AIDS Action Committee of Massachusetts, Inc.
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Our mission: To stop the epidemic and related health inequities by eliminating new infections, maximizing healthier outcomes for those infected and at risk, and tackling the root causes of HIV/AIDS.

August 21, 2017

Kaela Konefal
EOHHS Office of Medicaid
One Ashburton Place
11th Floor
Boston, MA 02108
RE: Comments for Demonstration Amendment

To the members of the Massachusetts Executive Office of Health and Human Services:

AIDS Action Committee of Massachusetts (AAC) would like to submit public comment in opposition to the Request to Amend the MassHealth Section 1115 Demonstration to the Centers for Medicare and Medicaid Services (CMS).

AIDS Action Committee strives to improve the health of LGBT people and people living with HIV/AIDS (PLWH). Founded in 1983, AIDS Action Committee (AAC) is New England's largest AIDS service organization. Our mission at AAC is to stop the epidemic and related health inequities by eliminating new infections, maximizing healthier outcomes for those infected and at risk, and tackling the root causes of HIV/AIDS. AAC has advocated for fair and effective AIDS policies, cutting edge HIV prevention programs, and comprehensive health and wellness services for PLWH for three decades, and we serve thousands of clients who come through our door every year.

Massachusetts currently leads the nation in our HIV care and prevention, in large part because of MassHealth policies. Our expansion of access to HIV medications has meant our population has achieved a 67% viral suppression rate, significantly higher than the national average. And because those that are virally suppressed are un-infectious to others, we have seen a nearly 50% decrease in new infections since we expanded MassHealth eligibility for those living with HIV in 2001. That remarkable progress was recently published as a model for the country, specifically citing our MassHealth access as critical to our success. [1] The reduction in new infections has not only saved lives, it has saved the state an estimated $1.8 billion in avoided lifetime HIV treatment costs. Our success to date has even allowed us to envision our ultimate goal, which is getting to zero new infections, death, and HIV-related stigma [2]. Last year we laid out a blueprint

[1] Cranston et al. 2017. "Sustained Reduction in HIV Diagnosis in Massachusetts, 2000-2014." *American Journal of Public Health.* Vol. 107, No. 5.

[2] www.gettingtozeroma.org

on how to achieve those goals. That ability depends on continued unfettered access to HIV care through MassHealth.

We are concerned that some of the proposed policies to reform MassHealth included in the Section 1115 waiver request will decrease access to crucial services for PLWH, which in turn will lead to negative health outcomes. In particular, we are concerned about policies that would establish a closed drug formulary under MassHealth and create restrictions on which pharmacies patients can utilize.

First, creating a closed drug formulary under MassHealth would decrease access to high quality treatment for many PLWH. Currently, MassHealth covers all drugs from manufacturers that participate in the federal Medicaid rebate program. The closed formulary would restrict the drugs that MassHealth covers. This is especially concerning for PLWH. The current system allows providers to choose the best medication for each patient based on individual experiences with side effects and resistance profiles. Each individual HIV patient may react in unique ways to antiretroviral medications, and a patient and provider may change medications several times in order to find the ideal treatment regimen. A complicating factor is polypharmacy and drug-drug interactions. Many PLWH have comorbidities and take multiple medications. This is especially true of PLWH age 50 and older, who comprise more than half of PLWH in Massachusetts.

It is difficult to see how a formulary could take into account the complex HIV treatment guidelines. According to federal "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents," a nearly 300 page document published by the U.S. Dept. of Health & Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents, there are no fewer than six medication combinations recommended for patients who are first initiating treatment, and an additional table of options for patients based on other complications and comorbidities[3]. There are separate guidelines for patients who have already had experience with HIV treatment but who may have developed various levels of resistance, and other subpopulations that have particular considerations. These guidelines were revised twice in 2016 alone.

Additionally, one medication, Truvada, is now FDA-approved for pre-exposure prophylaxis (PrEP) as a preventative medication for HIV-uninfected individuals. More medications are also coming down the research pipeline. Some insurance companies in other states have mistakenly denied claims for Truvada as PrEP because they were for HIV-uninfected individuals. Truvada was listed only as a treatment medication for those already infected, when in fact it is approved for both purposes. Any HIV-related formulary would need to take this into account.

The closed formulary would remove the flexibility that allows providers and patients to find the right regimen of antiretroviral medications, which in turn could lead to lower rates of adherence from patients who are forced to accept treatment regimens that are not best suited to their needs. We are also concerned that the closed formulary might restrict access to single tablet regimens for HIV treatment in favor of multi-tablet regimens, or restrict which single tablet regimens are accessible. Studies have shown that single tablet regimens improve adherence by lowering pill

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https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/37/whats-new-in-the-guidelines-

burden and increase the likeliness of achieving viral suppression compared to multi-tablet regimens.[4]

Second, creating restrictions on which pharmacies MassHealth patients can utilize would also decrease access to crucial services for PLWH. These restrictions could deny PLWH access to their pharmacies of choice, where they feel comfortable and know they will receive high quality and non-discriminatory care, and instead force them to use alternative pharmacies. Many of our clients, for example, utilize the pharmacies at Fenway Health and the Walgreens specialty pharmacies that specialize in HIV care because they are known to be competent, non-discriminatory, and have familiarity with dealing with the state's HIV Drug Assistance Program (HDAP). Furthermore, if MassHealth chooses to restrict to specialty mail-order pharmacies, this could create confidentiality issues for PLWH who may not want HIV medication sent to their homes because of the stigma associated with having HIV.

Ultimately, these policies to reform MassHealth would have negative consequences for PLWH by decreasing their access to care. Limiting coverage for medications and restricting access to pharmacies could create additional barriers to medication adherence, which is essential for treating HIV and preventing its transmission. This would undermine the all the efforts currently underway in Massachusetts to reduce new HIV infections and improve health outcomes for PLWH. **For these reasons we are opposed to applying formulary or pharmacy restrictions for this population, and would seek to exclude HIV from these changes, as has been proposed for other changes being considered in the waiver.**

Sincerely,

Carl Sciortino
Executive Director

[4] Clay P, Nag S, Graham C, Narayanan S. 2015. "Meta-Analysis of Studies Comparing Single and Multi-Tablet Fixed Dose Combination HIV Treatment Regimens." *Medicine.* (Baltimore) 94(42): e1677.