Public Comments to Proposed MassHealth Section 1115 Demonstration Amendment Request
July 20, 2017 – August 21, 2017

Konefal, Kaela (EHS)

From:	Taberner, Scott (EHS)
Sent:	Wednesday, July 26, 2017 12:32 PM
To:	Arnold, Elizabeth (EHS)
Cc:	Konefal, Kaela (EHS); Brown, Stephanie (EHS)
Subject:	FW: Waiver Amendment

Elizabeth – fyi; feedback from David regarding the proposed 1115 Amendment
Will look for an opportunity to discuss with you and then others within MassHealth
Thanks
Scott

From: DMatteodo@aol.com [mailto:DMatteodo@aol.com]
Sent: Monday, July 24, 2017 5:34 PM
To: Taberner, Scott (EHS); Brown, Stephanie (EHS)
Subject: Waiver Amendment

Hi Scott and Stephanie, I was going over this Amendment Request from MassHealth and hoping that it could be broadened to include a provision to remove/amend the IMD Safety Net payment problem. I think this is probably one of the best chances we may have to address this issue with CMS so I am very interested in what you guys think. I hope that you could support such a proposal and that you can speak to it when you come Wednesday, Thanks,

http://www.mass.gov/eohhs/gov/commissions-and-initiatives/healthcare-reform/masshealth-innovations/1115-waiver.html

David Matteodo
Executive Director
Mass. Association of Behavioral Health Systems, Inc.
115 Mill St.
Belmont, Ma. 02478
(617) 855-3520
www.mabhs.org

Mass Home Care

Testimony Before the Executive Office of Health & Human Services
And the Massachusetts Health Connector
Request to Amend the MassHealth Section 1115 Demonstration and the
Requests for Federal Flexibility to Support Commercial Market Stability & Reforms
Mass Home Care, August 4, 2017

For the record, this testimony is submitted by Mass Home Care, a non-profit network of 29 agencies whose goal is to help elderly and disabled individuals to live in the least restrictive setting possible, at their highest level of functioning possible, for as long as possible. We manage long term supports for roughly 70,000 elders and disabled individuals across the Commonwealth. Our network is a form of "managed fee for service" using the 'independent agent' model.

We thank EOHHs and the Connector for giving us to opportunity to testify today on the Section 1115 "MassHealth reform" amendments to CMS.

One of the most critical functions of state government in our Common Wealth is to maintain the physical and mental well being of all of our citizens, through access to health care which is accessible, affordable and adequate to meet their needs. I can think of very few roles of government that are a higher priority.

The Affordable Care Act has had a significant impact on health insurance coverage rates, especially in the 27 states--including Massachusetts--that accepted Medicaid expansion. Between 2013 and 2015, more than 15 million people nationally were added to the health insurance coverage rolls because of the ACA.

Medicaid is truly the "people's health plan," because the people who are on it cannot afford any other form of insurance. The state's FY 18 budget includes approximately $16.6 billion for MassHealth, which is around 37% of the total state budget. But after federal match, the net cost to the state for MassHealth is around $8 billion, or 24% of the total net budget. The federal government has paid for almost 90% of the spending for MassHealth members who are covered due to Affordable Care Act expansion. Medicaid reimbursements from the federal government are the largest source of federal revenue to Massachusetts.

But now we are faced with an effort by the White House and some members of Congress to cut Medicaid benefits, and cut Medicaid reimbursements. They are threatening to withdraw subsidy support to insurers, which will undermine the individual market. We cannot ignore this reality—but we should not respond by simply cutting Medicaid benefits as our only choice.

Let us state at the outset that we strongly support the Governor's plan to establish new mid-level practitioners, like Dental Therapists, to expand access to dental care. These practitioners or "extenders" can widen the circle of members who are able to get these health care services, and reduce costs by avoiding the severity of health conditions that go untreated. The mid level practitioners plan should apply to commercial plans as well as to MassHealth.

The Governor's MassHealth reform plan moves 230,000 parents out of MassHealth Standard, and into CarePlus, which was created for people without children. The future of CarePlus is in doubt if Congress repeals—or defunds-- the ACA.

The Governor's MassHealth reform plan will also cause 140,000 people to lose their MassHealth coverage, as the income ceiling is dropped back from 133% of poverty to 100% of poverty. This affects childless adults as well as parents. They will be "transitioned" to ConnectorCare plans, which have higher copays and weaker benefits. ConnectorCare provides no dental benefits, eyeglasses, and no long term services and supports.

The Governor's plan also proposes a Employer Sponsored Insurance (ESI) lock out, which removes adults at the poverty level from MassHealth if they have access to employer sponsored health insurance (ESI) that is considered "affordable". This could affect 6,800 home care aides in Massachusetts who rely on MassHealth, who will also lose a special work incentive now available to them, and, if their employer offers them a health plan whose employee share costs 5% (or 9.69% for ConnectorCare) of their income--even if they don't want their employer's plan--they will still lose their right to receive MassHealth or Connector Care.

Example: A single woman with one child working as a home care aide can earn up to $21,599 and still be at 133% of the federal poverty level this year. That worker needs to limit her hours to 30 per week or less in order to remain eligible for MassHealth. At 30 hours per week, she has $57.92 a day to live on. These people cannot afford any health care premiums. If the employee share of their workplace health plan is no more than the 5% "affordable" MassHealth threshold (or below 9.69% under ConnectorCare) the aide could lose MassHealth or ConnectorCare. This home care aide earning $13.50 an hour for 30 hours per week would have to be offered employer sponsored insurance (ESI) that costs no more than $88 a month for a family plan. There is no such plan on the market, for a family or a single plan, unless her employer pays 100% of the premium. So it is not clear what the practical impact of the ESI lock out will be. Perhaps more workers will lose their MassHealth coverage due to filing requirements than due to the threshold.

Current Medicaid policy encourages low income women who work as Home Care aides to limit their work hours in order to keep their family on Medicaid, because it is cheaper and better coverage for their family than buying a plan through their employer. This is a strategy born of financial necessity, not from love of public assistance.

If EOHHS lowers MassHealth eligibility to 100% of poverty in FY 19, the home care aide cited above will likely cut back her work hours even more to avoid losing Medicaid insurance. Using FY 17 figures, if the Administration cuts

MassHealth eligibility for a 2 person household from $21,600 per year (133% of FPL) to $16,240 (100% of FPL), that aide will have to cut her work hours to 23 hours or less per week in order to keep MassHealth coverage. This creates an incentive for workers to reduce their level of employment—which clearly is not the message we want to send.

To the home care aide trying to provide health coverage for her family, MassHealth insurance is a survival strategy---and we should not punish her for making such a decision. If the Commonwealth wants more of the working poor to buy employer sponsored insurance, we should increase the level of "premium assistance" to cover the employee's share of their ESI premium, and allow them to use MassHealth as a wrap around plan to their ESI. Or conversely, we should allow employers to pay a premium into MassHealth, a "Medicaid buy in" plan, that covers any deductibles or copays to the employee under MassHealth. We should not blame low income people for the failure of the commercial health insurance markets.

On the employer side, the Governor's plan imposes a temporary two year "employer contribution" tax on employers with 6 or more workers, for each employee on public coverage, calculated as 5% of wages up to $15,000 in annual wages, or a maximum per worker charge of $750. We have seen one estimate which says that the home care aide industry could see $6 million in new Tier 2 employer medical contributions---an unfunded mandate from the state which is not built into these agencies' rates.

In Governor Deval Patrick's FY 14 budget the history of "employer responsibility" for health insurance costs was presented this way:

"The transition of the Massachusetts health care system under ACA provided the Governor with the opportunity to reduce costs for businesses through the elimination of both the Fair Share Contribution and the Medical Security Program. The Fair Share Contribution was established under the Commonwealth's 2006 health care reform law and mandates that employers with 11 or more full-time equivalent employees make a "fair and reasonable" contribution toward the health care costs of their full-time workers, or pay a $295 per FTE assessment. The ACA includes a similar policy for employers with over 50 employees, effective in 2014, that could result in double-penalties if the two policies were to coexist.

The Commonwealth will discontinue the Fair Share Contribution policy, but employers continue to share in the responsibility for health reform in Massachusetts. In order to ensure employers are contributing their share of maintaining quality, affordable health care for all residents, the legislation creates an "employer responsibility contribution" for employers which will, starting in 2014, help finance the cost of subsidized care for low-income state residents. The funding, estimated to total $94 M in FY 2014, will be directed to the MassHealth and the subsidized plans offered under the Health Connector.

We support requiring most private employers to pay a tax to help pay for the cost of their workers on MassHealth. Wal-Mart, for example, has historically had the largest number of workers on MassHealth in the state. Such corporations can well afford to pay this fee. But a small home care aide agency which has its compensation rate set by the state, is in a very different situation. The state has boxed them into a corner by years of inadequate rates. We propose that any human services agency which can demonstrate that it relies on state or federal revenues for 75% or more of its annual revenue, should be exempt from the Tier 2 EMAC.

We are also concerned with the following additional proposals, some of which are found in the Governor's 1115 waiver request---and others which were proposed during the FY 18 budget process:

- applying the 5% cost sharing limit annually rather than monthly or quarterly, which makes it harder to members to qualify.
- waiving the requirement that people can choose from at least 2 MCOs in some parts of state where most PCPs are in the ACO, which limits member choice of plans.
- charging cost-sharing over the 5% maximum for enrollees >300% FPL (impacts CommonHealth members)
- allowing MassHealth to use "commercial plan" mechanisms to control drug costs, including selecting preferred and covered drugs through a closed formulary and procuring a selective specialty pharmacy network. This will limit choice of medications for the member.
- implementing "narrow networks" for the PCC Plan, which results in narrower choice for members.

- giving EOHHS unilateral authority to restructure "optional services" under MassHealth (like prescriptions, physical therapy, occupational therapy, speech therapy, Personal Care Attendants)—a proposal with the General Court has rejected in past budgets.

There are other options for addressing MassHealth reform that focus on cost efficiencies to control cost. Here are 5 such options:

- While the goal of the 1115 Accountable Care waiver is to reduce cost growth through better coordination of care, the plan is weak in coordinating long term supports and services, and gives medical corporations total control over non-medical supports, and social determinates.
- The 1115 ACO plan lacks the "independent agent" approach for LTSS found in the two existing managed care plans in Massachusetts, the Senior Care Organization Plan and the One Care Plan. We can reduce our post acute care placement rate by diverting more members away from nursing facilities. Massachusetts ranks 34th in the nation for the percentage of new new Medicaid members who use home and community care as their first LTSS benefit. But 54% of new MassHealth members are referred to nursing facilities as their first LTSS option. We are also above the national average of members who go from hospital to nursing facility as the default mode.
- The 1115 plan should also incorporate the existing state law (Ch. 118E, s.9) which allows any consumer likely to need nursing facility care to get a free, pre-admission counseling session on their options for community-based care instead. Some of the ACOs have already expressed a reluctance to contract with LTSS Community Partners. These Community Partners are the best positioned to implement the types of changes that will lead to lower LTSS costs.
- Massachusetts ranks 23rd in the nation for the percentage of nursing facility residents with "low care" needs, around 11% of those in facilities. That's close to 3,000 residents who might have a good shot to return home if we use the Comprehensive Service and Supports Management (CSSM) program available to nursing facility residents through EOEA, to identify lowneeds

residents, and develop care plans to bring them home. We should also focus more attention on using the MDS Q mechanism to identify residents who want to return home.

- Every ACO and MCO should offer their members a care transitions program similar to the Community Care Transitions Model (CCTP) that CMS funded. The CCTPs in Massachusetts demonstrated that they can reduce ER visits and rehospitalizations by providing more continuous and coordinated care in the community, where the real threat of rehospitalization starts.

There are also a series of non-health policies that should be adopted to improve our revenue capacity to support the MassHealth program:

- The Commonwealth's annual spending on business tax breaks reportedly to support economic development in Massachusetts exceeded $1 billion for the first time in FY 2017. Adjusting for inflation, these costs have increased from $370 million in FY 96 to $1.028 billion in FY 18. A report from the Pew Trust in May of 2017 found that Massachusetts was "trailing other states because it has not adopted a plan for regular evaluation of tax incentives."
- In addition, the "single sales tax formula," which changes the method for determining what portion of multi-state companies' profits should be considered state income for tax purposes, has allowed companies to pay taxes on a percent of their profits based only on the sales they make in the state, regardless of how much manufacturing, research, design, marketing, or other activities occur in the state. According to a 2016 report from the Mass Budget and Policy Center, "the existing Single Sales Factor tax break costs the state over $200 million a year...evidence from Massachusetts and the rest of the country doesn't support the idea that Single Sales Factor will boost jobs...this corporate tax break is likely a very inefficient way to spend...dollars annually on economic development."

- Our capacity to sustain MassHealth spending has been impacted by a series of tax cuts that go back nearly a decade. In 2013, the U.S. Census Bureau Update of State and Local Government Finances, found that the amount of

state and local taxes paid in Massachusetts as a share of total personal income was 10.1% in FY 2013. Massachusetts had lower taxes than 24 other states and was below the national average of 10.4%.
http://massbudget.org/report_window.php?loc=tax_cuts_factsheet.html

In the period from 1998 through 2002, a number of significant changes to the state tax code were adopted, including a series of phased cuts to the state personal income tax. These cuts reduced the revenue available to fund the state budget, and limited the capacity to fund essential services in the Commonwealth. The tax rate applied to wage and salary income was cut from 5.95% to the 5.15%. The tax rate applied to dividend and interest income was cut from 12% to the current 5.15% and the amount people can deduct from their taxable income was doubled from $2,200 to $4,400 for single filers and from $4,400 to $8,800 for married couples. The combined effect of these three cuts now amounts to a loss of some $3.3 billion in annual revenue.
(http://massbudget.org/report_window.php?loc=tax_cuts_factsheet.html).

Conclusion:

We began this testimony by noting that access to affordable and adequate health care should be a top priority for state government. We must use the economic power of our common wealth, and innovative forms of care coordination in the acute, post acute and LTSS setting, to ensure that the most disadvantaged among us are not also the most disadvantaged when it comes to health care security.

Thank you again for the opportunity to present this testimony.

Mass Home Care, August 4, 2017

Massachusetts League
of Community Health Centers

August 2, 2017

Marylou Sudders, Secretary
Executive Office of Health and Human Services
Commonwealth of Massachusetts
One Ashburton Place, 11th Floor
Boston, MA 02108
Re: Proposed MassHealth Reform Package

Dear Madam Secretary:

On behalf of the Commonwealth's 50 community health centers, serving over 988,000 patients at more than 300 sites, we are writing with regard to the MassHealth reform package the Baker Administration submitted to the Legislature's FY2018 Conference Committee for consideration, as well as in response to the combined Ways and Means and Health Care Finance hearings held last week.

First, it is important that we express our appreciation to you, former Secretary Lepore and Governor Baker for your efforts in maintaining the progress made under Massachusetts and national health reform, while the state continues to face fiscal challenges and great uncertainty with efforts to repeal and replace the Affordable Care Act (ACA). We know that these reforms are intended to manage costs, achieve savings, generate additional revenue and adjust to the inevitability of some action by Congress in the coming months. In addition, we appreciate this Administration's willingness to work with us on increasing MassHealth reimbursement and minimizing the impact of changes to 340B pharmacy.

As health safety net providers, community health centers will be the first to witness the consequences of any reforms that eliminate benefits, shift coverage, increase patient liability and result in less access to affordable care. As you know, we serve a sizable number of MassHealth beneficiaries and have been working with the state to help people navigate the health care system and determine their coverage options. In this role, it is critical that we communicate the impact of these potential changes.

We have identified the following specific concerns for community health centers, and look forward to discussing solutions that preserve healthcare access and affordability for our patients.

Good health. Right around the corner.
40 Court Street, 10th Floor
Boston, MA 02108
phone 617-426-2225
fax 617-426-0097
www.massleague.org

Transfer of 140,000 people from MassHealth to ConnectorCare Coverage

We estimate that approximately 80,000 people, or 60% of the 140,000-person target group, are already being served at community health centers, and expect that this transfer may result in the following issues:

- **Loss of revenue related to the loss of MassHealth FQHC rate protection**

The Health Center Medicaid Prospective Payment System (PPS) was established by Congress with the intent of ensuring appropriate payment for covered individuals, while not forcing health centers to cross-subsidize MassHealth out of their federal grant funds. This unique payment system is integral to health centers' continued success in providing cost-saving primary and preventive care, as well as the support services necessary to make a difference when serving low-income populations. The state also has recognized this through its rate-setting regulations.

ConnectorCare does not include that payment protection, despite the fact that the people being moved out of MassHealth are just as poor and in need of the same array of community health center services as those patients who would remain MassHealth-eligible. Past experience with individuals close to the poverty line is that they move back and forth between private insurance and MassHealth as a result of their fluctuating employment status. Adequate reimbursement for care provided to these patients is critical for Massachusetts health centers. We would appreciate your perspective on approaches for insuring that ConnectorCare rates are set in a way that provide incentives or require health plans to cover the full array of health center services. Unless this provision is put into their rates, it is quite possible that they will forego health center contracts, dislocating patients from their primary care medical homes and ultimately disrupting their care.

- **Loss of care continuity**

Prior to the state's recent healthcare system transformation efforts, health plans that were serving MassHealth patients also served ConnectorCare patients. These were the same plans that contracted with health centers in various regions of the state. Now, because the majority of health centers will participate as members of Accountable Care Organizations (ACOs) by early 2018, most health centers will no longer have MassHealth plan contracts. It is unclear whether, without MassHealth business, the ConnectorCare plans will continue to contract with health centers. It is also unclear as to whether elimination of a great deal of MassHealth business will further shrink the availability of ConnectorCare health plans in some regions, disrupting relationships not only with health centers but also with hospitals and other health care providers.

Continuity of care is critical for health center patients, many of whom are dealing with complex co-morbidities that require greater coordination of services and care management. Currently, when a patients' financial status changes, they are able to remain in the same health plan, for both MassHealth and ConnectorCare. In the new environment, patients will need to switch enrollment from an ACO plan to a ConnectorCare plan. In the case where a health center does not have a contract with a ConnectorCare plan, it will mean that a patient becomes uninsured or is forced to leave their long-term provider. Past experience has shown that these patients ultimately return to the health center that they view as their medical home, and are cared for by the health center without reimbursement.

Copayments within the ConnectorCare Health plans can be a major factor in discouraging poor people from accessing and utilizing needed services. In addition, administrative requirements of third-party managers for behavioral health, eye care and pharmacy services are complicated. We are concerned that in many cases the combination of expense and administrative requirements will lead many patients to forego care, which they would have received at lesser expense and far less hassle within an ACO at a community health center.

- **Loss of dental coverage**

Loss of MassHealth dental coverage is another significant issue. It is questionable as to whether very low income patients will be able to afford dental coverage unless that premium is also subsidized. We appreciate your support of Health Safety Net (HSN) coverage for dental care at community health centers. However, we are extremely concerned that it is not an adequate substitute for statewide dental care availability. At present, dental services are not available at every health center, nor is dental care readily accessible in parts of the state not served by a community health center. Although health centers have continued to expand availability, lack of capacity and underpayment remain major issues. Since most health centers have oral health waiting lists, it would be difficult to accommodate all of the non-community health center-patients who will be transferred to ConnectorCare from MassHealth. In the case of patients who change coverage, this will add to the amount of HSN funding spent on health center dental services.

- **Potential for an increase in health center bad debt and depleted grant resources**

Connector plans have significantly higher cost-sharing requirements than MassHealth; the enrollment process combined with the tax credit system is much more complicated; and the possibility of a lock-out from coverage for non-payment of premiums make it likely that health centers will incur increasing bad debt, as well as an increased drain on already burdened grant resources in order to continue to serve patients currently covered by MassHealth. We would like to continue to work with the Executive Office of Health and Human Services and the Connector, particularly with respect to improving the enrollment process to attempt to minimize these effects. What's more, copayments within the ConnectorCare health plans can be a major factor in discouraging poor people from accessing and utilizing needed services. In addition, administrative requirements of third-party managers for behavioral health, eye care and pharmacy services are complicated. We are concerned that in many cases the combination of expense and administrative requirements will lead many patients to forego care, which they would have received at lesser expense and far less hassle within an ACO at a community health center.

- **Impact on health center viability within ACOs**

Our health center members have also expressed concern with the potential impact this change could have on our transition to accountable care systems. At this point, it is hard to pinpoint which ACOs would experience a reduction in their number of covered lives. It is clear that for the smaller ACOs (or smaller aggregations with an ACO), losing a significant number of enrollees could affect their reimbursement and risk arrangements. We request the opportunity to work with you and Assistant Secretary Tsai to get a better sense of the impact of the proposed changes on the effectiveness of the state's ACOs.

With respect to the other changes proposed in the MassHealth Reform package, we offer the following concerns:

Transfer of 230,000 people from MassHealth Standard to CarePlus: As we understand it, persons moving from MassHealth to CarePlus will still be eligible to remain in ACOs, but they may be susceptible to losing optional services, including non-emergency transportation, dental services, and eye glasses. Transportation is an important factor in patient compliance, particularly for patients with the most serious conditions. We have already presented our position and thoughts around dental services above. Health centers have greatly expanded their eye-care capacity, and lack of reimbursement for eye glasses will most likely mean that health centers will have to provide these at their own expense. Although we oppose elimination of these services for all MassHealth enrollees, we would also like to explore ways of continuing them exclusively at community health centers, if this proposal moves forward in the coming weeks.

Employer-sponsored insurance requirements: On the July 27, 2017 Baker Administration's conference call, we were pleased to hear that the proposal that persons eligible for employer-sponsored insurance (ESI) would not be allowed to apply for MassHealth coverage had been withdrawn. This proposal was a major concern, given the state's prior experience with a "gate" for MassHealth that was a frequent source of enrollment confusion and resulted delay, particularly with a population with very high job turn-over. We think a better solution rests with improving and streamlining the Premium Assistance program. Moving patients with MassHealth coverage to ESI raises the same issues as mentioned earlier regarding ConnectorCare coverage (lack of reimbursement protection, non-availability of contracts with various insurers; and high deductibles and copayments leading to bad debt). We believe that recognizing the need to make sure that low-income people get the care they need in an affordable way and that providers are adequately reimbursed in implementing this proposal could ensure that reform is successful. The League staff is already included in a MassHealth working group to explore this option.

As you know, the League membership, along with our Board of Directors, is very active within their communities and engaged on a range of policy issues. We anticipate they will be meeting with key legislative leaders over the coming weeks to share our concerns and to pursue positive solutions that will still allow the Administration to meet its goal of curbing costs.

While the transformation of the MassHealth delivery system presents tremendous challenges for all the state's providers and insurers, those faced by community-based systems of care -- like health centers -- are even greater. Consequently, the same statewide investments made to hospitals need to be extended to community health centers. As we have discussed, targeted investments in community health center financing, workforce, and transformation will generate both short- and long-term savings for the Commonwealth. I hope to discuss these ideas in greater detail with you and your team at your earliest convenience.

Sincerely yours,

James W. Hunt, Jr.
President & CEO

ABH

ASSOCIATION FOR BEHAVIORAL HEALTHCARE

251 West Central Street
Suite 21
Natick, MA 01760

T 508.647.8385
F 508.647.8311
www.ABHmass.org

Vicker V. DiGravio III PRESIDENT / CEO
Karin Jeffers, LMHC CHAIR

August 10, 2017

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

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

RE: MassHealth Section 1115 Demonstration Amendment Request of July 20, 2017

Dear Assistant Secretary Tsai:

Thank you for the opportunity to offer testimony on the MassHealth Section 1115 Demonstration Amendment Request proposed July 20, 2017. The Association for Behavioral Healthcare (ABH) appreciates the Baker Administration's continued commitment to the principle of universal coverage and understands the fiscal reality the Commonwealth faces at this time in trying to maintain meaningful access to health insurance for all of the residents of Massachusetts.

ABH is a statewide association representing more than eighty community-based mental health and addiction treatment provider organizations. Our members are the primary providers of publicly-funded behavioral healthcare services in the Commonwealth, serving approximately 81,000 Massachusetts residents daily, 1.5 million residents annually, and employing over 46,500 people.

As you know, the opioid crisis continues to affect individuals and families across Massachusetts in staggering numbers. The Massachusetts Department of Public Health (DPH) estimates there were approximately 1,526 opioid overdose deaths in 2016, and 402 in January-March of this year.[1] Behavioral health boarding in Emergency Departments (ED) continues to be a problem. The number of behavioral health-related ED visits per Massachusetts resident has grown steadily, increasing 13 percent from 2011 to 2015. In 2015, almost a quarter of all ED patients with a primary behavioral health-related condition had a length of stay in the ED of more than 12 hours, compared to only 1 percent of patients without a primary behavioral health-related condition.[2] These issues affect individuals across the health care coverage spectrum.

[1] "Data Brief: Opioid- Related Overdoes Deaths Among Massachusetts Residents", Massachusetts Department of Public Health, May 2017.
[2] "Annual Health Care Cost Trends Report 2016", Massachusetts Health Policy Commission. February 2017.

We commend the Baker Administration for its continued focus on both of these challenges facing the behavioral health field, but ABH is concerned that moving large groups of current MassHealth members from their current coverage to more commercially-aligned plans will jeopardize access to the large and diverse MassHealth provider network and robust continuum of behavioral health benefits for individuals in need of services. We outline specifics about these proposals below.

MassHealth Coverage Essential to Individuals with Behavioral Health Conditions

It is important to highlight the vital role Medicaid plays in the Commonwealth and nationally for those with mental health and addiction disorders. Nationally, Medicaid funded 25% of all mental health spending and 21% of all addiction spending in 2014. The Kaiser Family Foundation has noted that limits on Medicaid coverage could set back efforts to treat individuals with behavioral health conditions. In 2011, nearly half of Medicaid spending was for enrollees with behavioral health conditions.[3]

Low-income adults, children and their families from across the Commonwealth rely on the robust set of mental health and addiction treatment benefits offered in the MassHealth program. In contrast, commercial insurance coverage for mental health and addiction treatment services in Massachusetts continues to lag behind the comprehensive coverage offered to the individuals, children and families served by the MassHealth program.

Among non-elderly adults with mental illness and serious mental illness, those with Medicaid are more likely than those without insurance or with private insurance to receive treatment.[4] Commercial insurance plans in Massachusetts do not cover the many diversionary levels of care that are covered by MassHealth which help individuals live safe, stable lives in the community.

We ask the Administration to closely consider this as the MassHealth/Medicaid program in Massachusetts has long been a leader in offering comprehensive behavioral health benefits, and innovative diversionary services that are not covered in the commercial market.

Aligning Coverage for Non-Disabled Adults with Commercial Insurance Plans

The 1115 Waiver proposal includes multiple components to reach the Administration's goal of aligning coverage for non-disabled adults with commercial insurance plans. There are specific behavioral health concerns in the following three parts of the proposal.

Transferring Individuals from MassHealth to ConnectorCare

The proposal includes transferring 140,000 individuals with incomes between 100-133% of the federal poverty line (FPL) from MassHealth to ConnectorCare. ***ABH reluctantly supports this proposal provided the Legislature and Administration include the following provisions to protect access to care for this vulnerable population*** by easing the transition from MassHealth to the Connector:

---

[3] http://www.kff.org/infographic/medicaids-role-in-behavioral-health/

[4] http://www.kff.org/medicaid/fact-sheet/facilitating-access-to-mental-health-services-a-look-at-medicaid-private-insurance-and-the-uninsured/

1.) The Connector implement a clear and concrete plan to limit premiums, copays, and deductibles for this low-income population. Our understanding is that the current affordability schedule only applies to premiums;

2.) The Connector implement auto enrollment for this population into the currently available no-cost plan and reduce coverage gaps as Connector coverage begins on the first of each month;

3.) The Legislature does not enact a prohibition on new mandated benefits for commercially-insured individuals;

4.) The Legislature does not implement an Employer Sponsored Insurance (ESI) gate as included in the Governor's original package; and

5.) MassHealth commit to an ongoing review of the utilization of diversionary behavioral health services by this population. It may be worth additional discussions with the Connector Board regarding mental health and addiction treatment parity enforcement and/or establishing clear expectations for ConnectorCare plans to cover such additional behavioral health services.

It is important to note that behavioral health benefits available to MassHealth members and Connector Care members varies. Plans offered through ConnectorCare must meet the Essential Health Benefits (EHB) benchmark established in the ACA, which includes the broad category of mental health and substance use disorder services. ConnectorCare plans, however, are not required to cover a specific package of behavioral health benefits. For example, all MassHealth plans currently cover methadone maintenance treatment for opioid addiction. This is not a requirement of ConnectorCare plans.

As you know, MassHealth has recently expanded coverage of residential recovery home services to individuals on MassHealth and is able to draw down federal match funding to cover these services. Residential treatment is designed for individuals who have recently stopped using alcohol and/or other drugs, have been stabilized medically and are able to participate in a structured residential treatment program. In addition to providing clinical supports, Recovery Homes work with clients to get their lives back on track in terms of employment, education, interpersonal relationships and longer-term housing.

ConnectorCare plans do not currently cover residential recovery home services. Commercially-insured individuals do have access to a Residential Recovery Home beds through DPH's Bureau of Substance Addiction Services (BSAS). In such cases, however, the costs of providing these services through BSAS will be **100% state funded**.

Lastly, MassHealth covers important diversionary services like the Emergency Service Programs (ESPs) and Community Support Programs (CSP) that individuals with mental health and addiction disorders rely on to receive care. These benefits are not a part of traditional commercial insurance benefit packages and therefore are not available to most individuals covered through ConnectorCare plans.

Transferring Individuals from MassHealth Standard to MassHealth CarePlus

The MassHealth Section 1115 Demonstration Amendment Request includes the proposal of shifting 230,000 individuals under 100% FPL from MassHealth Standard to MassHealth CarePlus. MassHealth recently asked for federal approval to remove the non-emergency transportation (NEMT) benefit from MassHealth CarePlus coverage (except for substance use services), so this would leave 230,000 more individuals with very limited access to non-emergency transportation. We greatly appreciate the Baker Administration's continued commitment to access to addiction treatment services by preserving this portion of the benefit, but do know that transportation can be a lifeline for individuals to access services, including critical outpatient and diversionary mental health services.

ABH had previously submitted comments to MassHealth on the importance of non-emergency transportation for this population (see attachment) and ***we urge MassHealth to reconsider this proposal given the expansion of the CarePlus population through this latest waiver request.***

If and when MassHealth moves forward with these proposed changes, ABH requests an opportunity to provide feedback to MassHealth on the implementation of a substance use services only transportation system. As you know, many people who struggle with SUDs also have co-occurring mental health disorders, and require mental health services to move forward in their recovery. These mental health services may be provided at a different location and/or time from the SUD services, and it is important for consumers and providers to understand how MassHealth plans to implement these changes.

Ending the Medicaid Benefit Wrap for Individuals on MassHealth Premium Assistance

The MassHealth Section 1115 Demonstration Amendment Request also asks the federal government to allow MassHealth increased flexibility in administering the Medicaid benefit wrap for individuals on MassHealth Premium Assistance.

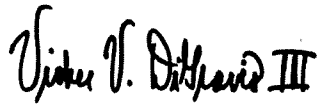
This program has existed for some time and has always included the additional benefit of "wrapping" MassHealth benefits around the commercial insurance product offered by the MassHealth member's employer. MassHealth is asking the federal government for "flexibility not to provide any additional benefit wrap, except for a limited number of services not typically covered by commercial."

Our understanding is that MassHealth intends to continue to wrap behavioral health benefits for those individuals on premium assistance, but the permissions being sought from the federal government appear to allow MassHealth, or another administration in the future, to drop these benefits. ***ABH requests MassHealth amend the proposed waiver language to explicitly protect the behavioral health benefit wrap currently offered in the premium assistance program.***

Benefits that are highlighted above that are typically provided as a wrap benefit for the premium assistance program include methadone maintenance coverage, ESPs, Recovery Home Services, and other diversionary services like psychiatric day treatment. Children who receive Children's Behavioral Health Initiative (CBHI) services at MassHealth are offered an array of services not covered by commercial services. Many children have MassHealth as secondary insurance.

Thank you for your consideration. Please do not hesitate to contact me if you have any further questions or concerns.

Respectfully,



Vicker V. DiGravio
President/CEO

cc: Secretary Marylou Sudders, Executive Office of Health & Human Services
Scott Taberner, Chief of Behavioral Health & Supportive Care, MassHealth
Stephanie Jordan Brown, Director, Office of Behavioral Health, MassHealth

American Heart Association | American Stroke Association
life is why™

you're the cure

August 11, 2017

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

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

Re: Comments for 1115 Demonstration Amendment

Dear Assistant Secretary Tsai,

The American Heart/Stroke Association (AHA) is the largest voluntary health organization in the world who is working to build healthier lives, free of cardiovascular disease (CVD) and stroke. We thank you for the opportunity to comment on the MassHealth 1115 Demonstration Waiver Amendment, but must express our deep concerns that that if implemented, this waiver will hurt efforts to build healthier lives in the Commonwealth. We share your commitment to a sustainable MassHealth program and to maintaining the gains Massachusetts has made in access to affordable health coverage for low-income residents. While we understand the significant fiscal challenges the Commonwealth currently faces, and the intent of the Administration to keep people covered, we are concerned that many of the proposals included in the 1115 Waiver Amendment will decrease access to affordable coverage and care for low-income consumers.

Individuals with Medicaid coverage are more likely to have cardiovascular conditions than those who have other types of health insurance coverage.[1] For example, low-income adults over age 65 with Medicaid coverage are more likely to have a history of high blood pressure, coronary heart disease and stroke than seniors with only Medicare coverage. Similarly, individuals enrolled in the program between the ages 18 to 64 are more likely to have a history of high blood pressure, angina, heart attack, stroke or coronary heart disease than individuals with private health insurance.[1] These findings are consistent with the overall trend that individuals who rely on the Medicaid program are generally sicker and have poorer health status than other Americans, highlighting how critical this coverage is for low-income Americans with CVD. In this way, Medicaid provides important financial protection to low-income individuals with CVD, covering critical health services and ensuring that these services remain affordable.

Transferring Non-Disabled Adults to ConnectorCare

MassHealth proposes to shift coverage for non-disabled adults ages 21 to 64 with incomes over 100% FPL to ConnectorCare as of January 1, 2019. Currently, this population includes 100,000 parents in MassHealth Standard and 40,000 childless adults in MassHealth CarePlus. ConnectorCare is a valuable program, integral to Massachusetts' health coverage system, as it

offers more affordable coverage than even the federal Advanced Premium Tax Credits (APTCs) and Cost-Sharing Reductions (CSRs) alone would provide. However, ConnectorCare coverage is costlier and presents more enrollment barriers than MassHealth coverage. We strongly urge EOHHS to reconsider shifting non-disabled adults with incomes over 100% FPL from MassHealth to ConnectorCare, as this will result in a loss of benefits, higher premium and copays, and an increased number of uninsured.

The detrimental health effects that result from being uninsured are well documented. The uninsured with CVD experience higher mortality rates[2,3] and poorer blood pressure control than their insured counterparts.[4] Similarly, those who suffer a stroke experience greater neurological impairments, longer hospital stays[5] and up to a 50% higher risk of death than the insured.[6] They are also less likely to have access to life-saving medications because of costs.[6] Uninsured and underinsured patients are more likely to delay seeking medical care during an acute heart attack.[7] One study found that people who had trouble paying their medical bills did significantly worse after heart attacks than patients who were not under such financial duress. Researchers also found 12% more cases of angina among financially distressed patients. In addition, these individuals were readmitted to the hospital at an 11% higher rate than other patients.[8] A 12-year study of more than 7,000 Americans showed that individuals without health insurance, especially those with heart disease, stroke, high blood pressure, or diabetes, experienced a dramatic improvement in health when they become eligible for Medicare coverage at age 65.[5] Another study found that those without insurance coverage before enrolling in Medicare were more likely to be hospitalized for heart attack, heart failure, or stroke.[9]

This problem is further exacerbated by the growing number of people who are underinsured, meaning that their insurance does not provide adequate financial protection when they are sick or experience a catastrophic illness, such as a heart attack or stroke. In a survey commissioned by the American Heart Association, more than half (56%) of all CVD patients – and 52% of patients with insurance coverage – reported difficulty paying for prescription drugs or other medical care in recent years. Of those patients who had difficulty paying medical expenses, nearly half said they had delayed getting needed health care and 43% had not filled a prescription.[10]

ESI and Student Health Insurance "Gate"

In the 1115 Waiver Amendment, EOHHS proposes to preclude otherwise eligible residents from qualifying for MassHealth if they have access to affordable employer sponsored insurance (ESI) or student health insurance. In a recent public presentation, MassHealth clarified that the 5% of income test to determine affordability of other coverage includes both premiums and deductibles. While this is a welcome change from the original proposal of using a 9.69% of income affordability test, considering only the premium cost, this metric does not account for other forms of cost-sharing, including copays and coinsurance, that may present substantial access barriers to low-income workers, particularly those with chronic diseases.

There is no precedent for this type of restriction in Medicaid; access to other health insurance has never been a bar to MassHealth coverage. Rather, MassHealth acts as a secondary or tertiary payer when other coverage is available, which protects low-income members from unaffordable medical bills. We urge EOHHS to remove the ESI and SHIP "gate" from its proposed 1115 Waiver Amendment.

Instead, we support increased participation in the MassHealth Premium Assistance program as the best way to leverage employer contributions and reduce state spending while also ensuring that low-income workers have affordable and comprehensive coverage. Through programs like Premium Assistance, MassHealth has remained an important support for low-income families striving to work themselves out of poverty. We are hopeful that the use of the Health Insurance Responsibility Disclosure (HIRD) form to streamline the Premium Assistance process for MassHealth, consumers, and employers alike.

MassHealth Premium Assistance "Wrap" Benefits

The MassHealth Premium Assistance program has always provided a benefit "wrap" in addition to assistance with the ESI premiums and cost-sharing. Commercial health insurance coverage is often not sufficient to meet the needs of low-income families, especially with regards to behavioral health and other community-based services. Thus, these "wrap" benefits are critical to ensuring MassHealth-eligible individuals and families enrolled in commercial coverage have access to the same level of benefits as if they were enrolled in MassHealth.

We are concerned that MassHealth seeks "flexibility not to provide any additional benefit wrap, except for a limited number of services not typically covered by commercial insurance" in the 1115 Waiver Amendment. We are concerned that the state seeks to eliminate the standard of care currently provided through wrap services but it is unclear which services would be preserved or eliminated. The association cannot adequately evaluate this measure without additional detail and urges the Department to preserve in its current form, these wrap services

MassHealth Limited and ConnectorCare Coverage

Under the waiver request, MassHealth proposes to eliminate MassHealth Limited coverage 90 days after an individual is determined eligible for ConnectorCare, as is done with access to the Health Safety Net. We understand the purpose of this change and believe it may help mitigate confusion for individuals currently eligible for both coverage types. However, we are concerned that those who remain eligible for ConnectorCare but unenrolled will not have access to even emergency coverage after 90 days. Therefore, we suggest that MassHealth amend its request to clarify that MassHealth Limited coverage is terminated only when the coverage is truly redundant; that is, after an individual has successfully enrolled in ConnectorCare.

Closed Drug Formulary and Selective Specialty Pharmacy Network

As a key health care cost driver, we understand the need to manage prescription drug costs. However, we are concerned that more limited specialty pharmacy networks and a closed formulary, as proposed in the 1115 Waiver Amendment, would impose unnecessary barriers to needed medications. Unlike many of the other proposed changes, these changes apply to all

MassHealth members, including people with disabilities, children, and seniors. Prescription drugs are a lifeline for people with chronic diseases especially those with cardiovascular disease.

Lastly, MassHealth proposes to implement narrower networks in the PCC Plan to encourage enrollment in Accountable Care Organizations (ACOs) and MCOs. While the differential is decreasing, people with complex medical needs choose the PCC Plan over MCOs. Most often, applicants choose the PCC Plan because their preferred providers are not all included in Managed Care Organization (MCO) networks, or are not included in the same network. We request that MassHealth provide more detail about how the narrower PCC Plan networks will be established, identify impacts on people with complex needs or disabilities, and demonstrate how the narrower networks will continue to meet Medicaid network adequacy requirements. Similar to the proposed PCC Plan network changes, we request more details about the proposal to waive the requirement for multiple managed care options in certain areas of the state.

We appreciate the dialogue the Administration has opened to discuss our concerns, and look forward to working with you to ensure that any changes to MassHealth do not adversely impact members. Thank you for your time and consideration.

Sincerely,

Allyson Perron Drag
American Heart Association/ Stroke Association
Senior Government Relations Director
300 5th Avenue, Suite 6
Waltham, MA 02451-8750

References
1 Leighton Ku and Christine Ferguson. Medicaid Works: A Review of How Public Insurance Protects the Health and Finances of Low-income Families and Individuals. Forthcoming, First Focus and George Washington University.
2 Shen JJ, Washington EL. Disparities in outcomes among patients with stroke associated with insurance status. Stroke 38(3):1010-1016.
3 McWilliams JM, Zaslavsky AM, Meara E, Ayanian JZ. Health insurance coverage and mortality among the near-elderly. Health Affairs 2004; 23(4): 223-233.
4 Duru OK, Vargas RB, Kerman D, Pan D, Norris KC. Health Insurance status and hypertension monitoring and control in the United States. Am J Hypertens 2007;20:348-353.
5 Rice T,LaVarreda SA,Ponce NA, Brown ER. The impact of private and public health insurance on medication use for adults with chronic diseases. Med Care Res Rev 2005; 62(1): 231-249.
6 McWilliams JM, Meara E, Zaslavsky AM, Ayanian JZ. Health of previously uninsured adults after acquiring Medicare coverage. JAMA. 2007; 298:2886 –2894.
7 Smolderen KG, et al. Health Care Insurance, Financial Concerns in Accessing Care, and Delays to Hospital Presentation in Acute Myocardial Infarction. *JAMA* 2010;303(14)1392-1400.
8 Rahimi AR, Spertus JA, Reid KJ, et. al. Financial barriers to health care and outcomes after acute myocardial infarction, JAMA 2007; 297:1063-1072.
9 McWilliams JM, Meara E, Zaslavsky AM, et al. Medicare Spending for Previously Uninsured Adults. Annals of Internal Medicine. Published online October 6, 2009.
10 American Heart Association-commissioned survey. January 2010.

