March 23, 2018

Chairman Jeffrey Sánchez

House Committee on Ways and Means

State House

Room 243

Boston, MA 012133

**Re: Comments on MassHealth Formulary Provisions of House 2**

Dear Chairman Sánchez,

On behalf of the Center for Health Law and Policy Innovation (CHLPI) of Harvard Law School, the Massachusetts Law Reform Institute (MLRI), and the undersigned organizations, we are grateful for the opportunity to provide the Committee on Ways and Means with feedback on the provisions of Governor Baker’s proposed FY 2019 budget (House 2) that seek to control drug prices in the MassHealth program.

For the reasons discussed below, we particularly urge the Committee to take the following actions with respect to the FY 2019 budget:

* **The Committee should adopt Section 42 of House 2, which would allow MassHealth to use direct negotiation and increased transparency as levers to contain drug costs.**
* **The Committee should reject Section 68 of House 2, which would allow MassHealth to restrict medication access through the use of a closed formulary.**

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.

MLRI is a statewide nonprofit poverty law and policy center. Its mission is to advance economic, racial and social justice through legal action, policy advocacy, coalition building, and community outreach. MLRI specializes in large-scale legal initiatives and systemic reforms that address the root causes of poverty, remove barriers to opportunity, and create a path to economic stability and mobility for low-income individuals, families and communities. In addition, MLRI serves as the statewide poverty law support center for the Massachusetts civil legal services delivery system, providing expertise and support to local legal aid programs and also to social service, health care and human service providers, and other community organizations that serve low income people.

We, the undersigned organizations, understand that rising pharmaceutical prices are placing an increasing strain on the MassHealth program. We are therefore broadly supportive of attempts to rein in drug spending. However, we also recognize that attempts to limit spending should not come at the cost of limiting access to critical care and treatment for our Commonwealth’s most vulnerable populations. For these reasons, we urge the Committee to adopt the Governor’s proposal to increase MassHealth’s ability to control prices through transparency and direct negotiation with pharmaceutical manufacturers (Section 42), but reject any measure that would allow MassHealth to entirely exclude certain drugs from its formulary (Section 68).[[1]](#footnote-1)

## **Support for Provisions Promoting Use of Increased Transparency to Control Costs (Section 42)**

Section 42 of the Governor’s budget proposal aims to give MassHealth additional leverage to negotiate lower prices with drug manufacturers for high-cost drugs. Under the provisions of this section, MassHealth would directly negotiate supplemental rebates with manufacturers.[[2]](#footnote-2) In the event that such negotiations fail, MassHealth could require manufacturers to disclose information to justify its prices and testify at a public hearing. If the manufacturer refuses to comply with these measures or the Secretary of the Executive Office of Health and Human Services (EOHHS) determines that the proposed price is excessive or unreasonable, the Secretary could impose sanctions, including monetary penalties.

We support this proposal as an innovative and thoughtful approach to controlling drug costs. It is modeled after a similar procedure currently being implemented in New York,[[3]](#footnote-3) which has proven successful in bringing manufacturers to the table and driving down drug prices. The transparency measures and potential sanctions would act as strong deterrents to unreasonable and excessive pricing. Further, the measure would not cut costs on the backs of MassHealth beneficiaries, as this exchange between MassHealth and manufacturers would not limit access to drugs for beneficiaries.

## **Opposition to Provisions Allowing MassHealth to Establish a Closed Formulary (Section 68)**

Section 68 of the Governor’s budget proposal would empower MassHealth to implement a closed formulary. The proposal would give MassHealth the ability to exclude drugs from its formulary, provided there is at least one drug covered per therapeutic class. This same proposal was included in the Administration’s package of MassHealth reforms introduced last summer. However, the legislature refused to enact this provision after consumer groups expressed concerns that it would result in MassHealth beneficiaries being denied access to crucial medications. For the following reasons, we urge the Committee to continue to reject this proposal in the 2019 budget.

### **The creation of a closed formulary would violate federal law.**

Historically, Congress has played a critical role in controlling Medicaid drug prices. Through Section 1927 of the Social Security Act (42 U.S.C. § 1396r–8), Congress established a drug rebate program in which pharmaceutical manufacturers must provide a national rebate, or discount, on the price of drugs in the Medicaid program. Congress takes this program quite seriously, and as recently as 2010 raised the standard rebate amount from 15.1% to 23.1%.[[4]](#footnote-4) Through this program, Congress ensures, with few exceptions, that state Medicaid programs receive the best price for covered drugs. Individual states also have the ability to negotiate additional rebates beyond the federal floor to drive prices even lower. In exchange for participation in the rebate program, Congress requires state Medicaid programs to cover almost all drugs produced by participating manufacturers. Thus, the drug rebate program has the effect of not only guaranteeing low prices to states, but also ensuring broad access to crucial medications for our most vulnerable populations.

