

October 20, 2017

The Honorable Eric Hargan, Acting Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Hargan:

The undersigned organizations appreciate the opportunity to comment on Massachusetts' request to amend the Massachusetts Section 1115 Demonstration Project.

Massachusetts argues that the amendment is needed to “build on” the state’s demonstration project that was approved in November 2016. However, the amendment doesn’t explain why these changes are needed to implement the state’s current demonstration. Moreover, the state justifies several of the policies it is proposing on the basis that they will ensure “the long-term financial sustainability of the MassHealth program and reduce the shift in enrollment from commercial health insurance to MassHealth through the alignment of coverage for non-disabled adults with commercial plans, adoption of widely-used commercial tools for prescription drugs, and changes to cost sharing requirements for higher income members.” Saving money is not an appropriate basis for an 1115 waiver. Massachusetts has a statutory obligation to provide mandatory benefits to all those who are eligible. Saving money by restricting eligibility or benefits does not promote the objectives of the Medicaid program.<sup>1</sup>

Aligning coverage with commercial insurance is also an inadequate basis for changing Medicaid policies without further justification. Medicaid beneficiaries have characteristics and needs that are significantly different from those of the commercially insured population,<sup>2</sup> which is why Congress established protections and rights for Medicaid beneficiaries that differ from those enrolled in private coverage.

### **Ending Medicaid eligibility for adults with incomes above the poverty line would lead to loss of coverage for Medicaid beneficiaries**

Massachusetts’ proposal would lower Medicaid eligibility for non-disabled adults ages 21 to 64 with incomes above 100 percent of the federal poverty line. This change would apply to both adults newly eligible for Medicaid under the Affordable Care Act as well as parents and caretaker relatives who have had longstanding Medicaid eligibility under Massachusetts’ waiver. The state indicates

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<sup>1</sup> Centers for Medicare & Medicaid Services, accessed on October 10, 2017, <https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html>; see also Judith Solomon and Jessica Schubel, “Medicaid Waivers Should Further Program Objectives, Not Impose Barriers to Coverage and Care,” Center on Budget and Policy Priorities, August 29 2017, <https://www.cbpp.org/research/health/medicaid-waivers-should-further-program-objectives-not-impose-barriers-to-coverage>; see also *Beno v. Shalala* 30 F.3d 1057, 1069 (9th Cir. 1994) (stating that “a simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy” the statutory requirement that an 1115 Waiver be an experimental, demonstration or pilot project).

<sup>2</sup> Julia Paradise, “10 Things to Know About Medicaid: Setting the Facts Straight,” Kaiser Family Foundation, June 9 2017, <https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/>

that approximately 140,000 adults would be affected by this change, which would take effect in January 2019.

In addition, the state wants to continue receiving the enhanced Medicaid expansion federal match for eligible adults with income below the poverty line — a policy that CMS has said isn't permissible and has never been approved. In 2012, CMS issued guidance stating that while it would consider partial expansion proposals, the enhanced Medicaid expansion match rate wouldn't be available for a partial expansion.<sup>3</sup> This means that a state's regular Medicaid match rate would apply, as is the case in Wisconsin's partial expansion waiver.

Regardless of the federal match rate that would be available, we urge you to reject this request, which would not promote the objectives of the Medicaid program because it would likely lead to loss of coverage. Experience from other states that have lowered Medicaid eligibility, such as Wisconsin, Connecticut and Rhode Island, shows that even when efforts are made to assure a smooth transition to marketplace coverage, people get lost in the transition. In Rhode Island, despite considerable efforts, 1,271 parents of the 6,574 (or 19 percent) who lost Medicaid when the state rolled back eligibility never applied to enroll in a qualified health plan (QHP), and likely became uninsured.<sup>4</sup> During the first round of a similar parent eligibility rollback in Connecticut, only one in four parents losing Medicaid coverage enrolled in a QHP.<sup>5</sup> In Wisconsin, only one-third of those losing Medicaid coverage purchased QHPs although the state had predicted that 90 percent would.<sup>6</sup>

Massachusetts states that its proposed rollback in Medicaid eligibility would “improve continuity and reduce churn as long their income remains above 100 percent of the federal poverty line,” but there are other ways to address churn other than lowering Medicaid eligibility. For example, Massachusetts could request expenditure authority to provide 12 months of continuous Medicaid eligibility for adults, or test innovative delivery system reform efforts to improve continuity of care, such as encouraging Medicaid managed care plans to participate in the state's marketplace or vice versa (i.e., encouraging QHPs to participate in MassHealth). These alternative approaches are consistent with HHS' criteria for Medicaid waivers as they increase and strengthen overall coverage, improve health outcomes, and increase the efficiency and quality of care for Medicaid beneficiaries and other low-income populations rather than causing people to lose coverage as the state's proposal would likely do.<sup>7</sup>

