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

Submitted on-line to Medicaid.gov

Re: Comments on Massachusetts' 1115 Demonstration Amendment
Request of September 8, 2017

Dear Acting Secretary Hargan,

These comments are submitted by the Massachusetts Law Reform Institute (MLRI), a statewide nonprofit poverty law and policy center and seven other Massachusetts legal aid and consumer advocacy organizations on behalf of our clients and members. We appreciate the opportunity to comment on the most recent Massachusetts request to amend its 1115 Demonstration. Massachusetts, in partnership with the federal government, has been successful in expanding health insurance coverage and is poised to implement an innovative delivery system reform that builds upon its success in expanding coverage while aiming to improve quality and control costs. We are supportive of the current Demonstration, but cannot support the amendments now being proposed.

We urge CMS not to approve the policies described below because they fail to satisfy the waiver criteria in Section 1115 of the Social Security Act. Several of the requests ask the Secretary to exceed the scope of his authority by waiving federal statutory mandates that Congress has placed in sections of the Act outside of Section 1902, and that therefore cannot be waived. These and other requests also fail to identify a legitimate experimental purpose. Further, these requests are not likely to assist in promoting the objectives of the Medicaid Act. On the contrary, in most instances the requested waivers will make current and future MassHealth beneficiaries worse off with fewer benefits, more costs, fewer choices and more barriers to coverage and care.

Policy 1. Enroll non-disabled adults (including ACA expansion enrollees and non-pregnant parents and caretakers) > 100% FPL in subsidized commercial plans through the state's exchange.
Waive: § 1902(a)(10)(A)(i)(8)
Goal: # 3 Maintain near-universal coverage
Hypothesis: #3A The waiver's investment in improved enrollment procedures and insurance subsidies will be associated with the continued maintenance of near-universal coverage.

It is apparent, although not explicitly stated, that Massachusetts seeks to lower the income standard for the ACA expansion group and for the parent/caretaker group from the current 133% to 100% of the federal poverty level (FPL). The state seeks a waiver of the provision of the Act defining the ACA expansion group as including individuals with income that does not exceed 133% FPL. Through a waiver of section 1902(a)(10)(A)(i)(VIII), the state seeks to remain eligible for the increased FMAP available to expansion states for coverage provided to "individuals described in section 1902(a)(10)(A)(i)(VIII) who are nonpregnant childless adults" pursuant to Section 1905(z) even though Massachusetts would no longer be providing coverage to all such individuals.

Lowering income eligibility for non-disabled adults to 100% FPL will not maintain near universal coverage or promote the objectives of the Medicaid Act

The state proposes to lower Medicaid eligibility for non-disabled adults to 100 percent from 133 percent of FPL, beginning January 1, 2019, resulting in an estimated 100,000 parents/caretakers and 40,000 childless adults losing MassHealth some of whom would regain subsidized coverage (ConnectorCare) through the state Exchange known in Massachusetts as the Health Insurance Connector or the Connector. We oppose this proposal. It will certainly not further the goal of achieving near universal coverage as claimed On the contrary, this request will lead to loss of coverage for individuals who are not eligible for premium tax credits for coverage through the Connector, and also for those who may be eligible, but who will not be able to successfully enroll.

Further, for those who do succeed in enrolling in ConnectorCare, they will have fewer benefits, significantly higher cost-sharing, fewer affordable plan choices and will lose a host of special Medicaid protections designed to meet the needs of very low-income people. This significant drop in MassHealth enrollment will also adversely affect the state's delivery system reform approved as part of the current demonstration. In March 2018, these 140,000 adults will be specially assigned to new Accountable Care Organizations (ACOs) under the terms of the current demonstration, but in January 2019, if this request is approved, they will lose MassHealth and the ACOs in turn will lose a significant share of their expected enrollees.

We firmly believe that ConnectorCare furthers the goal of universal coverage in Massachusetts. However, the September 8, 2017 waiver request is not seeking authority for ConnectorCare, it is seeking a waiver of the Medicaid Act in order to lower the income standard for the ACA expansion group while continuing to receive increased FMAP. This request does not meet the conditions for approval of an 1115 waiver. The state's contention that reducing Medicaid eligibility will advance the goal of universal coverage is not supportable. Valuable as ConnectorCare is for those otherwise ineligible for Medicaid, it is not equivalent to Medicaid for those losing its protections.

1. **Many of the 140,000 losing MassHealth will not be able to successfully transition to subsidized coverage through the Connector**

    a. **Some Medicaid-eligible individuals are not eligible for premium tax credits**

There are eligibility rules for premium tax credits that will prevent some individuals losing MassHealth from qualifying for ConnectorCare. Because of the low income levels of these individuals, and the high cost of living in Massachusetts, few of those ineligible for premium tax credits will be able to afford any other form of coverage.

