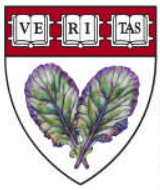

CENTER FOR HEALTH LAW
& POLICY INNOVATION
Harvard Law School

August 21, 2017

Daniel Tsai
Assistant Secretary for MassHealth
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

Submitted by email to kaela.konefal@state.ma.us

Re: Comments for Demonstration Amendment

Dear Assistant Secretary Tsai,

On behalf of the Harvard Law School Center for Health Law and Policy Innovation (CHLPI), we are grateful for the opportunity to comment on the MassHealth 1115 Demonstration Waiver Amendment Request posted on July 20, 2017.

CHLPI advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with HIV, Hepatitis C (HCV), and other chronic health conditions. As part of our work, we partner with advocates across the country and in Massachusetts to expand access to care for vulnerable populations. In particular, we frequently collaborate with the HIV and HCV communities to ensure that individuals are able to access the lifesaving treatments they need. In Massachusetts, we have helped lead the End Hep C MA Coalition and have been involved in state HIV advocacy for over twenty-five years.

With your support, Massachusetts has established itself as a national leader in the fight to end the HIV and HCV epidemics. As a state, we have reduced both reported HIV diagnoses and deaths by over 40% since 2000.[1] We have also become one of the first states in the nation to ensure that Medicaid enrollees have true and equitable access to curative, breakthrough treatments for HCV.[2]

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[1] *Massachusetts HIV/AIDS Data Fact Sheet: The Massachusetts HIV/AIDS Epidemic at a Glance,* MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH OFFICE OF HIV/AIDS, http://www.mass.gov/eohhs/docs/dph/aids/2014-profiles/epidemic-glance.pdf.
[2] *See* Daniel Tsai, *MassHealth Managed Care Organization Bulletin 6* (July 2016), http://www.mass.gov/eohhs/docs/masshealth/bull-2016/mco-6.pdf.

We share your commitment to maintaining the gains Massachusetts has made in these areas and in access to affordable health coverage for all low-income residents. However, we are concerned that certain policies put forth in this 1115 Demonstration Waiver Amendment Request would decrease both the access to and affordability of crucial services for low-income individuals living with HIV, HCV, and other chronic health conditions. These policies are particularly concerning from a public health perspective, as they have the potential to deter those with limited means from getting treated, increasing the likelihood that new transmissions of HIV and HCV may occur and undercutting the significant progress that Massachusetts has made in addressing the burden of these serious chronic and communicable illnesses.

In particular, we are concerned with the following proposals and urge MassHealth to remove them from the 1115 Demonstration Waiver Amendment Request:

Eliminate MassHealth Eligibility for Non-Disabled Adults with Incomes Above 100% FPL

MassHealth proposes to eliminate eligibility for approximately 140,000 non-disabled adults with incomes above 100% of the federal poverty level (FPL). Instead, these individuals would generally be transitioned to subsidized private health insurance plans available via the ConnectorCare program. While we appreciate that this proposal would not simply leave these individuals without access to needed care, we are concerned that it will result in new and significant cost-sharing requirements for many vulnerable, low-income people. Additionally, while those living with HIV are exempt from this proposal, people living with HCV are not and this will ultimately result in decreased HCV treatment adherence and increased likelihood of new transmissions.

Under this proposal, many individuals living with HCV would be transitioned into the private insurance market through the ConnectorCare program. These individuals would see their out-of-pocket cost-sharing obligations increase dramatically, including cost-sharing for curative HCV treatments that can prevent further transmission of the virus.[3] For example, MassHealth members currently pay a maximum copayment of $3.65 per prescription.[4] However, once transitioned to the ConnectorCare program, individuals with incomes between 100-133% FPL would instead pay $40 each time they fill a prescription for their lifesaving HCV medications.[5]

We strongly urge MassHealth to reconsider eliminating eligibility for non-disabled adults with incomes over 100% FPL. This proposed change is broadly concerning for four primary reasons:

Financial barriers to obtaining care and treatment. Research has consistently demonstrated that imposing even minimal levels of cost-sharing on low-income populations serves as a barrier to obtaining and

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[3] *FAQs about Sustained Virologic Response to Treatment for Hepatitis C*, U.S. DEPARTMENT OF VETERANS AFFAIRS, VETERANS HEALTH ADMINISTRATION, https://www.hepatitis.va.gov/pdf/sustained-virological-response.pdf.