Section 68’s proposal to create a closed formulary would violate Section 1927 by allowing MassHealth to exclude any manufacturer’s drugs from coverage, even if the manufacturer has agreed to participate in the national rebate program. Notably, MassHealth itself has recognized the legal barrier that Section 1927 creates. Massachusetts is therefore currently seeking authority from the federal government to waive the provisions of Section 1927 under a Section 1115 Demonstration Waiver.[[5]](#footnote-5) However, in the unlikely event that the federal government approves the closed formulary proposal, the Massachusetts legislature should reject it, as the rebate provisions of Section 1927 cannot legally be waived. The D.C. Circuit court 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.”[[6]](#footnote-6) The proposal to institute a closed formulary therefore violates federal law and cannot be legalized without a change to that law, even through the 1115 Waiver process.

But beyond being simply illegal, this proposal would also potentially undermine Massachusetts’s ability to call upon the basic protections that Section 1927 creates. Currently, Massachusetts utilizes not only the basic 23.1% rebate, but also has been successful in negotiating additional rebates beyond the federal floor. If Massachusetts establishes a closed formulary, it may, in some instances, be able to negotiate even greater discounts on some drugs than are available under the current system, but it would do so at the cost of arguably breaking the contract that Section 1927 creates with manufacturers. As a result, manufacturers may no longer be obligated to provide the baseline 23.1% rebate, meaning that while some prices could fall, others could rise, jeopardizing both state finances and access to care for our most vulnerable populations.

1. **Section 68 fails to protect particularly vulnerable populations, including those living with chronic conditions like HIV, HCV, and behavioral health conditions.**

MassHealth has indicated through secondary materials that it plans to establish certain guardrails to the closed formulary proposal in order to protect access to care for vulnerable populations. The creation of these guardrails would not change the fact that a closed formulary would be fundamentally illegal under federal law. However, it is also worth noting that almost none of these guardrails have been outlined in a legally enforceable way. As a result, these guardrails are in some ways dangerous in their own right, as they give the misleading impression that the program will be far less onerous than it actually could turn out to be.

For example, MassHealth stated in its September 8, 2017 1115 Waiver Amendment Request that it would implement the closed waiver “with a strong emphasis on ensuring continued access, especially with respect to vulnerable populations who require medications to treat mental health and substance use, HIV, Hepatitis C, and other serious conditions.”[[7]](#footnote-7) However, this language is not only vague but also appears only in a section of the Request responding to public comments, and not in the substance of the Request itself. This language also does not appear in the legislative text of Section 68.

Similarly, MassHealth states in its summary of Section 68 that “no drug will be excluded unless it is also excluded on either the Commonwealth’s Group Insurance Commission (GIC) plan or at least one national pharmacy benefits manager (PBM).” Like many of the protections that MassHealth cites in its summary, there is nothing in the text of Section 68 that would hold MassHealth to this standard. If Section 68 is enacted, there is nothing in the legislative language that would prevent MassHealth from imposing a more restrictive formulary than the GIC plans or a national PBM.

Additionally, even if this protection were built into the legislative language, this standard would do little to truly protect access to care. For example, an analysis of national PBM and GIC formularies shows that several exclude many critical hepatitis C (HCV) drugs in their formularies, including some of the newest treatments that are most effective at treating the disease. Complex conditions such HIV, HCV, and behavioral health issues require treatment regimens tailored to each individual patient’s needs – there is no such thing as a “one size fits all” medication for these conditions. Refusing to cover even some drugs for these chronic conditions will interfere with the doctor-patient relationship, lead to worse outcomes for MassHealth patients, undermine public health advances, and potentially even drive up costs in the Commonwealth by limiting access to early care and treatment that can prevent the need for more intensive services.

### **Section 68 also fails to include purported procedural protections.**

MassHealth has also used secondary materials to lay out certain procedural guardrails that would theoretically limit the impact of the closed formulary proposal. However, like the medical guardrails described above, these guardrails would not change the fundamentally illegal nature of the closed formulary proposal or guarantee access to care for Medicaid populations. Furthermore, they have once again not actually been built into the legislative language, making them potentially misleading and unenforceable.

MassHealth has published a summary of Sections 42 and 68 in which it frames the closed formulary provision as a follow-up step that is only to be taken if the direct negotiation and transparency measures under Section 42 fail or if the drug has no proven clinical efficacy.[[8]](#footnote-8) However, the Governor’s budget proposal, as written, does not actually require MassHealth to engage in the negotiations and public hearing that Section 42 calls for. Instead, Section 68 gives MassHealth the authority to “determine, subject to required federal approvals, the extent to which to include within its covered services federally-optional coverage of prescribed drugs,” provided that at least one drug is covered per therapeutic class, and more than one drug is covered in certain, unspecified, therapeutic classes.

As with the protections described above, nothing in the current language of the proposed budget itself actually establishes this relationship between Sections 42 and 68. As written, Section 68 is a distinct provision that would allow MassHealth to exclude a drug from its formulary without subjecting it to the negotiation and transparency process. Furthermore, in the absence of a clearly defined relationship between these two sections, Section 42 could be repealed without any impact to Section 68, leaving only the closed formulary provisions. In either scenario, MassHealth could choose to exclude a drug before engaging in direct negotiations with a manufacturer under Section 42.