Individuals offered employer sponsored insurance (ESI) that will cost less than 9.56% (2018) of family income for self-only coverage and the spouse of such an individual regardless of the added cost of coverage for a spouse, are ineligible for premium tax credits. According to a recent report by the Center for Health Information and Analysis, Massachusetts workers at lower wage firms face higher purchasing costs and cost-sharing on their employer plans than their counterparts in higher wage firms.[1]

Given the high cost of living in Massachusetts, individuals with income under 133% of poverty are often unable to pay for their basic needs and have no disposable income available to pay for health care. See Table 1 which compares the cost of living in Massachusetts with the income at 100%, 133% and 300% FPL. Even if it were true that non-disabled adult MassHealth members have greater potential than other MassHealth beneficiaries for higher incomes in the future, they don't have higher incomes now. Now, as a condition of qualifying for MassHealth, their incomes are under 133% of poverty or $16,040 for one person in 2017. The median income in Massachusetts in 2015 was $ 70,628.[2]

The high cost of housing in Massachusetts is a particular challenge for working poor and near poor individuals. In Massachusetts, rent at 40% of median for a two-bedroom apartment is $1,424.[3] At $1702 per month (100% FPL for a household of four), rent for a two- bedroom unit at $1,424 represents 84% of family income. Subsidized housing is in short supply with over 100,000 families on the waiting list for Section 8 vouchers to help with high rental costs.

Many of the unique features of Medicaid, such as affordability protections are a direct consequence of this income disparity. Medicaid's premium and cost-sharing limitations for those under 150% of the poverty level are supported by decades of research showing how even modest premiums and cost sharing applied to the poor and near poor lead to steep enrollment declines and reduced access to medically necessary care.[4]

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[1] CHIA Research Brief, The Benefits Divide: Workers at Lower-Wage Firms and Employer-Sponsored Insurance in Massachusetts, August 2017, http://www.chiamass.gov/assets/docs/r/pubs/17/mes-research-brief-august-2017.pdf

[2] American Community Survey, 1-year estimate

[3] National Low Income Housing Coalition, Out of Reach 2017 : the High Cost of Housing, p. 116 http://nlihc.org/sites/default/files/oor/OOR_2017.pdf

[4] Artiga, S. et al, "The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings," Kaiser Family Foundation, June 2017, http://www.kff.org/medicaid/issuebrief/the-effects-of-premiums-and-cost-sharing-on-low-incomepopulations-updated-review-of-research-findings/

Table 1. Comparison of MA Cost of Living with Income at Various FPLs				
	Required Annual Income for Living Wage in MA[5]	**100% FPL**	**133% FPL**	**300% FPL**
Family Size 1 Adult	$23,080	$12,060	$16,040	$36,180
Family Size 2		$16,240	$21,600	$48,720
1 Adult 1 Child	$47,842			
2 Adults	$34,193			

b. Many MassHealth members even if eligible for premium tax credits are unlikely to successfully enroll

Other individuals may not be barred from ConnectorCare but will find it difficult to navigate the greater complexity of the Exchange eligibility and enrollment system. We know this both from our experience in Massachusetts with ConnectorCare and the experience of other states that rolled back Medicaid eligibility for adults in January 2014 in expectation that individuals losing Medicaid would enroll in subsidized coverage through an Exchange.

In Medicaid programs like MassHealth, unlike coverage through the Exchanges, there are no open enrollment or special enrollment periods, and coverage is not dependent on applicants taking the second step of enrolling in a Managed Care Organization (MCO). MassHealth members are eligible and covered right away and if they are required to enroll in managed care and fail to do so, MassHealth will automatically enroll them.

Information we obtained from the Health Connector for July 14, 2017 shows that in Plan Type 2A, (100-150% FPL), over 40% of those found eligible for ConnectorCare were unenrolled. See, Table 2. Some of these individuals may still have been within their 60-day special enrollment period, but most were likely unable to enroll in ConnectorCare until 2018. If 40% of 140,000 former MassHealth members similarly miss ConnectorCare enrollment deadlines, an additional 56,000 may become uninsured.

Table 2. ConnectorCare Plan Types 1 & 2A Eligible Counts: 7/14/17		
	Plan Type 1 (0-100% FPL)	**Plan Type 2A (100-150% FPL)**
PT1 and 2A Eligible	24,627	49,006
PT 1 and 2 A Enrolled	15,021	29,082
PT1 and 2A Unenrolled	9,606	19,924

The experience of other states also demonstrates the difficulty individuals have enrolling in subsidized coverage through an Exchange compared to Medicaid. 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 in 2014 (on the theory that they could get premium tax credits) never

[5] From the MIT Living Wage Calculator (living costs are shown here minus estimated medical costs), http://livingwage.mit.edu/states/25

applied for a premium tax credit.[6] During the first round of a similar parent eligibility rollback in Connecticut only one in four parents losing Medicaid coverage enrolled in a QHP.[7] In Wisconsin only one-third of those losing Medicaid coverage purchased QHPs although the state had predicted that 90 percent would.[8]

