reports. We recommend that these annual reports be posted on the CMS website as well as the State’s public website as described in (b)(2).

If you have any questions about these comments please contact Joan Alker at Georgetown Center for Children and Families at 202-784-4075.

National Organizations

AARP
American Academy of Pediatrics
American Art Therapy Association
American Health Care Association
American Network of Community Options and Resources
Bazelon Center for Mental Health Law
Center for Self-Determination
Center on Budget and Policy Priorities

Community Access National Network
Community Catalyst
Easter Seals
Families USA
Family Voices
Gateway Healthcare
Georgetown Center for Children and Families
HIV Medicine Association
Long Term Care Community Coalition
Lutheran Services in America Disability Network
Moveable Feast
National Association of Children's Hospitals
National Alliance of State and Territorial AIDS Directors
National Alliance on Mental Illness
National Association for Children's Behavioral Health
National Association of Community Health Centers
National Association of Pediatric Nurse Practitioners
National Association of State Long-Term Care Ombudsman Programs
National Center for Assisted Living
National Council for Community Behavioral Healthcare
National Council on Aging
National Disability Rights Network
National Partnership for Women and Families
National Senior Citizen's Law Center
National Women's Law Center
noflacweb.org
Opportunities Unlimited for People With Differing Abilities, Inc.
Planned Parenthood Federation of America
Service Employees International Union
Southwest CARE Center
The AIDS Institute
The Arc of the United States
The Association for Addiction Professionals
The National Consumer Voice for Quality Long-Term Care
TLC 4 Long Term Care Residents
Treatment Access Expansion Project
U.S. Positive Women's Network
United Cerebral Palsy
Voices for Quality Care (LTC), Inc.
Women Organized to Respond to Life-threatening Diseases

State Organizations

100% Campaign, California
Advocates for Children of New Jersey
Arkansas Advocates for Nursing Home Residents
Baltimore County Association of Senior Citizens Organizations
Center for Public Policy Priorities, Texas
Children Now, CA
Children's Defense Fund - California
Colorado AIDS Project
Delaware Nursing Home Residents Quality Assurance
Commission
Delaware State Long-Term Care Ombudsman Program
Florida Keys HIV Community Planning Partnership
Florida Legal Services, Inc.
Indiana Office of the LTC Ombudsman
Kentuckians for Nursing Home Reform, Inc.
Kentucky Coalition of Nurse Practitioners and Nurse Midwives
Kentucky Voices for Health
Legal Services of Eastern MO
Lower East Side Harm Reduction Center
Massachusetts Advocates for Nursing Home Reform
Massachusetts Law Reform Institute
Mental Health Association of Rhode Island
Puerto Rico Department of Health
Resident Councils of WA
Rhode Island Disability Law Center
Rhode Island Health Center Association
Rhode Island Parent Information Network
RICARES, Inc
The Children's Partnership, CA
The Poverty Institute, Rhode Island
Utah Health Policy Project
Vermont Legal Aid