Mental Health America
#B4Stage4

August 13, 2017

The Honorable Daniel Tsai
Assistant Secretary for MassHealth
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place
Boston, Massachusetts 02108

Dear Mr. Tsai:

Mental Health America (MHA) urges Massachusetts not to limit access to psychotropic medications based on cost in MassHealth. Empirical research repeatedly finds that restricting access to psychotropic medications is not an effective strategy for reducing overall state expenditures. It could, however, impact the effectiveness of MassHealth in making recovery a reality for the people it serves.

Mental Health America (MHA) – founded in 1909 – is the nation's leading community-based nonprofit dedicated to addressing the needs of those living with mental illness and to promoting the overall mental health of all Americans. Our work is driven by our commitment to promote mental health as a critical part of overall wellness, including prevention services for all, early identification and intervention for those at risk, integrated care, services, and supports for those who need it, with recovery as the goal. With our years of experience in state and federal policy, we find that cost-based restrictions on access to medication injure individuals and end up not being an effective cost-saving strategy.

Cost-based access restrictions are not appropriate for psychotropic medications because each molecule is unique and each individual responds differently.[1] The process of finding a medication that an individual responds to with tolerable side-effects can take months or even years.[2] This is true not only between molecules, but between formulations as well, such that generic formulations have different therapeutic effects than their name-brand counterparts.[3] On this backdrop, cost-based restrictions, and especially restrictions that only guarantee access to a single drug in a therapeutic class, are not appropriate

Empirical research on cost-based restrictions to psychotropic medication access bears out this claim – states have not saved money, and in some cases even paid more, and hospitalizations increased for the

---

[1] *See, e.g.*, Julia Kirchheiner *et al.*, *Pharmacogenetics of antidepressants and antipsychotics: the contribution of allelic variations to the phenotype of drug response*, 9 MOLECULAR PSYCHIATRY 442 (2004) ("At present, antidepressant and antipsychotic drug responses can best be explained as the combinatorial outcome of complex systems that interact at multiple levels.");
[2] *See* Jeffrey A. Lieberman and John K. Hsiao, *Interpreting the Results of the CATIE Study*, 4 FOCUS 564-564 (2006) ("It is crucial to point out that equivalent does not mean identical: 25 percent of patients may respond to risperidone and 25 percent to perphenazine, but they are not the same 25 percent.").
[3] *See, e.g.*, Yiu Lam *et al.*, *Branded versus generic clozapine: bioavailability comparison and interchangeability issues*,62 J. CLIN. PSYCHIATRY 18, 23 (2001); S. van Os, M. Relleke, and P.M. Piniella, *Lack of bioequivalence between generic risperidone oral solution and originator risperidone tablets*, 45 INT'L J. CLINICAL PHARMACOLOGY AND THERAPEUTICS 293, 298 (2007).

individuals affected.[4] Each instance of crisis will hurt the individuals, their families, and their communities throughout Massachusetts, without providing benefit to the taxpayers.

Instead, MHA recommends that MassHealth build on its existing capacity to intervene early and prevent health care utilization by capitalizing on a recent development. MassHealth has the opportunity to be the first to cover the Collaborative Care Model (CoCM) billing codes created by the Centers for Medicare and Medicaid Services (CMS) in the last Medicare Physician Fee Schedule.[5] This evidence-based model for early intervention in primary care would supplement the Child Psychiatric Access Project by offering a flexible billing system for coordination while requiring measurement-based care and a focus on outcomes – driving down costs. In combination with the First Episode Psychosis programs, CoCM enables MassHealth to have a robust behavioral health system that can reduce high-cost health care utilization.

MHA thanks you for your consideration of this important issue. Please do not hesitate to contact Nathaniel Counts, JD, Senior Policy Director, at ncounts@mentalhealthamerica.net with any questions.

Sincerely,

Nathaniel Counts, J.D.
Senior Policy Director
Mental Health America
500 Montgomery St, Suite 820
Alexandria, VA 22314
ncounts@mentalhealthamerica.net

---

[4] *See, e.g.*, Chris Koyanagi, Sandra Forquer and Elaine Alfano, *Medicaid Policies To Contain Psychiatric Drug Costs*, 24 HEALTH AFF. 536, 542 (2005) ("As demonstrated in New Hampshire, denying access to a full array of antipsychotics can increase other Medicaid service costs resulting from ineffective treatment."); Edward Kim, Richard Levy, Andrei Pikalov, *Personalized treatment with atypical antipsychotic medications*, 24 ADVANCES IN THERAPY 721 (2007) ("The considerable pharmacologic differences among atypical antipsychotic agents and the specific clinical circumstances of individual patients with psychiatric illness require the availability of a full range of agents in this class. Restrictions in the availability of atypical agents may prove to be counterproductive, both clinically and economically."); Safiya Abouzaid *et al.*, *Economic Impact of Prior Authorization Policies for Atypical Antipsychotics in the Treatment of Schizophrenia*, 14 POPULATION HEALTH MANAGEMENT 247 (2010) ("Sensitivity analyses show that small increases in hospitalizations will make PA the more costly option."); Joel F. Farley *et al.*, *Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications*, 30 CLINICAL THERAPEUTICS 1524 (2008) (finding dramatic cost off-sets in Georgia for outpatients visits after prior authorization policy); *See* Michael R. Law, Dennis Ross-Degnan, Stephen B. Soumerai, *Effect of Prior Authorization of Second-Generation Antipsychotic Agents on Pharmacy Utilization and Reimbursements*, 59 PSYCHIATRIC SERVICES 540 (2008); Yuting Zhang *et al.*, *Effects of Prior Authorization on Medication Discontinuation Among Medicaid Beneficiaries With Bipolar Disorder*, 60 PSYCHIATRIC SERVICES 520 (2009); Joyce C. West *et al.*, Clinically unintended medication switches and inability to prescribe preferred medications under Medicare Part D, 26 J. PSYCHOPHARMACOLOGY 753 (2012); Seth A. Seabury *et al.*, *Formulary restrictions on atypical antipsychotics: impact on costs for patients with schizophrenia and bipolar disorder in Medicaid.* 20 AM. J. MANAGED CARE e52 (2014)

[5] Matthew J. Press *et al.*, *Medicare Payment for Behavioral Health Integration*, 376 N. Engl. J. Med. 405 (2017)

PhRMA
RESEARCH • PROGRESS • HOPE

950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

August 15, 2017

Secretary Marylou Sudders
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

Dear Secretary Sudders:

We are writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding PhRMA's concerns with the MassHealth Section 1115 Demonstration Amendment Request, which was posted for comment on July 20, 2017. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA has a long-standing interest in promoting Medicaid beneficiaries' access to quality care and is concerned that the Commonwealth's proposal to waive sections of the Medicaid drug rebate statute will reduce and ration access to lifesaving medicines.

Specifically, the Executive Office of Health and Human Services is requesting an amendment to the MassHealth Section 1115 Demonstration to make changes " . . . to ensure the sustainability of the MassHealth program while retaining access for vulnerable populations." Of particular concern to PhRMA is the Amendment's proposal to:

6. Select preferred and covered drugs through a closed formulary that assures robust access to medically necessary drugs
   - 6a. Adopt a commercial-style closed formulary with at least one drug available per therapeutic class
   - 6b. Exclude from the formulary drugs with limited or inadequate evidence of clinical efficacy

While PhRMA supports state efforts to expand insurance coverage for state residents, a key element of Massachusetts' amendment fails to meet its intended goal of ensuring robust access to medically necessary drugs and raises serious concerns about the long-term impact on some of the sickest and poorest individuals in need of medical assistance. As described in section 5 of the Demonstration Amendment, Massachusetts' proposal to waive "§1902(a)(54) insofar as it incorporates §1927(d)(1)(B)" would allow the state to impose a closed formulary that would potentially exclude a vast number of FDA-approved drugs and restrict drug access for the most vulnerable populations. Further, the Commonwealth already has cost containment tools available under Section 1927 to control pharmacy expenditures. This proposal is ill-advised for both legal and policy reasons and should be withdrawn from the Amendment Request. Our comments follow the outline below:

1. The Demonstration Amendment Request Does Not Meet the Requirements for Approval Under Social Security Act (SSA) § 1115
    A. SSA §1115 Does Not Permit Waiver of Any Requirements in the Medicaid Rebate Statute
    B. The Medicaid Rebate Statute Is a Package Deal that Cannot Be Torn Apart by a Selective Waiver of Its Coverage Requirements Alone
    C. Waiving the Rebate Statute's Drug Coverage Requirements Would Not Promote Medicaid Objectives
    D. The Closed Formulary Initiative is Not an "Experimental, Pilot, or Demonstration Project" Authorized Under § 1115
        1. Restrictions on Vulnerable Patients' Access to Medications Have Already Been Extensively Studied (and Found Counter-Productive for Medicaid and Risky for Beneficiaries)
        2. The Closed Formulary Initiative Does Not Involve Legitimate Research
    E. Massachusetts Has Not Followed the Transparency Requirements in 42 CFR § 431.408
2. The Demonstration Amendment Arbitrarily Rations Access to Life-Saving Medicines, Mischaracterizing the FDA Approval Process, Undermining Congressional Intent, and Contradicting Science-Based Decision Making
3. The Demonstration Amendment Fails to Consider the Importance of Individualized, Patient-Centered Care
4. The Demonstration Amendment Ignores Research Showing that Closed Formularies Hurt Patients, Lower Adherence, and Do Not Reduce Health Care Costs
5. State Flexibility to Control Costs Already Exists under the Medicaid Drug Rebate Statute

1. The Demonstration Amendment Request Does Not Meet the Requirements for Approval Under Social Security Act (SSA) § 1115

Our comments focus chiefly on the request to waive the Medicaid rebate statute's drug coverage requirements (specifically, SSA § 1927(d)(1)(B)).[1] Under the Medicaid rebate statute, drug manufacturers pay rebates on Medicaid utilization of their products in return for state Medicaid programs covering their products, subject only to certain "permissible restrictions" listed in the statute. Massachusetts proposes to waive these coverage requirements and establish a closed formulary. The closed formulary would include at least one drug in each therapeutic class and would not comply with the rebate statute's more patient-protective formulary standards. The description of which drugs would be excluded from the formulary is unclear, but it appears that a drug could be excluded for two different reasons: (1) to reduce the number of drugs in a class to one so that "the State could offer manufacturers an essentially guaranteed volume in exchange for a larger rebate"; or (2) because a drug has "limited or inadequate evidence of clinical efficacy."[2]

As explained below, this waiver request cannot be granted for five different reasons. First, the requested waiver is foreclosed by PhRMA v. Thompson, which held that SSA § 1115 does not authorize waivers of the Medicaid rebate statute.[3] Second, even if a waiver of the rebate statute were permitted, waiving its coverage requirements alone (without waiving the requirements for manufactures to pay rebates) would impermissibly tear apart the legislative bargain reflected in the rebate statute. Third, the Demonstration Amendment would not meet the requirements that a § 1115 demonstration program be "likely to assist in promoting [Medicaid] objectives."[4] Fourth, the Demonstration Amendment is not a legitimate pilot program and does not have research value.[5] Last, the Demonstration Amendment Request must comply fully with the transparency and public notice requirements in SSA § 1115 and its implementing regulations, but does not meet those standards.

A. SSA § 1115 Does Not Permit Waiver of Any Requirements in the Medicaid Rebate Statute

SSA § 1115(a)(1) provides that, "[i]n the case of any experimental, pilot, or demonstration program which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [Medicaid or certain other programs], in a state or states— (a) the Secretary may waive compliance with any of the

---

[1] Social Security Act § 1927(d)(1) describes the permissible restrictions State Medicaid programs can place on the drugs of a manufacturer with a Medicaid Rebate Agreement. It provides in full as follows:

> (d) LIMITATIONS ON COVERAGE OF DRUGS. —
>
> (1) PERMISSIBLE RESTRICTIONS.—
>
> (A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)
>
> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if —
>
> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));
>
> (ii) the drug is contained in the list referred to in paragraph (2) [drugs for eleven specified purposes, *e.g.* for weight loss or gain or for fertility];
>
> (iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or
>
> (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

[2] Demonstration Amendment Request at 9-10.

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

[4] SSA § 1115(a).

[5] Newton-Nations v. Betlach, 660 F.3d 370, 381 (9th Cir. 2011) (quoting Beno v. Shalala, 30 F.3d 1057, 1071 (9th Cir. 1994)).

requirements of section 402, 454, 1402, 1602, or 1902 . . . to the extent and for the period he finds necessary to enable such state or states to carry out such project." SSA § 1927 (the Medicaid rebate statute, codified at 42 U.S.C. § 1396r-8) is not on the list of waivable provisions. Accordingly, the D.C. Circuit held in PhRMA v. Thompson that CMS had no authority to waive requirements of the rebate statute under § 1115:

> The Social Security Act, of which the Medicaid statute is a part, authorizes HHS to approve experimental "pilot" or "demonstration" projects that the Secretary determines are "likely to assist in promoting the objectives of [Medicaid]." [42 U.S.C.] § 1315(a). 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 [SSA 1927's] rebate provision . . . *See id.* § 1315(a)(1).[6]

PhRMA v. Thompson is the only case that has addressed whether SSA § 1115 permits waivers of rebate statute requirements. The D.C. Circuit's ruling has never been overturned or questioned by later cases.

B. The Medicaid Rebate Statute Is a Package Deal that Cannot Be Torn Apart by a Selective Waiver of Its Coverage Requirements Alone

Even if CMS could waive the rebate statute under § 1115, it still could not selectively waive the rebate statute's coverage requirements while leaving in place the requirement for manufacturers to pay rebates on Medicaid utilization. Such a one-sided waiver would tear up the careful legislative bargain Congress created in the Medicaid rebate statute. As CMS has explained:

> [The Medicaid rebate statute] sets forth requirements for covered outpatient drugs, whereby drug manufacturers must pay statutorily-defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.[7]

The rebate statute's legislative history similarly emphasizes that the statute links manufacturer rebate obligations and Medicaid coverage obligations:

> The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require states that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.[8]

Congress thus required states to cover all products of a manufacturer with a Medicaid rebate agreement (with specified exceptions), to ensure beneficiary access to the full range of drugs that are available to

---

[6] PhRMA v. Thompson, 251 F.3d at 222 (emphasis added).
[7] 78 Fed. Reg. 4594, 4631 (Jan. 22, 2013) (emphasis added).
[8] H. Rpt. 101-881, 101st Congress, 2d Session (Oct. 16, 1990) (emphasis added).

private patients. Accordingly, the statute purposely coupled the rebate requirements on manufacturers with the coverage requirements on states; it was described by Congressman Henry Waxman, a key sponsor, as a "government-industry compact."[9] The standard Medicaid Rebate Agreement between CMS and each manufacturer that participates in the rebate program also emphasizes this bargain: it details manufacturers' obligations to calculate and pay rebates, and recognizes that manufacturers must be able to rely on states fulfilling their end of the statutory bargain (and to enlist CMS's assistance if a state does not fulfill its coverage obligations).[10]

As the Supreme Court has emphasized, "strict adherence to the language and structure of an act is particularly appropriate where . . . a statute is the result of a series of carefully crafted compromises."[11] Many cases similarly hold that when a statute reflects a legislative bargain, it must be interpreted to uphold that bargain, not tear it asunder.[12] Applying this principle here, the rebate statute is a package—with benefits and obligations for both manufacturers and Medicaid—and CMS cannot authorize a state to keep the benefits of the package, but jettison its coverage responsibilities. Thus, even if SSA § 1115 permitted waiving the whole rebate statute, it still would not permit waiving the state coverage requirements in Section 1927(d) without waiving the manufacturer rebate requirements in Sections 1927(a)-(c); that would tear up a legislative bargain. Congress would not have passed the rebate statute's rebate payment requirements without its coverage requirements (or vice versa); the two cannot be separated.

The Demonstration Amendment Request states that Massachusetts "currently lacks basic formulary management tools available to commercial payers. Whereas commercial payers can elect whether or not to cover drugs based on clinical efficacy and affordability, MassHealth is required to cover any drug for which the manufacturer participates in the federal Medicaid rebate program. The requirement to cover any such drug hinders our ability to secure additional supplemental rebates."[13] This statement fails to acknowledge that the rebate statute already permits states to exclude or otherwise restrict coverage in a variety of circumstances (as discussed in section 5 of this letter) while guaranteeing them large rebates—rebates designed to reduce their net payment to an amount lower than the lowest net price the manufacturer negotiates with another customer. According to a Congressional Budget Office (CBO) report, in 2013 average rebates on brand name drugs were 63% of Average Manufacturer Price.[14]

---

[9] Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce, H. Hrg. 103-61, 103rd Cong. 453 (1993) (statement of Rep. Waxman).

[10] Medicaid Rebate Agreement § VI(a) ("A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act [establishing a notice and hearing process for CMS to stop or reduce payments to State Medicaid programs that are out of compliance with their State plan obligations]").

[11] Community for Creative Non-Violence v. Reid, 490 U.S. 730, 748 n.14 (1989).

[12] *See, e.g.*, General Motors Corp. v. Romein, 503 U.S. 181, 191 (1992) (upholding statutory provisions necessary to "preserve the delicate legislative compromise that had been struck by [prior] laws"); Mohasco Corp. v. Silver, 447 U.S. 807, 826 (1980) ("We must respect the compromise embodied in the words chosen by Congress. It is not our place simply to alter the balance struck by Congress"); Rodriguez v. Compass Shipping Co., 451 U.S. 596, 612 (1981) ("[in] interpreting the intent of Congress in fashioning various details of this legislative compromise, the wisest course is to adhere closely to what Congress has written"); Villarreal v. R. J. Reynolds Tobacco Co., 839 F.3d (11th Cir. 2016) (elevating general notions of purpose over statutory text "disregards the processes of [legislative compromise] and, in the end, prevents the effectuation of congressional intent") (citation omitted); United States v. Taylor, 487 U.S. 326, 336 (1988) ("the purposes of the Act and the legislative compromise it reflects [must be] given effect"); American Mining Congress v. EPA, 824 F.2d 1177, 1187 (D.C. Cir. 1987) (courts "must be loathe to tear asunder" the process of legislative compromise).

[13] Demonstration Amendment Request at 9.

[14] CBO, Options for Reducing the Deficit: 2017-2026, 255 (December 2016), available at: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/52142-budgetoptions2.pdf. This 63% of AMP figure includes the two components of the Medicaid rebate on a brand name drug: (1) the "basic rebate" (23.1% of AMP or [AMP minus Best Price], whichever is higher); and (2) the "additional rebate" (the current-quarter AMP minus the inflation-adjusted AMP from the drug's baseline period, which usually is the first full quarter after the drug's launch). This does not take

HHS similarly reported in 2016 that Medicaid rebates reduce the cost of drugs to Medicaid by about 50%.[15] No payer but Medicaid has such a rebate guarantee.

The Demonstration Amendment Massachusetts seeks—which would expand its power to restrict coverage—could thwart the core objective of the rebate statute, undermining the deal between states and manufacturers, and thus raise questions about the rationale for manufacturer participation in the rebate program.

C. Waiving the Rebate Statute's Drug Coverage Requirements Would Not Promote Medicaid Objectives

Any 1115 demonstration project must be "likely to assist in promoting the objectives of [Medicaid]."[16] Based on the language of the Medicaid statute, courts generally describe Medicaid's objectives as providing medical assistance to those whose income and resources are inadequate to meet the costs of such care.[17] The cases often cite SSA § 1901, which describes Medicaid's purposes as:

> enabling each state . . . to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.

Allowing a wholesale waiver of the drug coverage requirements in the rebate statute would not promote those purposes. Instead of enabling states to assist people who cannot afford necessary medical care, such a waiver would reduce beneficiaries' access to medicines and adversely affect their health in two ways: directly, by permitting the State to cut back on drug coverage; and indirectly, by eliminating or curtailing manufacturers' incentive to participate in the Medicaid rebate program—a program that has successfully provided Medicaid beneficiaries "access to the same range of drugs that the private patients of their physicians enjoy" since its start in 1991. The rebate program could unravel quickly if one selective waiver of the rebate statute's coverage requirements were granted, as other states would likely seek the same waiver once the precedent was established; this would be a serious setback for Medicaid objectives and for beneficiaries' health and well-being.

The direct damage from the waiver is also disturbing—and easy to anticipate—because the impact of formularies that restrict drug access for vulnerable populations has already been extensively studied. Importantly, these studies show that restricting access to drugs through closed formularies results in non-adherence or poor adherence to prescribed medication regimens; worsened health outcomes, and higher, long-run costs, both to Medicaid and other state and local programs. We summarize the research in section 4 of this letter.

Moreover, given how broadly the Demonstration Amendment Request defines drugs with "limited or inadequate evidence of clinical efficacy," allowing the closed Medicaid formulary to exclude these drugs could deny Medicaid beneficiaries access to many vital and innovative drugs. According to the Demonstration Amendment Request, "limited or inadequate clinical efficacy will be defined as when one or more of the following conditions exist:

---

into account supplemental rebates that States may negotiate from manufacturers on top of the federal rebate required under the rebate statute.

[15] HHS Office of the Assistant Secretary for Planning and Evaluation, Report to Congress, Prescription Drugs: Innovation, Spending, and Patient Access, 10 (Dec. 7, 2016)("About half of Medicaid gross spending on prescription drugs is returned to the federal government and the states in the form of manufacturer rebates").

[16] SSA § 1115(a).

[17] *See, e.g.*, Cal. Welfare Rights Org. v. Richardson, 348 F. Supp. 491, 496 (N.D. Cal. 1972).

- Primary endpoints in clinical trials have not been achieved;
- Only surrogate endpoints have been reported;
- Clinical benefits have not been assessed;
- FDA approval is contingent upon verification of clinical benefit in confirmatory trials; [or]
- The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives."

We detail the broad range of important drugs that fall within these categories in section 2 of this letter. The suggestion that this is a small group of medicines with doubtful benefits—that the 21st Century Cures Act expedited drug approvals "by reducing the level of evidence required for drugs to reach the market,"[18] and Medicaid patients will not suffer from losing access to these drugs—is incorrect. To mention just one example of the types of drugs that Massachusetts could exclude under the "limited or inadequate clinical efficacy" label, the last category in this list would include not just accelerated approval drugs, but most drugs, because FDA's drug approval framework does not require evidence of an "incremental benefit" over existing therapies for a demonstration of safety and efficacy. Drugs are approved in this country if they are shown to be safe and effective—that is what the law requires and accordingly what FDA requires manufacturers to demonstrate.

Additionally, Massachusetts acknowledges that the 21st Century Cures Act was enacted to accelerate the "discovery, development and delivery" of medical therapies, but disregards the rationale for this effort: that "the fight to treat and cure disease is an urgent, nonpartisan, national priority," because managing the 7,000 known diseases without cures "costs billions of dollars, and its personal costs are much higher, causing pain and heartbreak during the battle with disease and with each loss of life."[19] Massachusetts requests a waiver of its statutory coverage obligations in order to "exercise discretion about whether these drugs should be covered without being fully clinically proven."[20] Yet the safety and effectiveness of drugs available in the marketplace must be established through FDA's approval process, and nothing in the 21st Century Cures Act changed or diluted FDA's strict approval standards. The Cures Act "ensure[s] that our country remains on the forefront of medical innovation while maintaining the gold standard for approvals of medical products."[21] In fact, research has shown that drugs approved through expedited review "offered larger health gains, compared to drugs approved through conventional review processes,"[22] suggesting that FDA has prioritized drugs that offer the largest health gains.

Denying Medicaid beneficiaries access to these therapies would adversely affect their health—potentially in very serious and disturbing ways—and turn Medicaid into a second-class healthcare program whose beneficiaries lack the same access to treatment innovations "that the private patients of their physicians enjoy." This is just the opposite of promoting Medicaid objectives.

The conclusion that this closed formulary initiative, with an admitted focus on limiting access to innovative drugs that may warrant accelerated review from FDA, would not promote Medicaid objectives is even stronger given that the courts explicitly require consideration of "the impact of [the state's] project on the persons the Medicaid Act was enacted to protect."[23] Formulary restrictions aimed partly at blocking access to treatment innovations would inevitably have a negative impact on the health and well-being of the individuals the Medicaid statute was enacted to protect. And, this impact cannot be written off as a necessary consequence of reducing Medicaid costs in order to keep the

[18] Demonstration Amendment Request at 10.
[19] H.R. Rep. No. 114-190 Part I at 85 (July 7, 2015).
[20] Demonstration Amendment Request at 10.
[21] July 10, 2015 Congressional Record at E1036 (statement of Rep. Pallone).
[22] James D. Chambers et al., Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process, 36 HEALTH AFFAIRS 1408-1415 (2017).
[23] Wood v. Betlach, 922 F. Supp.2d 836, 848 (D. Az. 2013) (quoting Newton-Nations v. Betlach, 660 F.3d 370, 381 (9th Cir. 2011)).

program sustainable. The summary of research on the effects of formulary restrictions on vulnerable populations in section 4 of this letter shows that these restrictions are actually likely to increase these patients' total healthcare costs, as the savings from curbing access to drugs are typically offset (or more than offset) by increased costs of hospitalizations, ER visits, physician visits, and other non-drug costs. And, these unintended, but predictable, consequences must be factored into decisions about whether hoped-for savings from benefit cuts are actually likely to materialize and help to promote Medicaid sustainability—or instead to backfire and hurt patients' health without generating overall Medicaid savings.[24]

D. The Closed Formulary Initiative is Not an "Experimental, Pilot, or Demonstration Project" Authorized Under § 1115

1. Restrictions on Vulnerable Patients' Access to Medications Have Already Been Extensively Studied (and Found Counter-Productive for Medicaid and Risky for Beneficiaries)

In addition to promoting the objectives of Medicaid, demonstrations must be designed to learn something new and not merely to save money, as SSA § 1115 only authorizes "experimental, pilot, or demonstration project[s]." As the courts have explained,

> [t]he purpose of these [Section 1115] demonstrations, which give states additional flexibility to design and improve their programs, is to demonstrate and evaluate policy approaches such as: expanding eligibility to individuals who are not otherwise Medicaid or CHIP eligible; providing services not typically covered by Medicaid; using innovative service delivery systems that improve care, increase efficiency . . .[25]

Similarly, as the Ninth Circuit explained in Beno v.Shalala:

> [SSA § 1115] requires that the state project be an experimental, demonstration or pilot project. 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. Thus, the Secretary must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement . . . the Secretary must make at least some inquiry into the merits of the experiment—she must determine that the project is likely to yield useful information or demonstrate a novel approach to program administration.[26]

---

[24] *See, e.g.*, Wood v. Betlach, 992 F. Supp. at 850 (finding that CMS acted arbitrarily and capriciously in approving an 1115 demonstration increasing beneficiary copayments where a declaration that plaintiffs submitted to CMS showed that "extensive research on cost-sharing for the poor has shown that copayments are not an effective cost-saving tool for the states" due to higher drug copayments leading beneficiaries to use fewer drugs and more emergency room and inpatient hospital care, but CMS "made [no] effort to address Plaintiffs' administrative objections that copayments are not an effective cost-sharing measure").

[25] *See* Nazareth Hosp. v. Sec'y U.S. Dep't of Health & Human Servs., 747 F.3d 172, 181 (3d Cir. 2014) (emphasis added); Cooper Hosp. / Univ. Med. Ctr. v. Burwell, 179 F. Supp. 3d 31, 50 (D.D.C. 2016), *aff'd sub nom.* Cooper Hosp. Univ. Med. Ctr. v. Price, No. 16-5165, 2017 WL 2347695 (D.C. Cir. May 9, 2017) (quoting the Third Circuit).

[26] Beno v. Shalala, 30 F.3d at 1069.

The Ninth Circuit applied this reasoning in Newton-Nations v. Betlach and found CMS's approval of an Arizona demonstration increasing Medicaid copayments arbitrary and capricious.[27] Notably, the court questioned whether the initiative could have research or demonstration value given that "Plaintiffs' public health expert stated that over the last 35 years, a number of studies have looked at the effects of cost sharing on the poor" and that "[t]he administrative record contains no finding from the Secretary that Arizona's demonstration project will actually demonstrate something different than the last 35–years' worth of health policy research."[28]

A large body of research exists on how restrictions affect vulnerable populations, similar to the cost-sharing research cited in Newton-Nations. The topic has already been extensively studied. Section 4 of this letter provides a detailed summary of that body of research—which shows that imposing formulary restrictions on vulnerable populations generally produces adverse effects on beneficiaries' health; increases the risks of justice system contacts and other social problems; and increases overall healthcare costs, as beneficiary care increasingly shifts from outpatient drugs to hospitalizations and ER visits. Nothing in the Demonstration Amendment Request suggests that the requested waiver would advance knowledge in this area or do anything but replicate the negative outcomes found in the existing literature. This is not research, but "[a] simple benefits cut."[29]

2. The Closed Formulary Initiative Does Not Involve Legitimate Research

Even putting aside the fact that the consequences of limiting drug access for vulnerable populations are already well-known, the strategy proposed in the Demonstration Amendment Request cannot reasonably be deemed legitimate research. The "hypothesis" listed in the Demonstration Amendment Request is that "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."[30] To test this hypothesis, the evaluator will merely "compare expenditure growth rates for prescription drugs after the new purchasing strategies have been implemented to both historical growth rates and to projected expenditures in the absence of these new strategies." And, the evaluator "will also conduct an assessment of drug classes affected by the closed formulary to confirm that members continue to have access to medically necessary prescription drugs."[31]

Thus, the evaluator will simply: (1) examine drug spending (not total healthcare spending changes resulting from the formulary restrictions); and (2) look at the formulary classes on the closed formulary to confirm that the formulary complies with the Commonwealth's rules on assuring access to "medically necessary drugs" (rather than looking at actual health outcomes beneficiaries experience as a result of the formulary restrictions). This research would not examine how beneficiaries' health is affected by the change, or in any way "test out new ideas."[32] Further, Massachusetts does not propose studying non-drug costs resulting from the closed formulary, such as costs of hospitalizations, ER visits, increased services provided by state/local social services agencies, and increased contacts with the justice system. In fact, similar to the Congressional Budget Office's findings in Medicare, increased use of medicines among Medicaid patients decreases other Medicaid costs, such as inpatient hospital costs.[33] The evaluation is limited to a review of drug costs, which clearly will decline, and what appears to be a "desk

---

[27] Newton-Nations, 660 F.3d at 381.
[28] 660 F.3d at 381 (emphasis added).
[29] Beno v. Shalala, 30 F.3d at 1069.
[30] Demonstration Amendment Request at 18.
[31] Demonstration Amendment Request at 18.
[32] Beno v. Shalala, 30 F.3d at 1069.
[33] M.C. Roebuck et al, "Increased Use Of Prescription Drugs Reduces Medical Costs In Medicaid Populations," *Health Affairs*, September 2015 vol. 34 no. 9 1586-1593.

audit" of the closed formulary, which will confirm that it does not omit "medically necessary drugs" as the demonstration will define them.

This is not legitimate research, and the conclusions are pre-ordained. For this reason alone, the request to waive the Medicaid rebate statute's coverage requirements is not an "experimental, demonstration, or pilot project" authorized by SSA § 1115.

E. Massachusetts Has Not Followed the Transparency Requirements in 42 CFR § 431.408

Following years of concern about the transparency of § 1115 demonstration approvals, the Affordable Care Act amended § 1115 to require greater transparency and opportunity for public comment relating to proposed demonstrations that would affect "eligibility, enrollment, benefits, cost-sharing, or financing."[34] Pursuant to this mandate, CMS issued regulations requiring a public notice and comment process at the state and the federal levels meeting basic transparency standards specified in the regulations. The requirements for a state-level notice and comment process (which states must satisfy "prior to submitting an application to CMS") appear in 42 CFR § 431.408.

These regulations do not apply to a request for an "amendment" (which is not defined).[35] The Demonstration Amendment Request states that Massachusetts has "implemented certain of the transparency and public notice requirements outlined in 42 CFR 431.408, although the regulations are not specifically applicable to Demonstration Amendments."[36] But this is not an "amendment." We believe that (at least with respect to waiver request no. 6 regarding the closed formulary, which is our focus) this is just a new demonstration. It does not in any way adjust the terms of, or otherwise build on or modify, anything in Massachusetts' existing 1115 demonstration; it simply adds a new request to waive the coverage requirements of the Medicaid rebate statute and establish a closed formulary not permitted by the rebate statute.

A state cannot skirt the full transparency requirements that apply to 1115 waiver applications merely by requesting and receiving a waiver, and then calling any waiver request that follows an "amendment" that does not trigger applicable transparency rules. Such an interpretation of SSA § 1115(d) and its implementing regulations would thwart Congress' whole purpose in amending § 1115 to require (among other things) "a process for public notice and comment at the state level . . . sufficient to ensure a meaningful level of public input."[37] If the amendments to § 1115 could be circumvented so easily, Congress would have accomplished very little—but statutory provisions are not interpreted in a way that makes them ineffectual or meaningless.[38] Therefore, this document is not a mere "amendment" that escapes the transparency requirements attached to 1115 demonstration requests, and accordingly Massachusetts must fully comply with the requirements of 42 CFR § 431.408.

By stating that it only implemented "certain of the transparency and public notice requirements outlined in 42 CFR 431.408," Massachusetts acknowledges that it has not fulfilled some of these requirements; which requirements Massachusetts has in mind we cannot be sure. But, one section of the Demonstration Amendment Request that plainly falls short of satisfying § 431.408 is the section on the "hypothesis and evaluation parameters of the demonstration."[39] For reasons discussed above in

---

[34] SSA § 1115(d)(1).

[35] *See* Dep't of Health & Human Servs., Medicaid Program; Review and Approval Process for Section 1115 Demonstrations; Application, Review, and Reporting Process for Waivers for State Innovation, 77 Fed. Reg. 11,678, 11,690 (Feb. 27, 2012).

[36] Demonstration Amendment Request at 19.

[37] SSA § 1115A(d)(2)(A).

[38] It is well established that statutes should be construed "so that no part will be inoperative or superfluous, void or insignificant." Corley v. United States, 556 U.S. 303, 314 (2009). *See also, e.g.,* U.S. Steel Mining Co. v Director, OWCP, 719 F.3d. 1275, 1284 (11th Cir. 2013)(quoting United States v. Powers, 307 U.S. 214, 217(1939)("there is a presumption against a construction which would render a statute ineffective or inefficient").

[39] CFR § 431.408(a)(1)(i)(D).

section 1(D)(2) of this letter, this part of the Demonstration Amendment Request does not describe a true research hypothesis, or a legitimate evaluation.

Further, more explanation is needed of the statement that "MassHealth will maintain an exceptions process to cover drugs that are not on the formulary when medically necessary, similar to the existing clinical review process used for situations such as determining coverage of off-label indications."[40] This brief statement is less than a "comprehensive description" of the initiative that "contains a sufficient level of detail to ensure meaningful input from the public."[41] Among other things, it does not explain what this process is; whether beneficiaries currently use this process, and (if so) with what results; and how Massachusetts would adapt this process to the closed formulary environment and try to ensure that Medicaid beneficiaries could obtain the medications they needed.

The description of how the closed formulary would be developed and the types of drugs that could be excluded (*e.g.*, drugs labeled as having "limited or inadequate evidence of clinical efficacy" or an even broader group) is also insufficient to ensure meaningful public input. Finally, we are concerned that the listing of drug categories ostensibly having "limited or inadequate evidence of clinical efficacy" actually includes a broad and vitally important group of drugs, and the description of these drugs in the Demonstration Amendment Request may cause confusion about the scope of potential formulary exclusions and thereby prevent meaningful stakeholder comments on the closed formulary proposal.

2. The Demonstration Amendment Arbitrarily Rations Access to Life-Saving Medicines, Mischaracterizing the FDA Approval Process, Undermining Congressional Intent, and Contradicting Science-Based Decision Making

In addition to waiving the rebate statute's drug coverage requirements, the Demonstration Amendment would ration care by restricting access to drugs FDA has determined to be safe and effective and deserving of expedited approval because they are intended for treatment of "serious or life-threatening disease[s] or condition[s]," including areas of unmet medical needs. Under section 6b the Demonstration Amendment seeks to supplant the expert opinion of the FDA and an individual patient's treating physician with that of the Commonwealth. This rationing of treatment is particularly concerning given the type of drugs that would fall under 6b's exclusion. For example, several oncology drugs approved under the expedited approval pathway have been recognized by the American Society of Clinical Oncology as the treatment "Advance of the Year."[42] Indeed, a recent study found that drugs approved through the accelerated approval pathway (and other expedited pathways) offered greater health gains that drugs approved through the standard pathway.[43]

The Demonstration Amendment seeks to exclude from the formulary drugs with "limited or inadequate clinical efficacy," defined to mean drugs where one or more of the following conditions exist:

- Clinical benefits have not been assessed;
- Primary endpoints in clinical trials have not been achieved;
- Only surrogate endpoints have been reported;
- FDA-approval is contingent upon verification of clinical benefit in confirmatory trials;

[40] Demonstration Amendment Request at 9.
[41] 42 CFR § 431.408(a)(1)(i).
[42] American Society of Clinical Oncology. "Advance of the Year: Immunotherapy 2.0" 2017.
[43] Chambers et al., Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains than Drugs Approved by Conventional Process, Health Affairs 36, No. 8 (2017).

- The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives.[44]

As an initial matter, with regard to the first bullet, there are no drugs approved by FDA where the "[c]linical benefits have not been assessed" for the approved indications. By statute, FDA must find "substantial evidence" of effectiveness to approve a drug.[45] Thus, the first prong is a null set. Moreover, if it is an attempt, like the subsequent three bullets, to exclude coverage for drugs approved through the accelerated approval pathway, it still misses the mark. As explained in further detail below, drugs approved through that pathway are still subject to the substantial evidence standard.[46]

The subsequent three bullets— (1) primary endpoints in clinical trials have not been achieved; (2) only surrogate endpoints have been reported; and (3) FDA-approval is contingent upon verification of clinical benefit in confirmatory trials—are an unartful attempt to exclude drugs from the formulary that are approved through FDA's accelerated approval pathway. This pathway, established statutorily in 2012 but rooted in regulatory reforms FDA initiated in response to the HIV/AIDS crisis in the early 1990s, authorizes FDA to approve an application for a product "for a serious or life threatening disease or condition . . . upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit . . . taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative therapies."[47] Products approved through the accelerated approval pathway may be subject to the sponsor "conduct[ing] appropriate post approval studies to verify and describe the predicted effect" of the drug.[48]

Significantly, the Demonstration Amendment would directly undermine Congress' very purpose in enacting the accelerated approval pathway—speeding patient access to desperately needed treatments by allowing FDA to "implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious and life-threatening diseases or conditions."[49] However, instead of expediting patient access to safe and effective treatments, the Demonstration Amendment would restrict patient access to these medicines, undermining the intent of accelerated approval.

The Demonstration Amendment mischaracterizes the surrogate endpoints that form the basis for approval under FDA's accelerated approval pathway by proposing to exclude drugs for which primary endpoints have not be achieved. As an initial matter, primary endpoints are those endpoints that FDA deems essential to establish effectiveness for approval.[50] Accordingly, it is unclear that there are FDA-approved drugs for which "primary endpoints in clinical trials have not been achieved." Rather, the Demonstration Amendment seems to conflate surrogate endpoints with secondary endpoints. However, surrogate endpoints can be and often are primary endpoints in clinical trials. For example, drugs indicated for treatment of HIV are often approved on the basis of clinical studies showing a decrease in the overall amount of the HIV virus. Measuring reduction in viral load, a validated surrogate endpoint that demonstrates clinical benefit, allows more efficient clinical trials. As FDA has explained:

---

[44] Demonstration Amendment Request at 10.
[45] 21 U.S.C § 355(d)(5)
[46] *Id.* § 356(e)(2).
[47] *Id.* § 356(c)(1)(A).
[48] *Id.* § 356(c)(2)(A).
[49] *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 901(a)(1)(C), 126 Stat. 993, 1082 (2012). *See also* FDA, Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014) ("The provisions of FDASIA facilitate somewhat broader use of accelerated approval to expedite patients' access to important treatments for serious conditions.").
[50] *See, e.g.*, FDA, Draft Guidance for Industry, Multiple Endpoints in Clinical Trials at 9 (Jan. 2017).

> [A]ccelerated approval has been used extensively in the approval of drugs to treat a variety of cancers and human immunodeficiency virus (HIV) disease where an effect on tumor growth or viral load can be assessed rapidly, but demonstrating an effect on survival or morbidity generally requires lengthy and sometimes large trials because of the duration of the typical disease course.[51]

Second, by excluding drugs "for which only surrogate endpoints have been reported," the Demonstration Amendment again seems to fail to appreciate the significance of surrogate endpoints and suggests that approval based on reports of surrogate endpoints alone are suspect. Surrogate endpoints, however, are scientifically valid measures accepted by FDA and Congress. Again, under the Federal Food, Drug, and Cosmetic Act, FDA is afforded the authority to approve drugs based upon surrogate endpoints and such endpoints constitute substantial evidence. As the statute explicitly states, accelerated approval "shall not be construed to alter the standards of evidence" required for approval.[52] As FDA has further clarified in guidance, "[d]rugs granted accelerated approval must meet the same statutory standards for safety and efficacy as those granted traditional approval."[53] Surrogate endpoints are widely accepted endpoints and have served as primary endpoints supporting the approval of several life-saving medicines.

Third, while FDA "may" require the sponsor of a drug approved under the accelerated pathway to conduct "appropriate postapproval studies to verify and describe the predicted effect," the accelerated approval process allows patients to gain access to important treatments while those studies are ongoing, thus fulfilling the intent of accelerated approval: getting important new treatments for serious and life-threatening conditions to patients as soon as possible. Moreover, postmarketing requirements are not unique to the accelerated approval context. The agency has the authority to require postmarketing safety clinical trials and studies for all drugs.[54] Failure to comply with the postmarketing requirements may render a drug misbranded, and effectively render distribution of the drug unlawful. Even where FDA does not impose postmarketing requirements, sponsors continually study their products in the postmarket setting to try to gain the most complete understanding of the safety and efficacy profile of their products.