2. ConnectorCare offers fewer affordable premium choices, fewer benefits and charges higher copays than MassHealth

Under the demonstration, ConnectorCare is able to offer affordable coverage for those from 100-300% FPL and this has been an important factor in the success of the program. However, ConnectorCare, unlike Medicaid, was not designed for the poor and near poor, and does not offer coverage equivalent to MassHealth for adults from 100-133% FPL.

a. Fewer affordable premium choices

There are no MassHealth premium charges for non-disabled adults with income from 100-133% FPL regardless of their choice of managed care organization (MCO) or accountable care organization (ACO). In ConnectorCare, there is no premium contribution only for the lowest cost MCO. In 2017, an individual with income under 133% FPL would have to pay as much as 17% of his or her income for choosing an MCO other than the lowest cost option.

b. Fewer benefits

ConnectorCare does not cover entire categories of health services available in MassHealth such as dental services, non-emergency transportation or long-term services and supports. Further, even if a broad category of services are covered such as pharmacy benefits or inpatient and outpatient mental health and substance use disorder services, Qualified Health Plans do not offer a comparable amount, duration or scope of benefits compared to MassHealth.

One of the goals of the current demonstration is to address the opioid addiction crisis by expanding access to a broad spectrum of recovery-oriented substance use disorder services. Shifting 140,000 members from MassHealth to the Connector will reduce access to substance use disorder services. MassHealth now offers more substance use recovery services across the continuum of care including transitional support services and residential rehabilitation services that are not covered benefits in ConnectorCare.

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[6] Kate Lewandowski, "Parent Eligibility Roll-Back in Rhode Island: Causes, Effects and Lessons Learned," https://www.communitycatalyst.org/resources/publications/document/RI-parent-rollback-081215-KL.pdf?1439834245

[7] Langer, S. et al. *Husky Program Coverage for Parents: Most Families Will Feel the Full Impact of Income Eligiblity Cut Later ln 2016* http://www.ctvoices.org/sites/default/files/h16HUSKYIncomeEligibilityCut.pdf

[8] "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-inobamacare-b99312352z1-267339331.html

c. Higher copays

ConnectorCare Plan Type 2A also has substantially higher copays than MassHealth such as: $10 for an office visit, $50 for the ER, and drug costs of $10-$40 up to a $500 annual drug maximum compared to nominal Medicaid copays. The maximum out of pocket cost-sharing in ConnectorCare Plan Type 2A ($1250 for an individual or $2500 for a couple) as a percent of income represents up to 10% of income for an individual and 15% of income for couples at 100% FPL; and up to 7.7% of income for an individual and 11.5% of income for couples at 133% FPL. In Medicaid, cost-sharing cannot exceed 5% of income.

Given the high cost of living in Massachusetts, families under 133% of poverty have insufficient income to meet their basic needs without taking into account the added cost of health services. See Table 1 above which shows the basic cost of living in Massachusetts for different family configurations compared to various income levels as a percent of poverty. The research literature is clear that even small copayments negatively affect access to care for the poor and near poor.[9]

If CMS were to grant the state's waiver request, the representations made by the state both in the waiver request and in other public statements regarding the affordability of ConnectorCare should be made explicit conditions of the waiver. These conditions should minimally include a requirement that individuals under 138% FPL be offered coverage with no premium contribution and cost sharing no higher than that in MassHealth, and that individuals with special health needs such as the medically frail and those ineligible for premium tax credits such as veterans who are not eligible for subsidies due to "enrollment in veteran's health coverage" will be able to retain MassHealth eligibility. The state has also represented that dental benefits equivalent to those in MassHealth will be added to ConnectorCare coverage for those losing MassHealth.

Policy 2. Align MassHealth benefits for all non-disabled adults in a single plan that mirrors commercial coverage, by enrolling non-disabled parents and caregivers with incomes up to 100% FPL in MassHealth's CarePlus Alternative Benefit Plan.
Waive: § 1902(a)(10) insofar as it incorporates Section 1931 (eligibility); 1902(a)(10)(B), 1902(a)(10)(A) insofar as it incorporates Section 1905(a) (comparability), and 1902(a)(4) insofar as it incorporates 42 CFR 431.53 and 42 CFR 440.390 (assurance of transportation).
Goal: # 3 Maintain near-universal coverage
Hypothesis: #3A, The waiver's investment in improved enrollment procedures and insurance subsidies will be associated with the continued maintenance of near-universal coverage.