[4] *See Covered Services*, MASS. EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVS., http://www.mass.gov/eohhs/consumer/insurance/masshealth-member-info/covered-services.html.

[5] *ConnectorCare Health Plans*, MASS HEALTH CONNECTOR, https://www.mahealthconnector.org/wp-content/uploads/Guide_to_ConnectorCare.pdf.

maintaining care and treatment.[6] Lower-income individuals are more likely to reduce their use of even essential services in the face of increased financial burdens, leading to a rise in the use of other costlier services such as emergency room visits.[7] Increasing the financial burden associated with accessing HCV treatments may therefore deter low-income individuals from seeking or continuing treatment, or force these individuals to choose between filling their prescriptions and paying for other household necessities such as food, housing, and childcare. While MassHealth members may not be refused care or services due to nonpayment, enrollees in commercial health insurance plans offered through the ConnectorCare program do not share this protection, further adding to the likelihood that these individuals will be unable to access their medications due to financial hardship.[8]

Undermine efforts to end HCV in the Commonwealth. This proposal will reverse the progress Massachusetts has made towards ensuring that its low-income citizens have true and equitable access to the cure for HCV. The Massachusetts Office of Medicaid recently mandated that all enrollees participating in MassHealth via the fee-for-service program, primary care clinician plan, or a managed care organization (MCO) be provided with the same treatment policy for HCV: open access without the imposition of restrictions related to disease severity, alcohol and/or substance use abstinence, or prescriber specialty.[9] In adopting this policy, MassHealth eliminated the potential for arbitrary or discriminatory restrictions and created a uniform system in which low-income individuals have equal access to necessary HCV treatment.

In contrast, health plans offered through the ConnectorCare program do not appear to share this uniform open access policy. As a result, each participating insurer may manage their prescription drug benefits as they see fit, and, in particular, limit which drugs are covered and impose far more restrictive coverage rules for HCV medications than currently allowable in MassHealth. For example, Fallon Health, one insurer currently offering ConnectorCare plans, restricts access for Harvoni to only those patients who have advanced liver disease and mandates that individuals must be abstinent from drug and alcohol use for 12 months prior to initiating treatment.[10] Transitioning individuals above 100% FPL to ConnectorCare plans that impose these types of utilization management restrictions will limit access to HCV care, undermining the progress made under MassHealth's open access policy. Once again, these individuals will be at the mercy of private insurers and have to navigate each insurer's treatment policy and drug coverage rather than relying on MassHealth's open access standard.

Negative public health consequences. This proposal will negatively impact the public health of the

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[6] *See* Samantha Artiga, Petry Ubri, and Julia Zur, *The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings,* KAISER FAMILY FOUNDATION, http://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/.

[7] *Id.*

[8] 42 U.S.C. 1396o(e); *See Copayments Frequently Asked Questions*, MASS. EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVS., http://www.mass.gov/eohhs/provider/insurance/masshealth/claims/customer-services/copayments-faqs.html.

[9] *See* Daniel Tsai, *MassHealth Managed Care Organization Bulletin 6* (July 2016), http://www.mass.gov/eohhs/docs/masshealth/bull-2016/mco-6.pdf.

[10] *See Prior Authorization Approval Criteria: Harvoni (ledipasvir and sofosbuvir),* Fallon Health, http://www.fchp.org/providers/pharmacy/~/media/Files/FCHP/Imported/harvoni_ledipasvirsofosbuvir.ashx.

Commonwealth. When faced with greater cost-sharing and restrictive utilization management requirements, many individuals may be unable to realistically access the cure for HCV. As a result, this proposal has the potential to increase new transmissions of the virus. Treatment and cure of HCV is a highly-effective prevention method: once an individual achieves virologic cure, they can no longer transmit HCV to others through any means.[11] If fewer individuals are able to become cured of HCV due to the issues outlined above, more transmissions will occur, eroding the progress we have made to date towards eradicating the virus in Massachusetts.

Uncertain federal financial support. This proposal may negatively impact both the state and individuals involved because it depends upon a program that is currently at significant financial risk. In order to maintain affordable coverage, many of the individuals being transitioned off of MassHealth will need to choose ConnectorCare plans. However, the ConnectorCare program is partially funded with revenues from the Affordable Care Act's (ACA) cost-sharing reduction (CSR) subsidies and advance premium tax credits.[12] Currently, the Affordable Care Act's future is being debated in Congress, and the current Administration, regardless of efforts to repeal and replace the ACA, has consistently refused to commit to continued funding for the CSR program. Given the substantial uncertainty facing not only the CSR program but also the ACA as a whole, the future of the ConnectorCare program seems far from certain. Therefore, shifting a significant number of MassHealth enrollees into the ConnectorCare program could ultimately place either the state or individual enrollees at financial risk should federal funding end.