Finally, outside of the accelerated approval context, with respect to the Demonstration Amendment's intent to exclude from formulary coverage drugs that "provide[] no incremental clinical benefit within its therapeutic class, compared to existing alternatives," the Demonstration Amendment would supplant the considered judgment of the individual patient and their treating physician with that of the Commonwealth. Whether a treatment provides clinical benefit to an individual patient is a decision that should be made by the patient and the patient's treating physician; FDA has determined that the drug is safe and effective, so the Commonwealth should not undermine the authority of FDA and the autonomy of the patient-doctor relationship.

In summary, the Demonstration Amendment seeks to arbitrarily exclude certain FDA-approved medicines from primary formulary coverage. The Demonstration Amendment is based on a flawed understanding of federal law and the FDA approval process, is contrary to science-based decision-making, and seeks to supplant the expert opinion of the FDA and an individual patient's treating physician with that of the Commonwealth. The Demonstration Amendment would restrict patient access to novel FDA-approved therapies for populations most desperately needing treatment. Impractically, the Demonstration Amendment would restrict access to drugs FDA determined to be safe

---

[51] *See* FDA, Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics at 15 (May 2014).
[52] *See* 21 U.S.C. § 356(e)(2).
[53] *See* FDA, Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics at 19 (May 2014).
[54] *See* 21 U.S.C. § 355(o)(3).

and effective and deserving of expedited approval because they are intended for treatment of "serious or life-threatening disease[s] or condition[s]," including areas of unmet medical needs.[55]

3. The Demonstration Amendment Fails to Consider the Importance of Individualized, Patient-Centered Care

Also under section 6b of the Demonstration Amendment, Massachusetts is proposing to impose a one-size-fits-all standard for value on patients and physicians, which is inconsistent with the movement towards individualized, patient-centered health care. The amendment prioritizes one-size-fits-all judgements of clinical value over individualized treatment decision-making of the physician and patient. Whether a drug is clinically meaningful to a patient should be a decision made by the individual patient and the prescribing physician, not the Commonwealth. Requiring that a drug have incremental clinical value relative to peer drugs would result in the substitution of a prescribing physician's judgment with that of the Commonwealth.

Recent analysis noted that these types of government assessments and recommendations, based on population-averages, fail to properly adjust to the demands of an evolving health care system and do not reflect the rapid pace of the science or the needs and preferences of the patients.[56] These gaps in the appraisal process are particularly notable in the oncology space, where the impact of personalized medicine has never been greater.[57] Further, the methodology used to measure the value of treatments and the exceptions process have not been fully evaluated, so it is unclear whether this process establishes anything more than additional bureaucracy at the expense of personalized treatment for the most vulnerable patients.

4. The Demonstration Amendment Ignores Research Showing that Closed Formularies Hurt Patients, Lower Adherence, and Do Not Reduce Health Care Costs

The Demonstration Amendment threatens the health of Medicaid patients by limiting access to a host of medicines and imposing significant restrictions in creating a closed formulary. Medicaid patients, compared to those with other types of insurance, have complex and chronic health conditions that often require access to a broad range of medicines. Non-elderly Medicaid beneficiaries are more likely to be in poor health than those with private insurance.[58] Also, children with Medicaid are significantly more likely to be in fair or poor health as well as have a higher prevalence of certain behavioral health conditions as compared to children with private insurance.[59]

The Massachusetts Demonstration Amendment to restrict access to one drug per class would ration care and deny patients access to a diverse range of treatment options that would best suit patients' health, biology, and preferences. Research has found that allowing patients and doctors a choice of medicines can increase efficacy of treatments, lower incidence of adverse events, and lower the chances of drug interactions. [60,61,62]

---

[55] 21 U.S.C. § 356(c)(1)(A).

[56] Context Matters analysis, "NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling," May 2014.

[57] American Association for Cancer Research, "Cancer Progress Report 2013: Making Research count for Patients: A Continual Pursuit."

[58] MACPAC, "MACStats: Medicaid and CHIP Data Book," December 2016, Available at: https://www.macpac.gov/wp-content/uploads/2016/12/MACStats_DataBook_Dec2016.pdf

[59] MACPAC, "Chapter 4: Behavioral Health in the Medicaid Program –People, Use, and Expenditures" June 2015, Available at: https://www.macpac.gov/wp-content/uploads/2015/06/Behavioral-Health-in-the-Medicaid-Program%E2%80%94People-Use-and-Expenditures.pdf

[60] DiMasi JA1, Faden LB. "Competitiveness in follow-on drug R&D: a race or imitation?" *Nat Rev Drug Discov*. 2011;10:23-7.

[61] Turner RM, Park BK, Primohamed M. Parsing interindividual drug variability: An emerging role for systems pharmacology. Wiley Interdiscip Rev Syst Biol Med. 2015 Jul-Aug; 7(4): 221-41.

- A New England Journal of Medicine study found that patients who had capped benefits were more likely to have higher blood pressure and cholesterol levels compared to those without capped benefits. [63]
- For patients with depression, many studies have shown that a substantial number of patients who fail to respond to first-line selective serotonin reuptake inhibitors will achieve a clinically meaningful response when switched to another drug in the same class.[64,65,66]
- New formulations of HIV medicines that combine up to four medicines with different mechanisms have increased adherence and worked to avoid drug resistance, further reducing additional health care costs.[67,68,69]
- Without access to multiple drugs in a class as well as the latest formulations, patients, along with their physicians, cannot effectively treat or manage their conditions.

MassHealth patients do not have choice in health plans unlike patients who access coverage through their employers or the Connector. Under the Demonstration Amendment, if the Commonwealth chooses to adopt a closed formulary, MassHealth beneficiaries will have no other options if the formulary does not include a needed medication. Further, Medicaid providers in Massachusetts are reimbursed at lower rates than commercial or Medicare providers,[70] so Medicaid providers may have less time available to help their patients navigate the exceptions processes required to obtain coverage for an off-formulary medication. This may be particularly challenging for many Medicaid patients due to their lower levels of health literacy.[71]

Creating a closed formulary with severe access restrictions is not a pilot program. Massachusetts should not attempt to duplicate social sciences research that has shown that restricting access to prescription drugs harms patients and increases medical costs.

- Numerous studies have found strong evidence demonstrating that formulary restrictions are negatively correlated with medication adherence outcomes. [72] A New England Journal of

---

[62] Mullins CD, Shaya FT, Meng F, et al. Persistence, switching, and discontinuation rates among patients receiving sertraline, paroxetine, and citalopram. Pharmacotherapy. 2005;25:660-7.

[63] Hsu J, Price M, Huang J, et al. Unintended consequences of caps on Medicare drug benefits. N Engl J Med. 2006;354(22):2349-2359.

[64] Thase ME1, Feighner JP, Lydiard RB. Citalopram treatment of fluoxetine nonresponders. J Clin Psychiatry. 2001 Sep;62:683-7.

[65] Bauer M, Hellweg R, Baumgartner A. Fluoxetine-induced akathisia does not reappear after switch to paroxetine. J Clin Psychiatry. 1996;57:593-4.

[66] Mullins CD, Shaya FT, Meng F, et al. Persistence, switching, and discontinuation rates among patients receiving sertraline, paroxetine, and citalopram. Pharmacotherapy. 2005;25:660-7.

[67] Ickovics JR, et al. Consequences and determinants of adherence to antiretroviral medication: results from Adult AIDS Clinical Trials Group protocol 370. Antivir Ther. 2002. 7:185. http://www.ncbi.nlm.nih.gov/pubmed/12487386

[68] Bangsberg DR, Ragland K, Monk A, et al. A single tablet regimen is associated with higher adherence and viral suppression than multiple tablet regimens in HIV+ homeless and marginally housed people. AIDS. 2010;24:2835-40.

[69] Nachega JB, Parienti JJ, Uthman OA, et al. Lower pill burden and once-daily dosing antiretroviral treatment regimens for HIV infection: a meta-analysis of randomized controlled trials. Clin Infect Dis. 2014;58:1297-307.

[70] Kaiser State Health Facts, "Medicaid-to-Medicare Fee Index," 2016; W. Fox and J. Pickering, "Hospital & Physician Cost Shift Payment Level Comparison of Medicare, Medicaid, And Commercial Payers," Milliman, 2008.

[71] iTRIAGE, "Tracking American Health Literacy and Prescribing Improvement: Key findings from an independent survey," Available at: http://www.itriagehq.com/wp-content/uploads/2015/02/Health-Literacy-White-Paper_February-2015.pdf. (accessed Jan. 29, 2017).

[72] Happe LE, Clark D, Holliday E, Young T. A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. J Manag Care Spec Pharm. 2014;20(7):677-84.

Medicine article highlighted that medication non-adherence can lead to death as well as cost the U.S. economy up to $300 billion annually in "avoidable" health care costs. [73]

- Evidence has shown that formulary restrictions in Medicaid for patients with severe mental illness results in little savings in drug spending, and instead leads to negative patient outcomes, higher overall Medicaid spending, and increased incarceration rates.[74]
- One study found that restricting access to antidepressants in Medicaid was associated with a 16.6 percent increase in the likelihood of hospitalization for a mental health condition, with no evidence of total Medicaid savings.[75]
- Another study found that restricting access to schizophrenia and bipolar medicines increased the likelihood of inpatient and total costs to the Medicaid program by 10-23 percent, without lowering pharmacy costs.[76]
- Access restrictions to antipsychotics for Medicaid beneficiaries are estimated to cost $1 billion annually in societal costs due to increased incarceration rates.[77]

There is little or nothing for Massachusetts to "test" or learn by developing a closed formulary as there is ample evidence of negative consequences when other states restricted access to medicines. Researchers found that formulary restrictions for Medicaid beneficiaries in Arizona living with rheumatoid arthritis had unintended consequences including increasing hospitalizations by 50 percent and costing an additional $900 annually.[78]

5. State Flexibility to Manage Drug Costs Already Exists under the Medicaid Drug Rebate Statute

Finally, if the state seeks increased leverage to negotiate higher rebates from manufacturers, MassHealth should use the cost containment tools available under the drug rebate statute before taking such drastic action to remove drugs from coverage. In exchange for substantially reduced-price drugs, state Medicaid programs generally must cover outpatient drugs, but have access to numerous cost containment tools to restrict access and encourage responsible and cost-effective use of medicines within the Medicaid program. Medicaid prescription drug spending in the Commonwealth is 4 percent of total Medicaid spending, due in part to the rebates and other cost containment tools.[79]

If Massachusetts wants to establish a formulary, it can do so through existing authority in the Medicaid Drug Rebate Statute, yet it has chosen not to do so. Instead, the Demonstration Amendment is proposing to create a "closed formulary" that would exclude a wide range of drugs without making the clinical determinations required under the SSA, effectively vitiating formulary safeguard established by Congress for the protection of patients. Doing so is not "likely to assist in promoting the objectives of title XIX" of the SSA and fails to meet a basic requirement of Section 1115.[80]

---

[73] Zullig, LL, Bosworth, H, Engaging patients to optimize medication adherence. NEJM Catalyst, May 14, 2017.
[74] USC Schaeffer, "Medicaid Access Restrictions on Psychiatric Drugs: Penny-wise or Pound-Foolish?" February 2015. Available at: http://healthpolicy.usc.edu/documents/USC%20Issue%20Brief%20No.%202%20Final.pdf
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] Tricia J. Johnson, Stephanie Stahl-Moncada, "Medicaid Prescription Formulary Restrictions and Arthritis Treatment Costs," *American Journal of Public Health* 98, no. 7 (July 1, 2008): pp.1300-1305.
[79] Prescription drug pre-rebate expenditures tabulated by The Menges Group using FY 2015 CMS State Drug Utilization data files and CMS brand/generic indicators for each National Drug Code. Rebate information obtained from FY 2015 CMS-64 reports. Post-rebate expenditures derived through Menges Group tabulations using above information.
[80] SSA § 1115(a).

The cost containment tools available to states under SSA §1927 include the following:

- States may impose prior authorization requirements on any drug, provided they respond to prior authorization requests within 24 hours and dispense a 72-hour supply of the requested drug in an emergency;[81]
- States may exclude or restrict coverage of any drug that is not prescribed for a "medically accepted indication" (defined as FDA-approved indications plus off-label uses supported by specified compendia);[82]
- States may impose restrictions authorized by an agreement with the drug manufacturer, also known as the Medicaid Drug Rebate Agreement;[83]
- States may exclude or restrict coverage of any drug used for certain listed purposes (e.g., anorexia, weight loss, weight gain, to promote fertility, for cosmetic purposes, etc.);[84]
- States may create Medicaid formularies and exclude a drug from a Medicaid formulary if: (a) the drug's labeling or certain compendia establish that the drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome" over a drug included on the formulary, (b) there is a publicly-available written explanation of the basis for the exclusion, (c) the excluded drug is available with prior authorization, and (d) certain additional requirements relating to the committee that develops the formulary are satisfied;[85]
- States "may impose limitations, with respect to all . . . drugs in a therapeutic class, on the minimum or maximum quantity per prescription or on the number of refills, if . . . necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under [the Medicaid statute];"[86] and
- States may create Preferred Drug Lists (PDLs), which are lists of drugs that are not subject to prior authorization and are not "formularies" that must satisfy the rebate statute's requirements for formularies, and may demand supplemental rebates as the price for including a drug on the PDL.[87]

The leverage provided to states by these measures is so great that as of March 2017, 47 states (including Massachusetts) and the District of Columbia had supplemental rebate programs that allowed them to collect extra rebates above and beyond the large rebates required by the rebate statute.[88]

* * * * *

[81] SSA § 1927(d)(1)(A),(5).
[82] SSA § 1927(d)(1)(B)(i).
[83] SSA § 1927(d)(1)B)(iii).
[84] SSA § 1927(d)(1)(B)(ii),(2).
[85] SSA § 1927(d)(4).
[86] SSA § 1927(d)(6).
[87] PhRMA v. Meadows, 304 F.3d 1197 (11th Cir. 2002); PhRMA v. Thompson, 362 F.3d 817, 823-24 (D.C. Cir. 2004).
[88] Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services, 2017. *Medicaid Pharmacy Supplemental Rebate Agreements (as of March 2017),* available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf.

We understand the Commonwealth's desire for flexibility and the imperative to reduce costs throughout MassHealth. As Congress and the Administration continue to work with states to achieve these goals, the basic compromise of Section 1927 must remain in place, as it serves the dual goals of cost-control and access to treatment in the Medicaid program. Unwinding this statute would undercut the quality of patient care and is unnecessary in light of the significant flexibility states have under existing law. Further, formularies will not reduce the main cost drivers in Medicaid, such as long-term care and hospital stays and could lead to increased costs if treatment regimens are destabilized. Medicaid costs and broader state fiscal issues need to be addressed holistically. For these reasons the Commonwealth's proposal to waive "§1902(a)(54) insofar as it incorporates §1927(d)(1)(B)" should be withdrawn from the Demonstration Amendment.

Thank you for the opportunity to comment on this important matter. We welcome the opportunity to continue this conversation with you and your staff.

Sincerely,

Leslie Wood	Joanne Chan
Deputy Vice President	Assistant General Counsel
State Policy	Law

cc: Secretary Michael Hefferman, Executive Office of Administration and Finance
Ms. Kristen Lepore, Chief of Staff, Governor Charlie Baker
Ms. Leslie Darcy, Chief of Staff, EOHHS
President Stanley Rosenberg
Speaker Robert DeLeo
Chair Jeffrey Sanchez, House Committee on Ways and Means
Chair Karen Spilka, Senate Committee on Ways and Means
Chair James Welch, Joint Committee on Health Care Financing
Chair Peter Kocot, Joint Committee on Health Care Financing

Planned Parenthood®
Care. No matter what.

1055 Commonwealth Avenue
Boston, MA 02215
p: 800.258.4448 · f: 617.616.1665
www.pplm.org

Planned Parenthood League of Massachusetts

7 August 2017

Kaela Konefal
Executive Office of Health & Human Services
Office of Medicaid
Attn: Comments for Demonstration Amendment
One Ashburton Place, 11th Floor
Boston, MA 02108

Ms. Konefal:

Thank you for the opportunity to comment on the proposed 1115 Demonstration Amendment Request ("Amendment"). Planned Parenthood League of Massachusetts (PPLM) is committed to working with the Commonwealth toward MassHealth sustainability. We hope you will consider the following comments before filing with the Centers for Medicare and Medicaid Services (CMS).

Background

PPLM plays an important role in the Commonwealth's health care delivery system, serving as the largest freestanding reproductive health care provider in the state. PPLM provides birth control, testing and treatment for sexually transmitted infections (STIs), and abortion services. Each year, PPLM provides sexual and reproductive health care to more than 30,000 patients – 40% percent of these patients are insured through MassHealth.

PPLM also provides preventive health care services (including lifesaving cancer screenings), general behavioral health scoring, and addiction screening. As Massachusetts works toward more coordinated care for MassHealth patients, we are collaborating with ACOs, MCOs, and health systems in order to provide our lower cost, high quality services.

Comments:

MassHealth seeks the flexibility to adopt commercial tools to obtain lower drug prices and enhanced rebates by selecting preferred and covered drugs through a closed formulary. Specifically, the Amendment assures continued, robust access to medically necessary drugs through the adoption of a commercial-style closed formulary with at least one drug available per therapeutic class. In the listening session (August 4, 2017), representatives from MassHealth ensured continued access to all

medically necessary drugs through an exceptions process to cover drugs that are not in the formulary.

We understand that the intent is to focus on costly pharmaceutical drugs that have been significant cost-drivers to MassHealth. Currently, MassHealth maintains an open formulary for all contraceptive drugs, devices, and other products and provides such services without cost-sharing. The open formulary currently provides critical access to important preventive care that is cost-effective to the state. Additionally, the state receives a significant return on federal rebates for contraceptive coverage, as well as a 90% match rate in federal financial participation for family planning services.

It is important to preserve this high level of access to a wide range of contraceptives. As such, PPLM seeks to ensure that determinations of medical necessity, which will provide the basis for coverage through an exceptions process, begin and lie predominantly with the provider. Additionally, PPLM hopes that any such exceptions process would be easily accessible, transparent, and sufficiently expedient such that is not unduly burdensome on the individual or a provider.

Lastly, PPLM would like to express concern about the proposal to transition and enroll non-disabled adults with incomes over 100% FPL in subsidized commercial plans through the state's exchange (the Health Connector). As several other health care advocacy organizations pointed out in the listening session, it is very likely that many of these patients who will no longer qualify for MassHealth will not be able to afford the co-pays and deductibles under plans through the Connector, and as result may lose health insurance coverage altogether. PPLM plays a critical role in the state's family planning safety net; 30% of our patients are on MassHealth and up to 20% of the patients we see are on a self-pay or sliding scale basis. It is important to bear in mind that those who may lose coverage will continue to come to trusted, safety net providers like PPLM. As is stands, PPLM significantly subsidizes the care we provide to patients on the sliding scale and would like to express concern about any increased financial burden placed on critical safety net providers like PPLM.

Thank you sincerely for your time and consideration of these comments. Should you have any questions or want to discuss these comments further, please contact our Director of Public Affairs, Michael Falcone, at mfalcone@pplm.org.

Sincerely,

Jennifer Childs-Roshak, M.D., M.B.A.
Chief Executive Officer

August 17, 2017

Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place
Boston, MA 02108

Re: Comments for Demonstration Amendment

The Hemophilia Federation of America (HFA) is the leading patient-led advocacy group representing those with hemophilia and other bleeding disorders. HFA is writing in response to MassHealth's request for comments on its Section 1115 Demonstration Amendment Request ("Waiver Request") dated July 20, 2017. We are commenting, in particular, on MassHealth's proposals 6 and 7: to select preferred and covered drugs through a closed formulary, and to procure a selective and more cost effective specialty pharmacy network..

Closed formulary. HFA applauds MassHealth's efforts to "guarantee . . . members' access to high quality, medically necessary care, while minimizing unnecessary spending." But we strongly urge MassHealth, as it considers a possible move to a closed formulary, to adhere to the longstanding practice (widely followed across state Medicaid programs) of carving out hemophilia therapies from the standard drug utilization review/preferred drug list (PDL) process. Limiting product options for individuals with bleeding disorders via PDLs or otherwise would put patient health at risk and could actually result in higher overall medical costs with respect to this patient population.

HFA understands that MassHealth is necessarily concerned with containing costs. However, while hemophilia treatment is undeniably expensive, limiting product options for patients with bleeding disorders is neither an effective nor a therapeutically appropriate way to manage this class of patients. Clotting factors vary in a number of important respects, including half-life and immunogenicity, and as such are not therapeutically equivalent or interchangeable. No generic clotting factor exists. Patient bleeding patterns and responses to different clotting factors vary widely.

Recognizing this diversity of clotting factor products, the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) has stated that product selection for bleeding disorder patients "require[s] a complex decision making process" between a patient and his or her physician: "it is critical that the bleeding disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed."[1] Because the selection of the medically-optimal product for each patient is so individualized and so important,

[1] National Hemophilia Foundation, Medical and Scientific Advisory Council. *MASAC Recommendation Regarding Factor Concentrate Prescriptions and Formulary Development and Restrictions,* Document #159. Accessed August 8, 2017. MASAC Document #159

MASAC urges third-party payers to cover whichever factor product is prescribed by the patient's treating physician rather than resorting to a PDL or formulary approach.[2]

By contrast, a one-size-fits-all approach (for example, requiring patients, for non-medical reasons, to switch from a prescribed product to a different, PDL-listed product) can undermine adherence to therapy, weaken the doctor-patient relationship, and worsen patient outcomes in both the short and long term – while also raising payer costs due to additional doctors' visits, hospitalization, and/or extra required factor usage. Closing off access to certain factor products for Medicaid patients could thus end up costing more for state programs and impairing patient care.

We respectfully request that in lieu of bringing hemophilia therapies within its PDL framework, MassHealth consider other utilization tools currently under consideration and study in other states.

In 2015, Washington State funded $600k in the 2015-2016 Washington State Budget to support the Bleeding Disorders Collaborative of Care, which is a consortium of doctors, patients and representatives from the Washington State Health Care Authority to examine utilization practices in factor consumption among state Medicaid patients. Instead of limiting choice, the state chose to examine other means of saving the system needed funds. Currently, the state is reviewing whether patients should be dosed on the basis of ideal rather than actual body weight. (Because factor dosing is based on patient weight, overweight patients receive higher doses of factor compared to non-overweight patients; however, since fatty tissues contain less blood volume than muscle, dosing patients with reference to their ideal rather than actual body weights may reduce the amount of factor used without increasing the risk of bleeding or other adverse events.) While this study is still under way (a final report is expected this Fall), it is possible that its results could eventually impact how patients consume factor, and implementation of these evidence-based policies may prove more effective at cost-saving than instituting a PDL. In addition, the state has looked at a number of questions facing hemophilia care using the Center of Evidence-Based Policy Medicaid Evidence-Based Decisions Project (MED) at Oregon Health & Science University. The website and all current data can be located at http://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/bleeding-disorder-collaborative-care.

Selective specialty pharmacy network. Clotting factor – a complex biological product that requires specialized storage, handling, and dispensing – is typically dispensed by specialty pharmacies. Standards to ensure appropriate pharmacy services have been spelled out by MASAC.[3] Any pharmacy provider that dispenses clotting factor for home use is expected to be knowledgeable about the different types of factor, and to maintain and track supplies of the medicine, in the full range of assays required by the

[2] National Hemophilia Foundation, Medical and Scientific Advisory Council. *MASAC Recommendation Regarding Factor Concentrate Prescriptions and Formulary Development and Restrictions,* Document #153. Accessed August 8, 2017. MASAC Document #153

[3] National Hemophilia Foundation, Medical and Scientific Advisory Council. *MASAC Recommendation Regarding Standards of Service for Pharmacy Providers of Clotting Factor Concentrates for Home Use to Patients with Bleeding Disorders,* Document #188. Accessed August 8, 2017. MASAC Document #188

pharmacy's patients; to provide ancillary supplies (e.g., needles and syringes) needed for the infusion of factor; to assist patients with safe medical waste disposal; to fill routine orders promptly, and to offer 24 hour on-call service and expedited delivery of emergency supplies of factor; and to maintain systems for accurate recordkeeping and product recall notifications.

HFA is concerned by language in the Waiver Request that MassHealth seeks to procure "***a*** selective network for specialty pharmacy." Specifically, HFA is concerned that patient care may suffer if MassHealth selects only one single pharmacy provider that cannot meet one or more of the relevant standards laid out by MASAC. It is essential that MassHealth hemophilia patients have access to specialty pharmacy care from providers that can offer the type of individualized support, including disease management and infusion help, that is necessary to their continued health (these services, moreover, are often provided at no extra cost to the state). We note, too, that sole source status would free the state-designated pharmacy provider from any competitive pressure to maintain the necessary level of patient service and would leave customers with no recourse if their needs are not met.

MassHealth's designation of a sole source pharmacy provider might also prevent Medicaid patients from obtaining their clotting factor from the 340B pharmacy programs associated with the federally-funded hemophilia treatment centers (HTCs) that serve bleeding disorders patients in the Commonwealth of Massachusetts. 340B pharmacies are an integral part of the HTC model of comprehensive care, and the income from 340B clotting factor sales allows HTCs to sustain much needed ancillary services for the patients that use them. HFA strongly believes that any network of specialty pharmacies should be as broad as possible, allowing patients who use HTCs access to their 340B pharmacy, as well as specialty pharmacies that provide individualized support for hemophilia.

Conclusion

In order to best serve the medical needs of Massachusetts' population of bleeding disorder patients, HFA respectfully requests that clotting factor products be carved out from any formularies adopted by MassHealth. HFA recommends that the Commonwealth instead look into other, potentially more therapeutically appropriate and more cost-effective, methods to manage this class of Medicaid beneficiaries, as for example suggested by the study under way in Washington State. We have attached information about the Washington study and would appreciate the opportunity to further discuss with you alternative ways to manage this class.

We also respectfully urge Massachusetts to offer its Medicaid patients access to more than one specialty pharmacy provider, and to include the HTC-affiliated 340B pharmacies in the list of qualifying pharmacy providers. Limiting Medicaid hemophilia patients to a single pharmacy provider may jeopardize patient care if the designated provider lacks hemophilia expertise. A sole source award that excludes the Commonwealth's HTC-associated 340B pharmacies likewise undercuts the provision of quality care for MassHealth's hemophilia patients.

If you have any questions, please do not hesitate to call Katie Verb at 202-570-0408 or email k.verb@hemophiliafed.org.

Sincerely,

Kathleen Verb

Richard Pezzillo

Katie Verb
Director, Policy & Government Relations
Hemophilia Federation of America

Richard Pezzillo
Executive Director
New England Hemophilia Association

Massachusetts Association of Behavioral Health Systems

115 Mill Street
Belmont, MA 02478
Phone: 617-855-3520

Michele Gougeon, MSS,MSc
Chairman

David Matteodo
Executive Director

August 18, 2017

Kaela Konefal, EOHHS
Office of Medicaid
One Ashburton Place, 11th Floor
Boston, Ma 02108

Re: Comments for Demonstration Amendment

Dear Ms. Konefal:

On behalf of the Massachusetts Association of Behavioral Health Systems (MABHS), I am submitting these comments relative to the MassHealth Section 1115 Demonstration Amendment Request. The MABHS represents 45 inpatient behavioral health units and freestanding hospitals throughout Massachusetts. In addition to these comments, MABHS has also testified at both of the MassHealth Listening Sessions this month.

We understand that MassHealth is asking the Centers for Medicare and Medicaid Services (CMS) for a number of Amendments to the current Waiver. These comments are limited to Request # 9: Remove Barriers to effective behavioral health care by waiving federal payments restrictions on care provided in Institutions for Mental Disease (IMDs). We support and appreciate MassHealth's request to allow flexibility on the 15-day limit on IMDs in the managed care rule. MassHealth correctly notes that the rule will impede access to medically necessary care. It is essential that CMS approves this request to insure access to the more than 1000 beds in the free-standing psychiatric hospital system in Massachusetts.

It also is imperative that MassHealth includes as part of its request for payment flexibility approval to include a waiver from the 1115 Cost Limit Protocol for IMDs. There are many reasons why MassHealth and CMS should not include IMDs in the Cost Limit Protocols, including the following points:

- Including IMDs in the Cost Limit Protocol interferes with the payment structure our hospitals have operated under for over 20 years and must count on in the future. Private psychiatric hospitals and the MassHealth MCOs and MBHP willingly negotiated and agreed to contracts at certain reimbursement rates to support their operations. There has been no mandate for the MCOs or MBHP to negotiate with the private psychiatric hospitals; however they chose to for a variety or reasons including more access for MassHealth clients at lower costs than general acute hospitals. In determining rates, there was no explicit notice or warning to the psychiatric hospitals that these rates would be included in the Cost Limit calculation. However, as cost reports are now being analyzed pursuant to the Cost Limit Protocol, it appears that the psychiatric hospitals could be at a loss of at least $7 million per year beginning in 2014 and continuing until 2022. That is, the psychiatric hospitals, because they are subject to the Cost Limit Protocol, could be at risk of having to forfeit funds that the MCOs and MBHP willingly agreed to and have already paid to the hospitals in addition to future revenues. And, none of the IMDs were aware of this potential huge liablility. This seems far beyond the intent of what the Cost Limit Protocol limitations were structured to address.

- Section 51(f) of the Waiver states that the DSH audit rule was the framework for the cost protocol. As implemented, the cost protocol is an inappropriate application of the DSH audit rule. The DSH audit rule is intended to provide the framework for an appropriate ***supplemental*** payment to a base per diem for those facilities who serve a disproportionate share of indigent patients. The DSH audit rule is not intended to recoup a base per diem payment for services provided to an indigent patient. As currently applied, the cost protocol may result in 100% of a base per diem payment being recouped, resulting in a facility receiving $ -0- payment for services provided to the indigent patient.

- If the psychiatric hospitals are at risk of such a substantial payback, the entire inpatient psychiatric MassHealth program could be jeopardized. <u>According to our calculations, between 200-250 MassHealth Adults (21-65) are treated in psychiatric hospitals on a given day</u>. If the hospitals are unable to continue to provide this service because of the negative financial implications due to the Cost Limit Protocol, these patients will add to the many stuck patients in hospital emergency rooms. Already in Massachusetts we have issues regarding Emergency Department boarding and elimination of the psychiatric hospitals as an option for MassHealth patients could only make this problem worse. The psychiatric hospitals provide a significant resource for MassHealth patients and the MCOs, Emergency Departments, and ESPs depend heavily on them to accept patients for inpatient care. This resource should not be jeopardized or overall access could be impeded and MassHealth/CMS costs would likely increase.

- The use of the psychiatric hospitals through the Waiver of the IMD provision has been in place for almost 25 years and has been a tremendous benefit to Massachusetts. It has been good for MassHealth patients because it has allowed them better access to more hospitals; good for MassHealth and CMS because the psychiatric hospitals allow managed competition at lower costs; and good for the hospitals because it allows them the opportunity to treat MassHealth adults in a single-tiered system of care. It has been very successful and should not be jeopardized because of the Cost Limit Protocol methodology.

- Recently MassHealth removed the day limits for fee for service MassHealth recipients in psychiatric hospitals. This initiative should allow for better access for patients as it allows the psychiatric hospitals to provide appropriate care and is consistent with Parity provisions for behavioral health. However this initiative, due to the Cost Limit Protocol would basically increase the financial exposure for the hospitals as the payments for these patients could be recovered if a hospital exceeded the Cost Limit Protocol. Again, the Protocol Limit seems to be unfair and not consistent with MassHealth's and CMS's overall goals for better access and Parity of coverage.

- There is a great deal of concern about how the Cost Limit Protocol would impact the Non-Acute Hospital Assessment in the FY 18 State Budget (Chapter 47 of the Acts of 2017). We fear the Cost Limit Protocol, if applied as currently structured

could impede any efforts to limit the impact of the assessment on the psychiatric hospitals. If the Cost Limit Protocol is not addressed, the Non-Acute Assessment will significantly increase the negative impact of the Assessment on the psychiatric hospitals.

- Finally, new reimbursement systems, including case rate payments and capitation payments all depend on migrating away from the traditional fee-for-service payments to shared risk. It is essential that the psychiatric hospitals are able to participate in these arrangements, which will be extremely difficult if there are limitations of payments to costs.

For all of the above reasons we urge MassHealth to ask CMS to remove the psychiatric hospitals from the Cost Limit Protocol. Based on our discussions with CMS we believe they would show a willingness to engage in such a discussion with MassHealth. **We urge MassHealth to request that the Cost Limit Protocol not be applied at any point, including any retroactive settlements.** The hospitals have tremendous financial exposure here and we urge MassHealth to do everything possible to address this matter.

Thank you for your consideration of these comments. The MABHS and our hospitals stand ready to assist you in any way possible on this vital issue. Please do not hesitate to contact me.

Sincerely,

David Matteodo
Executive Director
DMatteodo@aol.com (617) 855-3520

HEALTH CARE FOR ALL

www.hcfama.org

One Federal Street
Boston, MA 02110

617.350.7279 **Office**
617.350.0974 **TTY**
800.272.4232 **HelpLine**

August 18, 2017

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

Submitted by email

Re: Comments for Demonstration Amendment

Dear Secretary Sudders and Assistant Secretary Tsai,

Health Care For All (HCFA) appreciates the opportunity to provide comments on the MassHealth 1115 Demonstration Waiver Amendment ("1115 waiver amendment"), released on July 20, 2017. We share your commitment to a sustainable MassHealth program and to maintaining the gains Massachusetts has made in access to affordable health coverage for low-income residents, but we are concerned that many of the proposals included in the 1115 waiver amendment will likely decrease access to affordable coverage and care for low-income consumers.

With this waiver amendment, the Executive Office of Health and Human Services (EOHHS) requests broad flexibility to make significant changes to the MassHealth program. However, the draft document does not include a level of specificity needed to ascertain the intent and impact of the proposed changes. We ask that you make available more information on the estimated impact of these proposals in terms of the number of people affected, associated costs and cost savings, as well as more details about how the changes will be implemented and administered. In addition, the proposal seeks broad authority to waive important protections in the Medicaid Act without committing to the kinds of safeguards necessary to mitigate harm to affected populations. Before any of the proposed changes referenced below are submitted for approval, clear and strong safeguards should be included as part of the request and in any authorizing legislation.

ESI and Student Health Insurance "Gate"

MassHealth proposes to preclude otherwise eligible residents from qualifying for MassHealth if they have access to "affordable" employer sponsored insurance (ESI) or student health insurance. In a recent public presentation, MassHealth stated that it intends to apply their current thinking on affordability: the employee share of premiums and the deductible for the ESI is less than 5% of family income.[1] While this is a welcome change from the original proposal of using a 9.69% of income affordability test, taking into account only the premium cost, this metric does not account for other forms of cost-sharing, including copays and coinsurance, that may present substantial access barriers to low-income workers. Nor is even 5% of income affordable for adults with income below the poverty level given the high costs for housing and other life necessities. In addition, individuals who are locked out of MassHealth coverage will not have access to the same level of benefits as people at the same income levels who have access to unaffordable ESI and thus can qualify for MassHealth Premium Assistance.

[1] EOHHS and Health Connector, *MassHealth and Health Connector Requests for Federal Flexibility*, August 4, 2017. Available at: http://www.mass.gov/eohhs/docs/eohhs/healthcare-reform/masshealth-innovations/masshealth-1115-waiver-hearing-slides.pdf.

There is no precedent for this type of restriction in MassHealth; access to other health insurance has never been a bar to MassHealth coverage. Rather, MassHealth acts as a secondary or tertiary payer when other coverage is available, which protects low-income members from unaffordable medical bills and reduces MassHealth spending. In addition, many of the concerns outlined below regarding to the proposal to shift eligibility for non-disabled adults between 100-133% FPL also apply to the ESI and SHIP gate policy, particularly with regards to affordability of cost-sharing and access to certain benefits. We urge MassHealth to remove the ESI and SHIP "gate" from its proposed 1115 waiver amendment.

Instead, we support increased participation in the MassHealth Premium Assistance program as the best way to leverage employer contributions and reduce state spending while also ensuring that low-income workers have affordable and comprehensive coverage. Through programs like Premium Assistance, MassHealth has remained an important support for low-income families striving to work themselves out of poverty. We are hopeful that the use of the Health Insurance Responsibility Disclosure (HIRD) form to streamline the Premium Assistance process for MassHealth, consumers, and employers alike.

MassHealth Eligibility Changes for Non-Disabled Adults

MassHealth proposes to shift coverage for non-disabled adults ages 21 to 64 with incomes over 100% of the federal poverty level (FPL) to ConnectorCare as of January 1, 2019, including 100,000 parent and caretakers currently eligible for MassHealth Standard and 40,000 childless adults enrolled in MassHealth CarePlus.[2] ConnectorCare is a valuable program, integral to Massachusetts' health coverage system, as it offers more affordable coverage than even the federal Advanced Premium Tax Credits (APTCs) and Cost-Sharing Reductions (CSRs) alone would provide. However, ConnectorCare coverage provides fewer benefits, is more costly to consumers and presents more enrollment barriers than MassHealth coverage.

We strongly urge MassHealth to reconsider shifting non-disabled adults with incomes over 100% FPL from MassHealth to ConnectorCare, as this will result in:

- *Loss of benefits*:
    - *Dental care*: While the Health Connector offers stand-alone dental plans, the cost of these plans is not subsidized, and would be out of reach for most. In addition, the Health Safety Net – which provides "wrap" dental coverage to ConnectorCare enrollees – already has long wait times for patients to receive dental services, and adding more people to ConnectorCare will exacerbate this problem. Many people will have no choice but to seek services at hospital emergency departments, which are ill-equipped to provide comprehensive dental care.
    - *Behavioral health:* ConnectorCare plans are required to cover inpatient and outpatient mental health and substance use disorder services; however, not all ConnectorCare plans offer the same range of behavioral health services as MassHealth. In particular, access to diversionary services, such as Community Support Programs (CSPs) and Emergency Services Programs (ESPs), are not a part of traditional commercial insurance benefit packages and therefore may not be available to individuals covered through ConnectorCare plans.
    - *Prescription drugs*: ConnectorCare plans are able to implement more restrictive formularies than current MassHealth rules allow, and may impose more utilization management techniques, which create barriers to both obtaining needed medications and continuing on a course of treatment.
- *Higher premiums for consumers for all but one MCO*: In MassHealth, only members with incomes above 150% FPL are charged a premium. In ConnectorCare, anyone eligible for a plan with no premium contribution who does not switch to the new lowest cost plan at next year's open enrollment will be

[2] EOHHS Presentation: *FY18 MassHealth and Commercial Market Reform Package*, July 25, 2017. Available at: http://www.mass.gov/eohhs/gov/commissions-and-initiatives/healthcare-reform/masshealth-innovations/1115-waiver.html.

assessed a premium and terminated after ninety days of non-payment of premiums.[3] Unlike Medicaid or the former Commonwealth Care program, in ConnectorCare there is no legal requirement that the Connector continue to offer a $0 premium contribution plan to low-income individuals. The premiums for plan options other than the lowest cost plan are substantial – up to $174 per month in 2017.[4] Many MassHealth members transitioning to ConnectorCare will not be able to continue enrollment in their current health plan or maintain continuity of care due to the higher cost. Data from the 2017 open enrollment period showed that nearly 3,000 members with no premium in December 2016 who did not switch to the new lowest cost plan in 2017 were terminated for non-payment of premiums on March 31, 2017.[5]

- *Higher copays:* ConnectorCare copays for enrollees in Plan Type 2A are substantially higher than those in MassHealth, impacting access to services for members. For example, MassHealth copays for prescription drugs are $1 or $3.65 per medication, and MassHealth members cannot be turned away for inability to pay.[6] ConnectorCare Plan Type 2A members are required to pay between $10-40 to fill each prescription. ConnectorCare imposes copays for a wider range of services than MassHealth, including $10 for a primary care or mental health/substance use disorder visit, $18 for a specialist visit, and $50 for emergency room and other hospital services.[7]
- *Splitting up families*: With the introduction of MassHealth Accountable Care Organizations (ACOs), and the re-procurement of MassHealth MCOs in 2018, there may be less overlap between MassHealth and ConnectorCare provider networks. Different networks will disrupt continuity of care and may split up care for families who currently receive care in the same provider system.
- *Reconciliation and tax debts*: ConnectorCare enrollees must reconcile the federal APTC portion of their subsidies, which can lead to a tax debt if the advance credit amount was incorrect or loss of coverage if ConnectorCare members failed to file the right forms with their taxes to reconcile for the prior year.
- *Loss of work incentives for the working poor.* MassHealth has work support programs like Premium Assistance to enable low income individuals to afford ESI and Transitional Medical Assistance to allow working poor parents whose earnings put them over 133% FPL to qualify for twelve months of transitional MassHealth Standard to help them work their way out of poverty without an abrupt increase in the cost of coverage. ConnectorCare does not offer these programs.
- *Enrollment barriers:* MassHealth allows continuous open enrollment throughout the year, and individuals are covered back to the date of application prior to enrolling in a health plan. The former Commonwealth Care program under Chapter 58 also allowed continuous open enrollment. However, the ConnectorCare program is partially governed by federal Exchange rules, and does not allow for continuous enrollment. Being determined newly eligible for ConnectorCare is considered a qualifying event and allows individuals a 60-day special enrollment period, but this does not mitigate enrollment barriers for those who have previously been determined eligible.
- *Increased number of uninsured*: Unlike MassHealth, Connector enrollees must take the step of choosing a plan and paying a premium before their coverage is effectuated. In fact, the most recent numbers provided by the Health Connector for a point in time show that 40% of people eligible for ConnectorCare Plan Type 2A remain unenrolled. ConnectorCare, unlike MassHealth, does not automatically enroll eligible individuals into a health plan. In addition, ConnectorCare has eligibility rules that would bar certain people from qualifying, such as those who have access to employer

---

[3] Connector Policy #NG-6B, available at: https://www.mahealthconnector.org/wp-content/uploads/policies/Policy_NG_6B.pdf.

