



**THE AIDS INSTITUTE**

October 17, 2017

Ms. Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Ave SW  
Washington, DC 20201

Re: Comments on Massachusetts Medicaid Section 1115 Waiver Request

Dear Administrator Verma:

The AIDS Institute, a national, non-partisan, non-profit organization dedicated to supporting and protecting health care access for people living with HIV/AIDS, hepatitis, and other chronic and serious health conditions, is pleased to submit comments on the Commonwealth of Massachusetts request to amend its Section 1115 Medicaid Waiver for MassHealth (11-W-00030/1).

**We are extremely concerned that if the Centers for Medicare and Medicaid Services (CMS) approves aspects of this Waiver Request, MassHealth beneficiaries living with HIV, hepatitis, and other serious and chronic conditions will not have access to the life-saving and curative medications their providers prescribe to keep them healthy and alive.** While we truly understand the need to control costs in the Medicaid program, limiting beneficiaries' access to needed medications is not the answer. Massachusetts has at its disposal other means to reduce prescription drugs costs. We encourage the Commonwealth to pursue these other mechanisms rather than take drastic steps that, if approved, would run contrary to current law and undermine the Medicaid program not only for Massachusetts, but potentially throughout the country, as well.

Access to medications is central to the well-being of all people living with HIV, who now can live a relatively healthy, normal life if they have access to the antiretroviral treatment prescribed to them and take them on a daily basis for the rest of their life. Access to direct acting antivirals for the treatment of hepatitis C now provides a cure to patients in as little as eight weeks for a once deadly virus. Daily treatment is also available for people living with hepatitis B, who can also lead a normal, healthy life if they have access to medications that they must take daily for

the rest of their life. Each of these viruses are infectious diseases that in the interest of public health must be controlled. With the medications now available, we can actually end HIV and hepatitis as a public health threat.

Due to the income levels of many of the people living with these viruses, Medicaid is the primary payer for their healthcare. In fact, nationwide, Medicaid is now responsible for 42 percent of all people living with HIV who are in care. This is why we are so focused on each state's Medicaid program and work to ensure they meet the needs of their beneficiaries.

### **Massachusetts Waiver Request for Prescription Medications**

It is understandable that MassHealth is seeking ways to reduce its costs, which has dramatically risen due to increased enrollment and healthcare costs, and people living longer. As part of the Waiver Request, the Commonwealth is proposing to fundamentally and dramatically change the coverage of prescription medications by creating a restricted prescription drug formulary. **This not only violates current Medicaid law, but would be harmful to beneficiaries. The AIDS Institute urges CMS to soundly reject this proposal.**

First, while we share MassHealth's concern about rising healthcare costs, according to a recent Kaiser Family Foundation report, prescription drugs spending is responsible for only 1 percent of MassHealth's spending in 2016. In order to better manage spending and rein in costs, perhaps other healthcare expenditures should be examined instead of restricting access to lifesaving medications.

If MassHealth chooses to focus on prescription drug spending, it has at its disposal under current law and regulations opportunities to control costs and seek additional rebates from pharmaceutical manufacturers. While we are not always supportive of such practices since they are not beneficial to patients, state Medicaid programs can create preferred drug lists, institute certain prior authorization requirements, and take advantage of additional supplemental rebates from the pharmaceutical companies. While MassHealth received \$640 million in rebates in 2016, which reduced its drug spending by 50 percent, it is our understanding that MassHealth is not fully taking advantage of additional rebates available that other states take. **Before instituting a closed formulary, The AIDS Institute urges MassHealth to take advantage of current tools to manage its formulary that can lead to cost savings and additional rebates.**

**What MassHealth is requesting violates current Medicaid law.** Currently, Section 1927 requires states to cover all drugs of a pharmaceutical manufacturer that participates in the federal Medicaid rebate program, while allowing them to use "permissible restrictions". In exchange for this requirement, states receive a minimum 23.1 percent rebate plus additional rebates when manufactures increase the price of their drug above inflation. As described above, states may receive supplemental rebates by using a preferred drug list. In violation of this law, MassHealth is proposing to institute a closed formulary with at least one drug available per therapeutic class. Since this would be in violation of current Medicaid law and is not a

provision that can be waived, The AIDS Institute urges CMS to reject this aspect of the Waiver Request.