Select Preferred and Covered Drugs Through a Closed Formulary

MassHealth proposes to establish a closed formulary with preferred and covered drugs across the entire program. Currently, MassHealth is required to cover any drug for which the manufacturer participates in the federal Medicaid rebate program. This requirement ensures that patients have access to the highest standard of care available and allows physicians to prescribe the course of treatment they and their patients believe is most appropriate. A closed formulary would restrict the drugs MassHealth covers, with as few as one drug available per therapeutic class. Unlike several of the changes proposed elsewhere in this 1115 Waiver Amendment Request, this would apply to all MassHealth members, including people living with disabilities, children, and seniors. Prescription drugs are a lifeline for people living with chronic and complex conditions, and further restrictions on access to medications will only serve as a barrier to obtaining the treatment regimens that are most appropriate for these individuals.

This proposal is particularly concerning for continued access to HIV and HCV medications. Physicians choose which drugs to prescribe their HIV and HCV patients based on a wide range of

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[11] *FAQs about Sustained Virologic Response to Treatment for Hepatitis C*, U.S. DEPARTMENT OF VETERANS AFFAIRS, VETERANS HEALTH ADMINISTRATION, https://www.hepatitis.va.gov/pdf/sustained-virological-response.pdf.

[12] Jaimie Bern, Stephanie Chrobak & Tom Dehner, *Implementing the Affordable Care Act in Massachusetts: Changes in Subsidized Coverage Programs*, BLUE CROSS BLUE SHIELD OF MASS. FOUND. 8-10, 13-14 (2015), http://bluecrossmafoundation.org/sites/default/files/download/publication/Changes%20in%20Subsidized%20Coverage%20Programs_final.pdf.

factors, including co-occurring illnesses, medical history, and previous treatment tolerance.[13] It is important to note that HIV and HCV drug regimens are not interchangeable. HIV and HCV are complex diseases and treatment options must take into account several individualized medical factors as well as concerns regarding a patient's medication adherence. Before initiating treatment, physicians must consider drug interactions, coexisting conditions, and side effect profiles. Therefore, it is important that doctors are able to provide treatment based on patients' needs, not on availability in MassHealth.

Implementing an exceptions process to a closed formulary through which an individual can attempt to access coverage for a drug not on the formulary would also fall far short of ensuring that people living with HIV or HCV and their providers can access the appropriate treatment regimen. This is true because of the uncompensated cost to providers of going through the exceptions process, because this coverage is not guaranteed, and because the process of obtaining this coverage is often opaque.[14] Given these concerns, we urge MassHealth to consider alternative strategies to lower prescription drug spending that will not adversely impact beneficiaries' access to medically necessary medications.

Procure a Selective Specialty Pharmacy Network for PCC and Fee-for-Service

We are concerned that 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 may have the unintended effect of imposing unnecessary barriers to obtaining lifesaving specialty medications. While specialty pharmacies can provide care coordination benefits to those that prefer them, they often present physical access problems for those experiencing homelessness and people in transient living situations. This is especially true where no brick-and-mortar locations are readily accessible and members are forced to receive their medications in the mail. 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.[15] 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.

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,

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[13] *See generally Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents,* DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf; *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*, American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, http://www.hcvguidelines.org/.

[14] *See* James L. Raper et al., *Uncompensated Medical Provider Costs Associated with Prior Authorization for Prescription Medications*, 51 CLINICAL INFECTIOUS DISEASES 718, 720 (2010).

[15] 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.

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. Further, individuals are often 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.

Given these concerns, we urge you to ensure that members covered in the fee-for-service program and the PCC plan continue to have access to their medications through brick-and-mortar pharmacy locations and are not forced to receive them through mail order. This enhanced choice of pharmacy is particularly important for people living with complex medical needs, as these individuals frequency choose the PCC plan instead of enrolling with an MCO.

