FEDERAL AIDS POLICY PARTNERSHIP
HIV HEALTH CARE ACCESS WORK GROUP

October 20, 2017

Eric Hargan
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Submitted electronically

Re: Comments for Massachusetts 1115 Demonstration Amendment Request

Dear Acting Secretary Hargan:

The undersigned organizations are writing as members of the HIV Health Care Access Working Group in response to the MassHealth 1115 Demonstration Waiver Amendment Request posted on September 20, 2017 (the MassHealth Request). Thank you for this opportunity to submit our comments. For the reasons discussed below, we strongly oppose the MassHealth Request and urge the Department of Health and Human Services (HHS) not to approve it.

We particularly urge the following actions with respect to the MassHealth Request:

- **HHS should reject MassHealth's request to use a closed formulary for the selection of preferred and covered drugs.**
- **HHS should reject MassHealth's request to procure a selective specialty pharmacy network for the fee-for-service and the Primary Clare Clinician (PCC) plan.**
- **HHS should reject MassHealth's request to establish narrower networks in the PCC plan.**
- **HHS should reject MassHealth's request to eliminate MassHealth eligibility for non-disabled adults with incomes above 100% of the Federal Poverty Level (FPL).**

In 2014, an estimated 1.1 million Americans were living with an HIV infection, with approximately fifteen percent unaware of their HIV status.[1] The Medicaid program is an especially critical source of life-saving care for people living with HIV in Massachusetts and throughout the United States. More than forty percent of people living with HIV in care rely on the Medicaid program for the health care and treatment that keeps them healthy and productive.[2] Ensuring uninterrupted access to

[1] U.S. Centers for Disease Control and Prevention, HIV Surveillance Report: Statistics Overview (September 22, 2017), available at https://www.cdc.gov/hiv/statistics/overview/index.html
[2] Kates, Jennifer and Lindsey Dawson. Insurance Coverage Changes for People with HIV Under the ACA. Kaiser Family Foundation. February 2017.

effective HIV care and treatment is also important to public health goals as when HIV is effectively managed, the risk of transmitting the virus drops to near zero.[3]

The HIV Health Care Access Working Group (HHCAWG) is a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates and people living with HIV, who are all committed to ensuring access to critical HIV-related health care and support services for Medicaid beneficiaries. While our organizations are national in scope, we also affiliate with strong regional, state, and community based advocacy networks. Based on our extensive experience advocating on behalf of the nearly half of all Americans who live with HIV,[4] we strongly oppose the MassHealth Request.

We urge HHS to reject these proposals in order to ensure that the waiver promotes, rather than undermines, the objectives of the Medicaid program and that vulnerable populations retain access to crucial medications and health care services. We share the commitment of MassHealth and HHS to maintaining the gains Massachusetts has made in access to affordable health coverage for all low-income residents. However, we are concerned that certain policies put forth in the MassHealth Request would substantially decrease meaningful access to care for low-income individuals living with HIV. In expressing these concerns, we stand with Massachusetts Senate leaders, who just this week chose not to include *any* of these troubling policies in their proposed package of reforms to control costs in the Massachusetts health care system.

Several of the proposed changes would also violate the basic conditions of a section 1115 waiver; thus, approval of the waiver would be unlawful. Section 1115(a) of the Social Security Act, codified at 42 U.S.C. § 1315(a), allows a federal waiver to facilitate a State's "experimental, pilot, or demonstration project" that, "in the judgment of the Secretary, is likely to assist in promoting the objectives" of the Medicaid program. One of the primary objectives of Medicaid, as explained by § 1901 of the Social Security Act and the courts, is to enable each State to furnish "medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." The Centers for Medicare & Medicaid Services (CMS) have further explained that for a demonstration to meet the objectives of the Medicaid program it should: "increase and strengthen overall coverage," "increase access to, stabilize, and strengthen providers and provider networks;" "improve health outcomes," or "increase the efficiency and quality of care."[5] Because several portions of the

[3] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.; Cohen, MS., et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. N Engl J Med 2016; 375:830-839. September 1, 2016.
[4] Wu S, Green A., Projection of Chronic Illness Prevalence and Cost Inflation, RAND Corporation (October 2000).
[5] Centers for Medicare and Medicaid Services (CMS), *About Section 1115 Demonstrations*, https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html (last visited Oct. 15, 2017).