[4] 2017 ConnectorCare Member Contributions, available at: https://www.mahealthconnector.org/wp-content/uploads/board_meetings/2016/2016-09-08/ConnectorCare-Placemat-090816.pdf.

[5] Health Connector presentation, *Recap of Open Enrollment and Community Outreach*, April 13, 2017. Available at: https://www.mahealthconnector.org/wp-content/uploads/board_meetings/2017/04-13-2017/OE2017-Outreach-Update-041317.pdf.

[6] 130 CMR §506.016 and 506.017.

[7] See: https://www.mahealthconnector.org/wp-content/uploads/ConnectorCare_Overview-2017.pdf.

sponsored insurance (ESI) with a premium that costs less than 9.69% of their family income in 2017; veterans with access to the VA Health System; Deferred Action Childhood Arrivals; and married couples living apart filing taxes separately (with limited exceptions).

In recent years, Connecticut, Maine, and Rhode Island attempted to shift parents from Medicaid to the Marketplace. Before the eligibility change, all three states covered parents at higher income levels than Massachusetts; after the shift, parents in Connecticut and Maine continue to be eligible at higher income levels than Massachusetts eligibility rules currently allow. Despite efforts on the part of these neighboring New England states to mitigate impacts, a substantial number of parents lost coverage. Rhode Island reduced parent eligibility for RIteCare from 175% FPL to 138% FPL beginning January 1, 2014. Of the 6,574 affected parents, 1,921 (29%) likely became uninsured – 650 chose a Qualified Health Plan (QHP) through the Exchange but never made a payment and 1,271 never submitted an application to enroll in a QHP.[8] In 2015, Connecticut reduced eligibility for the HUSKY program from 200% FPL to 150% FPL. Of the parents who lost coverage, just one in four enrolled in a QHP. [9] Maine reduced eligibility for MaineCare for working parents from 133% FPL to 105% FPL in 2012. As Marketplace coverage was not yet available, 28,500 parents lost coverage.[10] Based on Connecticut and Rhode Island's experiences and the fact that Maine has not restored coverage for parents nor expanded Medicaid, it is likely that the majority of these parents became uninsured.

Children are also impacted by interruptions in coverage for their parent(s). Children in low-income families are three time more likely to be uninsured if their parents are uninsured.[11] Data shows that children with uninsured parents have a greater risk of gaps in coverage, and are less likely to receive check-ups, preventative care and are other health services.[12]

MassHealth Premium Assistance "Wrap" Benefits

The MassHealth Premium Assistance program has always provided a benefit "wrap" in addition to assistance with the cost of ESI premiums and cost-sharing. Commercial health insurance coverage is often not sufficient to meet the needs of low-income families, especially with regards to behavioral health and other community-based services. Thus, these "wrap" benefits are critical to ensuring MassHealth-eligible individuals and families enrolled in commercial coverage have access to the same level of benefits as if they were enrolled in MassHealth as a primary payer.

We are concerned that MassHealth seeks "flexibility not to provide any additional benefit wrap, except for a limited number of services not typically covered by commercial" in the 1115 waiver amendment. We request that MassHealth amend the proposed waiver language to provide more specificity regarding the flexibility requested, and preserve the benefit wrap currently offered in the Premium Assistance program.

---

[8] Community Catalyst, *Parent Eligibility Roll-Back in Rhode Island: Causes, Effects and Lessons Learned*, September 2015. Available at: https://www.communitycatalyst.org/resources/publications/document/RI-parent-rollback-081215-KL.pdf?tr=y&auid=15902172.

[9] Connecticut Voices for Children, *HUSKY Program Coverage for Parents: Most Families Will Feel the Full Impact of Income Eligibility Cut Later in 2016 (Connecticut Voices)*, April 2016. Available at: http://www.ctvoices.org/sites/default/files/h16HUSKYIncomeEligibilityCut.pdf.

[10] Maine Children's Alliance, Ensuring Coverage for Maine Children with Families in 2014. Available at: http://www.mekids.org/assets/files/issue_papers/healthcoverage_children_2014.pdf.

[11] Connecticut Voices for Children, quoting Schwartz K, *Spotlight on uninsured parents: How a lack of coverage affects parents and their families,* Washington DC: Kaiser Commission on Medicaid and the Uninsured, June 2007. See also: DeVoe JE, Krois L, Edlund C, Smith J, Carlson NE, *Uninsured but eligible children: are their parents insured? Recent findings from Oregon*. Medical Care, 2008 Jan; 46(1): 3-8.

[12] Maine Children's Alliance, quoting Sara Rosenbaum and R.P.T. Whittington, Parental Health Insurance Coverage as Child Health Policy: Evidence from the Literature, 5-6 (George Washington University 2007).

MassHealth Limited and ConnectorCare Coverage

MassHealth proposes to eliminate MassHealth Limited coverage 90 days after an individual is determined eligible for ConnectorCare, as is done with access to the Health Safety Net. We understand the purpose of this change and believe it may help mitigate confusion for individuals currently enrolled in both coverage types. However, we are concerned that those who remain eligible for ConnectorCare but unenrolled will not have access to even emergency coverage after 90 days, and will be foreclosed from enrolling. Therefore, we suggest that MassHealth amend its request to provide that MassHealth Limited coverage is terminated only when the coverage is truly redundant; that is, after an individual has successfully enrolled in ConnectorCare. We support the proposed plan to open a special enrollment period for individuals enrolled in MassHealth Limited and eligible for – but unenrolled in – ConnectorCare.

Prescription Drug Benefit Changes

We understand that prescription drugs are a key driver of increasing health care costs and must be managed. However, we are concerned that more limited specialty pharmacy networks and a closed formulary, as proposed in the 1115 waiver amendment, would impose unnecessary barriers to needed medications and supplies. Unlike several of the other proposed changes, these changes apply to all MassHealth members, including people with disabilities, children, and seniors.

Closed Formulary

The move to a closed formulary with as few as one drug available per therapeutic class would create access barriers for members. Currently, MassHealth is required to cover any drug for which the manufacturer participates in the federal Medicaid rebate program. This requirement ensures that patients have access to the highest standard of care available and allows physicians to prescribe the course of treatment they and their patients believe is most appropriate, taking into account clinical indications, side effects, coexisting conditions, ease of adherence and interactions with other medications. The closed formulary removes this flexibility, which may lead to pushing patients into regimens not suited for their needs, resulting in more costly treatment, such as emergency room visits, hospitalizations or procedures. Even with an exceptions process, a closed formulary may unduly delay or limit the effectiveness of treatment.

HCFA is also concerned about the potential use of step therapy or "fail first" policies incorporated as part of the closed formulary, which may pose an insurmountable obstacle to certain drugs and may undermine the stability of a member's condition that has been managed well long-term with a certain medication regime. We suggest "grandfathering in" MassHealth members who are currently taking medications that will not be included in the closed formulary to ensure continuity of treatment.

In the event that MassHealth moves forward with a closed formulary, it is extremely important that there are strong consumer protections in place, including non-discrimination policies and an exceptions process reflective of individual need, perhaps building off of protections afforded to Medicare Part D and Medicare Advantage enrollees. Any exceptions process should include rapid turnaround to ensure timeliness of starting or continuing needed treatment. Expedited exceptions process must also be in place, especially for individuals who need a particular medication, but have a negative reaction to the MassHealth-approved drug. Access to medications obtained through the exceptions process should remain in effect throughout the course of treatment.

In addition, Massachusetts has historically recognized the unique status and needs of people mental health and substance use disorders and the need for collaboration between EOHHS and the Department of Mental Health (DMH) with regards to provision of behavioral health services. Section 113 of Chapter 58 of the Acts of 2006 requires EOHHS and MassHealth to consult with the commissioner of the DMH before making any changes to MassHealth behavioral health services. This intent should continue as MassHealth considers changes to its prescription drug benefits.

Selective Specialty Pharmacy Network
MassHealth's proposal to procure a selective specialty pharmacy network may impose barriers for members who do not live in the geographic area of the selected pharmacies. The mail order or home delivery option may also not be workable for MassHealth members. Specialty drugs are often delivered during the day when members may be working, and may need to take time off from work to ensure the medication is not stolen or does not go bad because it needs to be refrigerated. In addition, MasssHealth members who are homeless or face housing instability may not be able to access their medications through a mail order or home delivery system, and may not have transportation to pick up medication at the selected pharmacies.

Primary Care Clinician (PCC) Plan Network
MassHealth proposes to implement narrower networks in the PCC Plan to encourage enrollment in Accountable Care Organizations (ACOs) and MCOs. While the differential is decreasing, people with complex medical needs frequently choose the PCC Plan over MCOs. Most often, applicants choose the PCC Plan because their preferred providers are not all included in Managed Care Organization (MCO) networks, or are not included in the same network. We request that MassHealth provide more detail about how the narrower PCC Plan networks will be established, identify impacts on people with complex needs or disabilities, and demonstrate how the narrower networks will continue to meet Medicaid network adequacy requirements.

Managed Care Options
Similar to the proposed PCC Plan network changes, we request more details about the proposal to waive the requirement for multiple managed care options in certain areas of the state. Which areas of the state will be impacted? What are the implications for member choice and continuity of care? Without this information we cannot assess this proposal.

Premiums and Cost-Sharing

Cost-sharing greater than 5% for CommonHealth members
In this waiver request, MassHealth proposes to implement cost-sharing greater than 5% of income for members over 300% FPL, which would impact adults and children with disabilities enrolled in the CommonHealth program. We request that MassHealth amend its waiver proposal to include more specificity about how this change would be implemented. We have questions about how this policy will be implemented, and request that MassHealth include more details in its proposal. For CommonHealth members with other primary insurance, will the new cost-sharing levels take into account the cost of the primary coverage? What percentage of income does MassHealth anticipate using for enrollees with incomes over 300% FPL? Slides from the August 4th hearing indicate that cost-sharing will remain below the state affordability schedule as determined by the Health Connector. However, the affordability schedule only takes into account premiums. How does MassHealth anticipate accounting for copays?

Annual 5% cost-sharing limit
MassHealth proposes to implement the 5% cost-sharing limit on an annual basis rather than a quarterly or monthly basis. This change may impose barriers to seeking services for members who need to use care more often in one month or quarter compared to their usual yearly use. For example, someone may need recurring physical therapy visits for a few months, and then not for the rest of the year. We also urge MassHealth to put in place an automated system to track copays that is transparent to members and providers before making any changes to the copay structure.

Broad-based premium and copay changes
In the 1115 waiver amendment and extension approved on November 4, 2016, MassHealth received authority to charge higher cost-sharing to PCC plan members than those enrolled in ACOs, MCOs or fee-for-service (FFS). MassHealth also plans to raise premiums for all enrollees above 150% FPL to 3% of

income and cap copays at 2% of income, while exempting members below 50% FPL from copays, beginning January 1, 2019. MassHealth also plans to charge copays for more services.

Raising premiums to 3% of income for enrollees above 150% FPL will result in substantial premium increases, with the largest increases for the lowest income individuals and families. The proposed premium increase would result in Massachusetts families paying among the highest premiums of any state.[13] The proposed MassHealth premium at 3% of income for a family at 200% FPL will be at least $60 per month, which would give Massachusetts the second highest premium charge of any state, after Missouri.[14]

Instead of implementing premiums of 3% of income across the board, we urge MassHealth to institute a progressive premium schedule, with a percentage of income that starts below 3% of income for individuals and families at 150% FPL and increases at higher incomes. In addition, we ask MassHealth to consider capping the amount premiums increase from current levels, especially for members at the lower end of the income range. For example, a family of two (one adult, one child) between 150-200% FPL would see their premium increase from $12 per month to $45 per month, an 80% increase. Families earning between 150-300% FPL in a high cost state like Massachusetts cannot afford steeply increased health care costs and keep up with the cost of other necessities, particularly housing.

In addition, copays can add up quickly for low-income populations. Some consumers already face barriers in affording prescription medications, especially when they take more than one drug. Additionally, certain services, such as outpatient therapy (physical, speech and occupational therapy), are often utilized intensely for a relatively short period of time (although they may be ongoing for certain populations). Specialist copays may be onerous for people with complex conditions, who sees their specialist more often than their primary care physician (PCP) or designate a specialist as their PCP. One possible strategy to mitigate the impacts here is to institute sub-caps on copays for these services. MassHealth could also exempt from copay charges people with complex care needs who see a specialist as their PCP.

We appreciate that MassHealth proposes to eliminate copays for the lowest income members; maintain copays at a nominal level; continue to exempt currently exempt populations, including children and pregnant women; and ensure that a member's inability to pay a does not result in denial of service in any delivery system. We encourage MassHealth to continue to educate providers and pharmacies about these consumer protections.

We appreciate the dialogue the Administration has opened to discuss our concerns, and look forward to working with you to ensure that any changes to MassHealth do not adversely impact members. Should you have any questions or wish to discuss these comments further, please contact me at (617) 275-2977 or scurry@hcfama.org. Thank you for your time and consideration.

Sincerely,

Suzanne Curry
Associate Director, Policy and Government Relations

Cc: Marylou Sudders, Secretary, Executive Office of Health and Human Services
Robin Callahan, Deputy Director, MassHealth

---

[13] Kaiser Family Foundation, *Medicaid and CHIP Eligibility, Enrollment, Renewal, and Cost Sharing Policies as of January 2017: Findings from a 50-State Survey*. Available at: http://www.kff.org/report-section/medicaid-and-chip-eligibility-enrollment-renewal-and-cost-sharing-policies-as-of-january-2017-tables/.
[14] Ibid.

August 18, 2017

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

Sent by email

Re: Comments for Demonstration Amendment

Dear Assistant Secretary Tsai,

On behalf of the undersigned organizations and individuals, all dedicated to preserving and improving affordable health coverage for all Massachusetts residents, thank you for the opportunity to comment on the MassHealth 1115 Demonstration Waiver Amendment released on July 20, 2017. We share your commitment to a sustainable MassHealth program and to maintaining the gains Massachusetts has made in access to affordable health coverage for low-income residents. While we understand the significant fiscal challenges the Commonwealth currently faces, and the intent of the Administration to keep people covered, we are concerned that many of the proposals included in the 1115 waiver amendment will likely decrease access to affordable coverage and care for low-income consumers.

With this waiver amendment, MassHealth requests broad flexibility to make various eligibility and coverage changes. However, the draft document does not include a level of specificity needed to ascertain the intent and impact of the proposed changes. We ask that you make available more information on the estimated impact of these proposals in terms of the number of people affected and associated costs and cost-savings. In addition, the proposal seeks broad authority to waive important protections in the federal Medicaid Act without committing to the kinds of safeguards necessary to mitigate harm to affected populations. Before any of the proposed changes referenced below are submitted for approval, clear and strong safeguards should be included as part of the waiver request and in any authorizing state legislation.

Transferring Non-Disabled Adults to ConnectorCare

MassHealth proposes to shift coverage for non-disabled adults ages 21 to 64 with incomes over 100% of the federal poverty level (FPL) to ConnectorCare as of January 1, 2019. Currently, this population includes 100,000 parents in MassHealth Standard and 40,000 childless adults in MassHealth CarePlus. ConnectorCare is a valuable program, integral to Massachusetts' health coverage system, as it offers more affordable coverage than even the federal Advanced Premium Tax Credits (APTCs) and Cost-Sharing Reductions (CSRs) alone would provide. However, ConnectorCare coverage provides fewer benefits, is more costly to consumers and presents more enrollment barriers than MassHealth coverage.

We strongly urge the Executive Office of Health and Human Services (EOHHS) to reconsider shifting non-disabled adults with incomes over 100% FPL from MassHealth to ConnectorCare, as this will result in:

- *Loss of benefits*:
    - *Dental care*: While the Health Connector offers stand-alone dental plans, the cost of these plans is not subsidized, and would be out of reach for most. In addition, the Health Safety Net – which provides "wrap" dental coverage to ConnectorCare enrollees

– already has long wait times for patients to receive dental services, and adding more people to ConnectorCare will exacerbate this problem. Many people will have no choice but to seek services at hospital emergency departments, which are ill-equipped to provide comprehensive dental care.

- *Behavioral health:* ConnectorCare plans are required to cover inpatient and outpatient mental health and substance use disorder services; however, ConnectorCare plans may not offer the same range of behavioral health services as MassHealth. In particular, access to diversionary services, such as Community Support Programs (CSPs) and Emergency Services Programs (ESPs), are not a part of traditional commercial insurance benefit packages and therefore may not be available to many individuals covered through ConnectorCare plans.
- *Prescription drugs*: ConnectorCare plans are able to implement more restrictive formularies than MassHealth, and may impose more utilization management techniques, which create barriers to both obtaining needed medications and continuing on a course of treatment.

- *Higher premiums for consumers for all but one MCO*: ConnectorCare Plan Type 2A will offer only one $0 premium plan in 2018. Unlike Medicaid or the former Commonwealth Care program, in ConnectorCare there is no legal requirement that the Connector continue to offer a $0 premium contribution plan to low-income individuals. The premiums for plan options other than the lowest cost plan are substantial – up to $174 per month in 2017. Many MassHealth members transitioning to ConnectorCare will not be able to continue enrollment in their current health plan or maintain continuity of care due to the higher cost of ConnectorCare plans.
- *Higher copays:* In addition, ConnectorCare copays at this income level are substantially higher than those in MassHealth, impacting access to services for members. For example, MassHealth copays for prescription drugs are $1 or $3.65 per medication, and MassHealth members cannot be turned away for inability to pay. ConnectorCare Plan Type 2A members are required to pay between $10-40 to fill each prescription. ConnectorCare imposes copays for a wider range of services than MassHealth, including $10 for a primary care or mental health/substance use disorder visit, $18 for a specialist visit, and $50 for emergency room and other hospital services.
- *Increased number of uninsured*: Unlike MassHealth, Connector enrollees must take the step of choosing a plan and paying a premium before their coverage is effectuated. In fact, the most recent numbers we obtained from the Health Connector show that at one point in time, 40% of people eligible for ConnectorCare Plan Type 2A remain unenrolled. ConnectorCare, unlike MassHealth, does not automatically enroll eligible individuals into a health plan. In addition, ConnectorCare has eligibility rules that would bar certain people from qualifying, such as those who have access to employer sponsored insurance (ESI) with a premium that costs less than 9.69% of their family income in 2017; veterans with access to the VA Health System; Deferred Action Childhood Arrivals; and married couples living apart filing taxes separately (with limited exceptions).

ESI and Student Health Insurance "Gate"

MassHealth proposes to preclude otherwise eligible residents from qualifying for MassHealth if they have access to "affordable" employer sponsored insurance (ESI) or student health insurance. In a recent public presentation, MassHealth stated that it intends to apply their current thinking on affordability: the employee share of premiums and the deductible for the ESI is less than 5% of family income. While this is a welcome change from the original proposal of using a 9.69% of income affordability test, taking into account only the premium cost, this metric does not account for other forms of cost-sharing, including copays and coinsurance, that may present substantial access barriers to low-income workers.

Nor is even 5% of income affordable for adults with income below the poverty level given the high costs for housing and other life necessities.

There is no precedent for this type of restriction in MassHealth; access to other health insurance has never been a bar to MassHealth coverage. Rather, MassHealth acts as a secondary or tertiary payer when other coverage is available, which protects low-income members from unaffordable medical bills and reduces MassHealth spending. We urge EOHHS to remove the ESI and SHIP "gate" from its proposed 1115 waiver amendment.

Instead, we support increased participation in the MassHealth Premium Assistance program as the best way to leverage employer contributions and reduce state spending while also ensuring that low-income workers have affordable and comprehensive coverage. Through programs like Premium Assistance, MassHealth has remained an important support for low-income families striving to work themselves out of poverty. We are hopeful that the use of the Health Insurance Responsibility Disclosure (HIRD) form to streamline the Premium Assistance process for MassHealth, consumers, and employers alike.

MassHealth Premium Assistance "Wrap" Benefits

The MassHealth Premium Assistance program has always provided a benefit "wrap" in addition to assistance with the cost of ESI premiums and cost-sharing. Commercial health insurance coverage is often not sufficient to meet the needs of low-income families, especially with regards to behavioral health and other community-based services. Thus, these "wrap" benefits are critical to ensuring MassHealth-eligible individuals and families enrolled in commercial coverage have access to the same level of benefits as if they were enrolled in MassHealth as a primary payer.

We are concerned that MassHealth seeks "flexibility not to provide any additional benefit wrap, except for a limited number of services not typically covered by commercial" in the 1115 waiver amendment. We request that MassHealth amend the proposed waiver language to provide more specificity regarding the flexibility requested, and preserve the benefit wrap currently offered in the Premium Assistance program.

MassHealth Limited and ConnectorCare Coverage

MassHealth proposes to eliminate MassHealth Limited coverage 90 days after an individual is determined eligible for ConnectorCare, as is done with access to the Health Safety Net. We understand the purpose of this change and believe it may help mitigate confusion for individuals currently enrolled in both coverage types. However, we are concerned that those who remain eligible for ConnectorCare but unenrolled will not have access to even emergency coverage after 90 days, and will be foreclosed from enrolling in ConnectorCare. Therefore, we suggest that MassHealth amend its request to provide that MassHealth Limited coverage is terminated only when the coverage is truly redundant; that is, after an individual has successfully enrolled in ConnectorCare. We support the proposed plan to open a special enrollment period for individuals enrolled in MassHealth Limited and eligible for – but unenrolled in – ConnectorCare.

Closed Drug Formulary and Selective Specialty Pharmacy Network

We understand that prescription drugs are a key driver of increasing health care costs and must be managed. However, we are concerned that more limited specialty pharmacy networks and a closed formulary, as proposed in the 1115 waiver amendment, would impose unnecessary barriers to needed medications. Unlike several of the other proposed changes, these changes apply to all MassHealth members, including people with disabilities, children, and seniors. Prescription drugs are a lifeline for

people with chronic diseases; barriers should not imposed without an effective means for granting exceptions based on individual medical need. It is extremely important that there are strong consumer protections in place, perhaps building off of those afforded to Medicare Part D enrollees, before making any restrictions to the MassHealth formulary or limiting access to specialty pharmacies.

Narrower Primary Care Clinician (PCC) Plan Networks

MassHealth proposes to implement narrower networks in the PCC Plan to encourage enrollment in Accountable Care Organizations (ACOs) and MCOs. While the differential is decreasing, people with complex medical needs frequently choose the PCC Plan over MCOs. Most often, applicants choose the PCC Plan because their preferred providers are not all included in Managed Care Organization (MCO) networks, or are not included in the same network. We request that MassHealth provide more detail about how the narrower PCC Plan networks will be established, identify impacts on people with complex needs or disabilities, and demonstrate how the narrower networks will continue to meet Medicaid network adequacy requirements.

Limited Managed Care Options

Similar to the proposed PCC Plan network changes, we request more details about the proposal to waive the requirement for multiple managed care options in certain areas of the state. Which areas of the state will be impacted? What are the implications for member choice and continuity of care? Without this information we cannot assess this proposal.

CommonHealth Premiums and Cost-Sharing

MassHealth proposes to implement cost-sharing greater than 5% of income for members over 300% FPL, which would impact adults and children with disabilities enrolled in the CommonHealth program. We request that MassHealth amend its waiver proposal to include more specificity about how this change would be implemented. We have questions about how this policy will be implemented, and request that MassHealth include more details in its proposal. For CommonHealth members with other primary insurance, will the new cost-sharing levels take into account the cost of the primary coverage? What percentage of income does MassHealth anticipate using for enrollees with incomes over 300% FPL? Will there be exceptions for certain services? We also urge MassHealth to use a progressive cost-sharing schedule, charging a lower percentage of income at lower income levels.

We appreciate the dialogue the Administration has opened to discuss our concerns, and look forward to working with you to ensure that any changes to MassHealth do not adversely impact members. Should you have any questions or wish to discuss these comments further, please contact Suzanne Curry, Associate Director of Policy and Government Relations at Health Care For All at (617) 275-2977 or scurry@hcfama.org. Thank you for your time and consideration.

Sincerely,

Organizations:
AIDS Action Committee
American Heart Association and American Stroke Association
Boston Center for Independent Living
Boston Public Health Commission
The Center for Health Law and Policy Innovation of Harvard Law School
Community Servings
Council on American-Islamic Relations-Massachusetts

Disability Law Center
Disability Policy Consortium
Easter Seals Massachusetts
Greater Boston Legal Services
Health Care For All
Healthcare for Artists
Health Law Advocates
Healthcare Rights Coalition
Home Care Aide Council
JRI Health Law Institute
Massachusetts Communities Action Network
Massachusetts Law Reform Institute
Mass Home Care
Mental Health Legal Advisors Committee
MetroWest Center for Independent Living
National Alliance on Mental Illness of Massachusetts (NAMI Mass)
The National Multiple Sclerosis Society
Parent/Professional Advocacy League
Stavros

Individuals:
Louis Malzone
Nancy Turnbull
Celia Wcislo

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

Massachusetts League
of Community Health Centers

40 Court Street, 10th Floor Boston, MA 02108 phone: 617-426-2225 fax: 617-426-0097 www.massleague.org

August 21, 2017

TO: Daniel Tsai, Assistant Secretary for MassHealth
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor, Boston, MA 02108
FR: James W. Hunt, Jr., President & CEO
DT: August 21, 2017
RE: Comments on the proposed 1115 Demonstration Waiver Amendment

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

On behalf of the Commonwealth's 50 community health centers, serving over 988,000 patients at more than 300 sites, we are writing with regard to the MassHealth demonstration amendment noticed on July 20, 2017.

We have identified the following specific concerns for community health centers, and look forward to discussing solutions that preserve healthcare access and affordability for our patients.

Transfer of 140,000 people from MassHealth to ConnectorCare Coverage

We estimate that approximately 80,000 people, or 60% of the 140,000-person target group, are already being served at community health centers, and expect that this transfer may result in the following issues:

- **Loss of revenue related to the loss of MassHealth FQHC rate protection**

  The Health Center Medicaid Prospective Payment System (PPS) was established by Congress with the intent of ensuring appropriate payment for covered individuals, while not forcing health centers to cross-subsidize MassHealth out of their federal grant funds. This unique payment system is integral to health centers' continued success in providing cost-saving primary and preventive care, as well as the support services necessary to make a difference when serving low-income populations. The state also has recognized this through its rate-setting regulations.

  ConnectorCare does not include that payment protection, despite the fact that the people being moved out of MassHealth are just as poor and in need of the same array of community health center services as those patients who would remain MassHealth-eligible. Past experience with individuals close to the poverty line is that they move back and forth between private insurance and MassHealth as a result of their fluctuating employment status. Adequate reimbursement for care provided to these patients is critical

for Massachusetts health centers. We would support approaches for insuring that ConnectorCare rates are set in a way that provide incentives or require health plans to cover the full array of health center services. Unless this provision is put into their rates, it is quite possible that they will forego health center contracts, dislocating patients from their primary care medical homes and ultimately disrupting their care.

- **Loss of care continuity**

  Prior to the state's recent healthcare system transformation efforts, health plans that were serving MassHealth patients also served ConnectorCare patients. These were the same plans that contracted with health centers in various regions of the state. Now, because the majority of health centers will participate as members of Accountable Care Organizations (ACOs) by spring 2018, most health centers will no longer have MassHealth plan contracts. It is unclear whether, without MassHealth business, the ConnectorCare plans will continue to contract with health centers. It is also unclear as to whether elimination of a great deal of MassHealth business will further shrink the availability of ConnectorCare health plans in some regions, disrupting relationships not only with health centers but also with hospitals and other health care providers.

  Continuity of care is critical for health center patients, many of whom are dealing with complex co-morbidities that require greater coordination of services and care management. Currently, when a patients' financial status changes, they frequently are able to remain in the same health plan for both MassHealth and ConnectorCare. In the new environment, patients will need to switch enrollment from an ACO plan to a ConnectorCare plan. In the case where a health center does not have a contract with a ConnectorCare plan, it will mean that a patient becomes uninsured or is forced to leave their long-term provider. Past experience has shown that a large number of these patients ultimately return to the health center that they view as their medical home, and are cared for by the health center without reimbursement.

  Copayments within the ConnectorCare Health plans can be a major factor in discouraging low income people from accessing and utilizing needed services. In addition, administrative requirements of third-party managers for behavioral health, eye care and pharmacy services are complicated. We are concerned that in many cases the combination of expense and administrative requirements will lead many patients to forego care, which they would have received at lesser expense and far less hassle within an ACO at a community health center.

- **Loss of dental coverage**

  Loss of MassHealth dental coverage is another significant issue. It is questionable as to whether very low income patients will be able to afford Connector dental coverage unless that premium is also subsidized. Although we appreciate the Health Safety Net (HSN) coverage for dental care at community health centers, we are extremely concerned that it is not an adequate substitute for statewide dental care availability. At present, dental services are not available at every health center, nor is dental care readily accessible in parts of the state not served by a community health center. Although health centers have continued to expand availability, lack of capacity and underpayment remain major issues.

Since most health centers have oral health waiting lists, it would be difficult to accommodate all of the non-community health center-patients who will be transferred to ConnectorCare from MassHealth. In the case of patients who change coverage, this will add to the amount of HSN funding spent on health center dental services.

- **Potential for an increase in health center bad debt and depleted grant resources**

  Connector plans have significantly higher cost-sharing requirements than MassHealth; the enrollment process combined with the tax credit system is much more complicated; and the possibility of a lock-out from coverage for non-payment of premiums make it likely that health centers will incur increasing bad debt, as well as an increased drain on already burdened grant resources in order to continue to serve patients currently covered by MassHealth. We would like to continue to work with the Executive Office of Health and Human Services and the Connector, particularly with respect to improving the enrollment process to attempt to minimize these effects. What's more, copayments within the ConnectorCare health plans can be a major factor in discouraging poor people from accessing and utilizing needed services. In addition, administrative requirements of third-party managers for behavioral health, eye care and pharmacy services are complicated. We are concerned that in many cases the combination of expense and administrative requirements will lead many patients to forego care, which they would have received at lesser expense and far less hassle within an ACO at a community health center.

- **Impact on health center viability within ACOs**

  Our health center members have also expressed concern with the potential impact this change could have on our transition to accountable care systems. At this point, it is hard to pinpoint which ACOs would experience a reduction in their number of covered lives. It is clear that for the smaller ACOs (or smaller aggregations within an ACO), losing a significant number of enrollees could affect their reimbursement and risk arrangements.

With respect to the other changes proposed in the MassHealth Reform package, we offer the following concerns:

Transfer of 230,000 people from MassHealth Standard to CarePlus: As we understand it, persons moving from MassHealth to CarePlus will still be eligible to remain in ACOs, but they may be susceptible to losing optional services, including non-emergency transportation, dental services, and eye glasses. Transportation is an important factor in patient compliance, particularly for patients with the most serious conditions. We have already presented our position and thoughts around dental services above. Health centers have greatly expanded their eye-care capacity, and lack of reimbursement for eye glasses will most likely mean that health centers will have to provide these at their own expense. Although we oppose elimination of these services for all MassHealth enrollees, we would also like to explore ways of continuing them exclusively at community health centers.

Employer-sponsored insurance requirements: On the July 27, 2017 Baker Administration's conference call, we were pleased to hear that the proposal that persons eligible for employer-sponsored insurance (ESI) would not be allowed to apply for MassHealth coverage had been withdrawn. This proposal was a major concern, given the state's prior experience with a "gate"

for MassHealth that was a frequent source of enrollment confusion and resultant delay, particularly with a population with very high job turn-over. We think better solutions would be to improve and streamline the Premium Assistance program and create Employer Buy-in opportunities. Moving patients with MassHealth coverage to ESI raises the same issues as mentioned earlier regarding ConnectorCare coverage (lack of reimbursement protection, non-availability of contracts with various insurers; and high deductibles and copayments leading to bad debt). We believe that recognizing the need to make sure that low-income people get the care they need in an affordable way and that providers are adequately reimbursed in implementing this proposal could ensure that reform is successful. The League staff is already included in a MassHealth working group to explore this option.

While the transformation of the MassHealth delivery system presents tremendous challenges for all the state's providers and insurers, those faced by community-based systems of care -- like health centers -- are even greater. Consequently, the same statewide investments made to hospitals need to be extended to community health centers. Targeted investments in community health center financing, workforce, and transformation will generate both short- and long-term savings for the Commonwealth.

Thank you for this opportunity to comment. The League and its members look forward to continuing to work closely with the MassHealth to address the many challenges facing the health care system in a way that supports both the Administration and our member community health centers.

The Arc of Massachusetts
217 South Street
Waltham, MA 02453-2710

T: 781.891.6270
F: 781-891.6271
arcmass@arcmass.org
www.arcmass.org

Achieve with us.

For people with intellectual and developmental disabilities

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

August 15, 2017

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

Re: Comments for Demonstration Amendment

Dear Assistant Secretary Tsai,

Thank you for the opportunity to share The Arc of Massachusetts' comments on the MassHealth 1115 Demonstration Waiver Amendment released on July 20, 2017. I am writing both as the Director of Government Affairs and as a single mother of two young men with autism and complex medical issues.

As you know, The Arc of Massachusetts (The Arc) is a statewide advocacy organization representing 200,000 individuals and their families with 18 chapters in the state. Its mission is to enhance the lives of people with intellectual and developmental disabilities, including autism, and their families. We fulfill this through advocacy for community supports and services that foster social inclusion, self-determination, and equity across all aspects of society.

The Arc supports the need and movement toward making MassHealth as sustainable as possible. We specifically applaud the proposal to maintain people with disabilities as MassHealth Standard eligible. However, we are equally concerned with the changes to premium assistance coverage for caretakers who have children with disabilities and now will be required to accept "ESI" (Employer sponsored insurance) or be forced into different products with less subsidy. In the state's posted waiver draft, premium assistance is offered for those above 100 FPL by capping out of pocket expenses at $1,250 and $2,500 for individuals and families respectively. This is inadequate given that it would exceed 5% of income for those at 133% and !50% of FPL.

We recommend that the Commonwealth continue more substantial premium assistance for families between 150% and 300% of poverty level regardless of their present health insurance provider. Cap out of pocket expenses at 5% perhaps with a slight cap increase for those between 250% and 300%.

The respective poverty levels for a family of four ranges from $24,600 at 100% to $61,500 at 250%. Imagine have one or more children with disabilities and the additional fees or costs families assume separate from rent or a mortgage and vehicle in a family of 4. (FPL data: Families USA 2017 FPL).

The Arc understands that MassHealth proposes to implement narrower networks in the PCC Plan to encourage increased enrollment in Accountable Care Organizations (ACOs) and MCOs. Individuals with intellectual and developmental disabilities (I/DD) plus complex medical needs frequently choose the PCC Plan over MCOs often because their preferred providers are not all included in Managed Care Organization (MCO) networks, or are not included in the same network.

MassHealth should evaluate the impact upon people with disabilities and their health care prior to implementing "narrower networks". We recommend MassHealth fund a university or other entity to study where those with complex medical or behavioral conditions are obtaining their specialty care. The Arc would collaborate in recruiting families for this study. Barriers to quality care have been proven to exist and we recoil at the thought of narrower networks for our constituents without a solution to the underlying problem that results in higher PCC plan usage.

The Arc continues to advocate for the need to train these ACO/MCO networks in best practices for people with autism or I/DD.

In conclusion, our constituents depend on The Arc to help ensure individuals and families like my own have access to affordable and quality health care. If you have any further questions, please don't hesitate to contact myself or Leo Sarkissian, Executive Director. We urge you to support the healthcare rights of people with autism and I/DD here in the Commonwealth of Massachusetts.

Regards,

Maura Sullivan

Maura Sullivan, MPA, Director of Government Affairs
The Arc of Massachusetts
781 530-8274
sullivan@arcmass.org

CENTER FOR HEALTH LAW
& POLICY INNOVATION
Harvard Law School

August 21, 2017

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

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

Re: Comments for Demonstration Amendment

Dear Assistant Secretary Tsai,

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

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

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

---

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

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

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

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

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

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

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

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

---

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

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

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

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

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

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

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

---

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

[7] *Id.*

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

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

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

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

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

Select Preferred and Covered Drugs Through a Closed Formulary

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

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

---

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

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

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

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

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

We are concerned that the proposal to limit the choice of pharmacy to specialty pharmacies for members receiving care through the fee-for-service and the primary care clinician (PCC) plan may have the unintended effect of imposing unnecessary barriers to obtaining lifesaving specialty medications. While specialty pharmacies can provide care coordination benefits to those that prefer them, they often present physical access problems for those experiencing homelessness and people in transient living situations. This is especially true where no brick-and-mortar locations are readily accessible and members are forced to receive their medications in the mail. These individuals in particular may not be able to receive medications consistently in the mail, creating gaps in treatment and increasing the likelihood that members will not be able to adhere to their treatment regimens.[15] For many individuals, having medications delivered to their home or workplace where co-workers, neighbors, and other residents may discover their health conditions or medication needs could result in serious harm and social alienation, especially given the significant stigma still associated with HIV and HCV.

Provider and community health workers' experiences with MassHealth MCOs utilizing specialty pharmacies to dispense HCV medications demonstrates how mail order dispensing is inappropriate for members with unstable living situations. While patients may designate providers or other representatives to accept deliveries on their behalf, the process is often complicated, burdensome,

---

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

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

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

and difficult to navigate. Specialty pharmacies do not allow a patient's community service provider to order medications on their behalf, instead forcing the patient to make each phone call. For many, this is simply impractical. Medication orders are often lost or cancelled due to patients' frequent changes of addresses and phone numbers. Further, individuals are often told by specialty pharmacies that their medication will not be dispensed until payment information is provided, or that a refill will not be provided unless any pending balance has been paid. This presents a significant barrier, especially for enrollees that do not have access to funds other than limited cash resources that they rely on for other needs.

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

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

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

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

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

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

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

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

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

MassHealth proposes to implement narrower networks in the PCC plan to encourage members to enroll in Accountable Care Organizations (ACOs) and MCOs rather than the PCC plan. As noted in the 1115 Waiver Amendment Request, the PCC plan currently uses open provider networks. As a result, the PCC plan can be an important option for individuals living with chronic illnesses who require consistent access to a variety of health care providers that may not all participate in an a particular MCO or ACO network. By instituting narrow networks, MassHealth would introduce this same problem into the PCC plan, separating patients with complex conditions from providers that they know and trust and creating potential gaps in care as patients work to identify and access new in-network providers. We therefore request that MassHealth maintain its open networks for the PCC plan or provide more information on how it will address the potential impact of the narrower networks on individuals living with chronic disease.

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

---

[17] *Id.*

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

Thank you for your time and consideration.

Sincerely,

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

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

August 18, 2017

Kaela Konefal
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108
kaela.konefal@state.ma.us

Re: Request to Amend the MassHealth Section 1115 Demonstration Waiver

ViiV Healthcare appreciates the opportunity to submit comments to the Executive Office of Health and Human Services (EOHHS) regarding your proposed amendment to the MassHealth Section 1115 Demonstration Waiver. We commend the Commonwealth's efforts to expand eligibility to individuals who would not otherwise be eligible and offer services that are not traditionally covered by Medicaid. While we appreciate EOHHS' desire to ensure the sustainability of the MassHealth program while maintaining access for vulnerable populations, we are concerned that the waiver amendment would have the opposite impact on people living with HIV (PLWH) and other vulnerable populations who rely on Medicaid to treat chronic disease.

ViiV Healthcare is the only pharmaceutical manufacturer devoted exclusively to the treatment of HIV with a singular focus to improve the health and quality of life of people affected by HIV. From ViiV's inception in 2009, we have worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV Healthcare remains committed to developing meaningful treatment advances, improving access to our medicines, and supporting the HIV community to facilitate access to care and treatment.

Our greatest concern is the amendment's proposal to "[s]elect preferred and covered drugs through a closed formulary that assures robust access to medically necessary drugs." ViiV Healthcare supports the comments made in the Pharmaceutical Research and Manufacturers of America's August 15 letter, and we would like to further stress the specific impact a closed formulary would have on PLWH. Medicaid has played a vital role in HIV care since the epidemic began, and it is the largest source of coverage for people living with HIV.[i] It is imperative to preserve continuous access to comprehensive health care, including antiretroviral therapy (ART) for people living with HIV to improve health outcomes. However, studies show that restricting access to drugs through closed formularies results in non-adherence or poor adherence to prescribed medication regimens, worsened health outcomes, and higher, long-run costs, both to Medicaid and other state and local programs.[ii] [iii]

Continuous insurance coverage and access to lifesaving treatments are also essential for PLWH to reach viral load suppression and, as a result, lower transmission rates. HTPN052, a 2011 clinical study from the National Institutes of Health (NIH), found that treating HIV-positive people with ART reduces the risk of transmitting the virus to HIV-negative sexual partners by 93 percent.[iv] Moreover, treating to viral load suppression saves state Medicaid programs an estimated $2 million per treated patient by preventing an average of 5.3 transmissions over 100 years.[v] This can only occur, however, if PLWH are diagnosed, have access to medical care, receive treatment, and remain adherent to their prescribed therapy. According to the CDC, however, only 33 percent of PLWH are on ART, and only 30 percent are virally suppressed.[vi]

The ability to have choice among ARTs is crucial for a robust effort to combat HIV. Any reduction in those options has shown less flexibility and effectiveness in fighting the epidemic. The effective treatment of HIV is highly individualized and accounts for a patient's size, gender, treatment history, viral resistance, coexisting illnesses, drug interactions, immune status, and side effects. Thus, PLWH must have access to

a robust formulary that provides physicians with the ability to prescribe the right treatment for the right time for their patients.

Thank you for your consideration and your commitment to provide healthcare for low-income populations. PLWH are some of the most vulnerable patients and largest users of Medicaid, so it is imperative that we consider the impact of any significant programmatic changes on them. ViiV Healthcare looks forward to working with the EOHHS and other stakeholders to ensure that Massachusetts's public programs continue to ensure patients have access to quality care and to improve health outcomes. Please feel free to contact me at (919) 323-9084 or Cindy.C.Snyder@viivhealthcare.com should you have any questions.

