August 15, 2018

VIA ELECTRONIC SUBMISSION

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

Re: Request to Extend Maine Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS

Dear Sir/Madam:

The National Health Law Program (NHeLP) protects and advances the health rights of low-income and underserved individuals. We appreciate the opportunity to comment on Maine's request to extend its HIV/AIDS Demonstration Program (hereinafter "Extension Application").

We generally support Maine's request to continue providing needed services to individuals living with HIV/AIDS. However, we have several concerns and provide suggestions on how Maine can comply with federal requirements and improve its program to better serve people living with HIV/AIDS.

HHS authority and § 1115

To be approved pursuant to § 1115, Maine's demonstration extension must:

- propose an "experiment[], pilot or demonstration;"
- waive only provisions of 42 U.S.C. § 1396a;
- be likely to promote the objectives of the Medicaid Act;

and

- be approved only "to the extent and for the period necessary" to carry out the experiment.[1]

The purpose of Medicaid is to enable states to furnish medical assistance to individuals who are too poor to meet the costs of necessary medical care and to furnish such assistance and services to help these individuals attain or retain the capacity for independence and self-care.[2] As explained below, portions of Maine's extension of its HIV/AIDS Demonstration program are inconsistent with § 1115 and should be rejected.

HHS should deny Maine's request to waive EPSDT

Maine seeks to limit the provision of Early and Periodic Screening, Diagnostic and Treatment Services (EPDST) for the Demonstration Population 2 to examinations and other services specified in the limited benefits package offered to demonstration enrollees.[3]

Service limits for EPSDT are contrary to federal law and the goal of EPSDT to provide low-income children and youth under age 21 with comprehensive screening and treatment services to ensure the early discovery and treatment of children's illnesses and conditions. Moreover, EPSDT limits would undermine the stated intent of the HIV/AIDS Demonstration Program "to provide effective and earlier treatment to prevent, reverse, or delay disease progression."[4]

The Extension Application describes two populations:

- Medicaid/MaineCare members who live with HIV/AIDS and have incomes at or below 100% FPL, and
- Enrollees who are living with HIV/AIDS and have incomes at or below 250% of the Federal Poverty Level (FPL).[5]

Maine provides Medicaid coverage to children under age 19 with household incomes at or below 162% FPL, and young people ages 19 and 20 with household incomes at or below 161% FPL.[6] The Extension Application, as written, would impose limits on EPSDT services and reduce the level of services *currently available* to children living with HIV/AIDS whose household income is between 100% – 250% FPL.[7] Even if the EPSDT waiver provision were to apply only to children with household income above the state's current Medicaid eligibility threshold for children, such limits would nonetheless arbitrarily limit access to needed medical services for a highly vulnerable population.

---

[1] 42 U.S.C. § 1315(a).
[2] See 42 U.S.C. § 1396-1.
[3] Extension Application at 28.
[4] Extension Application at 2.
[5] Id. at 4.
[6] Including the 5% income disregard under Modified Adjusted Gross Income (MAGI) methodologies.
[7] It is unclear exactly how many children would be affected by the limit on EPSDT services. Maine tracks enrollees according to age, but the categories, under age 13, 13-19, 20-29, do not correspond to the EPSDT benefit provided to Medicaid eligible children under age 21. See *Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS,* No. 11-W-00128/1 Interim Evaluation Report (May 24, 2018).

The Secretary does not have authority to waive or impose limits on EPSDT. Congress has included EPSDT in the Medicaid Act as a detailed, comprehensive program to cover preventive and treatment services for children and youth under age 21.[8] Since 1967, Congress has targeted the EPSDT coverage standards to meet the particular health care needs that face low-income individuals under age 21. Limiting EPSDT has no valid experimental purpose.