proposed waiver are not "likely to assist in promoting the[se] objectives," federal law bars HHS from approving those sections of the waiver.[6]

I. HHS should reject MassHealth's request to use a closed formulary for the selection of preferred and covered drugs.

a. *MassHealth's Proposed Waiver of Formulary Requirements Is Unlawful*

MassHealth proposes to adopt a closed formulary with as little as a single drug per therapeutic class. Section 1927(d)(4) of the Social Security Act, codified at 42 U.S.C. § 1396r–8(d)(4), establishes rigid requirements for drug coverage in a state's formulary under the rebate program. MassHealth proposes to waive these requirements in order to implement the closed formulary,[7] but federal case law precludes this sort of waiver. Section 1115 of the Social Security Act, codified at 42 U.S.C. § 1315, permits waivers of only certain specified sections, which do not include any part of the rebate provisions. The D.C. Circuit made this clear in *PhRMA v. Thompson*: "Although the Act authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of section 1396r–8's rebate provision . . ."[8]

Moreover, the proposed closed formulary rests entirely on an economic justification of cost-cutting, which does not qualify as an "experimental, pilot, or demonstration project" as required by section 1115 of the Social Security Act, codified at 42 U.S.C. § 1315(a). As the Ninth Circuit explained: "The Secretary's obligation under § 1315 to 'make some judgment that the project has a research or a demonstration value' cannot be satisfied by '[a] simple benefits cut, which might save money, but has no research or experimental goal.'"[9] MassHealth does not even gesture toward any research or experimental objective, but rather candidly explains its request in purely economic terms: "Adopting a closed formulary with at least a single drug per therapeutic class would enable MassHealth to negotiate more favorable rebate agreements with manufacturers."[10] Accordingly, HHS should reject this proposal as failing to meet the law's requirements for an experimental or demonstration project.

b. *Closed Formularies Negatively Impact Individual Health and Do Not Save Money*

Aside from conflicting with current law, MassHealth's proposal to impose a closed formulary is severely misguided even as a cost-cutting measure. Reviews of over 90 recent studies demonstrate

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[6] *See, e.g.*, *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994) (striking down a section 1115 waiver due, in part, to an inadequate determination by HHS that the plan was likely to promote the Act's objectives). Furthermore, the law requires that the Secretary's decision is based solely on a substantive "judgment" as to whether the waiver "is likely to assist in promoting the objectives" of Medicaid. As the Supreme Court has made clear in *Massachusetts v. EPA*, "the use of the word 'judgment' is not a roving license to ignore the statutory text. It is but a direction to exercise discretion within defined statutory limits." 549 U.S. 497, 533 (2007).

[7] *See* MASS. EXEC. OFF. OF HEALTH AND HUMAN SERVS., OFF. OF MEDICAID, *MassHealth Section 1115 Demonstration Amendment Request* at 15 (Sept. 8, 2017).

[8] 251 F.3d 219, 222 (D.C. Cir. 2001).

[9] *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011) (citing *Beno v. Shahala*, 30 F.3d 1057, 1069 (9th Cir. 1994)).

[10] MASS. EXEC. OFF. OF HEALTH AND HUMAN SERVS., OFF. OF MEDICAID, *MassHealth Section 1115 Demonstration Amendment Request* at 8 (Sept. 8, 2017).

that formulary restrictions are a lose-lose proposition: they are harmful to people's health *and* they do not save money.[11] For some medications, such as atypical antipsychotics, the cost-benefit analysis of a formulary restrictions is *extremely* unfavorable: the pharmaceutical savings are negligible while other health and social costs are enormous, with estimates "that restrictive formulary policies in Medicaid led to over $350 million in prison costs per year" in addition to "poorer health outcomes."[12] If this is true of formulary policies that are merely restrictive, a fully closed formulary, as MassHealth proposes to allow, would likely exacerbate this dynamic, yielding even higher costs and worse health outcomes.