Sincerely,

Cindy Snyder

Cindy Snyder
Community Government Relations Director
ViiV Healthcare

---

[i] Kaiser Family Foundation. Medicaid and HIV, http://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/.

[ii] Happe LE, Clark D, Holliday E, Young T. A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. J Manag Care Spec Pharm. 2014;20(7):677-84.

[iii] Zullig, LL, Bosworth, H, Engaging patients to optimize medication adherence. NEJM Catalyst, May 14, 2017.

[iv] Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011;365:493-505, http://www.nejm.org/doi/full/10.1056/NEJMoa1600693#t=article.

[v] Skarbinski, et al. *JAMA Intern Med.* 2015;175(4):588-596.

[vi] HIV Care Saves Lives, CDC, http://www.cdc.gov/vitalsigns/hiv-aids-medical-care/index.html. Accessed December 2, 2014.

American Cancer Society
Cancer Action Network
30 Speen Street
Framingham, MA 01701
www.acscan.org/ma

August 17, 2017

Marylou Sudders
Secretary
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

Re: MassHealth Section 1115 Demonstration Amendment Request

Dear Secretary Sudders,

The Massachusetts American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on Massachusetts' proposal to amend the MassHealth demonstration waiver. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN supports Massachusetts' goal to provide near-universal coverage to low-income Massachusetts residents through the MassHealth program. However, we are concerned with many of the proposed amendments, most notably shifting non-disabled adults whose income is between 101 to 138 percent of the federal poverty level (FPL) from MassHealth to Health Connector. This change would cause an estimated 100,000 parents and 40,000 childless adults to lose affordable coverage, pushing them into a program with fewer benefits and greater cost sharing. We strongly urge the Massachusetts Executive Office of Health and Human Services ("the Department") to reconsider this proposal.

Over 37,000 Massachusetts residents are expected to be diagnosed with cancer this year[1] – many of whom are receiving health care coverage through the MassHealth program. It is imperative that low-income Massachusetts residents continue to have access to comprehensive health care coverage under the MassHealth program. We are concerned that individuals who are shifted from the MassHealth program to the Health Connector program will experience higher out-of-pocket costs and may be more likely to forgo needed care. Imposing copayments on low-income populations has been shown to decrease the likelihood that they will seek health care services, including preventive screenings.[2,3,4]

---

[1] American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta, GA: American Cancer Society; 2017.
[2] Solanki G, Schauffler HH, Miller LS. The direct and indirect effects of cost-sharing on the use of preventive services. *Health Services Research.* 2000; 34: 1331-50.
[3] Wharam JF, Graves AJ, Landon BE, Zhang F, Soumerai SB, Ross-Degnan D. Two-year trends in colorectal cancer screening after switch to a high-deductible health plan. *Med Care.* 2011; 49: 865-71.
[4] Trivedi AN, Rakowsi W, Ayanian JA. Effect of cost sharing on screening mammography in Medicare health plans. *N Eng J Med.* 2008; 358: 375-83.

Cancers that are found at an early stage through screening are less expensive to treat and lead to greater survival.[5] Uninsured and underinsured individuals already have lower screening rates resulting in a greater risk of being diagnosed at a later, more advanced stage of disease.[6] Proposals that place greater financial burden on the lowest income residents create barriers to care and could negatively impact MassHealth enrollees – particularly those individuals who are high service utilizers with complex medical conditions. We urge the Department to consider our recommendations to ensure that low-income Massachusetts residents continue to have access to quality, affordable, and comprehensive health insurance.

The following are our specific recommendations on the MassHealth demonstration amendment request:

Shifting Non-Disabled Adults to Health Connector

ACS CAN is deeply concerned with Massachusetts' proposal to reduce eligibility and transfer coverage for MassHealth enrollees whose incomes fall between 101 to 138 percent of the FPL to Health Connector – a subsidized commercial plan. Although we appreciate that the Department excludes those in the breast and cervical cancer treatment program and those determined by MassHealth to be medically frail, we are concerned that individuals with cancer and cancer survivors could still be at risk of losing access to affordable coverage as a result of this proposal.

Moving cancer patients and survivors out of a more robust MassHealth and into Health Connector's qualified health plans (QHP) will result in reduced benefits and a significant increase in out-of-pocket cost sharing - even with cost-sharing reduction subsidies - making coverage less comprehensive and unaffordable. Individuals enrolled in Health Connector are responsible for copays as high as $50 (for emergency room services and inpatient hospital services)[7] with annual out-of-pocket expenses capped at $1,250 for an individual and $2,500 for a family. While we appreciate the Department's proposal to offer some lower-income individuals $0 premium plan options, absent a similar reduction in out-of-pocket costs, we are concerned that the proposal would still leave individuals exposed to significant cost-sharing, beyond what is permitted under the federal requirements.

The level of the out-of-pocket maximum would be particularly burdensome for a high-utilizer of health care services, such as an individual in active cancer treatment or a recent survivor. Cancer patients in active treatment require many services shortly after diagnosis and thus incur a significant portion of cost-sharing over a relatively short period of time. It can be challenging for an individual – particularly an individual with limited means – to be able to afford their cost-sharing requirements. Likewise, a recent survivor may require frequent follow-up visits to prevent cancer recurrence. Having to pay the full cost up front would likely result in many cancer patients and survivors delaying their treatment and could result in them forgoing their treatment altogether.

---

[5] American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2016-2017.* Atlanta: American Cancer Society; 2017.

[6] Ibid.

[7] Powerpoint presentation by Marylou Sudders, Secretary Executive Office of Health & Human Services. FY18 MassHealth and commercial market reform package. Presented July 25, 017.

We strongly urge the Department to consider maintaining eligibility for individuals whose income falls between 101 and 138 percent of the FPL in the MassHealth program.

At the very least, if the Department decides to move forward with this provision, we ask that the definition of medically frail be amended to ensure that individuals in active cancer treatment and recent cancer survivors have access to health care coverage under MassHealth until they are no longer deemed "medically frail."

Consolidating Coverage for Non-Disabled Adults ≤100 Percent FPL

We ask for clarification regarding the consolidation of coverage for non-disabled adults (including parents and caregivers) with incomes up to 100 percent of the FPL from MassHealth Standard into MassHealth CarePlus, an Alternative Benefit Plan (ABP). It is unclear from the waiver whether individuals transferred to CarePlus would be required to pay cost sharing higher than what they currently pay under MassHealth Standard.

Studies have shown that imposing premiums or cost sharing on low-income individuals, particularly those below 100 percent of FPL, is likely to deter enrollment in the Medicaid program.[8,9,10] Proposals that place greater financial burden on the lowest income residents, especially those under 100 percent of the FPL, create barriers to care and could negatively impact MassHealth enrollees – particularly those individuals who are high service utilizers with complex medical conditions. Therefore, we seek clarification on the effect that this policy change will have on individuals out-of-pocket cost sharing. Further, we ask the Department to clarify what cost sharing will be required for enrollees in CarePlus and to ensure enrollees will not be denied access to services for an inability to pay their monthly premiums or other cost sharing requirements.

Transitioning Coverage & Continuity of Care

Cancer patients undergoing an active course of treatment for a life-threatening health condition need uninterrupted access to the providers and facilities from whom they receive treatment. Disruptions in primary cancer treatment care, as well as longer-term adjuvant therapy, such as hormone therapy, can result in negative health outcomes.

We note that the MassHealth 1115 waiver amendment fails to provide specific provisions to ensure that individuals transitioning from MassHealth to Health Connector or MassHealth CarePlus coverage, beginning January 1, 2019, can continue to see their health care provider if medically necessary. Failure to consider the care delivery and/or treatment regimen of patients, especially those individuals managing a complex, chronic condition like cancer, could have devastating effects on patients, their families, and providers.

---

[8] Hendryx M, Onizuka R, Wilson V, Ahern M. Effects of a Cost-Sharing Policy on Disenrollment from a State Health Insurance Program. *Soc Work Public Health*. 2012; 27(7): 671-86.

[9] Wright BJ, Carlson MJ, Allen H, Holmgren AL, Rustvold DL. Raising Premiums and Other Costs for Oregon Health Plan Enrollees Drove Many to Drop Out. *Health Affairs*. 2010; 29(12):2311-16.

[10] Office of the Assistant Secretary for Planning and Evaluation. Financial Condition and Health Care Burdens of People in Deep Poverty. Published July 16, 2015. Accessed April 21, 2016. http://aspe.hhs.gov/basic-report/financial-condition-and-health-care-burdens-people-deep-poverty.

As the 1115 waiver amendment is finalized, we ask the Department to consider adding additional continuity of care provisions that would minimize disruptions in coverage and care for individuals in active treatment for life-threatening illnesses, such as cancer. We urge the state to establish a clearly defined process through which MassHealth enrollees being transitioned to Connector or CarePlus or their physician can inform the Department that they are in active treatment; allowing them to maintain their cancer care treatment regimen and continue to see their providers through the same health care systems through the end of their treatment. This will ensure that the Department's goal of promoting "integrated, coordinated care" is met.

Non-Emergency Medical Transportation Waiver Request

We appreciate that the Health Connector QHPs and MassHealth CarePlus ABPs are required to cover the Essential Health Benefits, as well as state-mandated benefits. However, we are concerned that Health Connector enrollees and MassHealth CarePlus enrollees would not receive some of the wrap-around services typically required by Medicaid health plans, such as non-emergency medical transportation (NEMT).

ACS CAN is opposed to the Department's request to waive NEMT services for Connector and MassHealth CarePlus enrollees, particularly those childless, non-disabled adult enrollees below 100 percent of the FPL. Waiving NEMT creates barriers to CarePlus and Connector members accessing primary care and preventive services, such as cancer screenings and diagnostic testing services. NEMT is used by individuals to access preventive services and cancer screenings – especially colon cancer screenings and mammograms. Early detection of cancer through preventive services generally results in less expensive treatments and better health outcomes.[11] For example, colorectal and cervical cancer screenings can prevent cancer by detecting and removing pre-cancerous lesions. Community health centers and beneficiary advocates indicate that a lack of access to transportation through the Medicaid program results in patients missing appointments. Therefore, we strongly urge the Department to reconsider their request to waive NEMT to MassHealth CarePlus and Connector enrollees.

Modifying the Premium Assistance Program and Wrap-Around Services for Non-Disabled Adults

ACS CAN is concerned with the proposal to require the mandatory enrollment of non-disabled adults in an employer or student health insurance plan and the proposal to waive wrap-around benefits and cost-sharing protections for these individuals as required by Medicaid. This policy fails to consider the unique health care needs of Massachusetts residents and their families. Compared with MassHealth, commercial coverage – through employer sponsored insurance (ESI) or student health insurance (SHI) – often provides less generous benefits and imposes higher out-of-pocket costs.

We are concerned that the proposal fails to consider the unique health care needs of individuals and their families and could prevent low-income residents – who frequently have greater health care needs relative to other populations – from accessing lifesaving treatments. What is comprehensive for one individual may not be comprehensive for another. For example, not all ESIs or SHIs require coverage of all critical cancer treatments and/or all prescription drugs. By waiving wrap around benefits, the state

[11] American Cancer Society. Cancer Prevention & Early Detection Facts & Figures 2015-2016. 2016 Update. Atlanta: American Cancer Society; 2016.

could inadvertently prevent a cancer patient from receiving a lifesaving treatment or a survivor from receiving the maintenance therapies required to prevent recurrence of their disease.

We ask the Department to provide an appeals process through which individuals with unique medical needs can formally request approval to access specialized services and/or care from providers that do not participate in MassHealth, without being subject to additional cost-sharing. Some individuals with rare conditions – like some cancers – need access to specific specialized services and/or providers, who may not be included in a plan's network. It is critical that patients and their physicians are able to utilize the appeals and grievances process when warranted.

The request to waive the Medicaid cost sharing wrap-around coverage is particularly concerning for individuals with chronic and/or high-cost health care needs, such as cancer patients and survivors. Research from Milliman suggests that out-of-pocket costs for patients on ESI average between $1,000 to $5,000 per year, depending on the insurance coverage, cancer type, year of diagnosis, and time of year diagnosed,[12] compared to the much lower cost sharing requirements under Medicaid. For an adult at 175 percent of FPL who makes approximately $21,000 per year (or $1,759 per month),[13] out-of-pocket expenses at those costs could be unaffordable, as they may be required to pay those costs within the first month or so of their diagnosis. We urge the Department to reconsider the request to waive wrap-around cost sharing coverage for the MassHealth Premium Assistance population, as well as ensure that state residents have access to the appeals and grievances process to prevent denial of services or additional cost sharing requirements if the state chooses to continue forward with this proposal.

Closed Prescription Drug Formulary and Specialty Pharmacy Network

We are concerned with the Department's request to adopt a closed drug formula for MassHealth, as cancer patients are often appropriately prescribed off-label use drugs to treat their disease, a practice that is especially common with rarer cancers like pediatric cancer.[14,15,16] Congress has long recognized the need for off-label use of drugs in oncology.

Closed Formulary

The Department seeks a waiver to impose a closed formulary with at least a single drug per therapeutic class. ACS CAN is concerned that the proposed policy could hinder cancer patients' access to medically necessary prescription drugs.

---

[12] Dieguez G, Ferro C, Pyenson BS. *A multi-year look at the cost burden of cancer care*. Milliman Research Report. Published April 11, 2017. Accessed August 2017. http://www.milliman.com/uploadedFiles/insight/2017/cost-burden-cancer-care.pdf

[13] Office of the Assistant Secretary for Planning and Evaluation. U.S. federal poverty guidelines used to determine financial eligibility for certain federal programs. Published January 31, 2017. Accessed August 2017. https://aspe.hhs.gov/poverty-guidelines.

[14] Krzyzanowka MK. Off-label use of cancer drugs: A benchmark is established. *J Clin Oncol.* 2013; 31(9):1125-7.

[15] Bonifazi M, Rossi M, Moja L, et al. Bevacizumab in clinical practice: Prescribing appropriateness relative to national indications and safety. *Oncologist.* 2012; 17: 117-24.

[16] Conti RM, Bernstein AC, Villaflor VM, et al. Prevalence of off-label use and spending in 2010 among patent-protected chemotherapies in a population-based cohort of medical oncologists. *J Clin Oncol.* 2013; 31: 1134-39.

We note that the waiver cites to the Medicare Part D program as justification for permitting a closed formulary. However, we would suggest that this comparison falls short. The Medicare Part D program covers outpatient prescription drugs and it is not clear from the proposal whether the waiver seeks to impose a closed formulary for all prescription drugs or would only apply to outpatient prescription drugs. In addition, while the Medicare Part D program does allow plan sponsors to create a formulary with at least two drugs per therapeutic class, it also requires sponsors to cover all or substantially all drugs in six classes and categories of prescription drugs including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antitretrovirals, and immunosuppressants (the so-call "protected classes"). In fact, the Medicare Part D manual clearly states that "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[17] It does not appear that similar protections are contemplated under the waiver.

In addition, it should be noted that while Medicare Part D maintains a formulary system, Medicare Part B, which covers physician-administered prescription drugs including many forms of chemotherapy, are not subject to a formulary of any kind. Again, it is unclear from the text of the waiver whether physician-administered drugs would also be subject to the proposed formulary.

Finally, while we are pleased that the waiver states that MassHealth will continue to maintain an exceptions process, we are concerned that the proposal fails to articulate the safeguards needed to ensure that enrollees have access to the prescription drugs they need – including access to an expedited appeals process when warranted. We note that in moving to a closed formulary, as proposed, will likely result in a significant increase in the number of exceptions filed by or on behalf of enrollees and thus should this proposal be implemented as proposed, MassHealth will need to devote additional resources to ensure the process does not hinder enrollees' access to medically necessary drugs.

Evidence of Clinical Efficacy
We are concerned with the Department's assertion that use of FDA-accelerated approval results in less efficacious medicines. Evidence has actually shown the contrary, that drugs accessing expedited review pathways contribute more life-years than those that are reviewed under normal approval pathways.[18] FDA is the world standard for drug approval, and we are extremely concerned that the Department might attempt to create its own reviewing body to recreate FDA's review process rather than recognizing FDA approval decisions.

Implementing Narrower Networks in MassHealth's Primary Care Clinician (PCC) Plan
We are pleased that the draft 1115 waiver seeks to promote the use of primary care services. A significant proportion of cancers are preventable through lifestyle changes and screening.[19] However, the waiver fails to provide sufficient information to determine the extent to which enrollees

---

[17] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5.
[18] Chambers JD, Thorat T, et al., Drugs Cleared Through The FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process. Health Affairs. 2017; 36(8): 1408-1415.
[19] American Cancer Society. Cancer Facts & Figures: 2016. Atlanta: American Cancer Society, 2016.

transitioning from the Primary Care Clinician (PCC) plan to an Accountable Care Organization (ACO) or Managed Care Organization (MCO) will have access to specialized medical services and subspecialists. ACS CAN urges the Department to provide clarification on how it intends to ensure that health plan networks include an adequate number of specialists to ensure that enrollees have access to the specialists necessary to treat their medical condition, especially oncologists, cancer surgeons, and radiologists.

Additionally, as previously mentioned, cancer patients undergoing an active course of treatment for a life-threatening health condition need uninterrupted access to the providers and facilities from whom they receive treatment. Disruptions in cancer treatment care can result in negative health outcomes. Therefore, if the narrower network proposal for the PCC plan is accepted, we urge the Department to establish a clearly defined process through which a MassHealth enrollee can maintain their cancer care treatment regimen and continue to see their providers through the same PCC plan delivery system through the end of their treatment. Failure to consider the care delivery and/or treatment regimens of patients, especially those individuals managing a complex, chronic condition like cancer, could have devastating effects on patients, their families, and providers.

Conclusion

We appreciate the opportunity to provide comments on the MassHealth amendment request. The preservation of eligibility and coverage through MassHealth remains critically important for many low-income Massachusetts residents who depend on the program for cancer prevention, early detection, diagnostic, and treatment services. Upon further consideration of the policies that will be included in the final waiver application, we ask the Department to weigh the impact such policies may have on access to lifesaving health care coverage, particularly for those individuals with cancer, cancer survivors, and those who will be diagnosed with cancer during their lifetime.

Maintaining access to quality, affordable, accessible, and comprehensive health care coverage and services is a matter of life and survivorship for thousands of low-income cancer patients and survivors, and we look forward to working with the Department to ensure that all Massachusetts residents are positioned to win the fight against cancer. If you have any questions, please feel free to contact me at marc.hymovitz@cancer.org or 781-361-9661.

Sincerely,

Marc Hymovitz
Massachusetts Government Relations Director
American Cancer Society Cancer Action Network

National Alliance on Mental Illness
Massachusetts

August 21, 2017

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

Dear Assistant Secretary Tsai:

The National Alliance on Mental Illness of Massachusetts (NAMI Massachusetts) appreciates this opportunity to submit comments on the MassHealth Section 1115 Demonstration Amendment Request. NAMI Massachusetts is the leading grassroots mental health organization providing advocacy, education, support and public awareness in the Commonwealth. We support 21 local affiliates across the state. Our mission is to improve the quality of life for people affected by mental illness and to promote resiliency and recovery.

NAMI Massachusetts applauds the Commonwealth for its commitment to Medicaid expansion. Thanks to this program, thousands of people with mental health conditions have access to comprehensive health and mental health coverage. Access to coverage and care is essential to improve functioning, address extremely challenging symptoms, and stabilize the health of individuals with mental health conditions.

While we appreciate the Commonwealth's commitment to this program, this proposed amendment would make significant changes to the Medicaid expansion program. This will likely result in people with mental health conditions losing health coverage and access to essential care.

Requiring Adults with Incomes Over 100% of the FPL to Enroll in Commercial Plans

NAMI Massachusetts opposes the Commonwealth's proposal to move non-disabled adults ages 21 to 64 into subsidized commercial health plans through Health Connector. This proposal will likely lead to loss of coverage and worsening health outcomes for people with mental health conditions.

Medicaid provides coverage for the array of services that people with mental health conditions need to reach and sustain recovery. Medicaid connects people to lifesaving care and promotes mental health screening, early diagnosis and effective treatment that are essential to producing positive outcomes. Medicaid also covers research-based care that is not otherwise available in most commercial health plans. This coverage helps to keep people with mental health conditions out of hospitals and jails, and off the streets. Nearly one third of the Medicaid expansion population has a mental health or substance use condition and relies on this coverage for treatment and services.[i]

While we recognize that non-disabled adults above 100% of the FPL will have the option to enroll in subsidized coverage through Health Connector, there will be cost increases they will incur. Research shows that copayments and other forms of cost sharing can be barriers to care for low-income populations.[ii] The Commonwealth itself notes that individual expenses in ConnectorCare would be

The National Alliance on Mental Illness of Massachusetts
The Schrafft's Center • 529 Main Street • Suite 1M17 • Boston, MA 02129-1125
P: 617.580.8541 F: 617.580.8673 Toll free: 800.370.9085 E-mail: info@namimass.org W: www.namimass.org

capped at $1,250 per year (or $2,500 per family). Individuals between 100% and 133% of the FPL earn between $12,060 and $16,040, with a family of two earning between $16,240 and $21,599.[iii] As a result, people between 100% and 133% of the FPL (especially those who need regular care for chronic mental health conditions) could expect to spend nearly 10% of their annual income on health care costs alone, with a family of two potentially spending more than 10% of their annual income on health care.

This is a prohibitively high cost that will likely lead to people foregoing needed care. In addition, the transition from Medicaid to ConnectorCare creates high administrative hurdles that can be extremely challenging, especially for people with mental health conditions. These hurdles include selecting the right plan in the marketplace, completing the administrative requirements in signing up for a plan, understanding cost sharing, budgeting for out-of-pocket costs and more. This is likely to dissuade people from enrolling in coverage, leading to additional barriers in accessing care. Disruptions in mental health care create instability for people with mental illness, impede recovery and place unthinkable strain on individuals, families and communities.

In addition, people moved from Medicaid into the ConnectorCare program will likely face higher premiums,[iv] higher co-pays and lose essential benefits such as dental coverage. Comprehensive, integrated care is crucial to keeping people with mental health conditions healthy and stable. ConnectorCare offers stand-alone dental plans, but the additional cost puts services out of reach for people between 100% and 138% of the FPL.

Medicaid expansion was intended to cover people at or below 138% of the FPL. Moving people above 100% of the FPL into commercial plans amounts to a partial Medicaid expansion. Guidance issued by the Centers for Medicare and Medicaid Services (CMS) in December 2012 states that enhanced matching funds are not available for a partial expansion.[v] Section 1115 demonstration waivers are intended to expand coverage to individuals not otherwise eligible for Medicaid, and to test new and innovative practices in Medicaid.[vi] Limiting Medicaid expansion coverage to 100% of the FPL runs contrary to the intent of this waiver by restricting, rather than expanding, Medicaid coverage.

The partial Medicaid expansion proposal would shift state expenditures to the federal government, with the federal government assuming the full cost of covering the population that transition from Medicaid to ConnectorCare through premium tax credits and cost sharing reductions. The U.S. Department of Health and Human Services has made clear that any proposal to implement partial expansion after 2016 would have to maintain the "same level of coverage, affordability and comprehensive coverage at no additional cost to the federal government."[vii] NAMI Massachusetts opposes granting a partial expansion waiver because it sets a dangerous precedent that other states are likely to follow in shifting health care costs to the federal government.

Although this provision in the proposed amendment includes an exemption for people who are deemed "medically frail," seeking an exemption is administratively complex with extensive paperwork, appeals and waiting times. For people with mental health conditions, who often experience significant cognitive difficulties, this process can be overwhelming and especially burdensome. In addition, wait times and appeals often lead to disruptions in care with the likelihood that people with mental health conditions will slip through the cracks and lose Medicaid coverage.

NAMI Massachusetts urges the Commonwealth not to pursue approval of partial Medicaid expansion. Doing so places people with mental health conditions at risk of losing coverage, increases costs and serves as a barrier to people accessing services. Instead, we urge the Commonwealth to continue the existing Medicaid expansion program and provide the array of research-based care people with mental health conditions need to achieve stability, independence and self-sufficiency in their lives.

Requiring People to Enroll in Employer-Sponsored Insurance or Student-Based Health Plans

NAMI Massachusetts opposes the proposed plan to deny Medicaid coverage to individuals with access to employer-sponsored insurance coverage or student-based health plans. This request would create barriers to care for people with mental health conditions.

Medicaid provides access to comprehensive, affordable care, covering the array of services that people with mental health conditions need, and that are often not available in private insurance plans. Well-researched, effective programs and services like Assertive Community Treatment (ACT), case management, supported employment, and coordinated specialty care for early psychosis have been shown to substantially improve outcomes for people with mental illness. It is access to an array of effective services that allows them to reach recovery and return to work, school and life in the community. For this reason, NAMI Massachusetts opposes the Commonwealth's request to require people currently enrolled in Medicaid to enroll in employer-based or student health insurance coverage.

Restrictive Medication Formularies

NAMI Massachusetts opposes the Commonwealth's proposal to adopt a restricted psychiatric medication formulary limited to at least one drug in each therapeutic class. For most people with mental health conditions, medication is a critical component of treatment and promotes stability and recovery.

Medications used to treat mental health conditions are not interchangeable, even in the same therapeutic class. The effectiveness of psychiatric medications is highly individualized and can vary substantially from person to person.[viii] Many psychotropic medications have strong side-effects, and tolerance of these effects is highly individual and variable.[ix] Over time, people often require dosage adjustments, additional medication or a switch to more effective medication.[x] People with mental health conditions and their treating providers should be given the opportunity to work together to determine the most clinically effective, appropriate medication.

Restricting access to psychiatric medications is likely to create negative consequences for individuals with mental health conditions. A study by the American Psychiatric Association found that Medicaid recipients who had difficulty accessing medications were 3.6 times more likely to experience significant adverse events, including emergency room visits, repeat hospitalizations, incarceration and homelessness.[xi]

The Commonwealth's proposal to adopt a restrictive medication formulary threatens to harm people with mental health conditions. Any realized cost-savings achieved up front will be undermined by higher costs incurred through disruptions in care, which may cause people's conditions to worsen. Providing access to effective medications, as prescribed in close consultation with a mental health provider, helps people recover and become self-sufficient. Restricting access to psychiatric medications will ultimately shift costs to expensive hospital and crisis care, homeless services and the criminal justice system.

Eliminating Non-Emergency Medical Transportation

NAMI Massachusetts opposes the Commonwealth's request to waive Non-Emergency Medical Transportation (NEMT) for all non-disabled adults with the exception of transportation to substance use disorder (SUD) treatment. Each year, more than 3.6 million people nationwide delay or miss medical appointments because they lack access to reliable, affordable transportation. Data indicates that people with mental health conditions rely heavily on NEMT to make it to appointments. In fact, information reported by at least one company that provides NEMT services in 32 states showed that the most frequently cited reason for NEMT was transportation to mental health and substance use treatment.[xii]

Waiving NEMT would cause disruptions in care for people with mental health conditions who rely on this vital service to gain access to comprehensive, coordinated care. Although this may be viewed as a cost-saving measure, it will likely shift costs to more intensive and expensive forms of care.

Additionally, a high percentage of people with mental health conditions also experience substance use disorders. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), nearly 7.9 million Americans have co-occurring mental health and substance use conditions.[xiii] It makes little sense for the Commonwealth to provide transportation to SUD treatment without also providing transportation to mental health appointments. NAMI Massachusetts urges the Commonwealth to withdraw its request to waive Non-Emergency Medical Transportation and continue this vital service.

Although this provision includes an exemption for people deemed to be "medically frail," major concerns with the burdensome administrative process to meet that standard (referenced above) also apply to NEMT. People with mental health conditions and co-occurring substance use disorders will likely face major challenges in meeting the administrative requirements, potentially falling through the cracks and losing access to this vital service.

NAMI Massachusetts appreciates this opportunity to provide comments on the MassHealth Section 1115 Demonstration Amendment Request. We look forward to working with your office to ensure that people with mental illness get the care they need to lead full and productive lives.

Sincerely,

Karen Gromis
Interim Executive Director

cc: Secretary Marylou Sudders, Executive Office of Health and Human Services

---

[i] Mir M. Ali et al., Substance Abuse and Mental Health Services Administration, State Participation in the Medicaid Expansion Provision of the Affordable Care Act: Implications for Uninsured Individuals with a Behavioral Health Condition, https://www.samhsa.gov/data/sites/default/files/report_2073/ShortReport-2073.html (November 18, 2015).

[ii] Samantha Artiga et al., *The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings*, Kaiser Family Foundation (June 1, 2017), http://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/.

[iii] Families USA, 2017 Federal Poverty Guidelines, http://familiesusa.org/product/federal-poverty-guidelines.

[iv] It appears that ConnectorCare Type 2A will offer only one plan with a $0 premium in 2018. Unlike Medicaid, ConnectorCare is under no legal obligation to offer $0 premium plans.

[v] Centers for Medicare & Medicaid Services, *Frequently Asked Questions on Exchanges, Market Reforms and Medicaid* (December 10, 2012), https://www.medicaid.gov/federal-policy-guidance/downloads/FAQ-12-10-2012-Exchanges.pdf

[vi] Center for Medicare and Medicaid Services, About 1115 Waivers, https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html.

[vii] CMS envisioned that any successful partial expansion proposal must require a 1332/1115 waiver that considers projected federal costs and coverage estimates for Medicaid and the Marketplace together. CMS, Medicaid/CHIP Affordable Care Act Frequently Asked Questions: Exchanges, Market Reforms, and Medicaid, 11 (Dec. 2012).

[viii] Haiden A. Huskamp, *Managing Psychotropic Drug Costs: Will Formularies Work?*, 22 Health Affairs 84-96 (2003), http://content.healthaffairs.org/content/22/5/84.full.pdf.

[ix] Chris Koyanagi et al., *Medicaid Policies To Contain Psychiatric Drug Costs*, 24 Health Affairs 536-544 (2005), http://content.healthaffairs.org/content/24/2/536.full.pdf.

[x] Ibid.

[xi] Joyce C. West et al., Medicaid Prescription Drug Policies and Medication Access and Continuity: Findings From Ten States, 60 Psychiatric Services 601-610 (2015), http://ps.psychiatryonline.org/doi/full/10.1176/ps.2009.60.5.601.

[xii] MaryBeth Musumeci & Robin Rudowitz, *Medicaid Non-Emergency Medical Transportation: Overview and Key Issues in Medicaid Expansion Waivers*, Kaiser Family Foundation (Feb. 24, 2016), http://www.kff.org/medicaid/issue-brief/medicaid-non-emergency-medical-transportation-overview-and-key-issues-in-medicaid-expansion-waivers/.

[xiii] U.S. Department of Health and Human Services, *Substance Abuse and Mental Health Services Administration, Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health,*

Konefal, Kaela (EHS)

From: Robert Fallon <fallonrp@gmail.com>
Sent: Saturday, August 19, 2017 9:52 PM
To: Konefal, Kaela (EHS)
Subject: Comment on proposed shift of non-disabled adults with incomes over 100% FPL to the the Health Connector

This proposed shift is unwise for a number of reasons. The primary reason is what impact this shift would have on non-subsidized members in the merged market. Non-subsidized members will face an increased premium that may overwhelm the savings due to the differences in federal match. The non-disabled adults will likely have a significantly higher risk score than current members. This will result in a increase in the state-wide average risk score and higher premiums for all members. The Commonwealth's staff do not appear to have quantified this amount. Not only could the impact of these premiums overwhelm the state savings, it would shift the burden in inconsistent and unfair ways. Instead of the costs being born by taxpayers through income and sales taxes, the burden of increase premiums will fall on individual and small group insured members. Large group and self insured consumers would avoid these increased costs.

Second, the overall costs to taxpayers would increase because of the higher payments to providers. Massachusetts taxpayers are also Federal taxpayers. While the Massachusetts budget will improve, the overall cost to taxpayers will increase. Focusing only on the Massachusetts budget is myopic.

Third, with the potential uncertainties of this Federal administration of support of the ACA marketplaces, in particular the CSR payments, now is not the time to shift more persons to the merged market. Your analysis of costs if the CSR payments are too simplistic. It is based on the assumption that the end of a CSR would result in a 20% increase in premium. Your analysis does not include any cost to non subsidized members. Even the 20% assumption appears to be an arbitrary guess. Many analyses suggest that that level increase would occur under current participation in the market place. If the Medicaid population was added to it, the premium increase could be much higher.

DBSA

Depression and Bipolar
Support Alliance

August 21, 2017

The Honorable Daniel Tsai
Assistant Secretary for MassHealth
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place
Boston, Massachusetts 02108

Dear Mr. Tsai:

On behalf of the thousands of MassHealth beneficiaries receiving psychiatric services, the Depression and Bipolar Support Alliance (DBSA) welcomes the opportunity to provide comment on the MassHealth Section 1115 Demonstration Amendment Request.

The state of Massachusetts has been at the forefront of healthcare reform ensuring access to care for all of its citizens and should be commended. We write today however, to express concern about the proposed MassHealth Section 1115 Demonstration Amendment Request that will restrict clinicians' ability to work with individuals they treat and support their best paths forward to wellness.

DBSA is the leading national organization focusing on mood disorders: depression and bipolar disorder. The organization was founded over thirty years ago and has for its entire existence been led by people with lived experience of mood disorders. Today, DBSA reaches three million people, including free, in-person peer support provided to 54,000 individuals who attend the nearly 600 support group meetings led by our nationwide network of 250 chapters. This network includes seven chapters in Massachusetts.

The proposed demonstration amendment request would remove access to many of the antidepressants and antipsychotics used to treat serious mental health conditions. This policy would severely restrict both physicians' prescribing ability and patients' treatment options. As the leading peer-directed organization for individuals living with mood disorders—the most prevalent mental health conditions—DBSA has grave concerns as outlined below.

1. The proposed changes would severely limit access to medications that are commonly used to treat mental health conditions and create serious challenges for people who have these mental health disorders. When it comes to the treatment of mental health conditions, the clinical management of real world patients often involves "trial and error." Treating mental health conditions is not like treating pneumonia, where an oral antibiotic medicine is started and (in almost all instances) the illness goes away and the medication is stopped several weeks later. In contrast, the treatment of mental health conditions is almost always "trial and error," and in many instances requires long-term treatment. In fact, the available published evidence suggests that only 25 percent to 33 percent of people who have a mental disorder experience a complete clinical response to the first two to three medications, even when prescribed in the presence of ongoing psychotherapy. Not allowing patients to be treated with access to all FDA-approved treatments for their condition is both cruel as well as costly.

2. Comorbidity—medical conditions that exist simultaneously while independent from another condition—is common for people living with mood disorders. Individuals living with mood disorders are more likely to have life-threatening co-occurring conditions, such as heart disease, hypertension, and diabetes, for example. Those most vulnerable to cost related non-adherence are people living with four or more chronic conditions.

55 E. Jackson Boulevard, Suite 490 • Chicago, IL 60604 USA
(312) 642-0049 • Toll-free (800) 826-3632 • Fax (312) 642-7243 • DBSAlliance.org

Depression and Bipolar
Support Alliance

These comorbid conditions are a huge factor in why individuals with mental health conditions die, on average, 25 years younger than those without mental health conditions.

Given the proposed built-in plan burdens to medication compliance, this demonstration amendment request has the potential to:

- Raise the overall healthcare spend for MassHealth,
- Decrease positive healthcare outcomes, and
- Reduce the quality of life for MassHealth beneficiaries

DBSA thanks you for allowing us to provide comment on the MassHealth Section 1115 Demonstration Amendment Request. We look forward to working with your office to ensure that individuals living with mood disorders achieve true wellness and whole health and that the state of Massachusetts retains its excellent reputation as the model for successful healthcare reform.

Respectfully,

Phyllis Foxworth
Advocacy Vice President
Depression and Bipolar Support Alliance
pfoxworth@dbsalliance.org
312.988.1165

MASSACHUSETTS DENTAL SOCIETY

Two Willow Street
Southborough, MA 01745-1027
800.342.8747 • Fax: 508.480.0002
massdental.org

August 21, 2017

Marylou Sudders, Secretary
Executive Office of Health and Human Services
Commonwealth of Massachusetts
One Ashburton Place, 11th Floor
Boston, MA 02108

RE: Comments for Demonstration Amendment: MassHealth Section 1115 Demonstration

The Massachusetts Dental Society (MDS) applauds the Governor and the Executive Office of Health and Human Services (EOHHS) for considering several policy proposals aimed at stabilizing the Medicaid system in the Commonwealth. The MDS represents approximately 80% of dentists in Massachusetts. Additionally, the MDS and its member dentists are committed to supporting proven policies aimed at improving access to oral health care for all residents of the Commonwealth. Of particular interest to the MDS is the major proposal impacting oral health care for patients—transitioning 140,000 MassHealth adult non-disabled members into Connector Plans.

The MDS recognizes that changes must be made in order to ensure that the Medicaid system in our state remains fiscally solvent. As proposed, 140,000 current MassHealth, non-disabled adults who earn 100% of the federal poverty level would be moved to Connector Plans. Overall health coverage for these individuals would only change in one significant way: they would lose access to MassHealth adult dental benefits. Further, these residents would now be required to opt-in for dental benefits through the Connector at a cost of approximately $29 per month or $348 per year. For individuals earning $12,060 annually, $348 will be difficult to afford. Due to the insurance cost associated with this change, the MDS is concerned that individuals will be forced to entirely bypass oral health care, which may lead to future costlier health complications down the line.

Research shows, time and time again, that dental care for low-income populations is disproportionately influenced by geography, income, language or cultural barriers, lower levels of oral health education, and even fear of dental care. These 140,000 individuals may already face many of the listed barriers to oral health care. Adding costs, which do not exist now, will be a significant factor in discouraging low income residents from accessing and utilizing necessary services. We should not aim to increase the barriers they face in accessing health care, but work to eliminate these obstacles. The MDS opposes any initiative that will effectively lead to low-income residents losing access to affordable dental care.

As a way to bypass this additional cost, it has been suggested that these 140,000 residents could seek free care at community health centers. Unfortunately, this is not a viable option for this number of people. Community health centers are neither available everywhere in the state nor do all locations offer dental services. Furthermore, many health centers have long oral health waiting lists. Community health centers serve a significant public need, but they are just not able to accommodate such a drastic increase in patient volume.

Apart from the increased barriers to care created by this change, the transition process has not been clearly defined. If this proposal succeeds, it is unclear what would happen to patients currently undergoing treatment under the existing MassHealth program. Without clear processes to handle very real situations for these residents, it is not prudent for the state to move forward with this proposal.

The MDS respectfully urges lawmakers to reject any proposal that will cause residents to lose affordable dental care. We ask the legislature to only evaluate proposals that would allow these residents to maintain their current coverage.

Sincerely,

David P. Lustbader, DMD
President
Massachusetts Dental Society

Otsuka

Otsuka-people creating new products for better health worldwide

August 21, 2017

Secretary Marylou Sudders, Health and Human Services
Dan Tsai, Assistant Secretary for MassHealth
One Ashburton Place, 11th Floor
Boston, MA 02018

Dear Secretary Sudders and Assistant Secretary Tsai,

This letter is in response to the MassHealth 1115 Waiver Demonstration Amendment Request issued on July 20, 2017. We appreciate the opportunity to submit comments on behalf of our behavioral health patient constituency in regards to a proposal that will indisputably create significant challenges to their journey towards recovery.

Otsuka America Pharmaceutical, Inc. (OAPI) is much more than a pharmaceutical company delivering a diverse portfolio of first in class medications in neuroscience, oncology, and cardio-renal. OAPI is a healthcare solutions company committed to better health worldwide and to creating new and innovative ways to tackle the issues that patients face daily within our healthcare system. From class leading pharmaceutical compounds and medical devices to digital medicine, OAPI is forging ahead on behalf of patients in search of greater wellness for all. In particular, OAPI has been dedicated to the research and development of therapies and solutions for diseases of the central nervous system. People suffering from serious mental illnesses (SMI) can experience unique challenges ranging from discrimination to entanglements with the criminal justice system, and we are committed to being a partner in developing solutions to address these issues. A critical component of patients' journey toward recovery from SMI is access to the most effective medications available. Recognizing and understanding the biological heterogeneity of these disorders, in addition to addressing the obstacles patients face with medication adherence, are essential for recovery. We believe that the ability to manage these components of mental illness disorders will be sacrificed under a closed formulary such as the one proposed by the Baker administration in the MassHealth 1115 Waiver Amendment.

The MassHealth program is the largest payer of behavioral health services in the state of Massachusetts. In the Waiver Amendment, the Baker administration requests the kind of flexibility that Medicare and commercial plans have in utilizing closed formularies. A notable difference here is that the Medicaid program covers a significantly higher percentage of people with behavioral health disorders than Medicare and commercial plans. People with any signs of mental illness comprise 17-19% of the MassHealth population, and more serious conditions are reported for 4-5% of the population (Health, 2014). These patients are arguably among the sickest and the most vulnerable in the state. For this reason, it is imperative that Medicaid recipients have access to all behavioral health medications available on the market. The heterogeneity of these disorders demands full prescriber deference to guarantee the best medication therapy choice for each individual suffering from an SMI. While antidepressants and antipsychotics may have similar effectiveness overall, they generally do not show

Otsuka America Pharmaceutical, Inc.
2440 Research Boulevard • Rockville, Maryland 20850 • Phone: 301-990-0030 • www.otsuka-us.com

similar effectiveness from patient to patient. In many cases, doctors also have to prescribe based on the side effect profile determined by the individual needs of the patient.

Medication adherence is another pervasive challenge in the treatment of patients with SMI. There are a number of reasons for these challenges, including both patient and environmental factors, but often the issue is medication-related. Many patients experience a lack of efficacy or distressing side effects which cause them to stop taking their medications. Doctors need to be able to work with their patient to find the most appropriate and effective medical treatment. Adherence-related problems in the behavioral health population translate into a huge economic burden on the system overall due to relapses, re-hospitalizations, and recidivism. A closed formulary is antithetical to best practices for the behavioral health population.