Reducing benefits for 230,000 low income parents and caretaker relatives violates state and federal law and fails to promote the objectives of the Act

The 1115 amendments seeks to shift 230,000 full-benefit parents and caretaker relatives with income under the newly lowered 100% FPL limit to MassHealth Care Plus, an Alternative Benefit Program (ABP) authorized for ACA expansion adults. Currently, the CarePlus ABP does

[9] Artiga, S. et al, "The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings," Kaiser Family Foundation, June 2017, http://www.kff.org/medicaid/issuebrief/the-effects-of-premiums-and-cost-sharing-on-low-incomepopulations-updated-review-of-research-findings/

not include five types of long term services and supports available to parents/caretakers including personal care attendant and private duty nursing services. Massachusetts also provides a narrower scope of home health benefits in CarePlus than in the full benefit program (MassHealth Standard).[10] A currently pending 1115 amendment also seeks to eliminate non-emergency medical transportation from the CarePlus ABP.

As a threshold matter, reducing benefits to parents/caretakers violates state law. Under a state law enacted as part of the Massachusetts 2006 health reform law, "the division shall include within its covered services for adults all federally optional services that were included in its state plan or demonstration program in effect on January 1, 2002." [11] The state legislature must override this protection before the state Medicaid agency is empowered to reduce benefits. In 2002, parents/caretaker relatives were eligible for long term services and supports, a full home health benefit, and non-emergency medical transportation, all benefits they would lose if they received only CarePlus. Earlier in the year, the Governor proposed legislation to broadly amend this provision in state law, but to date no such amendment has been enacted.

Authorizing an alternate benefit program for parents/caretakers also violates Congressional intent in setting out which groups states cannot enroll in alternate benchmark benefits. The Deficit Reduction Act of 2005 first authorized alternative benchmark benefit plans in Section 1937 of the Social Security Act, later amended by the Affordable Care Act.[12] Section 1937 provides that states may not require certain groups to obtain benefits through an Alternative Benefit Plan and among the protected classes are parents and caretaker relatives under Section 1931.[13]

Section 1937 creates a state option, but the limitations on its application to parents/caretaker relatives uses mandatory language. The Secretary does not have authority to waive the provisions of Section 1937 which Massachusetts is effectively asking him to do. As the Ninth Circuit wrote in describing the scope of the Secretary's waiver authority:

> "[W]e doubt Congress would enact such comprehensive regulations, frame them in mandatory language, require the Secretary to enforce them, and then enact a statute allowing states to evade these requirements with little or no federal agency review. Rather, Congress intended that the Secretary would selectively approve state projects."
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> Newton-Nations v. Betlach, 660 F.3d 370, 380 (9th Cir. 2011) (quoting Beno v. Shalala, 30 F.3d 1057, 1068-69 (9th Cir. 1994)).

Further, this reduction in benefits cannot conceivably advance the goal of maintaining universal coverage and appears to be entirely unrelated to hypothesis # 3A. Elsewhere in the narrative portion of the request, the proposal justifies the benefit reduction as better aligning with commercial insurance. It is surely true that commercial insurance does not typically cover non-emergency medical transportation (NEMT). However, Massachusetts proposes no reasonable

[10] 130 Code of Mass. Regs. §403.415(C) (providing home nursing for CarePlus members only following an overnight hospital stay).
[11] M.G.L. c. 118E, § 53.
[12] 42 USC §§ 1396u-7 and 1396a(k)(1) (requiring ACA expansion adults to receive benchmark coverage)
[13] 42 USC 1396u-7(a)(2)(ix)

hypothesis for how aligning Medicaid with commercial insurance by eliminating NEMT and other benefits will advance universal coverage or promote any other objective of the Act.

Transportation is a greater access barrier for low income Medicaid beneficiaries than for the commercially insured.[14] The Medicaid program has required coverage of NEMT for a reason, studies have shown that it improves health outcomes and in some cases reduces costs.[15] Massachusetts has supplied no information about how many of the 230,000 parents use NEMT or other benefits unavailable in CarePlus and its evaluation includes no provision for monitoring how the loss of these benefits may affect access to care.

For all these reasons, Policy #2 fails to satisfy the requirement for a waiver, and we urge the Secretary not to approve this amendment.

Policy 3. Eliminate redundant MassHealth Limited coverage for adults who are also eligible for comprehensive, affordable coverage through the Health Connector
Waive: § 1902(a) insofar as it incorporates Section 1903(v)
Goal: # 3 Maintain near-universal coverage
Hypothesis: #3A, The waiver's investment in improved enrollment procedures and insurance subsidies will be associated with the continued maintenance of near-universal coverage

MassHealth Limited coverage is not waivable and provides essential support for safety net hospitals

Lawfully present immigrants who do not meet the stricter immigrant eligibility rules of MassHealth may be eligible for both premium tax credits and emergency Medicaid (MassHealth Limited). The amendment request describes emergency Medicaid as "redundant" but proposes to deny emergency Medicaid benefits to lawfully present aliens who are determined eligible for premium tax credits regardless of whether or not they are enrolled. As discussed above, approximately 40% of individuals with income under 150% of poverty are determined eligible for premium tax credits by the Connector but do not enroll. See, Table 2. For those who do enroll, emergency services are billed to the private coverage and not to Medicaid which is always the payer of last resort.