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<sup>3</sup> Centers for Medicare & Medicaid Services, “Frequently Asked Questions on Exchanges, Market Reforms and Medicaid,” December 10, 2012, <https://www.medicare.gov/federal-policy-guidance/downloads/FAQ-12-10-2012-Exchanges.pdf>

<sup>4</sup> Kate Lewandowski, “Parent Eligibility Roll-Back in Rhode Island: Causes, Effects and Lessons Learned,” September 2015, <https://www.communitycatalyst.org/resources/publications/document/RI-parent-rollback-081215-KL.pdf?1439834245>

<sup>5</sup> Langer, S. et al. *Husky Program Coverage for Parents: Most Families Will Feel the Full Impact of Income Eligibility Cut Later In 2016* <http://www.ctvoices.org/sites/default/files/h16HUSKYIncomeEligibilityCut.pdf>

<sup>6</sup> Guy Boulton, “One-third who lost BadgerCare coverage bought plans on federal marketplace,” *Journal Sentinel*, July 16, 2014, <http://archive.jsonline.com/business/almost-19000-badgercare-plus-recipients-enrolled-in-obamacare-b99312352z1-267339331.html>

<sup>7</sup> Centers for Medicare & Medicaid Services, “About Section 1115 Demonstrations,” accessed October 13, 2017, <https://www.medicare.gov/medicaid/section-1115-demo/about-1115/index.html>.

The state also notes that its proposal would support its efforts in maintaining universal coverage in the state through improved enrollment procedures. Lowering Medicaid eligibility for non-disabled adults with incomes above 100 percent of the poverty line is *not* an improved enrollment procedure — it simply ends Medicaid coverage and leads to higher rates of uninsurance. Moreover, Massachusetts’ stated goal of ensuring the “long-term financial sustainability of” MassHealth through this proposal does not further the objectives of the Medicaid program as saving money has been found to not be a permissible purpose for a section 1115 demonstration.

### **Waiver of Non-Emergency Medical Transportation Benefit Would Restrict Access to Care**

Massachusetts proposes to waive the non-emergency medical transportation (NEMT) benefit for all non-disabled non-elderly adults with incomes below the poverty line (which would include ACA expansion adults and parents and caregivers). Massachusetts has not articulated how waiving NEMT fits with their waiver’s demonstration hypotheses or how it would further the objectives of the Medicaid program. As noted, its stated reasons of saving money and aligning coverage with commercial plans are not acceptable justifications.

If approved, Massachusetts would become the third state to waive the NEMT benefit for the expansion population (Indiana and Iowa are the others). Evidence from Indiana shows waiving NEMT has a potentially harmful impact on beneficiaries with low incomes. For example, a November 2016 Lewin Group evaluation<sup>8</sup> of Indiana’s NEMT waiver found that Healthy Indiana Plan (or HIP, the state’s name for its Medicaid expansion) participants without access to NEMT were more likely to list transportation difficulties as a reason for missing an appointment than did HIP participants with access to the benefit. In addition, among HIP participants without the NEMT benefit who missed an appointment, the proportion who identified transportation as a reason was nearly double among those with incomes below the poverty line than those with incomes above the poverty line.

CMS granted short-term waivers to Indiana and Iowa so the impact on beneficiaries could be evaluated. The evidence thus far suggests the lack of transportation is an obstacle to getting needed care, and it is an even bigger obstacle for people with low incomes. We recommend that CMS reject Massachusetts’ waiver of NEMT until more is known about the impact on low-income beneficiaries in states where NEMT has been waived.

### **Unprecedented Closed Drug Formulary Would Limit Access to Needed Medication**

Massachusetts proposes an unprecedented change to Medicaid coverage of prescription drugs by waiving the requirement that the state comply with Section 1927 of the Social Security Act, which requires Medicaid to cover Food and Drug Administration (FDA) approved drugs (subject to certain conditions and exclusions) if the manufacturer of such drugs has signed an agreement to pay rebates (i.e. discounts) under section 1927. Under current law, states like Massachusetts can impose

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<sup>8</sup> The Lewin Group, “Indiana HIP 2.0: Evaluation of Non-Emergency Medical Transportation (NEMT) Waiver,” November 2, 2016, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-nemt-final-evl-rpt-11022016.pdf>.

preferred drug lists that require prior authorization before a prescription drug may be covered under Medicaid. But except for certain classes drugs that states may exclude under section 1927, states are barred from imposing a fully “closed” formulary under which drugs cannot be covered under any circumstances. Massachusetts’ waiver, however, proposes to exclude FDA-approved drugs entirely if it determines the drugs are not supported by adequate evidence of clinical efficacy. The state would only have to offer just one drug per therapeutic class.