Not only is what MassHealth is requesting through the 1115 Waiver Request illegal, it would also be **bad for beneficiaries, particularly those living with HIV, hepatitis and other serious and chronic conditions**. Treatment of many illnesses, including HIV and hepatitis, is tailored to each patient based on the unique health conditions experienced by each patient. Providers must prescribe the drugs that best meet their patients' needs. Limiting the number of drugs available to just one drug per class does not take into account that some individuals may develop side-effects to a particular drug, while another person may need a certain therapy to avoid a harmful interaction with a drug being taken for different health condition. Drug resistance can occur in people living with HIV and hepatitis, requiring them to have the ability to switch to another drug without interruption. Usually when resistance develops, it is for all drugs in that class, and patients must switch to another drug from another class. Furthermore, people living with HIV and hepatitis frequently have co-morbid conditions and are being prescribed multiple medications for different conditions that interact differently with their HIV and hepatitis drugs.

**Providers cannot be limited in prescribing what is the best drug to meet their individual patient's medical needs.** What MassHealth is proposing to do would do exactly that, limit a provider's ability to treat their patients. For people living with HIV and hepatitis, if patients do not have access to their medications, it can result in illness and death. Additionally, it would impede progress in controlling infectious diseases, which would be contrary to what is best for the public health.

**In another proposal that would circumvent current Medicaid law, MassHealth is proposing to not cover certain medications that came to market through the FDA's accelerated approval pathway.** First, this would be a violation of the law. Section 1927 does not allow states to pick and choose what types of medications that must be covered, but requires coverage of all FDA approved drugs of manufactures that participate in the rebate program. These drugs are FDA approved. Secondly, these accelerated approval drugs still must meet FDA standards for approval and are on the accelerated approval process in order to meet needs of patients who have rare or complicated diseases with few or no treatment options. In the interest of patient health, The AIDS Institute urges CMS to reject this aspect of the waiver as well.

**The MassHealth Waiver Request also seeks to utilize a specialty pharmacy network to distribute prescription drugs, potentially placing another restriction to access of medications for patients.** People living with HIV and hepatitis C are required to take their medications on a daily basis in order to remain healthy, and in the case of hepatitis C, be cured. While all patients may not require the attention of a pharmacy and their staff, many do, particularly since MassHealth beneficiaries are low income and have low health literacy levels. Patients are also accustomed to receiving their medications from pharmacies that they are already associated with, including those that are connected to the Ryan White HIV/AIDS Program. While mail order may suit some patients, beneficiaries must be given the opportunity to pick up

their medications at a brick and mortar pharmacy. For these reasons, we urge CMS to reject this aspect of the MassHealth Waiver Request as well.

The AIDS institute has other concerns with other aspects of the MassHealth Waiver Request as well, including limiting the provider network. People living with HIV and hepatitis often require access to clinicians who have a certain expertise and offer other services that fulfill the unique needs of their patients. Under the Waiver Request, MassHealth would limit patient access to only a select number of providers. What providers will be included and their areas of expertise are completely unknown at this time.

We thank you for the opportunity to submit these comments. If you have any questions or comments, please feel free to contact me at [cschmid@theaidsinstitute.org](mailto:cschmid@theaidsinstitute.org).

Sincerely,

A handwritten signature in blue ink, appearing to read "Carl E. Schmid II". The signature is fluid and cursive, written over a light blue horizontal line.

Carl E. Schmid II  
Deputy Executive Director

cc: Brian Neale, Center for Medicaid Services