Limits on EPSDT are not only unlawful; they are bad policy which would have adverse consequences for children and youth in Maine who are living with HIV/AIDS. For example, according to the Centers for Disease Control and Prevention (CDC), individuals ages 15 to 24 face the highest risk of acquiring Sexually Transmitted Infections (STIs) "for a combination of behavioral, biological, and cultural reasons."[9] CDC data show that individuals ages 15 to 24 account for 25% of the sexually active population, but 50% of new STIs.[10] In 2015, young people ages 13 to 24 accounted for more than 1 in 5 new HIV diagnoses, yet young people with HIV are the least likely to be linked to care and have suppressed viral load.[11]

Children living with HIV/AIDS are highly vulnerable and can have complex medical needs. Imposing arbitrary limits on needed Medicaid services prevents these children from obtaining necessary care and is contrary to federal law. HHS should reject this provision of Maine's waiver extension.

Use viral load suppression to monitor project performance

Maine tracks the frequency of opportunistic infections to measure the Demonstration Program's effectiveness in arresting the progression of HIV/AIDS and improving the health status enrollees.[12] This is an outdated measure. HHS should require Maine to implement a performance measure developed by the Health Resources Services Administration (HRSA) to evaluate the HIV care continuum – viral load suppression.[13]

Tracking viral load - amount of virus detectable in an individual's blood - is the current standard of care for HIV/AIDS treatment recommended by the National Institutes of

[8] 42 U.S.C. §§ 1396a(a)(43), 1396d(a)(4)(B), 1396d(r).
[9] Ctrs. for Disease Control and Prevention, Div. of STD Prevention, Sexually Transmitted Disease Surveillance 2015 62 (2016), https://www.cdc.gov/std/stats15/STD-Surveillance-2015-print.pdf.
[10] Ctrs. for Disease Control and Prevention, Fact Sheet: Incidence, Prevalence, and Cost of Sexually Transmitted Infections in the United States (2013), http://www.cdc.gov/std/stats/sti-estimates-fact-sheet-feb-2013.pdf.
[11] Ctrs. for Disease Control and Prevention, *HIV Among Youth*, http://www.cdc.gov/hiv/risk/age/youth/index.html?s_cid=tw_drmermin-00186(last updated Sept. 21, 2017).
[12] *See* Extension Application, Goals and Objectives, at 16. Other tracking mechanisms include physician visits, provider and member education, emergency department use, inpatient care, and treatment adherence.
[13] Dept. of Health and Human Srvs., Health Resources Servs. Admin., HIV/AIDS Bureau, Performance Measures, https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/coremeasures.pdf. Other measures include medical visit frequency, prophylaxis for pneumocystis pneumonia (PCP), and screenings for youth and adults.

Health.[14] The goal of HIV treatment is to suppress the amount of HIV patient's blood so that it is undetectable.[15]

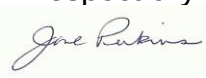
The Centers for Medicaid & CHIP Services included HRSA's HIV viral load suppression measure as part of its 2018 Core Set of Adult Health Care Quality Measures for Medicaid.[16] Although not part of the Child Core Set of health care quality measures, the measure has no age restriction and should also be used for children enrolled in Maine's HIV/AIDS Demonstration Program.[17]

HHS should work with Maine to develop the surveillance and data tracking capacity to report the viral suppression measure for Demonstration Program enrollees. The State purportedly already collects clinical data on viral load and CD4 counts from providers and the Maine Center for Disease Control and Prevention, so updating the Program's performance measures is unlikely to lead to increased implementation costs.[18]

Updating Maine's HIV/AIDS Demonstration Program to reflect 21st Century standard of care and performance measurement will provide officials and other stakeholders necessary data to evaluate the program and identify health care disparities, and coverage gaps. Moreover, it will help ensure that individuals living with HIV/AIDS have access to quality care.

We appreciate your consideration of our comments. If you have questions, please contact Wayne Turner (turner@healthlaw.org).

Respectfully submitted,



Jane Perkins
Legal Director

[14] Dept. of Health and Human Srvs.,*Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents*, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.
[15] Id.
[16] Ctrs. for Medicaid & CHIP Services, *2018 Updates to the Child and Adult Core Health Care Quality Measurement Sets* (Nov. 14, 2017), https://www.medicaid.gov/federal-policy-guidance/downloads/cib111417.pdf.
[17] See HRSA, note 14 *supra*.
[18] Extension Application at 16.