Denying emergency Medicaid to lawfully present aliens who do not enroll in private coverage with advance premium tax credits is beyond the Secretary's waiver authority. In section 1903(v), Congress provides that "payments shall be made under this section for care and services that are furnished to an alien described in paragraph (1)" and goes on to prescribe the eligibility for

[14] P. Cheung, J. Wiler, and et. al., National study of barriers to timely primary care and emergency department utilization among Medicaid beneficiaries, Annals of Emergency Medicine (July 2012), Retrieved from http://www.annemergmed.com/article/S0196-0644(12)00125-4/fulltext
S. Syed, B. Gerber, and L Sharp, Traveling Towards Disease: Transportation Barriers to Health Care Access, Journal of Community Health (Oct. 2013). Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265215
U.S. Government Accountability Office, Efforts to Exclude Nonemergency Transportation Not Widespread, but Raise Issues for Expanded Coverage (Jan 2016). Retrieved from http://www.gao.gov/assets/680/674674.pdf
[15] P. Hughes-Cromwick and R. Wallace, et al., Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation, Transit Cooperative Research Program (Oct. 2005), http://onlinepubs.trb.org/onlinepubs/tcrp/tcrp_webdoc_29.pdf.

emergency Medicaid (an alien otherwise eligible under an approved state plan), and the scope of services (emergency medical conditions other than organ transplants).[16] The Secretary does not have the authority to waive Section 1903(v).

In Massachusetts, if lawfully present aliens are determined eligible for premium tax credits and do not enroll, they lose eligibility for an uncompensated care program that reimburses acute hospitals and community health centers for providing services to uninsured and underinsured individuals.[17] Thus, to the extent that such punitive incentives may be effective in encouraging enrollment, Massachusetts already has such a policy in place.

Under the requested amendment, without either reimbursement from uncompensated care or emergency Medicaid, hospitals will lose revenue, and consumers will incur more medical debt. This will be a particular burden on hospitals that disproportionately serve the poor. It will also frustrate achievement of Goal 4 of the approved demonstration: "sustainably support safety net providers to ensure continued access to care for Medicaid and low-income uninsured individuals.

A far better way to encourage enrollment in coverage through the Connector would be enhanced outreach targeting low income lawfully present immigrants. Due to limited English proficiency and income under the tax filing threshold, immigrants eligible for emergency Medicaid are among those most likely to be confused by the concept of premium tax credits and the applicable enrollment deadlines in the Exchange. Outreach will be far more effective at encouraging enrollment than denying hospitals payment for providing emergency services.

Policy 4. Select preferred and covered drugs through a closed formulary that assures robust access to medically necessary drugs
Waive: § 1902(a) (54) insofar as it incorporates Section 1927(d)(1)(B); : § 1902(a) (14) insofar as it incorporates Section 1916 and 1916A; 1902(a)(23)(A)
Goal: New proposed Goal 6: Ensure the long-term financial sustainability of 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.
Hypotheses: #6A: The alignment of coverage for non-disabled adults with commercial plans, adoption of widely-used commercial tools for prescription drugs and the waiver of cost sharing limits for higher income members will result in slowing the shift in enrollment from commercial health insurance (as a percentage of the state's population) to MassHealth primary coverage (as a percentage of the state's population) while maintaining overall coverage
#6B: The waiver's initiatives for prescription drugs will result in lowered expenditure growth rates compared to what prescription drug spending would be without the waiver without reducing access to medically necessary drugs

[16] 42 USC 1396b(v)
[17] 101 Code of Mass. Regs. §613.04(7)(b) (Health Safety Net benefits are time-limited except for dental services)

The proposed pharmacy restrictions do not meet the requirements for approval under Section 1115

Section 1902 requires states to comply with Section 1927, but Section 1927 itself contains mandatory language and is not subject to waiver.[18] Section 1927 creates a Medicaid drug rebate program, and also prescribes the extent to which state Medicaid agencies can restrict coverage of drugs.[19] The D.C. Circuit Court has held that Section 1115 does not authorize waiver of any requirement of Section 1927.[20] The State's request to create a closed formulary cannot be granted for this reason alone. Further, a closed drug formulary does not promote the purposes of the Act.

A closed drug formulary is not needed to obtain supplemental rebates and will reduce access to necessary medication

A closed formulary would restrict the drugs MassHealth covers, with as few as one drug available per therapeutic class. Even if a waiver were possible, we believe this proposed restriction unduly restricts physicians' exercise of clinical judgment based on their treatment experience with individual patients who often have complex medical conditions. If implemented, this proposal could seriously undermine patients' health and thereby defeats the purpose of the Medicaid Act.