Massachusetts has a record of providing some of the best mental health care in the country. To implement a first-in-the-nation closed formulary for MassHealth would be to take huge steps backward. Additionally, any costs savings associated with this kind of change to the formulary would quickly be negated by the costs incurred to the system due to relapse and re-hospitalizations. OAPI's products add value to the healthcare system and value to many patients' lives. On behalf of our patient constituency, we strongly urge you to consider other cost-saving alternatives to the MassHealth system that are patient-centric and do not negate all of the positive work that the state has done to improve the lives of those suffering from mental illnesses.

Thank you,

8/17/2017

x Donna Erwin

Donna Erwin

Senior Director, State Government Affairs

Signed by: donna.erwin@otsuka-us.com

ORAL HEALTH ADVOCACY TASKFORCE

August 21, 2017

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

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

RE: MassHealth 1115 Demonstration Waiver Amendments

Dear Assistant Secretary Tsai,

On behalf of the Oral Health Advocacy Taskforce (OHAT), we would like to bring to your attention our concerns regarding proposed amendments to the MassHealth 1115 demonstration waiver. Created in 2002 in response to state budget cuts to MassHealth adult dental services, OHAT is a broad-based statewide coalition of consumers, advocates, health care professionals, academics, and insurers. We also work closely with the nation's first Legislative Caucus on Oral Health, chaired by Representative John Scibak and Senator Harriett Chandler, to help Massachusetts continue to be a leader in oral health equity and awareness.

We understand that there are significant financial challenges currently facing the Commonwealth and we share your commitment to developing a MassHealth program that is sustainable over the long term. We also appreciate your vision of maintaining the gains that Massachusetts has made in expanding access to affordable health coverage for all residents. Unfortunately, however, the proposed amendments to the MassHealth 1115 waiver will *decrease* access to affordable coverage (including dental coverage) for thousands of our most vulnerable and underserved populations.

Under the waiver amendments, MassHealth proposes to transition approximately 140,000 non-disabled adults with incomes between 100% - 133% FPL from MassHealth to the ConnectorCare program beginning on January 1, 2019. In doing so, 100,000 non-disabled parents/caregivers and 40,000 non-disabled childless adults will effectively lose the dental benefits that they currently receive as MassHealth enrollees. During this transition, there is no way to ensure that continuity of oral health care will be provided to the impacted individuals and families and that access to affordable dental services will be available. The reality is that most of these individuals will be unable to afford the expensive stand-alone, unsubsidized dental plans currently available on the Health Connector and will likely forgo treatment for their oral health needs.

Unfortunately, we already know that previous cuts to MassHealth adult dental benefits has resulted in a significant decrease in access to effective oral health care, causing needless pain, suffering, and illness. Additionally, poor oral health makes it difficult for people to manage chronic conditions such as diabetes and heart disease and to find and maintain employment in Massachusetts' service-based economy.

Cuts to dental services also waste millions of dollars in extensive and costly services in emergency and inpatient hospital settings and place an added burden on MassHealth and the Health Safety Net. In its report from last August, the Health Policy Commission found that MassHealth members disproportionately use the Emergency Department (ED) for preventable oral health conditions at a cost 4-7 times that of a community-based dental office visit. Non-elderly adults on MassHealth also use the ED for preventable oral health conditions 7 times more frequently than commercially-insured adults. Compounding these statistics is the fact that hospital EDs are ill-equipped to provide comprehensive dental care and most patients only receive antibiotics and pain medication, thereby leaving the underlying dental condition untreated. This is particularly concerning at a time when we are grappling with the ongoing opioid crisis that is impacting all corners of the Commonwealth.

We understand the need to have a sustainable MassHealth program, however, this should not come at the expense of oral health coverage. Therefore, on behalf of OHAT and the residents of Massachusetts, please do not include amendments to the MassHealth 1115 demonstration wavier that reduce MassHealth eligibility and force us to reverse the gains we have made to improve the state of oral health in the Commonwealth, particularly for our most vulnerable populations.

Going forward, we would like to explore proposals with you that may reduce the harms that these proposed amendments will cause, such as providing affordable access to dental care within ConnectorCare for low-income members. We would also like to discuss the opportunities to better integrate dental services within the MassHealth program to improve patient care coordination and health outcomes as well as to produce systems-level cost savings.

Thank you for your time and consideration of our concerns. If you have questions or would like more information, please contact Dr. Neetu Singh, Oral Health Project Manager, at 617-275-2801 or nsingh@hcfama.org.

Sincerely,

Neetu Singh on behalf of
The Oral Health Advocacy Taskforce (OHAT)

ORAL HEALTH OHAT ADVOCACY TASKFORCE

Cc: Marylou Sudders, Secretary, Executive Office of Health & Human Services
Robin Callahan, Deputy Director, MassHealth

EndHepCMA Coalition
c/o Richard Baker, Coalition Coordinator
Victory Programs, Inc.
29 Stanhope Street, Boston, MA 02116

August 21, 2017

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

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

Re: Comments for Demonstration Amendment

Dear Assistant Secretary Tsai,

On behalf of the End Hep C MA Coalition, we are grateful for the opportunity to provide comments on the MassHealth 1115 Demonstration Waiver Amendment Request posted on July 20, 2017. The End Hep C MA Coalition is a collection of consumers, advocates, organizations, and services providers committed to the achievable goal of ending Hepatitis C (HCV) in Massachusetts. We are fortunate to have strong partners at the Massachusetts Executive Office of Health and Human Services (EOHHS) who share this goal.

We have made remarkable medical progress in recent years with the development of new, highly effective cures for HCV with little to no side effects. These breakthrough therapies present us with an unprecedented opportunity to actively engage people living with HCV, reduce new transmissions, and eliminate the virus from our population. Massachusetts has engaged in outstanding efforts to provide unfettered access to these cures. MassHealth now provides perhaps the most open access to HCV treatments across all state Medicaid programs.

We share your commitment to a sustainable MassHealth program and to maintaining the gains Massachusetts has made not only in the fight to end HCV, but also in providing access to affordable health coverage for low-income residents in the Commonwealth. However, we are concerned that many of the proposals included in the 1115 Demonstration Waiver Amendment Request would decrease both the access to and affordability of the cure to HCV for low-income individuals. These policies are particularly concerning from a public health perspective, as they have the potential to deter those with limited means from getting treated, thus increasing the

likelihood that new transmissions of HCV may occur and undercutting the significant progress Massachusetts has made in addressing the burden of this serious chronic and communicable disease.

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

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

Under this proposal, many individuals living with HCV would be transitioned into the private insurance market through the ConnectorCare program. These individuals would see their out-of-pocket cost-sharing obligations increase dramatically, including cost-sharing for curative HCV treatments that can prevent further transmission of the virus.[1] For example, MassHealth members currently pay a maximum copayment of $3.65 to fill each prescription of their medications.[2] However, once transitioned to the ConnectorCare program, individuals with incomes between 100-133% FPL would instead pay $40 each time they fill a prescription for their lifesaving HCV medications.[3]

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

Financial barriers to obtaining care and treatment. Research has consistently demonstrated that imposing even minimal levels of cost-sharing on low-income populations serves as a barrier to obtaining and maintaining care and treatment.[4] Lower-income individuals are more likely to reduce their use of even essential services in the face of increased financial burdens, leading to a rise in the use of other costlier services such as emergency room visits.[5] Increasing the financial burden associated with accessing HCV treatments may therefore deter some low-income

---

[1] *FAQs about Sustained Virologic Response to Treatment for Hepatitis C*, U.S. DEPARTMENT OF VETERANS AFFAIRS, VETERANS HEALTH ADMINISTRATION, https://www.hepatitis.va.gov/pdf/sustained-virological-response.pdf.
[2] *See Covered Services*, MASS. EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVS., http://www.mass.gov/eohhs/consumer/insurance/masshealth-member-info/covered-services.html.
[3] *ConnectorCare Health Plans*, MASS HEALTH CONNECTOR, https://www.mahealthconnector.org/wp-content/uploads/Guide_to_ConnectorCare.pdf.
[4] *See* Samantha Artiga, Petry Ubri, and Julia Zur, *The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings,* KAISER FAMILY FOUNDATION, http://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/.
[5] *Id.*

tel: 617.927.0836 x188 | email: rbaker@vpi.org
www.vpi.org

individuals from seeking or continuing treatment, or force these individuals to choose between filling their prescriptions and paying for other household necessities such as food, housing, and childcare. While MassHealth members may not be refused care or services due to nonpayment, enrollees in commercial health insurance plans offered through the ConnectorCare program do not share this protection, further adding to the likelihood that these individuals will be unable to access their medications due to financial hardship.[6]

Undermine efforts to end HCV in the Commonwealth. This proposal will reverse the progress Massachusetts has made towards ensuring that its low-income citizens have true and equitable access to the cure for HCV. The Massachusetts Office of Medicaid recently mandated that all enrollees participating in MassHealth via the fee-for-service program, primary care clinician plan, or a managed care organization (MCO) be provided with the same treatment policy for HCV: open access without the imposition of restrictions related to disease severity, substance use abstinence, or prescriber specialty.[7] In adopting this policy, MassHealth eliminated the potential for arbitrary or discriminatory restrictions and created a uniform system in which low-income individuals have equal access to necessary HCV treatment.

In contrast, health plans offered through the ConnectorCare program do not appear to share this uniform open access policy. As a result, each participating insurer may manage their prescription drug benefits as they see fit, and, in particular, limit which drugs are covered and impose far more restrictive coverage rules for HCV medications than currently allowable in MassHealth. For example, Fallon Health, one insurer currently offering ConnectorCare plans, restricts access for Harvoni, one of the direct-acting antiviral medications used to cure HCV, to only those patients who have advanced liver disease and mandates that individuals must be abstinent from drug and alcohol use for 12 months prior to initiating treatment.[8] Transitioning individuals above 100% FPL to ConnectorCare plans that impose these types of utilization management restrictions will limit access to HCV care, undermining the progress made under MassHealth's open access policy. Once again, these individuals will be at the mercy of private insurers and have to navigate each insurer's treatment policy and drug coverage rather than relying on MassHealth's open access standard.

Negative public health consequences. This proposal will negatively impact the public health of the Commonwealth. When faced with greater cost-sharing and restrictive utilization management requirements, many individuals may be unable to realistically access the cure for HCV. As a result, this proposal has the potential to increase new transmissions of the virus.

---

[6] 42 U.S.C. 1396o(c); *See Copayments Frequently Asked Questions*, MASS. EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVS., http://www.mass.gov/eohhs/provider/insurance/masshealth/claims/customer-services/copayments-faqs.html.

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

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

Treatment and cure of HCV is a highly-effective prevention method: once an individual achieves virologic cure, they can no longer transmit HCV to others through any means.[9] If fewer individuals are able to become cured of HCV due to the issues outlined above, more transmissions will occur, eroding the progress we have made to date towards eradicating the virus in Massachusetts.

Uncertain federal financial support. This proposal may negatively impact both the state and individuals involved because it depends upon a program that is currently at significant financial risk. In order to maintain affordable coverage, many of the individuals being transitioned off of MassHealth will need to choose ConnectorCare plans. However, the ConnectorCare program is partially funded with revenues from the Affordable Care Act's (ACA) cost-sharing reduction (CSR) subsidies and advance premium tax credits.[10] Currently, the Affordable Care Act's future is being debated in Congress, and the current Administration, regardless of efforts to repeal and replace the ACA, has consistently refused to commit to continued funding for the CSR program. Given the substantial uncertainty facing not only the CSR program but also the ACA as a whole, the future of the ConnectorCare program seems far from certain. Therefore, shifting a significant number of MassHealth enrollees into the ConnectorCare program could ultimately place either the state or individual enrollees at financial risk should federal funding end.

Select Preferred and Covered Drugs Through a Closed Formulary

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

This proposal is particularly concerning for continued access to HCV medications. Physicians choose which drugs to prescribe their patients based on a wide range of factors, including co-

---

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

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

occurring illnesses, medical history, and previous treatment tolerance.[11] It is important to note that drug regimens are not always interchangeable. HCV is a complex disease and treatment options must take into account several individualized medical factors as well as concerns regarding a patient's medication adherence. Before initiating treatment, physicians must consider drug interactions, coexisting conditions, and side effect profiles. Therefore, it is important that doctors are able to provide treatment based on patients' needs, not on availability in MassHealth.

Implementing an exceptions process to a closed formulary through which an individual can attempt to access coverage for a drug not on the formulary would also fall far short of ensuring that people living with HCV and their providers can access the appropriate treatment regimen. This is true because of the uncompensated cost to providers of going through the exceptions process, because this coverage is not guaranteed, and because the process of obtaining this coverage is often opaque.[12] Given these concerns, we urge MassHealth to consider alternative strategies to lower prescription drug spending that will not adversely impact beneficiaries' access to medically necessary medications.

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

We are concerned that the proposal to limit the choice of pharmacy to specialty pharmacies for members receiving care through the fee-for-service and the primary care clinician (PCC) plan may have the unintended effect of imposing unnecessary barriers to obtaining lifesaving specialty medications. While specialty pharmacies can provide care coordination benefits to those that prefer them, they often present physical access problems for those experiencing homelessness and people in transient living situations. This is especially true where no brick-and-mortar locations are readily accessible and members are forced to receive their medications in the mail. These individuals in particular may not be able to receive medications consistently in the mail, creating gaps in treatment and increasing the likelihood that members will not be able to adhere to their treatment regimens.[13] 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 HCV.

Provider and community health workers' experiences with MassHealth MCOs utilizing specialty pharmacies to dispense HCV medications demonstrates how mail order dispensing is inappropriate for members with unstable living situations. While patients may designate

---

[11] *See generally 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/.

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

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

providers 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. Further, individuals are often told by specialty pharmacies that their medication will not be dispensed until payment information is provided, or that a refill will not be provided unless any pending balance has been paid. This presents a significant barrier, especially for enrollees that do not have access to funds other than limited cash resources that they rely on for other needs.

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

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

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

Additionally, many of the concerns applicable to the ConnectorCare program are echoed in the context of employer-sponsored insurance. As compared to MassHealth, employer-sponsored insurance may provide far less robust coverage HCV medications, restrict access to treatment through burdensome utilization management techniques, and impose significantly greater cost-sharing. These barriers may prevent individuals from getting treated, increasing the likelihood that new transmissions will occur. For all of these reasons, we urge MassHealth to remove the employer-sponsored insurance and student health insurance "gate" from its 1115 Waiver Amendment Request.

The End Hep C MA Coalition thanks you for this opportunity to provide comments on this MassHealth 1115 Demonstration Amendment Request. For the reasons we have identified, we urge you to reconsider the policies we have outline above and they will negatively impact access to care for individual living with HCV, and will ultimately undermine our ability to end the epidemic in Massachusetts. We would be happy to work with you to address any questions about the concerns we have outline here if that would be useful, and thank your office's continue commitment to improving the health of the Commonwealth.

Thank you for your time and consideration.

Sincerely,

The End Hep C MA Coalition

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

tel. 617.927.0836 x188 | email: rbaker@vpi.org
www.vpi.org

August 18, 2017

Kaela Konefal
EOHHS, Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108

Re: Comments for Demonstration Amendment

Dear Ms. Konefal,

I am submitting these comments on behalf of Universal Health Services ("UHS") in response to the Commonwealth Submission of a Request to Amend the MassHealth Section 1115 Demonstration (the "Request"), posted for public comment on July 20, 2017. UHS operates the largest private behavioral health system in Massachusetts. Our facilities include Arbour-HRI Hospital in Brookline, Arbour Counseling Services in Rockland, Arbour Hospital in Boston, Arbour Senior Care in Rockland, Arbour-Fuller Hospital in South Attleboro, Pembroke Hospital in Pembroke, and Westwood Lodge in Westwood.

We applaud the Commonwealth's effort to remove "all restrictions on payments to Institutions for Mental Disease (IMDs) for individuals ages 21 to 64." As the Request correctly points out, these restrictions are barriers to fully addressing the opioid epidemic, as "the majority of available inpatient detox services and psychiatric treatment are provided in freestanding psychiatric hospitals, many of which are IMDs." It is also true that current restrictions on payments to IMDs "act as a barrier to MassHealth's ability to provide the most appropriate, least restrictive and most cost effective care for members with significant behavioral health needs." Removing the 15-day limit in CMS' 2016 managed care rule, as the Request proposes, will contribute to utilizing "all available provider capacity" to ensure that MassHealth members are able to access treatment when they need.

We respectfully suggest, however, that serving the twin goals of addressing the opioid crisis and providing the most appropriate, least restrictive, and most cost effective care will require more than lifting restrictions on payments to IMDs, and so request also that the Commonwealth ask CMS to exclude IMDs from the Uncompensated Care Cost Limit Protocol ("Cost Limit Protocol") approved by CMS for addition to the Section 1115 Demonstration on December 17, 2013.

Prior to the renewal of the Section 1115 Demonstration effective July 1, 2014 (the "July 2014 Waiver"), IMDs were not subject to the Cost Limit Protocol, and payments to IMDs were not limited to those for uncompensated costs. After the July 2014 Waiver, payments by MassHealth to IMDs became limited "on a provider-specific basis to the cost of providing Medicaid state plan services and any other additional allowable uncompensated costs of care provided to Medicaid-eligible individuals and uninsured individuals, less payments received by or on behalf of such individuals for such services."

The Commonwealth, however, did not require IMDs to file Uncompensated Care Cost and Charge Reports ("UCCRs") pursuant to the Cost Limit Protocol until summer 2016. Accordingly, the Cost Limit Protocol did not inform rate negotiations for MassHealth members with MassHealth MCOs and with the Massachusetts Behavioral Health Partnership ("MBHP") for 2014, 2015 and 2016. Particularly, providers did not assume that the Cost Limit Protocol could significantly reduce revenues to IMDs and, in some circumstances, trigger repayment obligations to MassHealth. The expansion of IMD capacity since 2014 has proceeded on the same assumptions. Though a significant issue for 2014-2016 (as such repayment obligations, if any, have already been incurred), the financial limitations of the Cost Limit Protocol will continue to affect negotiations with MBHP and the MassHealth MCOs for treatment of MassHealth members going forward.

As the July 2014 Waiver notes, the Cost Limit Protocol was based upon "[t]he DSH audit rule definition of allowable inpatient and outpatient services and allowable uninsured costs and revenues." CMS wrote the DSH audit rule to assist in making "Medicaid payment adjustments for hospitals that serve a disproportionate share of low-income patients with special needs," as a supplement to base payments under Medicaid. 73 Fed. Reg. 77904, Medicaid Program; Disproportionate Share Hospital Payments Final Rule, Centers for Medicare & Medicaid Services, Dec. 19, 2008. Application of the same definitions to the Cost Limit Protocol, however, can result in a provider losing not only a supplemental payment, but some or all base payments as well.

Thus, continuing to subject IMDs to the Cost Limit Protocol is not in the interest of MassHealth members, particularly as the opioid epidemic has strained the Commonwealth's capacity to treat patients suffering from substance use disorders. IMDs keep such patients out of acute hospital emergency rooms, and provide many patients the "most appropriate, least restrictive and most cost effective care" available – over 200 MassHealth members on any given day.

The Commonwealth has long recognized the essential role that IMDs play in providing mental health care to the most vulnerable, and so has continually attempted to provide avenues for reimbursement to IMDs through successive Section 1115 Demonstrations. We urge the Commonwealth to ask CMS to exclude IMDs from the Cost Limit Protocol and continue to support the critical work that IMDs do every day.

Thank you for your consideration. We would welcome the opportunity to answer any questions you may have or discuss this matter further at your convenience.

Sincerely,

Dania O'Connor

Dania O'Connor
Group Director, Arbour Health System, Massachusetts
Universal Health Services

cc: Gary Gilbert, Senior Vice President, Universal Health Services

BOSTON PUBLIC HEALTH COMMISSION

Building a Healthy Boston

August 21, 2017

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

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

Re: Request for Comments to Amend the MassHealth 1115 Demonstration

Dear Assistant Secretary Tsai,

On behalf of the Boston Public Health Commission (BPHC), thank you for the opportunity to offer our comments on the proposed MassHealth 1115 Demonstration Amendment. The BPHC is the country's oldest health department, and is an independent public agency providing a wide range of health services and programs. Public service and access to quality health care are the cornerstones of our mission – to protect, preserve, and promote the health and well-being of all Boston residents, particularly those who are most vulnerable. We share your commitment to a sustainable MassHealth program and we understand the pressures of maintaining such a program. We are concerned that some of the proposed changes will have adverse effects on the populations we serve and will ultimately decrease access to affordable coverage and care for low-income consumers.

The proposed changes to the MassHealth 1115 Demonstration would lower MassHealth eligibility from 133% to 100% of the poverty level for non-disabled adults. This represents a major change in the income eligibility level, which has been 133% of poverty since 1997. Additionally, the Affordable Care Act set the income level for other adults at 133% of poverty in 2014. That means 140,000 people (100,000 parents and 40,000 childless adults) would lose eligibility for MassHealth. Many of those losing MassHealth may qualify for ConnectorCare, but its coverage provides fewer benefits and has co-pays that are almost five times higher than MassHealth. ConnectorCare offers good coverage for uninsured adults with income up to three times the poverty level but it is not nearly as good as MassHealth for the poor and near poor.

Furthermore, some MassHealth members will not qualify for ConnectorCare because of differences in eligibility rules in the two programs. Some MassHealth members will not be able to successfully enroll in ConnectorCare because of more complicated eligibility and enrollment rules in ConnectorCare and the deadlines for enrolling. For adults who do qualify and do successfully enroll in ConnectorCare, they will have much higher copayments than MassHealth,

fewer benefits and fewer affordable plan choices. For example, for medical maximum out of pocket expenses only, an individual would go from significantly reduced out of pocket expenses to being responsible for paying $750 out of pocket. A family would all of a sudden be responsible for paying $1500 out of pocket. The copay for a visit to a specialist would go from $0 to $18 a visit.

The Boston Public Health Commission works to ensure that all residents have an opportunity to access services and programs that promote health and wellness. To support the general health needs of residents of Boston, the Mayor's Health Line, a free, confidential, and multilingual information and referral service, offers advice about a variety of healthcare-related issues, including answering questions about health insurance eligibility, getting health insurance coverage, finding primary care providers, connecting to social services, locating free clinics, and more. Through this service, we interact with individuals and families with very limited resources and many very challenging issues. For a patient with complex health issues that require many visits, the increased cost of the Connector will be significant. The imposition of new copays, even at limited cost, and "administrative barriers" can wall off access even if people are still technically covered with insurance. For the poor and near poor in a state with a high cost of living like Massachusetts, only nominal copayments of MassHealth are affordable. Few of those losing MassHealth would have access to any commercial insurance, much less truly affordable insurance. Key benefits like dental would no longer be included in coverage. MassHealth proposes to define "affordable" to include monthly premiums, deductibles and other cost sharing that would not be truly affordable for those struggling.

Another major concern is the possibility that people will lose dental benefits and thereby lose access to oral health care. There is no way to ensure that continuity of oral health care will be provided to the impacted individuals and families and that access to affordable dental services will be available. The reality is that most of these individuals are be unable to afford the expensive stand-alone, unsubsidized dental plans currently available on the Connector and would likely forgo treatment for their oral health needs. The administration has said that people moved off MassHealth and onto commercial plans through the Connector will be able to purchase dental coverage for $29 a month but that may be unattainable for residents who are unable to afford that extra cost. Though theHealth Safety Net (HSN) will serve as a wrap around for dental services for some, community health centers serve as the primary providers of care to those eligible for HSN. There are not enough HSN dental providers to meet the increase in the number of people who will only have HSN dental as coverage. There is already a high demand to be seen by dental providers; further limiting access for patients would be detrimental. Unfortunately, the lack of comprehensive adult dental coverage leads to pain, tooth loss and preventable high-cost emergency department usage, to name a few. Oral health is critical for overall health. Routine attention to oral health can help prevent or improve many chronic conditions such as asthma, cancer, heart disease, diabetes, arthritis, stroke, kidney disease, high blood pressure and depression. Residents must have appropriate health care resources in order to preserve or improve their health. In order to eliminate chronic disease and health inequities, residents must have access to affordable care.

Thank you for your time and attention to these important matters of public health and health care access. The Boston Public Health Commission will continue to ensure that all residents have an opportunity to access services and programs that promote health and wellness. If you have any questions regarding these comments, please contact Heather Gasper, Director of Intergovernmental Relations at 617-534-2288 or by email at hgasper@bphc.org.

Sincerely,

Monica Valdes Lupi, JD, MPH

Dan Casserly
US Country Head
Government Affairs

Novartis Services, Inc.
701 Pennsylvania Ave., NW
Washington, DC 20004
Tel (202) 662-4361
Fax (202) 628-4764
E-Mail: dan.casserly@novartis.com
www.novartis.com

NOVARTIS

August 21, 2017

Electronic Submission

Kaela Konefal
EOHHS Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108
Kaela.Konefal@state.ma.us

Dear Ms. Konefal:

Novartis Services, Inc. strongly objects to Massachusetts's proposed MassHealth Section 1115 Demonstration Amendment Request ("Proposed Waiver"), which the Massachusetts Office of Medicaid posted for public comment on July 20, 2017. We submit the following comments regarding our concerns with the Proposed Waiver on behalf of Novartis Pharmaceuticals Corporation ("NPC"), Sandoz Inc. ("Sandoz") and Alcon Laboratories, Inc. ("Alcon"). We refer to NPC, Sandoz, and Alcon collectively herein as "Novartis." NPC researches, develops, manufactures, and markets innovative medicines aimed at improving patients' lives. NPC offers a broad range of medicines for cancer, cardiovascular disease, inflammatory disease, infectious disease, neurological disease, eye disease, organ transplantation, respiratory disease, and skin conditions. Sandoz is a leader in generic pharmaceuticals and biosimilars, providing access to a broad portfolio of high-quality, affordable prescription drugs. Sandoz launched the first biosimilar approved under the new Biologics Price Competition and Innovation Act pathway in the United States. Alcon is a leader in the research, development, manufacturing, and marketing of eye care products, including surgical devices and vision care products.

Novartis makes significant contributions to the economy of the Commonwealth. In 2016 alone, Novartis's estimated economic contributions to the Commonwealth totaled $904.5 million. As one example of our contributions to the local economy, Novartis's Institute of Biomedical Research carries out cutting-edge pharmaceutical research at eight locations across the globe, but is headquartered in Cambridge, Massachusetts. Novartis also plays a key role as a large employer in the state. As of December 31, 2016, Novartis had approximately 2,500 employees working in the Commonwealth. These employees have helped Novartis make vital contributions to Massachusetts' health sector.

Novartis also provides substantial support to residents of the Commonwealth. Last year, we provided $10.6 million in medications free of cost to patients with financial hardships who have limited or no prescription drug coverage. Additionally, we paid approximately $20 million in rebates to the Commonwealth's Medicaid program. Novartis's support to Commonwealth

residents and the local economy reflect the company's broader commitment to developing life-saving therapies and bringing those therapies to market to improve the well-being of patients in the Commonwealth and beyond.

Novartis expresses its support for the Proposed Waiver comments submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Innovation Organization ("BIO"). We write separately to share additional concerns about the potential consequences of the Proposed Waiver for patients in the Commonwealth. In the remainder of this comment letter, we share the following concerns:

- The Proposed Waiver is inconsistent with the bargain that Congress struck in enacting the Medicaid Drug Rebate Program.
- The Proposed Waiver excludes safeguards that Congress has affirmed as essential.
- The Proposed Waiver fails to satisfy the requirements for a Section 1115 Demonstration Program.

The Proposed Waiver is Inconsistent with the Bargain Underlying the Medicaid Drug Rebate Program.

First, the Proposed Waiver is inconsistent with the bargain struck by Congress in enacting the Medicaid Drug Rebate Program (Social Security Act ("SSA") § 1927). SSA § 1927 reflects a carefully-designed bargain between manufacturers and states. Under the federal statute, manufacturers provide generous rebates to state Medicaid programs in exchange for those programs' coverage of their covered outpatient drugs. SSA § 1927 has been amended over the years since the statute's 1990 enactment; yet, that fundamental bargain has endured. Over the past several decades, SSA § 1927 has helped provide Medicaid beneficiaries with access to critical therapies and has helped ensure that states receive substantial rebates on the price of those therapies.

The Proposed Waiver would introduce an unprecedented and inappropriate departure from this long-standing bargain. In simple terms, the Commonwealth is proposing to waive one side of the long-standing legal agreement between manufacturers and states. The Commonwealth proposes to waive the state's obligation to cover all covered outpatient drugs of a manufacturer that has entered into a rebate agreement with the Secretary of the U.S. Department of Health and Human Services, but it would still expect manufacturers to pay rebates in connection with the state Medicaid program's utilization of its drugs. This proposal is fundamentally inconsistent with the Congressional intent underlying SSA § 1927, and, as such, should not be pursued.

The Proposed Waiver Fails to Include Congressionally-Designed and -Mandated Safeguards.

Second, the proposed demonstration fails to include essential safeguards that Congress incorporated into SSA § 1927 and has since affirmed. In the plain text of SSA § 1927, Congress narrowly (and exhaustively) outlines the manners in which states may limit access to covered outpatient drugs. For instance, Congress has created an avenue through which states can limit

their coverage of covered outpatient drugs by creating a formulary.[1] Yet, Congress requires that the formulary have various safeguards for those in our health care safety net, including: i) a drug may only be excluded from a formulary on the basis of a clinical determination based on the drug's label, ii) the state must provide a written explanation of its decision to exclude a drug in such a manner, and iii) the state must still make such a drug available through a prior authorization process.[2]

Specifically, federal law establishes that a formulary must meet the following requirements:

> (A) The formulary [must be] developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State . . .
> (B) Except as provided in subparagraph (C), the formulary [must] include[ ] the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a)...
> (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) *only if*, based on the drug's labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.
> (D) The State plan permits coverage of a drug excluded from the formulary ... pursuant to a prior authorization program.[3]

As the Secretary of HHS has reinforced, states may not limit coverage of drugs in a formulary in a manner that ignores these key safeguards.[4]

The Proposed Waiver would disregard these safeguards. The Commonwealth has proposed to introduce a "closed formulary" that is not, in fact, a formulary as that term is recognized under SSA § 1927(d)(4). The "closed formulary" would restrict coverage in manners that are not permissible under federal law. For example, it would neither limit clinical determinations regarding a drug's therapeutic advantage to determinations based on a review of the drug's label, nor make available to the public a written explanation of the state's decision to exclude a particular drug from the formulary. Instead, the Commonwealth has proposed a "closed formulary" that radically departs from the federal requirements for formularies and from the

---

[1] *See* SSA § 1927(d)(4).
[2] *See id.*
[3] *Id.* (emphasis added).

state's historic approach to covering drugs for Medicaid beneficiaries. Under the proposal, the Commonwealth would exclude from the formulary drugs with "limited or inadequate evidence of clinical efficacy" – a term that is defined as being satisfied when one or more of the following conditions exist:

1) Primary endpoints in clinical trials have not been achieved;
2) Only surrogate endpoints have been reported;
3) Clinical benefits have not been assessed;
4) FDA-approval is contingent upon verification of clinical benefit in confirmatory trials; and/or
5) The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives.

The Commonwealth has failed to meaningfully describe how it would determine which drugs have "limited or inadequate evidence of clinical efficacy" for purposes of excluding those drugs from the "closed formulary." Novartis has significant concerns that the state will use the broad latitude afforded by such language to limit access to essential therapies and, in doing so, will not provide key stakeholders such as patients with meaningful transparency regarding how it is evaluating (and ultimately excluding from coverage) various drugs.

The proposed criteria for concluding that there is "limited or inadequate evidence of clinical efficacy" is flawed. A particular therapy may have a reported surrogate endpoint, rather than a clinical outcome, because it would be too challenging or inappropriate to measure a real clinical outcome for that therapy. For instance, a surrogate endpoint of bone mineral density might be utilized, rather than the clinical outcome of hip fractures, because requiring the clinical outcome would require an unreasonably large clinical trial given the relatively low incidence of hip fracture. In such instances, the Commonwealth should not exclude coverage of therapies merely because only surrogate endpoints have been reported. Further, the Commonwealth has not clarified how it would evaluate "existing alternative" drugs that are being used as comparators. Additionally, the proposed review process, in partnership with the University of Massachusetts, appears to lack essential safeguards that are in place with respect to formularies authorized under SSA § 1927(d)(4).

Notably, under the proposed review criterion, Massachusetts would exclude from coverage various therapies that have been approved by the FDA. The Commonwealth would thereby substitute its judgment regarding whether products meet certain clinical efficacy criteria over the judgments of the key regulatory agency tasked with making such determinations – the FDA. Indeed, a decision by the FDA to approve a drug based on surrogate endpoints, or contingent on

---

[4] *See, e.g.*, 60 Fed. Reg. 48442, 48454 (Sept. 19, 1995) (commenting that "it is necessary to prevent states from using a prior authorization program as a proxy for a closed formulary" other than as provided in SSA § 1927(d)(4)).

confirmatory trials, does not reflect a judgment by the agency that the drug has "limited or inadequate evidence of clinical efficacy;" it is improper for the Commonwealth to make such a judgment when the federal agency with legal authority to make such determinations has not done so. And the proposal subverts the U.S. Food and Drug Administration's ("FDA's") policy priority of accelerating patient access to innovative therapies. FDA has set forth an accelerated approval pathway in order to expedite the process for the agency's approval of drugs for patients with an unmet need; the Commonwealth would undermine this important policy objective under its Proposed Waiver.

On the whole, the Proposed Waiver threatens to deprive patients of appropriate therapies that they would likely have had access to in the absence of the waiver proposal. There are instances when a single drug in a therapeutic class is inappropriate for a particular patient, whereas another (potentially non-covered) drug would better meet the patient's medical needs. As just one example, providers may try multiple anti-psychotic therapies before finding an appropriate one for a particular patient. The Commonwealth's proposal would undermine such patients' access to the particular therapy that is best-suited for their needs. The Proposed Waiver would also undercut efforts to advance personalized medicine that provides patients with the therapy that responds to their unique medical needs and biological make-up. Under the Proposed Waiver, Medicaid beneficiaries may be functionally deprived of advances in personalized medicine, while other non-Medicaid beneficiaries in the Commonwealth would benefit from such innovations. Indeed, the proposed "closed formulary" threatens to exclude the state's most vulnerable residents from innovative therapies, which may afford better health outcomes and fewer side effects. Medicaid beneficiaries, unlike persons with greater financial means, are not afforded an opportunity to shop for alternative coverage when a drug is not available through the Medicaid program. As such, the Proposed Waiver threatens to create a brand of second-class health care – one that would widen the divide between the "haves" and "have nots" in the Commonwealth.

We note that should the Commonwealth wish to limit coverage of covered outpatient drugs, it can do so by establishing a "formulary" that comports with § 1927(d)(4)'s requirements, including the safeguards that Congress has affirmed as essential. To date, the Commonwealth has not tried to design coverage policies consistent with this federally created "roadmap." Novartis urges the Commonwealth to avail itself of such opportunities that already exist under federal law and abandon a Proposed Waiver that would deprive Medicaid beneficiaries' access to innovative therapies.

The Proposed Waiver Fails to Satisfy the Federal Criteria for a Section 1115 Waiver.

Finally, the proposed demonstration program fails to satisfy foundational requirements of demonstration projects under SSA § 1115. Under federal law, a demonstration program must be

"likely to assist in promoting the objectives of [the Medicaid program]"[5] – i.e., it must assist in providing support to low-income individuals who, in the absence of the Medicaid program, may lack coverage for health services. The "closed formulary" runs counter to this requirement. It would not assist these individuals in accessing health services. Rather, it would unquestionably lead to narrower drug coverage and, for many patients, could deprive them of appropriate therapies that they would have had access to in the absence of the Proposed Waiver. As mentioned, the "closed formulary" also lacks essential safeguards that Congress created to protect Medicaid beneficiaries' access to covered outpatient drugs.

The Proposed Waiver also arguably fails to set forth a true "experimental, pilot, or demonstration project" – another federal requirement for Section 1115 waivers. At least one court has affirmed that, in reviewing a proposed demonstration project, the "Secretary must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money but has no research or experimental goal, would not satisfy this requirement." *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994). The proposed demonstration would institute such a "simple benefits cut," without serving a research or experimental goal. Accordingly, it fails to meet an essential requirement of SSA § 1115.

* * * * *

We respectfully urge the Commonwealth to reexamine opportunities to design a true formulary under SSA § 1927(d)(4) and, in so doing, maintain essential patient safeguards. The Proposed Waiver poses a great risk to the well-being of Medicaid beneficiaries in the Commonwealth. It would mark a serious departure from the principles undergirding SSA § 1927, and from the Commonwealth's long-standing policy of ensuring Medicaid beneficiaries' access to essential therapies. As such, we strongly object to the Proposed Waiver.

We welcome any opportunity for further dialogue with the Commonwealth regarding these issues. To discuss these topics further, please contact Leigh Anne Leas, Vice President and US Country Head, Health Policy at 862-778-3284.

Thank you for your consideration.

Sincerely,

Dan Casterlik

cc: Leigh Anne Leas

---

[5] SSA § 1115(a).

MENTAL HEALTH FIRST AID
NATIONAL COUNCIL
FOR BEHAVIORAL HEALTH
Healthy Minds. Strong Communities.

Don Miskowiec, MBA, Board Chair
Linda Rosenberg, MSW, President and CEO

August 18, 2017

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

RE: MassHealth Section 1115 Demonstration Amendment Request

Dear Assistant Secretary Tsai,

I am writing today on behalf of the National Council for Behavioral Health (National Council) to express our strong opposition to the Commonwealth's proposal to adopt a closed formulary with only one drug available per therapeutic class.

The National Council for Behavioral Health is a national, non-profit association of over 2,900 behavioral health provider organizations. Our members serve over 10 million adults, children and families with mental health and addiction disorders. A clear majority of their clients depend on Medicaid for their mental health care.

The State argues that closed formularies are frequently used in both the commercial and Medicare Part D marketplace. However, while the Medicare Part D program generally limits access to only two medications per category, the program exempts six categories of clinical concern, known as the "protected classes": these medications are vital to the treatment of: (1) epilepsy; (2) mental illness; (3) cancer; (4) HIV-AIDS; and (5) organ transplants. For these protected classes, Part D plans must make available all, or substantially all drugs. We urge the Commonwealth to take a similar approach in its design of the formulary under the 1115 waiver, especially for medications related to the treatment of mental illness.

Restricting access to medications may have serious unintended consequences to both individuals' health and to overall healthcare costs. Without appropriate access to the most effective and well-tolerated medications, persons with mental illness may experience instability—and at a high personal and fiscal cost: increased risk of hospitalization and emergency room visits, loss of employment, homelessness, and, too frequently, incarceration.

An August 2016 study from researchers at Northwestern University's Kellogg School of Management and the University of Texas at Austin highlights how "profit-maximizing" Part D plans are incentivized to limit benefits or increase certain costs for which Part D plans are not responsible under Medicare (e.g., hospitalizations).[1] As detailed in the study, Part D plans are explicitly encouraged to reduce drug spending without bearing financial responsibility for the holistic health of the patient. The authors conclude that in covering drugs less generously, Part D plans end up costing traditional Medicare $475 million per year.[2]

---

[1] Starc, A., and Town, R.J. (August 2016). *Externalities and Benefit Design in Health Insurance*. Available at: https://kelley.iu.edu/BEPP/documents/starc_town_fall2016.pdf.
[2] *Ibid.*

Communications@TheNationalCouncil.org
202.684.7457
1400 K St. NW, Suite 400, Washington, DC 20005
www.TheNationalCouncil.org

The study reinforces the importance of Medicare's six protected classes in limiting future medical complications, hospitalizations, and additional costs to the Medicare program.

Further, a March 2016 literature review conducted by Avalere Health suggests little evidence exists to show that limiting formulary access leads to meaningful cost savings.[3] The authors observed that while formulary restrictions often led to lower drug spending, they were accompanied by increases to inpatient and outpatient medical care that outweighed savings achieved on prescription drugs.[4] They also found evidence to suggest that formulary restrictions led to increased rates of non-adherence, especially among older beneficiaries.[5] The authors further noted that studies indicate patients who were less adherent or who switched their therapies had higher hospitalization rates with longer stays.

Mental health medications play an important role in recovery for many individuals who live with mental illness and addiction. While psychiatric medications may have similar effectiveness overall, they are unique in their mechanisms of action and affect each person and a range of symptoms differently. Since effectiveness and side effects vary significantly, finding the most helpful medications and doses can take multiple trials and should be based on clinical judgment and informed consumer choice. According to the National Institute of Mental Health, individuals have unique responses to psychiatric medications and need more, not fewer, choices.[6]

People with serious mental illness, especially those who depend on Medicaid, need access to qualified professionals and a full range of medications to make recovery possible. By restricting low-income patients' access to psychiatric medications, preferred drug lists can limit recovery.

We oppose the creation of a closed formulary with only one drug per class because such a design would prevent doctors from making medication decisions based on medical necessity and medical history. The health of people with serious mental illness depends on access to a broader array of medication options. We urge you to make this important change.

Sincerely,

Linda Rosenberg

Linda Rosenberg, MSW
President and CEO
National Council for Behavioral Health

---

[3] Avalere Health (March 2016), *Impact of Formulary Restrictions on Adherence, Utilization, and Costs of Care*.
[4] *Ibid.*
[5] *Ibid.*
[6] National Institutes of Health, National Institute of Mental Health, *NIMH Perspective on Antipsychotic Reimbursement: Using Results From The CATIE Cost Effectiveness Study*, December 2006.

AIDS Action Committee of Massachusetts, Inc.
75 Amory Street
Boston, MA 02119

Our mission: To stop the epidemic and related health inequities by eliminating new infections, maximizing healthier outcomes for those infected and at risk, and tackling the root causes of HIV/AIDS.

August 21, 2017

Kaela Konefal
EOHHS Office of Medicaid
One Ashburton Place
11th Floor
Boston, MA 02108
RE: Comments for Demonstration Amendment

To the members of the Massachusetts Executive Office of Health and Human Services:

AIDS Action Committee of Massachusetts (AAC) would like to submit public comment in opposition to the Request to Amend the MassHealth Section 1115 Demonstration to the Centers for Medicare and Medicaid Services (CMS).