Furthermore, a closed formulary plan would not significantly add to MassHealth's negotiating leverage. MassHealth already has adequate leverage to negotiate with pharmaceutical manufacturers through the existing tiered formulary system, which provides substantial incentive for manufacturers to offer competitive rebates. A closed formulary would simply cause harm to people living with chronic and complex conditions such as HIV by restricting their access to necessary drugs. For people living with HIV, effective treatment often depends on the ability for a physician to exercise discretion in striking a personalized, delicate balance among many medications. Blocking access to the range of drugs in a therapeutic class would upset that balance and directly harm these vulnerable individuals.

For the reasons described above, HHS should reject MassHealth's request to use a closed formulary for the selection of preferred and covered drugs**.**

II. HHS should reject MassHealth's request to procure a selective specialty pharmacy network for the fee-for-service and the Primary Clare Clinician (PCC) plan.

HHS should reject the proposal to limit the choice of pharmacy to specialty pharmacies for members receiving care through the fee-for-service and the Primary Care Clinician (PCC) plan as it may have the unintended effect of imposing unnecessary barriers to obtaining lifesaving specialty medications. While specialty pharmacies can provide care coordination benefits to those patients who prefer them, they often present physical access problems for those experiencing homelessness and people in transient living situations. We applaud MassHealth for recognizing those challenges

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[11] *See* Yujin Park et al., *The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review* 23 J. MANAGED CARE & SPECIALTY PHARM. 893, 898 (2017) (reviewing 59 unique studies and finding a negative association of 92% between formulary restrictions and health outcomes, and observing that the majority of "studies that included total or medical costs (in addition to pharmacy costs) . . . showed either negative effect on total, medical, or pharmacy costs or no effect on pharmacy costs"); Laura E. Happe et al., *A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical outcomes, Economic outcomes, and Health Care Resource Utilization* 20 J. MANAGED CARE & SPECIALTY PHARM. 677, 681 (2014) (reviewing 93 studies and concluding "that formulary restrictions are negatively associated with medication adherence" and "there was no distinct trend in the direction of association of economic outcomes with formulary restrictions").

[12] Seth A. Seabury et al., *Formulary Restrictions on Atypical Antipsychotics: Impact on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid* 20 AM. J. MANAGED CARE e52, e58 (2014) ("Any cost savings from pharmaceuticals among atypical antipsychotic users appears to be more than offset by the higher medical costs associated with worth adherence and poorer health outcomes.").

and planning to ensure appropriate processes are put in place for members who are homeless or not stably housed. These individuals in particular may not be able to receive medications consistently in the mail, creating gaps in treatment and increasing the likelihood that members will not be able to adhere to their treatment regimens.[13]

However, without any evidence that specialty pharmacies have elsewhere created processes for members who are homeless or not stably housed or any detail from MassHealth about what such processes might be, MassHealth's current proposal poses too great a risk to the health of the homeless and unstably housed.

Provider and community health workers' experiences with MassHealth MCOs utilizing specialty pharmacies to dispense HCV medications demonstrates how mail order dispensing is inappropriate for members with unstable living situations. While patients may designate providers or other representatives to accept deliveries on their behalf, the process is often complicated, burdensome, and difficult to navigate. Specialty pharmacies do not allow a patient's community service provider to order medications on their behalf, instead forcing the patient to make each phone call. For many, this is simply impractical. Medication orders are often lost or cancelled due to patients' frequent changes of addresses and phone numbers. Furthermore, in our experience individuals have been inaccurately told by specialty pharmacies that their medication will not be dispensed until payment information is provided, or that a refill will not be provided unless any pending balance has been paid. This presents a significant barrier, especially for enrollees that do not have access to funds other than limited cash resources that they rely on for other needs.

Additionally, for many individuals, having medications delivered to their home or workplace where co-workers, neighbors, and other residents may discover their health conditions or medication needs could result in serious harm and social alienation, especially given the significant stigma still associated with HIV and HCV.

Given these concerns, we urge HHS to reject MassHealth's request to include a selective specialty pharmacy network.