The rationale given for this proposal is that a closed formulary will enhance the leverage EOHHS has in negotiating rebates with pharmaceutical companies by favoring highly discounted drugs over more expensive alternatives. Currently, all fifty States and the District of Columbia cover prescription drugs under the Medicaid Drug Rebate Program, which is authorized by Section 1927 of the Social Security Act. States may choose to layer individually negotiated supplemental rebates over the federal Medicaid drug rebates. States leverage their ability to subject certain drugs within classes to prior authorization using Preferred Drug List (PDL) status to drive deeper discounts from manufacturers looking for a competitive edge. As of December 2015, 47 states and the District of Columbia operate single and/or multi-state supplemental rebate arrangements. Only Hawaii, New Jersey, New Mexico and South Dakota do not have supplemental rebates in place; Arizona and Massachusetts began collecting supplemental rebates for the first time in 2015.[21] According to the Medicaid and CHIP Payment and Access Commission, the Medicaid Drug Rebate Program reduces gross spending on affected prescription drugs by almost half.[22] Given the extraordinary success nationally of drug rebate

[18] 42 USC 1396r-8(d) Limitations of Coverage of Drugs
[19] 42 USC 1395r-8(d)(1)-(6).
[20] PhRMA v. Thompson, 251 F. 3d 219, 222 (D.C.Cir 2002)
[21] Vernon K. Smith, Kathleen Gifford, Eileen Ellis, Robin Rudowitz, Laura Snyder & Elizabeth Hinton. (2015, October). "Medicaid Reforms to Expand Coverage, Contain Costs and Improve Care: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2015 and 2016." Kaiser Family Foundation and the National Association of Medicaid Directors. http://kff.org/medicaid/report/medicaid-reforms-to-expand-coverage-control-costs-and-improve-care-results-from-a-50-state-medicaid-budget-survey-for-state-fiscal-years2015-and-2016/
[22] Chris Park. (2015, October). "Trends in Medicaid Spending for Prescription Drugs." Medicaid and CHIP Payment and Access Commission. https://www.macpac.gov/wp-content/uploads/2015/10/Trends-in-Medicaid-Spending-for-Prescription-Drugs.pdf

programs, we fail to see why Massachusetts needs the added leverage of restricted formulary access to successfully negotiate substantial discounts through rebates in its pharmacy program.

In fact, recent MassHealth history involving Hepatitis C (HCV) demonstrates the effectiveness of state negotiations in reducing the cost of treatment through rebate agreements without closing the formulary to other HCV drugs[23] Here unnecessary and punitive prior authorization restrictions were removed from MCOs' treatment protocols which limited access to those patients with existing severe and untreatable liver impairment, and further limited access to patients without a sufficient period of drug and alcohol sobriety, extended HCV treatment to all MassHealth patients under an open access policy.

Unlike several of the changes proposed elsewhere in this 1115 Waiver Amendment Request, this proposed formulary restriction would apply to all MassHealth members, including people living with disabilities, medical frailty, HIV, and breast and cervical cancer, as well as 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. People with complex medical conditions are often treated for multiple ailments, requiring further balancing of patient histories and drug interactions to arrive at patient specific treatment plans.

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 factors, including co-occurring illnesses, medical history, and previous treatment tolerance[24] 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. Recent advances in HIV treatment have allowed for some patients to reduce their dauntingly complex pill burden by taking a single dose of combined HIV antiretroviral treatment. This greatly improves patients' adherence to treatment, reducing overall treatment costs and reducing further infections.[25] While these single dose HIV medications are sometimes more expensive than the older multi-drug combination therapies, they greatly simply patient adherence and are mostly highly tolerated medications with few side effects. Therefore, it is important that doctors are able to provide treatment based on patients' needs, not on availability in MassHealth driven solely by cost savings concerns.

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

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[23] https://www.bostonglobe.com/metro/2016/06/30/masshealth-pay-for-hepatitis-drugs-for-all-infected-members/DhQNZCf9WDZH5CM41V4vgI/story.html.

[24] *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/.

[25] http://www.aidsmap.com/Single-tablet-regimen-improves-antiretroviral-adherence-and-reduces-hospitalisation/page/2763722/

that people with a complex medical condition 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.[26] 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.

If Massachusetts does proceed with a limited formulary, we recommend that at a minimum it adopt the patient protections afforded Medicare Part D patients in their selection of a pharmacy plan with a closed formulary. Specifically, we ask that the formulary adhere to the guidelines set forth in the Medicare Prescription Drug Benefit Manual – Chapter 6 Part D Drugs and Formulary Requirements. See Section 30.2 which requires that two drugs per category or class be made available in a given formulary – not the single drug proposed by the formulary restrictions of the MassHealth proposed 1115 waiver.