AIDS Action Committee strives to improve the health of LGBT people and people living with HIV/AIDS (PLWH). Founded in 1983, AIDS Action Committee (AAC) is New England's largest AIDS service organization. Our mission at AAC is to stop the epidemic and related health inequities by eliminating new infections, maximizing healthier outcomes for those infected and at risk, and tackling the root causes of HIV/AIDS. AAC has advocated for fair and effective AIDS policies, cutting edge HIV prevention programs, and comprehensive health and wellness services for PLWH for three decades, and we serve thousands of clients who come through our door every year.

Massachusetts currently leads the nation in our HIV care and prevention, in large part because of MassHealth policies. Our expansion of access to HIV medications has meant our population has achieved a 67% viral suppression rate, significantly higher than the national average. And because those that are virally suppressed are un-infectious to others, we have seen a nearly 50% decrease in new infections since we expanded MassHealth eligibility for those living with HIV in 2001. That remarkable progress was recently published as a model for the country, specifically citing our MassHealth access as critical to our success.[1] The reduction in new infections has not only saved lives, it has saved the state an estimated $1.8 billion in avoided lifetime HIV treatment costs. Our success to date has even allowed us to envision our ultimate goal, which is getting to zero new infections, death, and HIV-related stigma[2]. Last year we laid out a blueprint

[1] Cranston et al. 2017. "Sustained Reduction in HIV Diagnosis in Massachusetts, 2000-2014." *American Journal of Public Health*. Vol. 107, No. 5.

[2] www.gettingtozeroma.org

on how to achieve those goals. That ability depends on continued unfettered access to HIV care through MassHealth.

We are concerned that some of the proposed policies to reform MassHealth included in the Section 1115 waiver request will decrease access to crucial services for PLWH, which in turn will lead to negative health outcomes. In particular, we are concerned about policies that would establish a closed drug formulary under MassHealth and create restrictions on which pharmacies patients can utilize.

First, creating a closed drug formulary under MassHealth would decrease access to high quality treatment for many PLWH. Currently, MassHealth covers all drugs from manufacturers that participate in the federal Medicaid rebate program. The closed formulary would restrict the drugs that MassHealth covers. This is especially concerning for PLWH. The current system allows providers to choose the best medication for each patient based on individual experiences with side effects and resistance profiles. Each individual HIV patient may react in unique ways to antiretroviral medications, and a patient and provider may change medications several times in order to find the ideal treatment regimen. A complicating factor is polypharmacy and drug-drug interactions. Many PLWH have comorbidities and take multiple medications. This is especially true of PLWH age 50 and older, who comprise more than half of PLWH in Massachusetts.

It is difficult to see how a formulary could take into account the complex HIV treatment guidelines. According to federal "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents," a nearly 300 page document published by the U.S. Dept. of Health & Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents, there are no fewer than six medication combinations recommended for patients who are first initiating treatment, and an additional table of options for patients based on other complications and comorbidities[3]. There are separate guidelines for patients who have already had experience with HIV treatment but who may have developed various levels of resistance, and other subpopulations that have particular considerations. These guidelines were revised twice in 2016 alone.

Additionally, one medication, Truvada, is now FDA-approved for pre-exposure prophylaxis (PrEP) as a preventative medication for HIV-uninfected individuals. More medications are also coming down the research pipeline. Some insurance companies in other states have mistakenly denied claims for Truvada as PrEP because they were for HIV-uninfected individuals. Truvada was listed only as a treatment medication for those already infected, when in fact it is approved for both purposes. Any HIV-related formulary would need to take this into account.

The closed formulary would remove the flexibility that allows providers and patients to find the right regimen of antiretroviral medications, which in turn could lead to lower rates of adherence from patients who are forced to accept treatment regimens that are not best suited to their needs. We are also concerned that the closed formulary might restrict access to single tablet regimens for HIV treatment in favor of multi-tablet regimens, or restrict which single tablet regimens are accessible. Studies have shown that single tablet regimens improve adherence by lowering pill

[3] https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/37/whats-new-in-the-guidelines-

burden and increase the likeliness of achieving viral suppression compared to multi-tablet regimens.[4]

Second, creating restrictions on which pharmacies MassHealth patients can utilize would also decrease access to crucial services for PLWH. These restrictions could deny PLWH access to their pharmacies of choice, where they feel comfortable and know they will receive high quality and non-discriminatory care, and instead force them to use alternative pharmacies. Many of our clients, for example, utilize the pharmacies at Fenway Health and the Walgreens specialty pharmacies that specialize in HIV care because they are known to be competent, non-discriminatory, and have familiarity with dealing with the state's HIV Drug Assistance Program (HDAP). Furthermore, if MassHealth chooses to restrict to specialty mail-order pharmacies, this could create confidentiality issues for PLWH who may not want HIV medication sent to their homes because of the stigma associated with having HIV.

Ultimately, these policies to reform MassHealth would have negative consequences for PLWH by decreasing their access to care. Limiting coverage for medications and restricting access to pharmacies could create additional barriers to medication adherence, which is essential for treating HIV and preventing its transmission. This would undermine the all the efforts currently underway in Massachusetts to reduce new HIV infections and improve health outcomes for PLWH. **For these reasons we are opposed to applying formulary or pharmacy restrictions for this population, and would seek to exclude HIV from these changes, as has been proposed for other changes being considered in the waiver.**

Sincerely,

Carl Sciortino
Executive Director

[4] Clay P, Nag S, Graham C, Narayanan S. 2015. "Meta-Analysis of Studies Comparing Single and Multi-Tablet Fixed Dose Combination HIV Treatment Regimens." *Medicine*. (Baltimore) 94(42): e1677.

August 21, 2017

By electronic delivery: kaela.konefal@state.ma.us

Mary Lou Sudders
Secretary of the Massachusetts Department of Health and Human Services
Executive Office of Health and Human Services (EOHHS)
One Ashburton Place
11th Floor
Boston, MA 02108

Via: Kaela Konefal, EOHHS Office of Medicaid

Re: MassHealth 1115 Demonstration Amendment Request

Dear Secretary Sudders,

Thank you for the opportunity to share AstraZeneca's perspective on the MassHealth Section 1115 Demonstration Amendment Request. We appreciate EOHHS's thoughtful approach as it considers how to deliver cost-effective care to MassHealth patients and we commend EOHHS for inviting diverse stakeholders to share their perspectives.

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory and oncology diseases. We are one of only a handful of companies to span the entire life-cycle of a medicine from research and development to manufacturing and supply, and the global commercialization of primary care and specialty care medicines.

AstraZeneca employs over 500 people in Massachusetts concentrated in our research and development facility ("BioHub") located in Waltham. We operate in more than 100 countries and our innovative medicines are used by millions of patients in the Commonwealth and worldwide.

While we understand and appreciate the Commonwealth's desire for increased flexibility in managing the MassHealth program, we share the concerns expressed by our trade association, PhRMA, that the approach outlined in the demonstration amendment request will have a significant negative impact on patient access to needed medicines. Specifically, we believe that the proposal to waive the permissible coverage restriction requirements for outpatient drugs through the adoption of a commercial-style formulary will inappropriately and unduly limit patient and provider access and choice to needed medicines. Additionally, we are concerned that the demonstration amendment request's provision to exclude drugs from the MassHealth formulary with limited or inadequate evidence of clinical efficacy would undermine the Food and Drug Administration's (FDA's) efforts to allow patients accelerated access to novel, breakthrough therapies when certain requirements are met.

I. Impact of a Closed Formulary on Patient Access

The implementation of a closed drug formulary that could make only one drug per therapeutic class available to a vulnerable patient population could significantly restrict access to innovative therapies for many patients in the Commonwealth. While AstraZeneca is not unfamiliar with the practice of Medicaid supplemental rebate negotiations, the MassHealth proposal would severely limit drug options for patients and providers beyond what current law permits. As outlined in PhRMA's comment letter, states can already negotiate with manufacturers to secure preferred treatment on their Medicaid formularies and

have several options for managing utilization, giving states significant leverage vis a vis manufacturers. Unfortunately, Massachusetts's proposal does not include the many patient protections that the current construct affords. We urge you to consider existing areas of flexibility in managing MassHealth's prescription drug benefit before adopting a closed formulary with its consequent impact on patient access and choice.

II. Patient Access to New Drugs Addressing Unmet Need

Also of great concern to AstraZeneca is your intent to exclude drugs from the MassHealth formulary with "limited or inadequate evidence of clinical efficacy." Per the Commonwealth, drugs which have been reviewed and approved by the FDA via the accelerated approval pathway have not fully proven their efficacy in clinical trials. Many drugs successfully gain approval in the US via this pathway and do so with the scientific rigor needed to ensure safety and efficacy for patients. Restricting these novel therapies that treat serious conditions goes against the original intent of the FDA which is to accelerate patient access to these medicines to treat significant unmet medical need and we urge you to reconsider this proposal.

III. Conclusion

As a company that works to develop life-saving medicines for patients around the world, we contend that the MassHealth proposals could place extremely restrictive barriers to drug access for many of your Medicaid patients. We therefore urge you to reconsider these proposals and explore ways across the MassHealth program- not only the prescription drug benefit- to deliver care in a more efficient and cost-effective manner.

Thank you again for this opportunity to share our perspective on the MassHealth Section 1115 Demonstration Amendment Request. We would be happy to answer specific questions that you have about our position in this matter.

Sincerely,

Richard Buckley
Vice President, Global Corporate Affairs
Member, Massachusetts Health Policy Commission Advisory Council

cc:

Chairman Jeffrey Sanchez, House Committee on Ways and Means

Chairwoman Karen Spilka, Senate Committee on Ways and Means

Chairman James T. Welch, Joint Committee on Health Care Financing

Chairman Peter V. Kocot, Joint Committee on Health Care Financing

MLRI MASSACHUSETTS LAW REFORM INSTITUTE

40 COURT STREET
SUITE 800
BOSTON, MA 02108

617-357-0700 PHONE
617-357-0777 FAX
WWW.MLRI.ORG

August 21, 2017

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

By email to kaela.konefal@state.ma.us

Re: Comments for Demonstration Amendment

Dear Assistant Secretary Tsai,

These comments are submitted by the Massachusetts Law Reform Institute on behalf of our low income clients who rely on MassHealth for access to medical care. Unlike most major amendments to the 1115 waiver, the changes proposed on July 20, 2017 will primarily restrict eligibility and services and shift costs to members and for this reason we strongly oppose such changes. We understand the financial challenges facing the MassHealth program, however many of these proposals, such as the ESI "gate" and the transfer of parents and caretaker relatives to MassHealth CarePlus from MassHealth Standard will not produce significant savings. For still other proposals, such as the reduction in the MassHealth wrap, there appear to be no savings estimates. Instead, for many proposals the rationale is "alignment with commercial insurance" with no evidence showing why such alignment is worthwhile. Where there is room for savings such as by leveraging employer contributions for the costs of coverage through premium assistance, or negotiating supplemental pharmacy rebates, the agency has not made the case that it needs the sweeping waiver of basic Medicaid protections that it seeks. The proposal as a whole does not meet the criteria for an 1115 waiver, and we urge EOHHS to rethink it.

I. Aligning coverage for non-disabled adults with commercial plans does not promote the objectives of the Medicaid Act

Section 1115 demonstrations are premised on "promoting the objectives" of the Medicaid Act.[1] The objectives of Medicaid are to enable states to furnish medical assistance to low-income individuals who cannot afford the costs of medically necessary services and to furnish rehabilitation and other services to help such individuals attain or retain capability for independence or self-care.[2] Increasing out of pocket costs and decreasing the scope of benefits for low income individuals to better align their coverage with commercial insurance does not promote the objectives of Medicaid. Medicaid exists to compensate for the limitations of

[1] 42 U.S.C.§ 1315a
[2] 42 U.S.C. § 1396-1.

commercial insurance for low income individuals not to replicate those limitations. Reducing MassHealth eligibility and services will also reduce state spending. However, courts have ruled that saving dollars cannot be the basis for a demonstration.[3]

A. Medicaid beneficiaries are not similarly situated to individuals who are commercially insured

The rationale for many of the proposals in the 1115 waiver is to align the coverage of current Medicaid beneficiaries with commercial insurance. Commercial insurance coverage differs from Medicaid coverage in many ways including charging higher premiums and cost sharing, covering fewer benefits, providing fewer consumer protections and paying providers more. The 1115 proposal seeks to align coverage of current Medicaid beneficiaries with commercial insurance by either disqualifying those with potential access to commercial insurance from MassHealth or providing MassHealth beneficiaries with fewer benefits, fewer provider choices and increased out of pocket costs.

EOHHS's premise is that non-disabled adults on MassHealth are similarly situated to commercially insured adults. But this is simply not true. First and foremost, non-disabled adults under 133% of the poverty level are much poorer than commercially insured adults. 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.[4]

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. Many of the unique features of Medicaid, such as affordability protections and the assurance of transportation, 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.[5] Similarly, research shows transportation is a greater access barrier for low income Medicaid beneficiaries than for the commercially insured. [6]

---

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

[4] American Community Survey, 1-year estimate

[5] 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/

[6] 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

Further, poverty and health are inter-related. "A significant body of literature has demonstrated that Medicaid beneficiaries are distinct from those covered by ESI…on a host of demographic, socioeconomic, and health status dimensions."[7] Compared to privately insured adults, Medicaid beneficiaries have more health limitations, higher prevalence of chronic conditions, non-chronic conditions, mental illness or substance abuse, and other conditions such as asthma, diabetes, heart disease, hypertension, back conditions, bronchitis/respiratory conditions, and gastrointestinal conditions.[8]

Even among adults who do not meet the Social Security definition of disability, Medicaid beneficiaries have complex and chronic care needs. A recent study by the Kaiser Family Foundation found that 35% of adult Medicaid enrollees who were *not* receiving disability benefits and did not have a job reported illness or disability as their primary reason for not working.[9] Further, individuals for whom alcoholism or addiction is a contributing factor to a determination of disability are not considered disabled under rules applicable to Social Security Disability, SSI and MassHealth's Disability Determination Unit.[10]

Medicaid is far better designed than commercial insurance to meet the health needs of the poor. For example, among non-elderly adults with mental illness, those with Medicaid are more likely than those with private insurance to receive treatment.[11]

Low income, even among workers, is linked with other differences compared to higher income workers. Low income workers under 250% FPL are more likely to be young, people of color, and female and to have lower levels of educational attainment compared to higher-income workers.[12] These differences are more pronounced for workers living below poverty. Further, a larger share of low-income workers are members of families with dependent children than higher income workers, and are far more likely to be single parents compared to higher income workers.[13]

---

[7] Coughlin, Teresa A., Sharon K. Long, Lisa Clemans-Cope and Dean Resnick, What Difference Does Medicaid Make? Assessing Cost Effectiveness, Access, and Financial Protection under Medicaid for Low-Income Adults, May 2013 , Kaiser Family Foundation, http://www.kff.org/medicaid/issue-brief/what-difference-does-medicaid-make-assessing-cost-effectiveness-access-and-financial-protection-under-medicaid-for-low-income-adults/

[8] Op. cit.

[9] Garfield, Rachel, Robin Rudowitz and Anthony Damico, Understanding the Intersection of Medicaid and Work, February 2017, Issue Brief (Kaiser Family Foundation) Figure 4. http://www.kff.org/medicaid/issue-brief/understanding-the-intersection-of-medicaid-and-work/

[10] Social Security Administration, Program Operations Manual, Section DI 90070.050 Adjudicating a Claim Involving Drug Addiction or Alcoholism (DAA) ("We do not consider a claimant disabled if drug addiction or alcoholism (DAA) is a contributing factor material to the determination that the claimant is disabled)." https://secure.ssa.gov/poms.nsf/lnx/0490070050

[11] Facilitating Access to Mental Health Services, Fact Sheet, June 2017, Kaiser Family Foundation, http://files.kff.org/attachment/Fact-Sheet-Facilitating-Access-to-Mental-Health-Services-A-Look-at-Medicaid-Private-Insurance-and-the-Uninsured

[12] Williamson, Alanna, Larisa Antonisse, Jennifer Tolbert, Rachel Garfield and Anthony Damico, ACA Coverage Expansions and Low-Income Workers, Issue Brief, June 2016, Kaiser Family Foundation, http://www.kff.org/medicaid/issue-brief/aca-coverage-expansions-and-low-income-workers/

[13] Op cit. Figure 1

A recent report by the Center for Health Information and Analysis(CHIA) shows that workers at lower wage firms have lower offer, eligibility and take up rates and face higher purchasing costs and cost-sharing on their employer plans than their counterparts in higher wage firms.[14] This is consistent with national studies that low income workers are less likely to have employer sponsored insurance for many reasons including being more likely to work in agriculture and service sectors or for small employers who are less likely to offer coverage or more likely to be part-time workers ineligible for employer coverage.[15]

B. For many adults, lowering the MassHealth income level will decrease continuity of coverage and increase churn

Besides the obvious disadvantages of reduced benefits and higher costs, the one and only asserted advantage of alignment with commercial insurance –increased continuity and reduced churn—will at best be true for only some, and not true for many others. It is true that if the Connector has a wider income range, more individuals will be able to remain in the same MCOs if their income goes up albeit with higher premiums and copays. However, such individuals will lose Medicaid's continuity of care protections for the working poor. Working parents whose income goes over 133% FPL can now remain in MassHealth for 12 months under Transitional Medicaid. Also, working parents with income up to 300% FPL whose employers offer family coverage may be eligible for Family Assistance Premium Assistance in MassHealth compared to losing all assistance in ConnectorCare.

Further, narrowing the income range in MassHealth will result in those from 100-133% FPL whose incomes fluctuate *down* below 100% FPL moving from ConnectorCare to MassHealth rather than remaining in MassHealth. Data on income fluctuations show that fluctuations in both directions are common at income levels below 150% FPL.[16] In addition, the initial transition of 140,000 members from MassHealth to ConnectorCare in 2019 will be highly disruptive. In 2019, MassHealth members under 133% FPL may be in one of 17 ACOs, but in ConnectorCare there will be only one affordable MCO available to them. Further, to have an affordable MCO, ConnectorCare members may have to change carriers annually to remain in the lowest cost MCO. Similarly, adults under 133 % FPL disqualified from MassHealth based on access to ESI will have more coverage disruptions if their income or family size drops or the ESI offerings change making ESI unaffordable, than if they had remained eligible for MassHealth secondary coverage.

II. Lowering income eligibility for non-disabled adults to 100% of the federal poverty level will reduce coverage and access to care

The state proposes to lower eligibility for non-disabled adults to 100 percent from 133 percent of the federal poverty level, beginning January 1, 2019, resulting in an estimated 100,000 parents/caretakers and 40,000 childless adults losing MassHealth some of whom would regain

---

[14] 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

[15] Op cit Figure 3

[16] Sommers, Benjamin D., and Sara Rosenbaum, Issues in Health Reform: How Changes in Eligibility May Move Millions Back and Forth Between Medicaid and Insurance Exchanges, Health Affairs 30, No. 2 (2011): 228-236, doi: 10.1377/hlthaff.2010.1000, Exhibit 4.

coverage in ConnectorCare. We oppose this proposal. It will not further the goal of achieving near universal coverage. On the contrary, this request will lead to loss of coverage for individuals who are not eligible for ConnectorCare, and for those who may be eligible but who will not be able to successfully enroll. This conclusion is based on our experience here in Massachusetts with the eligible but unenrolled in ConnectorCare and experience in other states that rolled back Medicaid income standards in 2014.

Further, for those who do succeed in enrolling in ConnectorCare, they will have fewer benefits, significantly higher copays, fewer affordable plan choices and will lose a host of special Medicaid protections designed to meet the needs of very low income people. They will lose out on the opportunity to benefit from new Accountable Care Organizations that we are told will transform MassHealth, and the ACOs in turn will lose a significant share of their expected enrollees. Finally, it is far from clear that CMS would approve a partial Medicaid expansion with an enhanced match for the 260,0000 expansion adults remaining in CarePlus. Without the enhanced match the Medicaid rollback will increase state spending.

A. Many of the 140,000 losing MassHealth will not be able to successfully transition to ConnectorCare

ConnectorCare has eligibility rules that MassHealth does not that will bar some individuals from qualifying for ConnectorCare. We have not seen any analysis from EOHHS estimating the number of people unable to transition or a plan for addressing the problem. The August 2017 EOHHS presentation indicates that "medically frail" individuals will be able to retain MassHealth eligibility. However, the 1115 proposal does not include a provision retaining Medicaid coverage for the medically frail or for any other adults who do not qualify for ConnectorCare on the basis of rules not applicable in Medicaid at the 100-133% income level.

1. Some MassHealth members are not eligible for ConnectorCare

Among the groups who now qualify for MassHealth but will not qualify under Connector rules are:

- 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.
    - In addition to the high percentage, the problem is that the definition of "affordable"—for both an individual employee and a family—is based on the cost of individual-only coverage and does not take into consideration the often significantly higher cost of a family plan. This is particularly problematic for low-income families, who pay a much higher share of their income to purchase ESI coverage than higher-income families. We note that the Connector is not contemplating waiver of the so-called "family glitch" in its proposed 1332 document.
- Veterans enrolled in the VA Health System but otherwise uninsured
    - The VA Health System is considered other coverage that disqualifies these veterans from ConnectorCare
- Married couples living apart who file taxes as married filing separately.

- Married couples filing separately are not eligible for ConnectorCare (unless the reason for not filing jointly is domestic violence or abandonment and the whereabouts of the spouse is unknown).
- If a married couple files jointly, the income of both spouses will be counted in determining eligibility even if they live apart and are financially independent

- "Dreamers" (Deferred Action Childhood Arrivals or DACA)
  - DACA is not an eligible immigration status for Connector, but it is eligible for state-funded MassHealth Family Assistance

2. Many MassHealth members eligible for ConnectorCare 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 ConnectorCare eligibility and enrollment system. We know this both from the experience in Massachusetts and the experience of other states that rolled back Medicaid eligibility for adults in January 2014.

Some otherwise eligible individuals may not qualify because they are confused by the tax-filing rules. This will include individuals who are not now required to file taxes, such as early retirees with taxable Social Security below the filing threshold. If they indicate on the application that they do not file taxes they will be unable to qualify for Connector Care.

There are also a large group of people who do not understand the additional steps required to affirmatively enroll in a ConnectorCare plan and the deadlines for doing so. People found eligible for ConnectorCare must either enroll during the "open enrollment period" or within 60 days of being determined eligible for ConnectorCare outside of open enrollment. If they fail to enroll by the deadline, in most cases, they will be unable to enroll until the following year.

While there is a special enrollment period for people eligible for ConnectorCare who missed open enrollment, there is still a deadline to enroll that if missed will foreclose enrollment for the balance of the calendar year. In the former Commonwealth Care program, eligible individuals were never foreclosed from reapplying and enrolling regardless of the time of year or whether they were previously found eligible and failed to enroll. Similarly, in MassHealth there is no open enrollment period or special enrollment periods, and coverage is not dependent on applicants taking the second step of enrolling in an 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. Some of these individuals may still be within their 60 day window to enroll, but most will be 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 be uninsured.

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

Another pitfall in ConnectorCare that has no equivalent in MassHealth is that anyone eligible for a plan with no premium contribution who does not switch to the new lowest cost plan at next year's open enrollment will be assessed a premium and terminated if the premiums are not paid. This not only disrupts continuity of coverage for those who switch, but ends coverage altogether for some who fail to switch. For example, this year, roughly 3,000 members with no premium in December 2016 who did not switch to the new lowest cost plan for 2017 were terminated for nonpayment of premiums on March 31, 2017.

The likelihood that many beneficiaries who lose Medicaid coverage would not successfully make the transition to private coverage, even if they are eligible for subsidized coverage, is also borne out by the experience of other states. Experience from other states such as Wisconsin, Connecticut and Rhode Island shows that even when efforts are made to assure a smooth transition, people get lost in the shuffle. 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 (on the theory that they could get premium tax credits) never applied for a premium tax credit.[17] During the first round of a similar parent eligibility rollback in Connecticut only one in four parents losing Medicaid coverage enrolled in a QHP.[18] In Wisconsin only one-third of those losing Medicaid coverage purchased QHPs although the state had predicted that 90 percent would.[19]

Finally, even adults who are eligible and successfully navigate the more complex rules required to enroll in ConnectorCare are more likely to experience gaps in coverage and medical debt for services incurred during gap periods than MassHealth beneficiaries. There is a built in gap period for new applicants who are eligible for ConnectorCare because eligibility and coverage are separate steps and coverage is only prospective on the first of the month after plan selection. In MassHealth, on the other hand, eligibility and coverage both are retroactive to 10 days prior to the date of application. Retroactive eligibility is one of the ways that Medicaid is better at protecting the poor and near poor from medical debt than commercial insurance.

---

[17] 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

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

[19] "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

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

1. Fewer affordable premium choices

There are no premium charges for the 140,000 adults between 100-133% FPL in MassHealth regardless of their choice of managed care plan, and in 2018 they will have additional choices for Accountable Care Organizations (ACOs) with no premium contribution. In 2018 the Connector plans to offer only one MCO with no premium contribution for those with income under 150% of poverty. Those choosing an MCO other than the lowest cost MCO will be charged a premium, regardless of income. In 2017, monthly premiums were as high as 17% of income for individuals or up to 25% of income for couples to remain in an MCO other than the lowest cost MCO.[20]

2. Fewer benefits

In addition, ConnectorCare plans do 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, ConnectorCare does not offer a comparable amount, duration or scope of benefits compared to MassHealth.

For example, in the area of behavioral health and substance use disorder services, MassHealth offers a scope of diversionary behavioral health services with no equivalent in ConnectorCare plans, and has just added coverage for more substance use recovery services across the continuum of care including transitional support services and residential rehabilitation services. Further, ConnectorCare plans charge Plan Type 2A members (including those from 100-133% FPL) a $50 copayment for inpatient services presumably including inpatient detoxification and $10 copayments for mental health and substance use outpatient visits. Importantly, individuals for whom alcoholism or addiction is a contributing factor to a determination of disability will not be able to regain access to more comprehensive and affordable MassHealth services by establishing a disability.[21]

3. 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 MassHealth copays of $3.65 for most drugs and $3 for an inpatient visit. 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.

Another important Medicaid protection for the poor and near poor that does not exist in ConnectorCare is the Medicaid rule that providers cannot refuse services based on a MassHealth

---

[20] ConnectorCare offers at least one no-premium option for the lowest cost MCO for people with income up to 150% of poverty in Plan Types 1 and 2A, but charges premiums for other MCO choices. The percentage shown here is for people at 100% FPL choosing a higher cost MCO currently offered through the ConnectorCare Plan Type 2A.

[21] See footnote 10

members' inability to pay the copayment on the date of service.[22] This does not protect MassHealth members from medical debt, but it does protect them from denial of services.

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 the table below 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:

> Even relatively small levels of cost sharing in the range of $1 to $5 are associated with reduced use of care, including necessary services. Research also finds that cost sharing can result in unintended consequences, such as increased use of the emergency room, and that cost sharing negatively affects access to care and health outcomes. For example, studies find that increases in cost sharing are associated with increased rates of uncontrolled hypertension and hypercholesterolemia and reduced treatment for children with asthma. Additionally, research finds that cost sharing increases financial burdens for families, causing some to cut back on necessities or borrow money to pay for care.[23]

Table 2. Comparison of MA Cost of Living with 150%-300% FPL

	Required Annual Income for Average Cost of Living in MA[24]	150% FPL	200% FPL	300% FPL
Family Size 2				
1 Adult 1 Child	$ 47,842	$24,360	$32,480	$48,720
Family Size 3				
2 Adults (1 Working) 1 Child	$ 41,648	$30,630	$40,840	$61,260
2 Adults 1 Child	$ 52,960			
1 Adult 2 Children	$ 56,527			
Family Size 4				
2 Adults (1 Working) 2 Children	$ 46,535	$36,900	$49,200	$73,800
2 Adults 2 Children	$ 61,694			
1 Adult 3 Children	$ 69,933			

[22] 130 CMR § 506.017

[23] 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/

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

C. MassHealth has legal protections to assure affordability and other consumer protections and work incentives that ConnectorCare does not

Federal Medicaid rules prohibit premium charges for individuals under 150% of poverty and limit copayments to nominal amounts. The authorizing statute for the former Commonwealth Care program created Medicaid-like protections for the poor: no premiums, copayments no higher than MassHealth, comprehensive benefits including dental and basic due process rights.[25] Individuals enrolled in the current ConnectorCare program have far fewer protections. The Affordable Care Act sets out the basic parameters of coverage, and state law authorizes added state premium and cost sharing subsidies but provides no other direction to the Connector board.[26] Over time, "affordable" MCO choices have become fewer and fewer. In 2018, the Connector will offer only one affordable MCO. Unlike Medicaid, ConnectorCare has no legal requirement to offer coverage at no cost to those under 150% of poverty.

The Connector also lacks other Medicaid protections specifically designed for the poor and near poor. For example, Medicaid is an important work support. Programs like Transitional Medical Assistance enable low income families with children to remain on Medicaid for 12 months if they have earnings that now exceed Medicaid financial income limits. There is no equivalent to these programs and a host of other Medicaid-specific features designed to meet the needs of the poor and near poor in ConnectorCare. ConnectorCare is based on a commercial insurance model and provides coverage to people with income up to three times the poverty level --$36,180 for one person in 2018 compared to $12,060 to $16,040 for someone between 100% and 133% of the poverty level.

D. The MassHealth ACO program will not have the opportunity to achieve savings and better health for 140,000 members

Another negative feature of the proposed transition is that these 140,000 adults would be removed from MassHealth just as the program is moving into delivery system reform designed to improve quality and control costs starting in early 2018 and to begin to address the social determinants of health. Accountable Care Organizations will need stable and expanded enrollment to succeed. Keeping this population in MassHealth will give ACOs the chance to achieve savings by addressing the underlying cost drivers and to produce better health outcomes for its members.

E. A partial expansion may jeopardize the enhanced matching rate

The shift in coverage for those from 100-133% FPL, only possible because of a drafting error in the ACA, will result in higher costs to the federal government.[27] It is far from clear that the federal government will approve an enhanced match for a partial expansion to 100% FPL. If Massachusetts forfeits the 90 percent enhanced matching rate for expansion adults, 260,000 of whom have income at or under 100% of poverty, it will offset any state savings for 100,000 parents at 100-133% FPL and result in a net increase in state spending. CMS guidance issued in

[25] Section 45, Chapter 58, St. 2006 (enacting G.L. c. 118H, §6)
[26] G.L. c. 176Q, §3
[27] Dylan Scott, Why one little waiver could be a big deal for Medicaid, August 10, 2017, Vox, https://www.vox.com/policy-and-politics/2017/8/10/16127264/voxcare-waiver-really-big-deal-medicaid

December 2012 states that enhanced matching funds are not available for a partial expansion.[28] This was the experience of Wisconsin which was unable to obtain an enhanced match for expanding to adults up to 100% FPL. In March 2017, CMS wrote to Governors promising support for rolling back many Medicaid protections, but notably did not invite requests for partial Medicaid expansions. Arkansas is the first state to request a partial expansion with an enhanced match from the new CMS administration; its request is pending. However, all states that expanded Medicaid and are now responsible for 10% of costs would benefit financially from a partial expansion to 100% FPL, and more can be expected to follow suit if CMS allow partial expansions. Given the potentially large added costs to the federal government of assuming the costs for subsidized coverage for those from 100-133% FPL, it seems highly doubtful that this approach for shifting costs to the federal government will succeed.

III. The ESI Lock-Out, even if it disqualifies only 5,000 people, does not promote the objective of the Medicaid Act

The proposed 1115 amendments seek authorization for the MassHealth agency to deny or terminate MassHealth eligibility for non-disabled adults who have access to affordable employer sponsored health insurance (ESI) as defined by the agency. Because these are individuals with income under 133% of the federal poverty level (FPL), few will be able to afford private commercial insurance, and we fear most of these individuals will become uninsured.

A. The proposed affordability test does not capture the costs of ESI

The 1115 proposal indicates that ESI will be considered affordable for those under 133% FPL if the employee share of the premium does not exceed 5% of income. More recently, at the August listening session, the agency said that ESI would not be considered affordable unless the deductible combined with the employee share of the premium were under 5% of income. Five percent of income is the upper limit for premiums and *all forms* of cost-sharing for those over 150% of poverty to pay for Medicaid coverage. However, even the if out of pocket maximums in ESI were added to the 5% of income calculation, it would not capture the higher costs of ESI because the proposal does not include any standards for the scope of ESI coverage.

If the ESI lock out were to be limited to ESI that met the Connector's standards for minimum creditable coverage, it still would not be comparable to MassHealth. Such coverage could exclude durable medical equipment, rehabilitative therapy (PT, OT, SLT), home health, short-term skilled nursing facility care, dental and hospice.[29] Further, even if benefits are covered in ESI, the amount, duration and scope of benefits may be severely limited compared to Medicaid coverage. In the area of mental health and substance use disorder services in particular, commercial coverage does not equal MassHealth. For adults under 133% FPL (or under 100% FPL if the income standard is lowered), these uncovered services impose additional costs and additional costs restrict access to care compared to comprehensive Medicaid coverage.

---

[28] Centers for Medicare & Medicaid Services, "Frequently Asked Questions on Exchanges, Market Reforms and Medicaid," (December 10, 2012), https://www.medicaid.gov/federal-policyguidance/downloads/FAQ-12-10-2012-Exchanges.pdf

[29] 956 CMR 5.03(1)

B. In Medicaid and the Massachusetts individual mandate, no premium contribution for someone under 150% FPL is affordable.

Federal Medicaid law and MassHealth regulations, as well as the Connector's affordability scale for both ConnectorCare premiums and for the individual mandate, recognize that NO premium contribution is affordable for individuals and families with income under 150% of the poverty level. The individual mandate standard was developed by the Connector pursuant to Chapter 58 with broad public participation and has stood the test of time.

C. Massachusetts families under 133% FPL have insufficient income to meet basic living costs without the added costs of health insurance premiums.

Under the proposal, a low-income parent with two children and income under $20,420 per year, $1702 per month (100% of poverty for a household of three) offered ESI at a monthly premium of $85 (5% of income) for individual coverage will no longer be eligible for MassHealth. The costs of coinsurance, copays and uncovered services will add hundreds more to the cost of ESI. At income levels under 133% of poverty, families cannot afford all the added costs of ESI after meeting their basic living costs. See, Table 2 above.

In particular, the high cost of housing in states like Massachusetts is not captured by the national federal poverty level standards. In Massachusetts, rent at 40% of median for a two-bedroom apartment is $1,424. In order to afford this level of rent and utilities — without paying more than 30% of income on housing — a household must earn $4,747 monthly or $56,967 annually.[30] At $1702 per month, rent for that two- bedroom is 84% of income. The waiting list for section 8 subsidized housing in Massachusetts is over 100,000 names long.

Not surprisingly, ample research documents how price sensitive poor and near poor families are to premium costs:

> Premiums serve as a barrier to obtaining and maintaining coverage among low-income individuals. These effects are largest among those with the lowest incomes, particularly among individuals with incomes below poverty. Some individuals losing Medicaid or CHIP coverage move to other coverage, but others become uninsured, especially those with lower incomes. Individuals who become uninsured face increased barriers to accessing care, greater unmet health needs, and increased financial burdens.[31]

The administration says the purpose of its proposal is to "promote the uptake of employer sponsored insurance." However, the more likely result is that families will have to forego insurance coverage in order to pay the rent or keep food on the table.

---

[30] 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

[31] Kaiser Family Foundation, **June 2017 | Issue Brief ,** The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings, http://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/

D. This is not a return to the way it was under chapter 58: MassHealth has always supported working poor parents

The ESI lock out will affect low income families with children who from 1997 until today have been able to rely on MassHealth as a work support. Under long standing MassHealth rules, there is no ESI lock out. Instead, if ESI is cost effective, families are required to participate in Premium Assistance which reimburses premium costs and cost sharing and provides services, like dental, that might not be in the employer plan. If a working parents on MassHealth no longer meet the family income standard, they are entitled to a further 12 months of transitional medical assistance as a work incentive. In addition, if working parents have access to family coverage from ESI, Family Assistance Premium Assistance may help reduce the ESI premium cost until family income exceeds 300% of poverty. These programs help families to work their way out of poverty without the abrupt "cliff effects" in other benefit programs. The ESI lock-out undermines a successful and important support for working families.

An ESI "gate" did exist in the Commonwealth Care program for people not eligible for MassHeatlh with income up to 300% of poverty, and today there is an ESI "gate" under the ACA for eligibility for Premium Tax Credits for individuals with income up to 400% of poverty. However, this kind of control is rarely found in programs with income levels at poverty or near poverty.

E. An improved Premium Assistance program is a better way to promote ESI

We support increased participation in MassHealth Premium Assistance as the best way to leverage employer contributions and reduce state spending while also assuring that low income workers have affordable and comprehensive coverage. According to EOHHS, MassHealth was providing coverage to about 200,000 more working people in 2015 than in 2011. However, to the best of our knowledge there has been no commensurate increase in Premium Assistance. On the contrary, according to the August presentation at the listening session, over 150,000 individuals lost MassHealth between June 2016 and June 2017 partly as a result of enforcing Premium Assistance. We presume this means individuals lost coverage, at least temporarily, for failing to return information regarding available ESI or failing to enroll in ESI when directed to do so. This kind of process-driven churning harms eligible members, destabilizes health plans, and wastes the time of MassHealth workers. It makes far more sense for EOHHS to improve the Premium Assistance program than to divert its limited time and resources to denying MassHealth coverage to the working poor.

IV. MassHealth Limited coverage is not waivable and provides important benefits

Lawfully present immigrants who do not meet the stricter immigrant eligibility rules of MassHealth are eligible for both ConnectorCare and MassHealth Limited. The proposal seeks a waiver to terminate MassHealth Limited for these individuals. Section 1903(v) of the Social Security Act requires states to provide emergency Medicaid. The Secretary's waiver authority is limited to Section 1902, therefore emergency Medicaid is not subject to the Secretary's waiver authority. In any event, terminating emergency Medicaid is not a good policy.

MassHealth Limited covers only emergency care which is redundant for those also enrolled in ConnectorCare, but since MassHealth is payer of last resort, this redundancy should impose no costs on MassHealth. MassHealth Limited is not redundant during the temporary period before ConnectorCare enrollment begins and the retroactive period10 days prior to application. Currently, if individuals do not enroll in ConnectorCare, their HSN ends but Limited is at least available to reimburse hospitals for ER services. Without HSN or MassHealth Limited, hospitals and community health centers will incur more uncompensated care costs, the state will have foregone federal revenue, and consumers will incur more medical debt. Terminating Limited is particularly unfair since individuals eligible for ConnectorCare who miss the enrollment deadline will in most cases be unable to enroll until the following year –a confusing situation for many people but particularly for recent immigrants and those not proficient in English. A better way to encourage enrollment into ConnectorCare than cutting off MassHealth Limited would be to create a Special Enrollment Period for MassHealth Limited members coupled with increased outreach on an ongoing basis.

V. 230,000 low income parents and caretaker relatives will have fewer benefits in MassHealth CarePlus than MassHealth Standard

The 1115 amendments also propose a shift of 230,000 parents and caretaker relatives with income under the newly lowered 100% FPL limit to MassHealth Care Plus, an Alternative Benefit Program authorized only for expansion adults that has fewer benefits than MassHealth Standard. CarePlus does not include long term services and supports or non-emergency medical transportation. Reducing benefits for parents and caretaker relatives does not promote the objectives of the Medicaid Act. Further, reducing benefits available to parents and caretaker relative in January 2002 violates state law.[32]

The proposal justifies the benefit reduction as better aligning with commercial insurance and promoting continuity and reducing churn. It is surely true that commercial insurance does not typically cover NEMT or LTSS. However, it is mystifying how aligning Medicaid with commercial insurance by eliminating NEMT and LTSS will promote continuity and reduce churn. Does EOHHS believe that MassHealth members under 133% of poverty who forego commercial insurance at an employee premium cost of $143 per month for single coverage will instead choose to enroll if the MassHealth coverage available to them at no added premium cost no longer covers NEMT or LTSS (which the employer coverage also fails to cover)?[33]

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.[34] The state's rationale for eliminating

[32] G.L. c. 118E § 53.
[33] $143 per month is the average employee share of cost for single coverage among lower wage firms. See footnote 14, Ex. 9.
[34] 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.

NEMT is to better align CarePlus with commercial insurance. However, transportation is a greater access barrier for low income Medicaid beneficiaries than for the commercially insured.[35] EOHHS has supplied no information about how many of the 230,000 parents use NEMT. In our experience, few MassHealth members are aware of the benefit. It is not described in the member booklet or on the MassHealth website. Most of those who use the benefit learn of it through their doctors who must obtain prior authorization in order for their patients without access to transportation to obtain a ride to health services. According to MassHealth, only 4% of CarePlus members use NEMT for other than SUD services. Eliminating NEMT cannot be a significant savings. Nor can the delay in providing LTSS until such time as the parents and caretakers who need LTSS succeed in establishing medical frailty or disability account for significant savings.

VI. Reducing the Premium Assistance wrap does not promote the objectives of the Medicaid Act

The 1115 proposal seeks to reduce MassHealth benefits for non-disabled adults receiving premium assistance for the costs of commercial coverage and to reduce cost-sharing assistance for students required to enroll in student health plans. We oppose reductions in the MassHealth wrap that will result in individuals in premium assistance arrangements being afforded fewer beneficiary protections than all other MassHealth enrollees.

