

August 17, 2022

Secretary Xavier Becerra
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Recommended Regulatory Actions for Section 1115 Medicaid Demonstration Process

Dear Secretary Becerra,

The undersigned organizations write to urge you to promulgate regulations regarding the section 1115 Medicaid demonstration process. A substantial and growing portion of Medicaid is funded through section 1115 and there is a critical need to develop a regulatory framework that clarifies the parameters of the authority, clears up confusion among states and courts, strengthens the transparency rules, and protects the integrity of the Medicaid program. This is among the most important things the administration can do for the long-term security of the Medicaid program and the millions of people who rely on the program for their health insurance.

CMS must set out a definition of “the objectives of Medicaid” and establish related principles to avoid harmful demonstration and waiver approvals, such as work requirements or premiums in Medicaid. CMS’s regulation should address several specific and important problems in the 1115 process.

Defining the Objectives of Medicaid for Purposes of Section 1115 Demonstrations

CMS should promulgate a regulation which requires that section 1115 demonstrations promote the objectives of Medicaid, with a definition of the objectives of Medicaid based primarily in the purpose of the program identified in section 1901, namely *to furnish medical assistance, rehabilitation, and other services*. CMS should also ensure that the new definition of the objectives of Medicaid explicitly affirms the Medicaid entitlement and open-ended matching payment structure.

CMS’s definition should also clarify that the clause “*rehabilitation and other services* to help such families and individuals attain or retain capability for independence or self-care” cannot be interpreted to allow demonstrations that “promote independence” if they do not furnish services or if they reduce access to services.

CMS Should Create 1115 Guardrails for Promoting the Objectives of Medicaid

CMS’s regulation should further operationalize the definition of the objectives of Medicaid by creating 1115 “guardrails,” similar to the section 1332 guardrails, that ensure demonstrations promote, not undercut, the purpose of Medicaid. Such guardrails should include:

1. Demonstrations cannot be approved if they would likely reduce the number of individuals covered by Medicaid in a state, or otherwise reduce the number of individuals who have health insurance in the state.

2. Demonstrations cannot be approved if they would likely reduce the available services, or amount, duration, and scope of any services, provided to Medicaid enrollees; this includes maintaining access to community-based services.
3. Demonstrations cannot be approved if they would reduce the affordability of services for enrollees, including cost-sharing, premiums, and any other costs, unless they comply with the standards in section 1916(f).
4. Demonstrations should not otherwise reduce access to care, such as by making application, enrollment, or renewal more difficult.

CMS should require that all demonstrations meet all four guardrails for the full population eligible for the demonstration and for specific sub-populations when the guardrail impacts are disaggregated by race/ethnicity and other factors. Existing regulations should be supplemented to require that state applications for section 1115 demonstrations include specific and disaggregated estimates for each of the guardrails as well as a comprehensive equity assessment, explaining the effect the proposal would likely have on health coverage and access to care.

Protecting the Integrity and Transparency of the Demonstration Process

We recommend that CMS's regulation additionally make three changes to strengthen demonstration processes.

*First, the regulation should require the full transparency process (including notice and comments) for all 1115 demonstrations that would impact eligibility, enrollment, benefits, cost-sharing, or financing – including new applications, extensions, **and amendments**.* Adding amendments is key as so many states have existing section 1115 demonstrations and major changes are frequently made through amendments. Just like CMS's current regulations include slightly different requirements for new applications and extensions, new regulations could specify reasonable requirements for significant amendments that balance transparency with states' needs to make timely changes. Meaningful changes to eligibility, benefits, cost-sharing, enrollment or financing all require public comment in our view.

Second, the permissible exceptions to the transparency process in the case of a public health emergency needs to be tightened up. The regulation should clarify or strengthen existing regulations to prevent pretextual exemptions from the transparency process. Exemption from the transparency process should be very rare, and only used for demonstrations that are directly related to emergency response (i.e., not just coincidentally contemporaneous) and when use of a comment period would materially delay such emergency response.

Third, CMS's regulation should set clear standards for the duration of demonstrations, not to exceed five years. Section 1115 authorizes "experimental, pilot, or demonstration" projects. Ten years are generally not needed to assess the value of an experiment, and ten years is a long time to have an unsuccessful waiver in place. Ten years also creates the possibility that an outgoing administration can bind a new administration for the entirety of its two terms. Some ten-year approvals do not comport with the statute. We recommend that, consistent with long-standing practice, CMS should implement an unambiguous 5-year limit for new demonstrations, extensions, and amendments.

Thank you for your consideration of our views. If you have questions, please contact Joan Alker (jca25@georgetown.edu) or Allison Orris (aorris@cbpp.org).

American Academy of Family Physicians
American Academy of Pediatrics
American Association on Health and Disability
American Cancer Society Cancer Action Network
American College of Obstetricians and Gynecologists
American Heart Association
American Lung Association
Arthritis Foundation
Asian & Pacific Islander American Health Forum (APIAHF)
Autism Society of America
Autistic Self Advocacy Network
Black Mamas Matter Alliance
CancerCare
Catholic Health Association of the United States
Center for Disability Rights
Center for Law and Social Policy (CLASP)
Center on Budget and Policy Priorities
Community Catalyst
Cystic Fibrosis Foundation
Easterseals
Epilepsy Foundation
Families USA
First Focus on Children
Georgetown University Center for Children and Families
Hemophilia Federation of America
Justice in Aging
Lakeshore Foundation
March of Dimes
Medical Transportation Access Coalition
Medicare Rights Center
NASTAD
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 Disability Rights Network (NDRN)
National Family Planning & Reproductive Health Association
National Health Care for the Homeless Council
National Health Law Program
National Immigration Law Center
National Multiple Sclerosis Society
National Network for Arab American Communities (NNAAC)
National Organization for Rare Disorders
National Partnership for Women & Families
National Patient Advocate Foundation

Physicians for Reproductive Health
Primary Care Development Corporation
The Arc of the United States
The Leukemia & Lymphoma Society
UnidosUS
Union for Reform Judaism