We further would recommend that the rule set forth in the Medicare Prescription Drug Manual at Section 30.2.5 "Protected Classes" be adopted. This rule states that "Part D sponsor formularies must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection) antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes." We also recommend the additional "protected class" category of "direct acting antivirals" which are so essential in the treatment of hepatitis C (HCV).

Policy 5. Procure a selective and more cost effective specialty pharmacy network
Waive: § 1902(a) (23)(A) (Freedom of Choice)
Goal: New proposed Goal 6: Ensure the long-term financial sustainability of 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.
Hypotheses: #6A: The alignment of coverage for non-disabled adults with commercial plans, adoption of widely-used commercial tools for prescription drugs and the waiver of cost sharing limits for higher income members will result in slowing the shift in enrollment from commercial health insurance (as a percentage of the state's population) to MassHealth primary coverage (as a percentage of the state's population) while maintaining overall coverage
#6B: The waiver's initiatives for prescription drugs will result in lowered expenditure growth rates compared to what prescription drug spending would be without the waiver without reducing access to medically necessary drugs

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

A Selective Specialty Pharmacy Network for PCC and Fee-for-Service Will Restrict Access for the Homeless and other Vulnerable Populations

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.[27] 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 demonstrate 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.

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 frequently choose the PCC plan instead of enrolling with an MCO.

Policy 6. Implement narrower networks in MassHealth's Primary Care Clinican (PCC) Plan to encourage enrollment in ACOs and MCOs
Waive: § 1902(a) (23)(A) (Freedom of Choice)
Goal: #1 Enact payment and delivery system reforms that promote integrated, coordinated care; and hold providers accountable for the quality and total cost of care.
Hypothesis: # 1c The waiver's support will lead to stronger aggregate provider networks in the ACO and MCO program relative to the Primary Care Clinician (PCC) plan in relation to types and breadth of providers, as well as quality and outcomes of services

[27] 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.

Restricting freedom of choice of providers in the PCC Plan is not necessary to promote ACO enrollment, will harm individuals with disabilities and frustrate the ability to evaluate the demonstration's success in achieving Goal #1

In 2016, the state initially sought to reduce benefits in the PCC Plan in order to encourage individuals required to enroll in managed care to not select the PCC Plan. The state withdrew the reduced benefit proposal but did obtain authorization to charge lower copayments in ACOs and MCOs compared to the copayment amounts in the PCC Plan. Restricting freedom of choice of providers in the PCC Plan is not needed as a further incentive for individuals to choose ACOs, and it will limit the ability of Massachusetts and HHS to evaluate Hypothesis #1c. How can the study design for delivery system reform test whether payment reforms have led to stronger provider networks in the ACO and MCO program relative to the PCC Plan if the state as a matter of policy limits providers in the PCC Plan? The Draft Evaluation Design repeatedly refers to comparisons between new delivery models and other models of care. The PCC Plan is particularly important for such an evaluation because its members are also required to enroll in managed care and will be more similar to those in ACOs than the population not required to participate in managed care consisting primarily of the elderly and those for whom MassHealth is secondary coverage.

As we wrote in our comments on the earlier 1115 proposal seeking to reduce benefits in the PCC Plan, the agency has presented no evidence that the PCC Plan provide poorer quality care than the MCOs, and none of the evidence in the public record substantiates such a claim. Further, with the massive delivery system change in store for 900,000 members whose primary care clinicians have joined ACOs, this is a terrible time for disrupting the PCC Plan which disproportionately serves people with disabilities.[28]

Policy 9. Implement the cost sharing limit of five percent of income on an annual basis rather than a quarterly or monthly basis
Waive: § 1902(a) (14) insofar as it incorporates Section 1916 and 1916A
Goal: Administrative simplification measure not tied to specific waiver goals
Hypothesis: None

Applying cost sharing limits on an annual basis will undermine the purpose of such limits

The state seeks to apply the cost sharing out of pocket limit on an annual rather than a monthly or quarterly basis as a matter of administrative convenience. However, the Medicaid Act specifically limits the Secretary's waiver authority with respect to cost-sharing. It provides that "no deduction, cost sharing, or similar charge may be imposed under any waiver authority of the Secretary, except as provided in subsections (a)(3) and (b)(3) and section 1396o–1 of this title,

[28] In 2016, 10.4% of all individuals enrolled in managed care (MCOs or the PCCP) were disabled compared to 17% individuals with disabilities in the PCC Plan. MassHealth Managed Care HEDIS ®, 2016 Report, Demographic Characteristics of MassHealth Members at 14. http://www.mass.gov/eohhs/docs/masshealth/research/mco-reports/hedis-2016.pdf

unless specific conditions are met.[29] Administrative convenience is not a sufficient basis for any 1115 waiver particularly a cost-sharing waiver.