### **Section 68 would allow MassHealth to undermine the Food and Drug Administration’s (FDA) approval process**

Section 68 also proposes to provide MassHealth with the authority to determine which drugs and drug classes have demonstrated clinical efficacy – a step that would allow MassHealth to overrule the judgment of the federal Food and Drug Administration (FDA) and eliminate coverage for certain classes of drugs entirely. Section 68 only requires MassHealth to cover at least one drug in a therapeutic class “where at least one drug in the class has demonstrated clinical efficacy.” This language would allow MassHealth to choose to completely eliminate coverage of a particular class if it determines by its own process that an FDA-approved class of drugs has no clinical efficacy.

MassHealth has provided no evidence that the FDA, which Governor Baker has criticized for its slow pace of approvals in other contexts, is allowing drugs with no clinical efficacy to come to market at significant rates, even through its accelerated approval process. Furthermore, there is no guarantee that MassHealth will limit its review of FDA approvals to just the small class of drugs that are approved through this accelerated process. Instead, Section 68 would provide MassHealth with the broad power to exclude access to entire classes of drugs that have received FDA approval, undermining both the authority of the FDA and access to vital care for MassHealth beneficiaries.

### **Enacting a closed formulary would set a dangerous national precedent.**

Massachusetts can be justifiably proud of our history of leading the country in expanding healthcare access. By enacting Section 68’s closed formulary proposal, Massachusetts would ignore this tradition and instead set a dangerous new standard for the rest of the nation. Rather than inspiring other states to work harder to provide care, this proposal would set the precedent for other states to restrict access to crucial medications, many of which would likely do so through even more sweeping and harmful measures. Enacting a closed formulary would therefore not only be harmful for individuals living with chronic conditions in Massachusetts, but also could be significantly damaging for Medicaid populations throughout the country.

## **Conclusion**

For the foregoing reasons, we urge the Committee to include Section 42 in its budget as an admirable step toward reducing drug costs without threatening the health of MassHealth beneficiaries. In contrast, we urge the Committee to follow the precedent set this past summer by continuing to reject Section 68 as a dangerous approach that could unduly restrict access to lifesaving care for Massachusetts’s most vulnerable populations.

We welcome the opportunity to discuss these provisions further or answer any questions that the Committee members might have. Please contact Neil Cronin at [ncronin@mlri.org](mailto:ncronin@mlri.org) or 617-357-0700 ext 309 to follow up.

Sincerely,

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Cc Members of House Ways and Means Committee

1. Mass. Off. of the Governor, *Fiscal Year 2019 (FY19) House 2 Budget Recommendation*,§§ 42, 68 (Jan. 24, 2018), *available at* <http://budget.digital.mass.gov/bb/h1/fy19h1/os_19/h68.htm>. [↑](#footnote-ref-1)
2. Mass. Off. of the Governor, *Fiscal Year 2019 (FY19) House 2 Budget Recommendation*,§ 42, *available at* <http://budget.digital.mass.gov/bb/h1/fy19h1/os_19/h42.htm>. [↑](#footnote-ref-2)
3. N.Y. Pub Health § 280 (McKinney 2018); *see also* Katherine Young and Rachel Garfield, *Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control*, The Henry J. Kaiser Family Foundation (Feb. 2018), *available at*: <https://www.kff.org/medicaid/issue-brief/snapshots-of-recent-state-initiatives-in-medicaid-prescription-drug-cost-control/>. [↑](#footnote-ref-3)
4. 42 U.S.C. § 1396r–8(c)(1)(B)(i)); *see also* *Health Policy Brief: Medicaid Best Price*, Health Affairs (Aug. 10, 2017), *available at:* <https://www.healthaffairs.org/do/10.1377/hpb20171008.000173/full/healthpolicybrief_173.pdf>. [↑](#footnote-ref-4)
5. *See MassHealth Section 1115 Demonstration Amendment Request*, Executive Office of Health and Human Services (Sept. 8, 2017), *available at*: <https://www.mass.gov/files/documents/2017/10/27/masshealth-section-1115-demonstration-amendment-request-09-08-17.pdf>. [↑](#footnote-ref-5)
6. 251 F.3d 219, 222 (D.C. Cir. 2001). [↑](#footnote-ref-6)
7. *MassHealth Section 1115 Demonstration Amendment Request*, Executive Office of Health and Human Services at 23 (Sept. 8, 2017), *available at*: <https://www.mass.gov/files/documents/2017/10/27/masshealth-section-1115-demonstration-amendment-request-09-08-17.pdf>. [↑](#footnote-ref-7)
8. Mass. Exec. Off. of Health and Human Servs., Off. of Medicaid *FY19 H.2 MassHealth Value-Based Pharmacy Purchasing Proposal* (Jan. 24, 2018), *available at* <https://www.mass.gov/files/documents/2018/01/24/masshealth-proposal-rx_0.pdf>. [↑](#footnote-ref-8)