III. HHS should reject MassHealth's request to establish narrower networks in the PCC plan.

MassHealth proposes to implement narrower networks in the PCC plan to encourage members to enroll in Accountable Care Organizations (ACOs) and Managed Care Organizations (MCOs) rather than the PCC plan. As noted in the MassHealth Request, the PCC plan currently uses open provider networks. As a result, the PCC plan is an important option for individuals living with HIV who require consistent access to a variety of health care providers that may not all participate in an a particular MCO or ACO network. By instituting narrow networks, MassHealth would introduce this same problem into the PCC plan, separating patients with complex conditions like HIV from

[13] Wayne Turner & Shyaam Subramanian, *Essential Health Benefits Prescription Drug Standard,* Nat'l Health Law Program, http://www.healthlaw.org/publications/browse-all-publications/ehb-prescription-drug-standard-mail-order-pharmacies#.VYimyGASe_d.

providers that they know and trust, and creating potential gaps in care as patients work to identify and access new in-network providers.

We therefore request that HHS reject MassHealth's request to establish narrower networks in the PCC plan.

IV. HHS should reject MassHealth's request to eliminate MassHealth eligibility for non-disabled adults with incomes above 100% of the Federal Poverty Level (FPL).

The MassHealth Request proposes to eliminate eligibility for approximately 140,000 non-disabled adults with incomes above 100% of the FPL. Instead, these individuals would need to enroll in subsidized private health insurance plans available via the ConnectorCare program. While individuals living with HIV would be exempt from this change, we remain concerned about the implications of this proposal for the thousands of other Massachusetts residents living with similar serious and complex chronic illnesses. We therefore urge HHS to reject the proposal to eliminate MassHealth eligibility for non-disabled adults with incomes above 100% of FPL for the following reasons:

a. *Not all individuals eliminated from MassHealth eligibility are eligible for ConnectorCare.*

Not all individuals eliminated from MassHealth are allowed to enroll in ConnectorCare. For example, individuals with Deferred Action Status (Deferred Action for Childhood Arrivals (DACA))[14] and married couples who file separately[15] are not eligible for coverage by ConnectorCare plans. As a result, these individuals would lose access to affordable health insurance, endangering their health and placing additional strain on Massachusetts' safety net systems.

b. *At current rates, over 54,000 individuals who are eliminated from MassHealth, but become eligible for ConnectorCare, will end up uninsured.*

Individuals who are eligible for ConnectorCare often struggle to enroll, leaving them without access to any coverage at all. As HHS is aware, enrolling in the Affordable Care Act (ACA) state exchanges is a persistent challenge both across the country[16] and within Massachusetts. The subsidized

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[14] To enroll in a qualified health plan (QHP) through the Exchange, an individual must be lawfully present. 45 C.F.R. § 155.305(a)(1). (2016). However, the definition of lawfully present does not include individuals with deferred action for childhood arrivals (DACA). 45 C.F.R. § 152.2(8) (2016).

[15] *See* 956 C.M.R. §§ 12.04, 12.08 (noting that individuals must be eligible for premium tax credits in order to be eligible for ConnectorCare plans); "If you are considered married for federal income tax purposes, you must file a joint return with your spouse to take the PTC [premium tax credits]." There are two exceptions: if individuals are married but "meet the requirements for married persons who live apart under head of household in the instructions for Form 1040 or 1040A" or are the victims of domestic abuse or spousal abandonment. DEP'T OF THE TREASURY, INTERNAL REVENUE SERV., Pub. No 974, *Premium Tax Credit: For Use in Preparing 2016 Returns* 6-7 (Jan. 3, 2017), https://www.irs.gov/pub/irs-pdf/p974.pdf.

[16] *See generally* THE HENRY J. KAISER FAMILY FOUND., *Marketplace Enrollment as a Share of the Potential Marketplace Population* (Mar. 31, 2016), https://www.kff.org/health-reform/state-indicator/marketplace-enrollment-as-a-share-of-the-potential-marketplace-population-2015/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

ConnectorCare program faces this same challenge. As of July 14, 2017, of the 24,627 individuals who were then eligible for ConnectorCare Plan Type 1, thirty-nine percent (9,606) were not enrolled in a plan.[17]