Section 1916A allows states to apply the 5 percent cap on monthly or quarterly basis.[30] The time frame is critical, as health expenses tend to concentrate into a single month or quarter. Researchers have found that on average among families with medical care, 49 percent of all care occurred in a single month, and 63 percent occurred in a single quarter, and utilization was even more concentrated among low-income families.[31] The consequence of this concentration of medical expenses is that low-income individuals will benefit far more from a monthly or quarterly out of pocket limit than an annual one. Administrative convenience is not a sufficient reason to deprive beneficiaries of the protection intended by Congress.

Policy 11. Limit premium assistance cost sharing wrap to MassHealth enrolled providers (waiver required by State Plan Amendment 16-0011)
Waive: § 1902(a) (23)(A) (Freedom of Choice); 1902(a)(14) insofar as it incorporates Section 1916 and 1916A
Goal: Administrative simplification measure not tied to specific waiver goals
Hypothesis: None

Denying freedom of choice of provider or increasing cost sharing for low income individuals with access to a student health plan does not promote the objectives of the Act

Administrative convenience does not meet the requirements for approval of a demonstration that will waive freedom of choice or increase cost-sharing beyond the limits specified in the Act. As the Ninth Circuit has written of Section 1115:

> "The statute was not enacted to enable states to save money or to evade federal requirements but to "test out new ideas and ways of dealing with the problems of public welfare recipients." [citation omitted]…. A simple benefit cut, which might save money, but has no research or experimental goal, would not satisfy this requirement."
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> Beno v. Shalala, 30 F.3d 1057, 1069 (9th Cir. 1994).

Currently, for all adults except students and Medicare recipients, MassHealth secondary coverage pays for cost-sharing in excess of Medicaid limits only if the provider bills MassHealth for the excess cost sharing amount. This essentially limits most MassHealth beneficiaries to

[29] 42 USC 1396o(f) specifies the following conditions, the demonstration (1) will test a unique and previously untested use of copayments, (2) is limited to a period of not more than two years, (3) will provide benefits to recipients of medical assistance which can reasonably be expected to be equivalent to the risks to the recipients, (4) is based on a reasonable hypothesis which the demonstration is designed to test in a methodologically sound manner, including the use of control groups of similar recipients of medical assistance in the area, and (5) is voluntary, or makes provision for assumption of liability for preventable damage to the health of recipients of medical assistance resulting from involuntary participation.
[30] 42 USC 1396o-1(b)(1)(B)(ii), (2)(A)
[31] Thomas M. Selden, "The Within-Year Concentration of Medical Utilization: Implications for Family Out-of-Pocket Expenditure Burdens,"*Health Services Research*, June 2009, v. 44(3), 1029-1051, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699920/

seeing providers who participate in both the commercial plan and in MassHealth. This policy eliminates one of the few advantages of commercial insurance compared to MassHealth, the participation of independent practitioners such as dentists and psychiatrists who may be in short supply in MassHealth. Further in the field of mental health, MassHealth fee for service has a very narrow network of independent providers. Fee for service essentially allows no independent licensed mental health professionals, other than psychiatrists, to bill for therapy services as independent providers.[32] Psychologists for example, can participate in MassHealth only for purposes of testing, and not for the provision of therapy services. By limiting the ability of providers who do not otherwise participate in MassHealth to bill for cost sharing, the state would unfairly require MassHealth members to pay costs in excess of permissible cost-sharing limits.

On November 18, 2016, when CMS approved the state plan amendment to make premium assistance mandatory for student health insurance plans (SHIP) in the individual market, it required the state to reimburse students for any out of pocket cost sharing in excess of Medicaid amounts while the state evaluated "the overlap of providers participating in both Medicaid and group/individual health insurance plans to ensure that the network is adequate to meet the health needs of premium assistance beneficiaries." If the networks are adequate, the State was then to submit a freedom of choice waiver in order to continue SHIP premium assistance beyond a Dec. 31, 2017 sunset date.

The state is now seeking a freedom of choice waiver to deny students and other individuals enrolled in premium assistance the same cost sharing protections provided to all other Medicaid enrollees without having conducted any evaluation of the overlap of providers in student health plans and other commercial insurance with participating providers in MassHealth fee for service. Without such an evaluation, the state has no basis for seeking a waiver.

Thank you for the opportunity to comment. We look forward to having additional opportunities to work with both EOHHS and CMS to strengthen and improve the MassHealth program without harming the vulnerable beneficiaries for whom it provides such essential services. For any questions about these comments, please communicate with Vicky Pulos, vpulos@mlri.org, 617-357-0700 Ext 318.

These comments are endorsed by the following organizations:

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Leticia Medina-Richman, Managing Attorney
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[32] Other entities such as mental health centers and outpatient hospitals can bill MassHealth fee for service for the services of licensed mental health professionals in their employ, and the MassHealth MCOs and the Partnership do include independent licensed mental health professionals in their networks.

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