Section 1927 is not waivable under Section 1115.<sup>9</sup> Moreover, as described above, Section 1115 gives the secretary authority to waive sections of the statute for demonstration projects that are “likely to assist in promoting the objectives of [Medicaid].”<sup>10</sup> The goal of the proposed policy is to reduce MassHealth’s expenditures by leveraging the threat of a closed formulary to obtain additional rebates from manufacturers. (States like Massachusetts are already permitted to use preferred drug lists to obtain “supplemental” rebates on top of those required under federal law.) This goal does not meet the criteria of an 1115 waiver. Furthermore, the proposal does not appear to be testing a specific hypothesis, which is the purpose of an 1115 demonstration project.

The proposed closed formulary threatens to significantly restrict Medicaid beneficiaries’ access to needed prescription drugs. While the proposal states that “members would continue to have access to the latest drugs that provide additional clinical benefits,” it fails to define or describe any process for demonstrating “clinical benefit,” or any specific consumer protections that would ensure access to needed treatments. Under the proposal, the state’s formulary could include as few as one prescription drug per therapeutic class, however the proposal doesn’t define “therapeutic class”. There is no statutory standard and such classes could be defined very broadly to encompass many kinds of drugs or treatments of certain conditions. However, our concerns with the proposal are significantly broader than the definition of the therapeutic class.

Massachusetts claims that some FDA-approved drugs may have “limited evidence of clinical quality.” However, the FDA is required by federal statute to ensure that drugs marketed in the United States are safe and effective.<sup>11</sup> Massachusetts’ proposal suggests that FDA is approving drugs that have not demonstrated clinical benefit — which, if true, would directly violate the agency’s own requirement that drug companies conduct studies to confirm clinical benefit prior to approval. Massachusetts’ proposal fails to cite any evidence to support these claims. Moreover, it ignores the fact that Massachusetts can already limit utilization of certain drugs based on clinical criteria through a preferred drug list and prior authorization requirements, which are typically designed by a Pharmacy and Therapeutics (P&T) Committee including clinicians. For example, a state Medicaid program can limit coverage of a drug unless a beneficiary has already tried another drug (known as step therapy) or a beneficiary satisfies certain clinical criteria (including severity of a condition). It also can require generic substitution (requiring a generic version of a drug be covered before a brand-name drug or before a brand-name competitor drug).

Nevertheless, Massachusetts cites the need to impose a “rigorous clinical review process” as justification for a closed formulary. As noted, the state does not describe this process, its clinical

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<sup>9</sup> PhRMA .v. Thompson, 251 F.3d 219, 222 (D.C. Cir. 2001).

<sup>10</sup> Social Security Act, § 1115(a).

<sup>11</sup> Food, Drug, and Cosmetic Act, § 505.

criteria, or beneficiary appeals rights. However, the proposal does imply that cost will be a key factor in these decisions, not only clinical considerations, stating, “the state could avoid exorbitant spending on high-cost drugs that are not medically necessary.”

Finally, eliminating the requirement that Medicaid cover all drugs subject to a rebate agreement under section 1927 (subject to certain exclusions and limitations, as described above) threatens to undermine the entire structure of the Medicaid drug rebate program. The rebates allow the federal government and the states to achieve savings of about 50 percent, according to analysis from the HHS Office of Inspector General (OIG).<sup>12</sup> But the key reason that Medicaid is able to achieve rebates of this magnitude is because in exchange for these considerable discounts, manufacturers that participate in the rebate program can generally have their drugs covered under Medicaid, although the state may impose restrictions or conditions on such coverage. If section 1927 can be waived in Massachusetts (and later in other states) it would likely create pressure to undo the entire Medicaid drug rebate program legislatively. Ultimately, that could result in states receiving less rebates than they do today and incurring greater prescription drug costs. That, in turn, would likely lead to states being even more restrictive in using closed formularies over time, and severely limiting access to needed medications by beneficiaries, particularly those with chronic conditions or severe illnesses.

### **Limiting Networks Will Be Disruptive to Beneficiaries’ Care**

Massachusetts is proposing to “implement narrower networks in MassHealth’s Primary Care Clinician (PCC) Plan networks to encourage enrollment in [Accountable Care Organizations, or ACOs] and [Managed Care Organizations, or MCOs].” The state claims, “It is important to strengthen controls on both the networks and the management of the PCC Plan, thereby incenting members to enroll in more managed, integrated plan ACOs and MCOs.” However, the proposed amendment does not include any support for this claim, the criteria by which the state will determine which hospitals and primary care providers are “high value,” or how this proposal will ensure sufficient beneficiary choice. This proposal could be particularly disruptive for individuals with disabilities and others with significant health care needs, yet the proposal does not include any discussion of appeal rights of affected beneficiaries.