Given the many challenges faced by the low-come individuals who will be forced to transition to ConnectorCare, we believe it is conservative to assume that eligible but unenrolled rates in ConnectorCare will be reflected among individuals who lose MassHealth eligibility at around forty percent.[18] With around 140,000 individuals estimated to lose MassHealth eligibility under the Amendment Request,[19] over 54,000 individuals are projected to not successfully enroll in ConnectorCare and instead become uninsured. MassHealth chose not to address these issues in their response to public comments, [20] and has not explained how over 54,000 individuals ending up uninsured furthers the purposes of the Medicaid Act or is an allowable outcome of an 1115 waiver.

c. *ConnectorCare provides worse treatment options for individuals living with serious medical issues, negatively impacting the public health of Massachusetts*

Finally, the proposal to eliminate MassHealth eligibility for non-disabled adults with incomes above 100% of the FPL will also significantly impact access to care *even* for individuals who successfully transition to ConnectorCare. As a program designed to meet the unique needs of low-income individuals living with disability or illness, MassHealth provides key protections—such as an open formulary—to ensure access to care. By pushing these vulnerable populations into plans with less comprehensive coverage and fewer consumer protections than MassHealth, the proposed change will undermine not only individual care but also the state's broader public health goals.

For all of the reasons described above, HHS should reject MassHealth's request to eliminate eligibility for MassHealth for non-disabled adults above 100% of the FPL.

The HIV Health Care Access Working Group thanks you for the opportunity to provide input on this MassHealth 1115 Demonstration Amendment Request. For all of the reasons discussed above, we urge you to reject the MassHealth Request, as it would negatively impact access to affordable care and treatment for individuals living with HIV.

Contact Robert Greenwald with the Treatment Access Expansion Project at rgreenwa@law.harvard.edu, Amy Killelea with the National Alliance of State and Territorial AIDS

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[17] Data from Health Connector presented in the Massachusetts Law Reform Institute public comment. MASS. EXEC. OFF. OF HEALTH AND HUMAN SERVS., *Public Comments to Proposed MassHealth Section 1115 Demonstration Amendment Request July 20, 2017 – August 21, 2017* 134 http://www.mass.gov/eohhs/docs/eohhs/healthcare-reform/masshealth-innovations/public-comments-to-proposed-masshealth-section-1115-demonstration-amendment-request.pdf.

[18] *See id.*

[19] *See See* MASS. EXEC. OFF. OF HEALTH AND HUMAN SERVS., OFF. OF MEDICAID, *MassHealth Section 1115 Demonstration Amendment Request* at 5 (Sept. 8, 2017).

[20] In response to public comments, MassHealth addresses concerns about affordability and coverage on commercial plans, but it does not address the likelihood that many current MassHealth members will not make it onto commercial plans in the first place. *See id.* at 21.

Directors at akillelea@NASTAD.org, or Andrea Weddle with the HIV Medicine Association at aweddle@hivma.org with any questions regarding how people living with HIV would be affected by Massachusetts' proposed waiver. Thank you for your time and consideration.

Respectfully submitted by the undersigned organizations,

ADAP Educational Initiative
African American Health Alliance
AIDS Action Baltimore
AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
AIDS Research Consortium of Atlanta
AIDS Resource Center of Wisconsin
AIDS United
American Academy of HIV Medicine
APLA Health
Cascade AIDS Project
Communities Advocating Emergency AIDS Relief (CAEAR)
Community Access National Network (CANN)
Community Research Initiative of New England, Inc.
Georgia AIDS Coalition
Harm Reduction Coalition
HealthHIV
HIV Medicine Association
Housing Works
Human Rights Campaign
Lambda Legal
Legal Council for Health Justice
Michigan Positive Action Coalition
Minnesota AIDS Project
National Alliance of State and Territorial AIDS Directors
National Latino AIDS Action Network
National Viral Hepatitis Roundtable
NMAC
Northwest FL AIDS/HIV Consortium Noflacweb.org
Positive Women's Network - USA
Project Inform
Rocky Mountain CARES
San Francisco AIDS Foundation
SisterLove
Southern AIDS Coalition
Southern HIV/AIDS Strategy Initiative

The AIDS Institute
Thrive Alabama
Treatment Access Expansion Project
Treatment Action Group
UCHAPS

cc: Seema Verma, Administrator for the Centers for Medicare and Medicaid Services (CMS)