Eliminate MassHealth Eligibility for Individuals with Access to Employer-Sponsored Insurance

MassHealth proposes to preclude non-disabled adults with access to "affordable" employer-sponsored insurance or a student insurance plan from being eligible for MassHealth coverage. We are deeply concerned that this eligibility "gate" would force some individuals to forego treatment or insurance coverage altogether, as they would not be able to relinquish even a modest percentage of their income to pay their share of premiums and out-of-pocket costs. Under the terms of the 1115 Waiver Amendment Request, a plan would be considered "affordable" if premium costs are less than five percent of an individual's income. MassHealth has since stated in a public presentation that plans will only be considered affordable if premium *and* deductible costs are less than five percent of income. We applaud MassHealth's recognition that affordability is dependent not only on premium costs, but also on expenses such as the plan deductible. However, we are concerned that this change does not go far enough as it fails to take into account an individual's full range of out-of-pocket costs, including copays and coinsurance that enrollees must pay on top of their deductible. For individuals living with chronic illnesses such as HIV and HCV, these additional costs are both unavoidable and significant.

We are concerned that even with the 5% threshold, this eligibility "gate" would leave some low-income individuals living with chronic illness without access to treatment, as they would find it overwhelmingly burdensome financially to relinquish even five percent of their income to pay their premium and out-of-pocket costs. According to a recent analysis by Massachusetts's Center for Health Information and Analysis (CHIA), in 2016 employees of lower-wage employers were 27% less likely to enroll in their employer's health plan than employees of higher-paying firms.[16] CHIA suggests that this difference in take-up rates may occur "because low-wage workers are less able to afford employer-based plans, especially because wages have not risen concomitantly with health

[16] *See* Center for Health Information and Analysis, *The Benefits Divide: Workers at Lower-Wage Firms and Employer-Sponsored Insurance in Massachusetts*, 12 (Aug. 2017), *available at* http://www.chiamass.gov/assets/docs/r/pubs/17/mes-research-brief-august-2017.pdf.

insurance costs."[17] Such cost concerns would be particularly severe for individuals living with chronic illness, leaving them to make painful choices between receiving the care they need and paying for other household expenses.

Beyond these issues of affordability, this new "gate" would also expose individuals to commercial insurance practices that will limit their ability to access care and treatment. As compared to MassHealth, employer-sponsored insurance may provide far less robust coverage of HIV/HCV medications and restrict access to treatment through burdensome utilization management techniques. These barriers may prevent individuals from getting treated, increasing the likelihood that new HIV/HCV transmissions will occur. For all of these reasons, we urge MassHealth to remove the employer-sponsored insurance and student health insurance "gate" from its 1115 Waiver Amendment Request.

Finally, while MassHealth has noted that it would establish a hardship waiver process for individuals with special circumstances, we do not currently have enough detail on the hardship waiver process to comment on it. Therefore, if MassHealth does choose to include the "gate" in its 1115 Waiver Amendment Request, we ask that MassHealth provide additional details on the hardship waiver program and how it will address the needs of individuals living with costly chronic illnesses.

Establish Narrower Networks in the Primary Care Clinician (PCC) Plan

MassHealth proposes to implement narrower networks in the PCC plan to encourage members to enroll in Accountable Care Organizations (ACOs) and MCOs rather than the PCC plan. As noted in the 1115 Waiver Amendment Request, the PCC plan currently uses open provider networks. As a result, the PCC plan can be an important option for individuals living with chronic illnesses 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 from 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 MassHealth maintain its open networks for the PCC plan or provide more information on how it will address the potential impact of the narrower networks on individuals living with chronic disease.

The Harvard Law School Center for Health Law & Policy Innovation thanks you for the opportunity to provide input on this MassHealth 1115 Demonstration Amendment Request. For all of the reasons included here, we urge you to reconsider the policies we have outlined above, as they will negatively impact access to care for low-income individuals living with chronic health conditions such as HIV and HCV, and ultimately undermine our ability to end these epidemics in Massachusetts. We appreciate the dialogue the Administration has opened to discuss our concerns, and look forward to working with you to ensure that any changes to MassHealth do not adversely

[17] *Id.*

impact members. Should you have any questions, please contact Robert Greenwald at (617) 877-3223 or rgreenwald@law.harvard.edu or Phil Waters at (617) 390-2568 or pwaters@law.harvard.edu.

Thank you for your time and consideration.

Sincerely,

Robert Greenwald
Clinical Professor of Law
Faculty Director, Center for Health Law and Policy Innovation
Harvard Law School

cc: Mary Lou Sudders, Secretary, Executive Office of Health and Human Services
Robin Callahan, Deputy Director, MassHealth