We have significant concerns about the benefit of Massachusetts’ proposal for its beneficiaries. However, if the state chooses to narrow the PCC Plan network, at a minimum it should ensure that individuals with health conditions have continuity of care by guaranteeing access to individuals’ prior providers for any current health conditions or treatments. Massachusetts should further ensure that individuals have a simple and expedient appeals process if the narrower network prevents any individual from seeing a needed provider, and the state should publicly report data for ACOs, MCOs, and the PCC Plan, including appeals and fair hearings, broad quality of care measures, and beneficiaries’ wait times to see providers.

### **Massachusetts Should Invest in Expanding Access to Outpatient Behavioral Health Services**

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<sup>12</sup> Office of Inspector General, Department of Health and Human Services, “Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates By a Substantial Margin,” April 2015, <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

Massachusetts' proposal requests a full waiver of Section 1905(a)(29)(B), the statutory prohibition against medical assistance payments to Institutions of Mental Disease (IMD). This provision of the statute is not waivable using Section 1115 demonstration authority.

Massachusetts, like many other states, is facing an increased need for behavioral health services. Several states, including Massachusetts and most recently West Virginia, have already received authority to provide limited, well-defined IMD services in conjunction with an evidence-based continuum of care through 1115 expenditure authority. We recommend that Massachusetts use its existing authority to invest in expanded access to the full continuum of mental health and substance use disorder services and as alternative to increased use of institutional services. There is no statutory or policy basis for a wholesale waiver of the IMD exclusion.

### **Waiver of Massachusetts' Obligations to Provide Payment of Emergency Services to Lawfully Present Immigrants Is Not Waivable and Would Result in Uncompensated Care**

Massachusetts is seeking to "eliminate redundant MassHealth Limited coverage for adults who are also eligible for comprehensive, affordable coverage through the Health Connector" by waiving the requirement to provide Medicaid payment of emergency services for lawfully present immigrants who do not meet the Medicaid immigration standard. Section 1903(v) requires states to provide payment of emergency services to individuals who meet all Medicaid requirements except for the immigration status requirement. This is not a waivable provision under 1115, which only allows waivers of provisions in section 1902.

The state's claim that providing emergency services is redundant coverage is not accurate. Medicaid eligibility is not restricted to people who are ineligible for other coverage. When people have other coverage Medicaid acts as the "payor of last resort" filling in by ensuring that beneficiaries aren't saddled with deductibles or copayments or payments for services not covered by the other plan. For example, a person can enroll in employer sponsored coverage and still qualify for Medicaid eligibility to wrap around the employer coverage. Massachusetts' proposal would treat immigrants differently than other people who qualify for both Medicaid and other forms of coverage.

Massachusetts' plan to encourage enrollment Health Connector plans by increasing outreach and engaging community partners should be pursued. Getting more people enrolled in comprehensive coverage may even help avoid preventable emergency-related costs but no outreach campaign reaches everyone, particularly immigrants who often experience additional barriers to enrollment and the state should not penalize those who do not enroll. Some consumers would likely miss out initially from extra outreach and still others would become eligible after the initial transition period the state proposes. The target audience is always changing as people move or have changes in their income or households. It's unrealistic to assume all eligible people will sign up especially under limited enrollment periods in the Health Connector. Given that many consumers would not enroll in Health Connector plans, waiver of this provision would ultimately result in increased uncompensated care for hospitals and may lead consumers to delay or not seek needed emergency services.

Thank you for your willingness to consider our comments. If you would like any additional information, please contact Joan Alker ([jca25@georgetown.edu](mailto:jca25@georgetown.edu)) or Judy Solomon ([Solomon@cbpp.org](mailto:Solomon@cbpp.org)).

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American Association on Health and Disability  
American Music Therapy Association  
Center for Autism and Related Disorders  
Center on Budget and Policy Priorities  
Children's Defense Fund  
Community Catalyst  
Community Transportation Association of America  
Epilepsy Foundation  
Epilepsy Foundation New England  
Georgetown University Center for Children and Families  
HIV Medicine Association  
Justice in Aging  
Lakeshore Foundation  
National Alliance on Mental Illness of Massachusetts  
National Association of Community Health Centers  
National Center for Law and Economic Justice  
National Council for Behavioral Health  
National Health Care for the Homeless Council  
National Health Law Program  
National Multiple Sclerosis Society  
United Way Worldwide