Reduced benefits

The rationale for restricting the benefit wrap is that the process used to verify that the scope of commercial coverage meets a basic benefit level is sufficient to assure adequate coverage.[36] However, the definition of a basic benefit level does not consider the amount, duration and scope of benefits. For example, if ESI covers only 10 rehabilitative therapy visits and 20 visits are both medically necessary and covered by MassHealth, under the proposal, the added visits will not be covered. It is fundamentally unfair that non-disabled adults will be denied medically necessary care available to similarly situated MassHealth members without access to ESI. If ESI imposes unreasonable medical necessity criteria, rather than deny a member a covered service, MassHealth can enforce its subrogation rights against the insurer. Similarly, rather than deny services in those cases where ESI has appropriately denied prior authorization on medical necessity grounds, MassHealth can design a system to trigger its own prior authorization process to determine MassHealth medical necessity criteria are satisfied prior to payment. Denying coverage altogether is unfair and furthers no purpose other than reducing state spending.

---

[35] 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

[36] Commercial insurance must satisfy a "basic benefit level" defined as equivalent to the Connector's "minimum creditable coverage" standard. 130 CMR 501.01 (definition of basic benefit level cross-referencing to 956 CMR 5.03(1)(a). The current review also requires coverage for certain additional benefits: DME, Home Health, Early Intervention, Medical Nutrition Therapy, and Hospice.

Increased cost sharing

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 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.[37] Psychologists for example, can participate in MassHealth only for purposes of testing, and not for the provision of therapy services. Thus limiting the ability of providers who do not otherwise participate in MassHealth to bill for cost sharing, unfairly shifts costs to members.

When CMS approved the state plan amendment to provide premium assistance for student health insurance plans (SHIP) in the individual market on November 18, 2016, 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.

VII. The proposed pharmacy restrictions do not promote the objectives of the Medicaid Act

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

We oppose the MassHealth proposal to create a closed formulary. Currently, MassHealth is required to cover any drug for which the manufacturer participates in the federal Medicaid rebate program. The current open formulary guarantees patients access to the highest standard of care available and allows physicians to prescribe the course of treatment they and their patients believe is most appropriate. A closed formulary would restrict the drugs MassHealth covers, with as few as one drug available per therapeutic class. We believe this proposed restriction

[37] 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.

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.[38] 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.[39] Given the extraordinary success nationally of drug rebate 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[40] 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

---

[38] 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/

[39] 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

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

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[41] 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 bill 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.[42] 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 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.[43] 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

---

[41] *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/.

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

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

must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection) antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes."

B. 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.[44] 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.

VIII Narrowing provider networks, limiting MCO choices, and increasing cost-sharing do not further the objectives of the Medicaid Act

A. Restricting the provider network in the PCC Plan is not necessary to promote ACO enrollment and will harm individuals with disabilities

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. Almost all stakeholders who commented on this aspect of the proposal objected to it, particularly people

[44] 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.

with disabilities. The state withdrew the reduced benefit proposal but did obtain authorization for a "carrot" rather than a "stick" enrollment incentive: Charging lower copayments in ACOs and MCOs compared to the nominal copayment amounts in the PCC Plan. MassHealth now seeks to use another stick: Reducing the provider networks in the PCC Plan. The rationale purports to be delivery system reform, but the agency has not sought any similar incentives to discourage members from enrolling in MCOs whose providers are not in ACOs.

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. Finally, as we said in our 2016 comments, the PCC Plan provides an opportunity to evaluate the effect of different delivery systems and actually learn something from the DSRI demonstration which is after all the purpose of the 1115 statute.

B. Insufficient information has been provided to assess the proposal to restrict MCO choices in certain parts of the state

The proposal to restrict MCO choices based on limited available primary care physicians in certain areas of the state is being made in anticipation of new ACO and MCO networks. The MCO contracts are still in procurement and we have not been able to obtain enough information to assess the effects of this proposal.

C. 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. Administrative convenience is not a sufficient basis for an 1115 waiver. It is far more likely that individuals will benefit from a monthly (or even a quarterly) out of pocket limit than an annual one. Presumably that is why a monthly or quarterly limit is required, and that is why we oppose an annual limit.

D. The premium schedule for those over 150% FPL should be progressive based on income at both the low and high end of the income range

The CommonHealth program for people with disabilities charges premiums on a sliding scale with no upper income limit. The agency plans to convert all of its premium charges to a percentage based system and seeks a waiver to exceed the 5% limit for CommonHealth members with income over 5% of poverty. In the August listening session the state said it would not exceed the highest percentage of affordability set by the Connector for purposes of the state individual mandate which in 2018 will be 8.05%. This is a reasonable upper limit for the CommonHealth program.

However, it is important that any premium schedule be progressive based on income. A premium range that starts at 3% of income for people at 150% of poverty and rises to 8.05% of income for those with income over 400% of income is starting out too high. We recommend starting the premium schedule at a much lower percentage than 3% of income and also capping the size of premium increases by a reasonable amount to avoid steep increases in premiums and a likely drop off of enrollment. The presentations related to the current 1115 proposals were also our first opportunity to see the proposed copayment schedule. With respect to copayments, we recommend sub-caps for certain services or other ways to address what may be burdensome amounts for both members and providers particularly for some specialty services and outpatient therapy services.With regard to both the planned changes in the premium and the copayment schedule planned for 2019, we request an opportunity for a more detailed discussion with the MassHealth agency.

Thank you for the opportunity to comment. We look forward to having additional opportunities to meet with EOHHS and Office of Medicaid staff to strengthen and improve the MassHealth program without harming the vulnerable beneficiaries for whom it provides such important and essential services.

Yours truly,

Vicky Pulos and Neil Cronin

THE GENERAL COURT OF MASSACHUSETTS
STATE HOUSE, BOSTON 02133-1053

August 21, 2017

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

Re: Comments on 1115 Demonstration Amendment

Dear Assistant Secretary Tsai,

On behalf of the House Progressive Caucus, we oppose a number of changes in the MassHealth 1115 Demonstration Waiver Amendment released on July 20, 2017. These changes will reduce access to affordable care for individuals and families and, if implemented, would mean Massachusetts would be one of the first states to roll back Medicaid expansion. We are proud of our first-in-the-nation role in health care expansion and do not want to reverse course now.

We write to you to request that EOHHS reconsider the proposed changes to eligibility and benefits in the waiver amendment. These provisions will harm low-income MassHealth members by lowering the income limit, and disqualifying families who have access to insurance through work. These changes will make it even harder for families to rise out of poverty. It is the our job as public officials to ensure programs that positively impact Massachusetts's families are the last items on the chopping block. There is no truer example than access to health care. Instead, we urge EOHHS to concentrate on cost-savings reforms that do not reduce access to care, including the Accountable Care Organizations (ACOs) model that EOHHS is already undertaking and could save costs this fiscal year.

The waiver amendment proposes to shift coverage for non-disabled adults between the ages of 21 to 64 with incomes over 100% of the federal poverty level (FPL) to ConnectorCare as of January 1, 2019. This change would affect about 140,000 low-income adults and working parents. A family of three with one working parent earning between $21,000 and $27,000 would no longer qualify for MassHealth, and would be transitioned to less comprehensive ConnectorCare coverage with greater cost-sharing. ConnectorCare does not serve the needs of low-income individuals as well as MassHealth. We have significant concerns, as also raised at a legislative hearing in July,

that many of these families will not access care due to copayments, or not purchase insurance due to unaffordable premiums.

We strongly urge EOHHS to reconsider shifting non-disabled adults with incomes over 100% FPL from MassHealth to ConnectorCare.

The waiver amendment also introduces a requirement for all low-income adults to accept their employer's insurance, and disqualifies families who have access to insurance through work from MassHealth. It is currently unclear by which measures EOHHS would deem ESI "affordable," and if these would account for only premiums or other cost sharing, including copays and deductibles that could greatly impact access to care for low-income families. While we support leveraging employer coverage through premium assistance, it must be affordable for the family to be able to stay insured and go to the doctor. Using MassHealth as a secondary payer to help families avoid unaffordable medical bills is a long-standing policy of Massachusetts that has made the Commonwealth's Medicaid program an important support for low-income families with children as they work their way out of poverty.

We urge EOHHS to remove the ESI "gate" from its proposed 1115 waiver amendment, and to instead focus on strengthening the existing MassHealth Premium Assistance program which helps reduce MassHealth costs without eliminating benefits.

We support ways to lower costs and create efficiencies. But the proposed changes undermine our state's commitment to near-universal health coverage, for which we have been a leader throughout the nation. Instead, we should be focusing on recent bipartisan reforms to improve our health system *without* cutting benefits. In particular, MassHealth's move to ACOs promises savings due to better management by providers and plans, as well as incentives to address social determinants of health. We look forward to the start of the program in early 2018, and know that EOHHS is working with many groups to make these ACOs a success. It would be premature to cut eligibility and benefits for a significant portion of the MassHealth population before the ACOs have had a chance to demonstrate what might be significant cost savings for the entire MassHealth population. Implementation could provide savings to MassHealth this fiscal year.

Given the uncertainty about the future of health care coverage at the federal level, these changes are premature. In particular, we have concerns about shifting people to subsidized plans that may not exist if federal reforms are made. With the failure of the repeal and replace the Affordable Care Act, we now have the opportunity to address the issue of cost without the immediate threat of a massive withdrawal of federal funds.

For the past decade, we have had bipartisan support for universal health coverage. Our commitment to Medicaid expansion has increased access to health care for hundreds of thousands in Massachusetts. Moreover, it has helped all of us, by investing in our local hospitals and health centers, and by ensuring our premium contributions do not pay for the uninsured.

For these reasons, we oppose the waiver amendment. We hope to work with you to ensure that Massachusetts continues to be a leader in health coverage and support families and providers in the Commonwealth. Thank you for your consideration of this request.

Sincerely,

Christine P. Barber
34th Middlesex

Ruth B. Balser
12th Middlesex

Jay Livingstone
8th Suffolk

Byron Rushing
9th Suffolk
Co-Chair, House Progressive Caucus

Tricia Farley-Bouvier
3rd Berkshire
Co-Chair, House Progressive Caucus

American Diabetes Association®

August 21, 2017

Ms. Kaela Konefal
EOHHS Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108

Dear Ms. Konefal:

On behalf of the more than 30 million Americans with diabetes and the 84 million more with prediabetes, the American Diabetes Association (Association) appreciates the opportunity to submit comments on the MassHealth Section 1115 Demonstration Amendment Request (Amendment Request).

According to the Centers for Disease Control and Prevention, over 480,000 adults in Massachusetts have diagnosed diabetes and nearly 300,000 have prediabetes. Adults with diabetes are disproportionately covered by Medicaid.[1] Access to affordable, adequate health coverage is critically important for all people with, and at risk for diabetes. For low income individuals, access to Medicaid coverage is essential to managing their health. When people are not able to afford the tools and services necessary to manage their diabetes, they scale back or forego the care they need, potentially leading to costly complications and even death.

While the Association shares the commonwealth's goal of improving the quality and integration of health care delivery for low-income Massachusetts residents, we have deep concerns regarding the commonwealth's proposed changes to the MassHealth program prescription drug benefit and offer the following comments and recommendations.

Proposed Changes to Drug Formulary Rules

A wide array of medications and supplies are correlated with improved glycemic outcomes and a reduction in the risk of diabetes-related complications. Because no single diabetes treatment regimen is appropriate for all people with diabetes, providers and patients should have access to a broad array of medications and supplies to develop an effective treatment modality. **The Association is strongly opposed to the commonwealth's proposal to implement a closed formulary for the MassHealth program**. We are particularly concerned that important types of medications for people with diabetes could be left out if the commonwealth chooses to cover only one medication per therapeutic class.

Diabetes care should be patient-centered, and requires a close working relationship between the patient and clinicians involved in treatment. Developing an individual's diabetes management plan should take into account the patient's age, cognitive abilities, school/work schedule and conditions, health beliefs, support systems, eating patterns, physical activity, social situation, financial concerns, cultural factors, literacy and numeracy skills, diabetes complications, comorbidities, health priorities, other medical conditions, preferences

American Diabetes Association®

for care, and life expectancy. As it relates to medication therapy, the Association's *Standards of Medical Care in Diabetes - 2017* identifies multiple factors which must be considered by a clinician when determining the appropriate medications for an individual with diabetes, including efficacy, risk of hypoglycemia, impact on weight, side effects, and cost.[2] Implementing a closed formulary will severely hinder prescribers' and MassHealth enrollees' ability to choose the most appropriate diabetes medication(s) for the individual.

Should the commonwealth move forward with developing a closed formulary, the Association has deep concerns with the factors the state will consider when determining which drugs to exclude. Specifically, in the Amendment Request, the commonwealth requests flexibility to "exclude drugs with limited or inadequate clinical efficacy from its primary formulary." Factors the commonwealth will consider when determining which drugs have limited or inadequate clinical efficacy include drugs for which "[o]nly surrogate endpoints have been reported." For diabetes medications, efficacy is determined based on reduction of blood glucose levels, as measured by HbA1c. According to the Food and Drug Administration, HbA1c is the "primary endpoint of choice, albeit a surrogate."[3] So the "primary" endpoint used to assess the efficacy of diabetes medications is actually a surrogate endpoint. A policy to exclude from the MassHealth formulary drugs approved based solely on surrogate endpoints would negatively impact the availability of diabetes medications.

Rather than implementing a closed formulary, the Association recommends the commonwealth focus on ensuring providers and patients have access to a broad array of diabetes medications and supplies to develop an effective treatment modality, which can be done using existing authorities under the Medicaid program.

Thank you for the opportunity to provide our comments on the proposed MassHealth Section 1115 Demonstration Amendment Request. If you have any questions please contact me at shabbe@diabetes.org .

Sincerely,

Stephen Habbe

Stephen Habbe
Director, State Government Affairs and Advocacy

---

[1] Kaiser Commission on Medicaid and the Uninsured, The Role of Medicaid for People with Diabetes, November 2012. Available at http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8383_d.pdf.

[2] American Diabetes Association, Standards of Medical Care in Diabetes – 2017, Diabetes Care, January 2017. Available at: http://care.diabetesjournals.org/content/40/Supplement_1.

[3] Food and Drug Administration, Guidance for Industry, Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention, February 2008.

EPILEPSY FOUNDATION

August 21, 2017

Kaela Konefal
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108

Re: Comment for Demonstration Amendment

Dear Ms. Konefal:

On behalf of the Epilepsy Foundation and our affiliate in Massachusetts, Epilepsy Foundation New England, we are writing to comment on the proposed amendment to the MassHealth Section 1115 Demonstration. We commend the Massachusetts Executive Office of Health and Human Service (EOHHS) for its stated goal of ensuring the sustainability of the Medicaid program while retaining access for vulnerable populations; however, we have significant concerns that some aspects of the proposal will limit access to care for many vulnerable patients.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of at least 3.4 million Americans with epilepsy and seizures. We foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime.

We are particularly concerned with proposals in the amendment that would (1) create a closed drug formulary, (2) narrow provider and specialty pharmacy networks, and (3) allow increased cost sharing – these proposals are likely to limit access to care. It is important to ensure that any limits to provider networks will not result in significant barriers to care, especially to specialty care, which is already a challenge to access for many with epilepsy. Also, closed formularies could mean that Medicaid will not cover a medication that a physician prescribes for a patient. Limiting access to certain medications is dangerous to patients, especially individuals living with epilepsy, and it leads to higher overall health care costs. Epilepsy medications are not interchangeable and treatment of epilepsy is highly individualized. Epilepsy medications are lifesaving for individuals with epilepsy, and they help avoid unnecessary hospitalizations and ensure individuals can live well with epilepsy.

For the majority of people living with epilepsy, epilepsy medications are the most common and most cost-effective treatment for controlling and/or reducing seizures, and they must have meaningful and timely access to physician-directed care. There is no "one size fits all" treatment option for epilepsy, and the response to medications can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions, and it requires careful evaluation and monitoring by physicians and their patients. A treating physician is in the best position to make the judgment about which medication is most appropriate.

8301 Professional Place East, Suite 200
Landover, MD 20785-2353
1-800-332-1000
301-459-3700
FAX: 301-577-2684
epilepsy.com

To change, limit, or deny access to epilepsy medications could be extremely dangerous. People living with epilepsy who have their medications switched, or who experience a delay in accessing their medication, are at a high risk for developing breakthrough seizures and related complications including death. Limits to physician-directed care can also significantly increase medical costs related to preventable seizures, along with lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities.

While proposals to limit access to medications through formulary design or utilization management are designed to create savings in a payer's pharmacy budget, these initiatives end up costing more for the entire program due to other costs like avoidable hospitalizations – this is why the federal Medicare program provides for open access to all epilepsy medications. Currently, the Medicare Part D program includes a protection for six classes of medications, including anticonvulsants for epilepsy. The six protected classes policy has enjoyed strong, bipartisan support since its inception in 2006 and has proven to be cost-effective while improving access to care for the most vulnerable and medically fragile Medicare beneficiaries.

The Epilepsy Foundation and Epilepsy Foundation New England oppose policies intended to restrict access to physician-directed care. These policies unnecessarily prolong ineffective treatment and/or prevent individuals from accessing the treatment that their physicians, who provide care based on their expert knowledge and experience, think is best.

Further, we are concerned with aspects of the amendment that would essentially allow the state to eliminate coverage for some long-term care services and non-emergency medical transportation for some Massachusetts Medicaid beneficiaries. Any elimination of services can be problematic, especially limits on non-medical transportation services which would impede access to care for some individuals living with epilepsy who do not have seizure control, and thus, cannot drive.

The Epilepsy Foundation and Epilepsy Foundation New England urge you to reconsider the amendment to the MassHealth Section 1115 Demonstration and ensure that individuals have meaningful access to physician-directed care. Please do not hesitate to contact Bill Murphy, Director, Advocacy and Public Policy at Epilepsy Foundation New England at murphy@epilepsynewengland.org or 617-506-6041, ext. 104 with any questions or concerns.

Sincerely,

Susan Linn
President & CEO
Epilepsy Foundation of New England

Philip M. Gattone, M.Ed
President & CEO
Epilepsy Foundation

MassBio
MASSACHUSETTS BIOTECHNOLOGY COUNCIL

main: 617 • 674 • 5100 fax: 617 • 674 • 5101

Massachusetts Biotechnology Council
300 Technology Square, Eighth Floor
Cambridge, MA 02139

August 21, 2017

Kaela Konefal
EOHHS Office of Medicaid
One Ashburton Place
11th Floor
Boston, MA 02108
Kaela.konefal@state.ma.us

Re: Comments on Draft 1115 Demonstration Amendment Request

Dear Ms. Konefal:

The Massachusetts Biotechnology Council (MassBio) and our members appreciate this opportunity to submit written comments addressing important concerns raised by the MassHealth Section 1115 Draft Demonstration Amendment Request, which was posted for public comment by the Executive Office of Health and Human Services (EOHHS) on July 20, 2017. MassBio represents more than 1000 life sciences companies, academic institutions, service providers and patient organizations -- the majority of which are directly engaged in the research, development and manufacturing of innovative products that solve unmet medical needs for patients both in Massachusetts and around the world.

As explained in more detail below, the Commonwealth's proposal to dramatically restructure the MassHealth pharmacy benefit (Demonstration Amendment Request, Section 6) disrupts the grand bargain that has existed for years between the federal government, states, and drug manufacturers, which is designed to guarantee open access in drug coverage for the most vulnerable of patient populations in return for favorable pricing for state Medicaid programs. As a result, the proposal needlessly places MassHealth patients at risk for increased access restrictions to needed therapies, all with dubious benefits in terms of cost savings or other enhanced programmatic efficiencies. As the Commonwealth continues to work with the Centers for Medicare & Medicaid Services to reduce long-term cost in the MassHealth program, we urge you to retract the proposed restructuring of the pharmacy benefit.

As proposed, the Demonstration Amendment Request would restructure the MassHealth pharmacy benefit in three ways: (1) in lieu of the open formulary access for MassHealth recipients that is the hallmark of the Medicaid drug rebate program, the Commonwealth proposes to adopt a "commercial-style" closed formulary with "at least one drug available per therapeutic class"; (2) products approved through FDA's accelerated approval pathway would be subject to additional review requirements prior to, and as a condition of, coverage; and (3) MassHealth would approve narrow, specialty pharmacy networks designed to limit beneficiary access to certain high-cost therapies. If included in the final Demonstration Request, these changes would dramatically limit MassHealth enrollees' access to lifesaving therapies, erecting unnecessary barriers to care for the Commonwealth's most vulnerable citizens.

The Commonwealth believes that adopting these commercial-style utilization and access tools will lower programmatic costs and improve the overall efficiency of the MassHealth program. Instead, it is our view that these proposed tools would prioritize state fiscal concerns over patient health and lives, harm

biopharmaceutical innovation in the Commonwealth, and sidestep the real long-term drivers of costs in the MassHealth program. In addition, there is a significant likelihood that the purported "savings" envisioned by the Commonwealth under its proposal will not materialize at all given the fact that the Commonwealth may no longer be able to rely upon mandatory rebates if the proposed Demonstration is enacted.

The Demonstration Request Requires State Authorization by the Legislature.

As EOHHS has noted, absent explicit authorization from the legislature, the Commonwealth lacks authority under state law to adopt the proposed restructuring of the MassHealth pharmacy benefit. In particular, under Mass. Gen. L. c. 118E, § 53, MassHealth is required to offer coverage for all federally optional services (which includes drug coverage) that were included in the state Medicaid plan in effect on January 1, 2002. Because MassHealth had no waiver from the requirements of Section 1927 of the Social Security Act in 2002 that would have restricted drug coverage through a closed formulary or other means, this plan required MassHealth to maintain an open formulary for prescription drugs (subject to certain prior authorization criteria for drugs not listed on the MassHealth Drug List). While MassHealth can and does impose certain prior authorization measures in the administration of its Preferred Drug List (PDL), all drugs subject to a rebate agreement must generally be available.

It is also worthwhile to consider the reasons for the enactment of GL c. 118E, § 53 in the context of the proposed Demonstration Request. In adopting the coverage protections in Section 53, the Legislature clearly intended to ensure, by codification in state law, that MassHealth recipients would be guaranteed a robust set of minimum services designed to care for this acutely vulnerable population. That the Commonwealth now plans to chip away at these services appears contrary to both public policy and legislative intent. Should the Commonwealth proceed with the Demonstration Request as planned, prior legislative authorization would still be necessary.

Closed Formularies in Medicaid Hurt Patients Already at Risk.

Under current State and Federal law, while MassHealth (including Medicaid MCOs operating in Massachusetts) is permitted to apply certain prior authorization measures to drug coverage (for example, fail-first or step-therapy techniques), a patient must still be able to access a therapy once they fulfill these prior authorization requirements, or else are granted access on appeal. Under the proposed Demonstration Request, some therapies would simply be unavailable to patients based on criteria applied by MassHealth without the brand new requirement of undertaking an exception process, potentially risking the lives of patients in need of lifesaving therapies. Compounding this concern is the fact that MassHealth enrollees in fee-for-service tend to be the most at-risk patients in the state. MassHealth is designed to be the Commonwealth's safety net. Introducing commercial-market techniques (like closed formularies) into the state's program for the most disadvantaged puts the state's most vulnerable patients at risk, and is counter to the goals of the Medicaid program.

These risks are even more acute for the MassHealth population because, unlike many commercially insured patients, MassHealth enrollees lack the freedom to shop for drug coverage that best fits their personal medical needs. Although commercial plans are able to manage their drug formularies with more discretion than MassHealth, many commercially insured patients have a choice of health plans offered through the Connector or through their employers. MassHealth patients, particularly in the fee-for-service program, do not have such options, and instead rely solely on MassHealth's coverage decisions. Currently, this limitation is neutralized by State and Federal requirements mandating an open formulary design for drugs, subject to rebates, in Medicaid – the very policy that the Demonstration

Amendment seeks to upend. Any decision by MassHealth to change this requirement by closing its formulary will unfairly impact its patients who, unlike the commercially insured population, are without other options for drug coverage. This one-size-fits all coverage can only work if beneficiaries are given more, not fewer choices. In truth, the Commonwealth's insistence that the MassHealth program adopt commercial market techniques is a double-edged sword – on the one hand, it imposes strict limitations on coverage for individuals already at a greater healthcare risk than the general population; and on the other hand, it imposes these limitations without any of the associated benefits (such as consumer choice) available in the commercial market.

MassHealth has Significant Tools to Manage Drug Costs.

While we can all agree that the Commonwealth has a legitimate interest in lowering overall healthcare spending and getting the "best deal" for the program, MassHealth already has measures in place to ensure that patients are only receiving effective prescription drug treatments. Under current State and Federal law, MassHealth (including Medicaid MCOs operating in Massachusetts) is permitted to apply certain prior authorization measures to drug coverage (for example, fail-first or step-therapy techniques).

In addition, MassHealth is already permitted (absent any waiver authority) to create Medicaid formularies and exclude drugs from such a formulary if (a) the drug's labeling or certain compendia establish that the drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome" over a drug included on the formulary, (b) there is a publicly-available written explanation of the basis for the exclusion, and (c) the excluded drug is made available with prior authorization. Moreover, Massachusetts and other states have at their disposal other commercial-like tools used to manage costs including the ability to limit the minimum or maximum quantity per prescription, and the ability (which Massachusetts already leverages) to create Preferred Drug Lists (PDLs). These tools both drive enrollees toward lower cost therapies, while empowering states to negotiate substantial supplemental rebates on covered drugs that are deeper than statutory rebates.

MassHealth's longstanding prescription drug system has successfully ensured that the Commonwealth's most vulnerable citizens have access to the lifesaving therapies they need. Instead of radically restricting this system, the Commonwealth should consider employing tools that are already available to manage drug costs in the Medicaid system.

The Demonstration Request Disrupts the Grand Bargain of the Medicaid Drug Rebate Program.

The Medicaid Drug Rebate statute (Section 1927 of the Social Security Act) reflects a "grand bargain" between manufacturers and state Medicaid programs. That is, open access in drug coverage is available in return for favorable pricing, and in some cases very steep discounts, for state Medicaid programs. The proposed restructuring of the MassHealth pharmacy benefit would disrupt this nearly 20-year-old bargain, putting both innovation, and patients' lives, at risk. In return for open formulary access, MassHealth currently accesses the lowest of a minimum discount or the manufacturer's best price – an arrangement that is not available to commercial payers. This arrangement can and does in many cases drive down the cost of prescription drugs in MassHealth as compared to commercial plans. If the Commonwealth's proposal is approved and implemented, the Demonstration would introduce uncertainties into a system that currently guarantees access in return for favorable pricing. Moreover, this disruption in the grand bargain that resulted in the enactment of Section 1927 would likely result in the Commonwealth losing rebates for drugs excluded from preferred coverage status under the closed

formulary. That loss in revenue, of course, must be considered in connection with any cost savings calculations.

MassHealth Cannot and Should Not Restrict Access to FDA Approved Breakthrough Lifesaving Treatments

One of the more concerning elements of the proposed Demonstration Amendment request is its proposal to "exclude from the formulary drugs with limited or inadequate evidence of clinical efficacy" that have been subject to accelerated FDA approval. As a general concern, this proposal would effectively replace the expert opinion of the FDA and an individual patients' treating physician with that of the Commonwealth. More specifically, and putting aside the clear legal concerns with the proposal (for example, whether it can even withstand preemption by Federal law), the proposal ignores that very policy underpinnings of FDA's expedited approval procedure, which is to ensure access by patients to lifesaving therapies for serious conditions where no other treatment options are available. Indeed, the proposal is particularly suspect considering that FDA's requirement that products subject to the accelerated approval pathway show significant improvement over existing therapies. As a result, products approved under FDA's expedited approval pathway can generally offer greater benefits than those approved under the standard pathway. Accordingly, the Commonwealth's proposed restrictions on access to these products would completely contravene and undermine Congress' intended goal in creating the accelerated approval pathway. What's more, a proposal that imposes such restrictions on the highly diverse and relatively more vulnerable MassHealth population would unfairly deny them the access to lifesaving therapies that are afforded to commercially insured patients. In sum, the proposal illustrates both what appears to be a fundamental misunderstanding of the FDA approval process, as well as a shortsighted disregard for patient choice and expert opinion.

* * * * *

We appreciate the opportunity to offer our public comments as the Commonwealth considers ways to improve the efficiency of the MassHealth program, while ensuring access and coverage for enrollees. As noted in our comments, we believe the proposed restructuring of the MassHealth pharmacy benefit to resemble "commercial" coverage is a clear step in the wrong direction. The Commonwealth can and should introduce innovation into the MassHealth program – but the proposed changes to the pharmacy benefit will harm, not help, patients and upend a long-held compact between the Commonwealth and its citizens to provide low-cost, high-quality care to its most vulnerable patients.

Sincerely,

MassBio and our member companies
Alexion
AstraZeneca
Biogen
Bristol-Myers Squibb
Pfizer
Sanofi Genzyme
Sarepta Therapeutics
Shire

By Electronic Submission

August 21, 2017

Kaela Konefal
EOHHS Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108
Kaela.konefal@state.ma.us

Dear Ms. Konefal:

We are writing you to express our concerns with the MassHealth Section 1115 Demonstration Amendment Request which was posted for comment on July 20, 2017. Specifically we object to the amendment request that would undermine the authority and processes of the FDA by overlaying it with a new Commonwealth-based drug approval system and use that system to enact a closed drug formulary for MassHealth recipients.

Sanofi is a global life sciences company committed to improving access to healthcare and supporting the people we serve thru the continuum of care. Sanofi has facilities in Cambridge, MA employing 4574 people and are involved in seven active research and development studies in the Commonwealth.

Sanofi has a long-standing commitment to supporting solutions for increasing access to care and improving the quality of health care here in the United States and abroad. Because of this we are particularly concerned with the proposed amendment to waive sections of the Medicaid drug rebate statute and its potential impact on access to innovative care for the most vulnerable patients in the Commonwealth. We also concur with the extensive legal and structural arguments put forth by MassBio and PhRMA on this amendment request.

While we support the Commonwealth's leadership and sustained efforts to expand access to coverage thru integrated and coordinated care, this particular proposal could harm the most vulnerable patients the Commonwealth seeks to protect by denying them access to life-saving treatments with a limited closed formulary.

Our company is a leader in innovation for underserved patients suffering from rare and extremely complicated diseases and conditions. We are committed to supporting reforms that strike a balance between the value a treatment provides to the patient and the cost of their overall care and health. Overlaying the current FDA process with a Commonwealth-based one is both duplicative and inefficient. MassHealth already has the tools under current Federal statute and regulatory guidance to manage access to pharmaceuticals and to ensure that the appropriate patients receive clinically appropriate treatments. The time and resources of the Commonwealth

SANOFI

and MassHealth are better utilized with existing tools rather than creating their own unique process. We thank you for the opportunity to provide comment on this proposal and respectfully request that the department does not move forward with this particular amendment request.

Respectfully Submitted,

Liz Cirri
Head, US Reimbursement and Public Policy

cc: Secretary Marylou Sudders, Executive Office of Health and Human Services
Secretary Michael Hefferman, Executive Office of Administration and Finance

Biotechnology Innovation Organization

August 21, 2017

VIA ELECTRONIC SUBMISSION

Ms. Kaela Konefal
EOHHS Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108
Kaela.konefal@state.ma.us

Re: Comments for Demonstration Amendment: DRAFT 1115 Demonstration ("Waiver") Amendment Request (As posted for Public Comment July 20, 2017)

Dear Ms. Konefal,

The Biotechnology Innovation Organization ("BIO") is pleased to submit the following comments related to the Commonwealth's draft Medicaid 1115 Demonstration Waiver Amendment Request. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

Although BIO appreciates the Commonwealth's efforts to reform the MassHealth program to control costs, the formulary proposals included in the Waiver Amendment Request Draft are not effective solutions. As further detailed in the paragraphs below, BIO is especially concerned with Section 6 of the amendment draft, which seeks to alter the pharmaceutical benefit currently provided to MassHealth beneficiaries. If implemented, the proposals would significantly impede patient access to needed treatments, while likely increasing overall expenditures on these medications, given that the Commonwealth may ultimately lose the mandatory rebates provided for under the Medicaid Drug Rebate Program. We urge the Commonwealth to consider the implications of such a proposal, and to withdraw the provisions intended to institute a closed and restrictive formulary.

At the outset, BIO would like to shed some light on the current state of prescription medicines in the United States, because, unfortunately, many popular press accounts focus an overly narrow view on the list prices of a small subset of innovative biopharmaceutical products, rather than focusing on the marketplace as a whole. A brief overview of the *complete* picture of the biopharmaceutical marketplace is helpful in framing the issue. Specifically, according to the trade association representing the generic drug industry in the United States, almost 90% of prescription

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 P
202.488.6301 F
bio.org

medicines dispensed in the U.S. are generic.[1] And with FDA's approval of a fifth commercially-available biosimilar medicine earlier this year, the marketplace for lower-cost biologic products is rapidly expanding. In short, the amazing innovations seen in the biopharmaceutical marketplace over the past several decades are also rapidly matriculating to the lower-cost generic market.

Further, the innovative side of the biopharmaceutical marketplace is strong, but challenges exist. The cost of developing a new drug has increased exponentially since the 1970s. A recent study conducted by the Tufts Center for the Study of Drug Development found that developing a drug that gains market approval can take over 10 years, and cost roughly $2.6 billion.[2] There is a high failure rate in biopharmaceuticals research and development (R&D), so investments take into account the funds spent on products that never make it to market. Furthermore, biopharmaceutical development is increasingly relying on outside private and public market capital as an investment source. Investors, however, have a range of diverse industries to choose from when making capital allocation decisions. Issues like government-imposed price controls are significant detractions for the investment community when evaluating investment options.

The enormous resources required to sustain and drive forward the innovation ecosystem is reflected in the reality that the pharmaceutical industry spends significantly more than almost every other industry on R&D. On average, pharmaceutical companies spend 18 percent of revenue on R&D; when looking just at the U.S., one study found that, in 2013, 23.4 percent of domestic sales went to domestic R&D.[3] Complementing this research is a survey conducted by the National Science Foundation and the Census Bureau that showed that among manufacturers, the pharmaceutical industry spent the most on R&D annually, averaging $70 billion.[4] In short, while the innovation necessary to continue to drive development of new treatments continues, the process is increasingly more difficult – and more expensive. But hope for patients with previously untreatable diseases continues to rise – that is, as long as patients continue to have insurance programs that permit the access to these medicines.

It is the topic of access that gives industry the most concern when reviewing the Draft Waiver Amendment. Specifically, in section 6a, the Commonwealth proposes to "[s]elect preferred and covered drugs through a closed formulary" and "adopt a commercial-styled formulary" in administering its proposed Medicaid amended program. In other words, the Commonwealth seeks to limit patient access to certain medicines under its Medicaid program. In essence, the Commonwealth has taken the legally suspect position that it can waive the access protocols outlined in Section 1927 of the Social Security Act.

---

[1] Association for Accessible Medicines, *2017 Generic Drug Access & Savings in the U.S. available at: http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf*

[2] Lamberti M. and Getz, K. Profiles of New Approaches to Improving the Efficiency and Performance of Pharmaceutical Drug Development. Tufts Center for the Study of Drug Development. May 2015.

[3] Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA annual membership survey. Washington, DC: PhRMA; 2015, as reported here: http://phrma-docs.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf (last accessed March 10, 2017).

[4] US Businesses Report 2008 Worldwide R&D Expense. https://wayback.archive-it.org/5902/20160210142717/http://www.nsf.gov/statistics/infbrief/nsf10322/. May 2010.

The Medicaid rebate provisions of the Social Security Act represent a carefully balanced compromise made by Congress to ensure the Government has access to the lowest available price for covered outpatient prescription medicines – via a statutorily mandated rebate – with the understanding that the benefit of this bargain was that manufacturers' products would be accessible to Medicaid recipients if medically necessary and subject to statutorily defined access restrictions. Currently, the benefits of the program are being realized by the Commonwealth. In fiscal year 2015, rebates reduced total pharmacy spending by 50.1 percent. More specifically, in that same year, the total gross rebate revenue invoiced to manufacturers for all MassHealth pharmacy programs, including both Primary Care Clinician Plan/fee-for-service and managed care organizations, was more than $591,000,000.[5]

MassHealth is also optimizing its return from manufacturer rebates by requiring supplemental rebates in selected therapeutic classes. Currently, MassHealth has four supplemental rebate agreements in place, is evaluating bid responses from a fifth solicitation, and has five additional bid solicitations in preparation. The annualized gross value of the current supplemental rebate agreements is approximately $25 million, with a potential for an additional revenue of $4 million annually when all supplemental rebate agreements are actualized. Yet for the first time in history, Massachusetts has proposed to ignore the statutory mandate, disrupting the agreement, and risking losing access to the statutorily defined rebates. The impact of such an action would not only eviscerate the underlying incentives built into the Medicaid rebate program, likely increasing the Commonwealth's overall expenditures on these medications, but would unquestionably lead to access problems for Medicaid patients.

What is more, Section 1927(d)(4) already outlines a process for a state Medicaid program to implement a formulary. And yet the Commonwealth's proposal seeks to skip right over the statutorily defined program – without even attempting it in the first place – in favor of a legally suspect access restriction effected through a demonstration waiver program. In short, such an action is unlikely to benefit patients in the long run.

Furthermore, in section 6b, the Commonwealth proposes to "[e]xclude from the formulary drugs with limited or inadequate evidence of clinical efficacy." This is frankly alarming. The proposal raises significant concerns related to patient access to new FDA approved treatments. Specifically, the waiver amendment defined limited or inadequate clinical efficacy to refer to drugs for which:

- Primary endpoints in clinical trials have not been achieved;
- Only surrogate endpoints have been reported;
- Clinical benefits have not been assessed;
- FDA-approval is contingent upon verification of clinical benefit in confirmatory trials;
- The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives.

---

[5] MassHealth Report to the Legislature Concerning Cost Savings on Prescription Drugs. February 1, 2016.

BIO raises significant objection to the Commonwealth's proposed attempt to thwart access to new and innovative therapies, based upon the Commonwealth bureaucracy's apparent ability to better determine efficacy of a particular product than the U.S. Food and Drug Administration (FDA). Efforts to restrict availability of therapies reviewed through an accelerated approval pathway effectively undermines the purpose of expedited approval pathways to address unmet medical need by expanding patient access to treatments for serious conditions. Excluding these drugs from a closed formulary would impede Congress' express purpose in codifying the FDA's accelerated approval pathway, and contradict a series of congressional initiatives designed to spur the development of innovative treatments to enable Americans with serious diseases and limited treatment options – or no treatment options – to obtain novel therapies. Furthermore, drugs receiving a Breakthrough Therapy Designation are only granted such a designation due to the significant improvement over existing therapies shown early on in the clinical trial process. Regardless of their approval pathway, all approved therapies have met extensive testing and rigorous evaluation by the FDA – a process that not only ensures patient safety, but also clinical effectiveness. In fact, a recent study found that drugs approved through one of the FDA's expedited review programs offered greater health gains than drugs reviewed through conventional processes.[6] If implemented, the proposal to deny Massachusetts Medicaid beneficiaries access to critical medicines could rob patients of access to approved medicines that could be their only treatment option, and would break sharply with the Commonwealth's history of leading the way in the effort to assure necessary care for vulnerable patients.

Section 6b plainly targets for formulary exclusion drugs approved by FDA under its accelerated approval pathway, and suggests that this would only exclude drugs "that are not medically necessary." Moreover, this section indicates that the 21st Century Cures Act "expedite[d] the drug approval process by reducing the level of evidence required for drugs to reach the market." These statements are demonstrably incorrect. Drugs approved under the accelerated approval process are critically necessary to patients, as accelerated approval is used for drugs "for a serious or life-threatening disease or condition …upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit … taking into account the severity, rarity, or prevalence of the condition and availability or lack of alternative treatments."[7] Further, by law, such drugs must satisfy the same safety and effectiveness standards FDA applies to other drugs, including "substantial evidence" of effectiveness.[8] And FDA and Congress have both made clear that neither the process for accelerated approval nor the 21st Century Cures Act diluted FDA's approval standards. In fact, the 21st Century Cures Act was designed to "ensure that we remain "on the forefront of medical innovation while maintaining the gold standard for approvals of medical products."[9]

Moreover, excluding coverage for drugs through expedited approval pathways, such as accelerated approval, could discourage manufacturers from developing innovative therapies if substantial portions of the population will no longer be able to access those therapies after they are

---

[6] Chambers, et al. Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains than Drugs Approved by Conventional Process. Health Affairs Vol. 36, No. 8, 2017.
[7] 21 U.S.C. 356(e)(2), (c)(1)(A).
[8] 21 U.S.C § 355(d)(5).
[9] July 10, 2015 Congressional Record at E1036 (statement of Rep. Pallone).

developed. This is especially true for orphan diseases, as developing treatments for these diseases poses unique challenges, and the potential rewards for innovation dwindle if the already small patient population effectively gets smaller due to payors targeting novel treatments for coverage restrictions. Formulary restrictions targeting accelerated approval drugs could deter development of treatments for serious diseases.

Additionally, section 6b of the waiver amendment request seeks to rely on the Commonwealth's assessment of which drugs are clinically effective, rather than allow providers to determine the best course of treatment for their individual patients. As we move towards the era of personalized medicine and patient-centered healthcare, it becomes increasingly important that we allow providers to use their best clinical judgment, and not be constrained by the bounds of a restrictive formulary that fails to recognize the benefits of products approved under the FDA's accelerated approval pathway and assesses access based on a macro-level population.

It is critical that Medicaid patients – who represent some of the sickest and poorest residents in the Commonwealth – have access to these new-to-market therapies, which are often surpassing the current standard of care making it increasingly difficult to compare them with older products already on the market. Denying access to such products, many of which are treating a serious disease for which there are no other alternatives, unduly harms patients. This policy is shortsighted as delaying access to the latest and most effective treatments may only further worsen a patient's condition, leading to additional doctors' visits, hospitalizations, and even surgeries, increasing healthcare costs in the long run. A one size fits all approach is insufficient for a population as diverse as the one represented by the Medicaid program, and BIO urges the Commonwealth to consider the adverse effects of not supporting the provider-patient decision making process by implementing a restrictive formulary.

***

While BIO appreciates the Commonwealth's concern about the affordability of healthcare and the sustainability of the Medicaid program, the formulary proposals included in the recently released 1115 Waiver Amendment Request Draft are not the appropriate mechanisms to achieve this goal. We have serious concerns regarding how these proposals will inevitably restrict access for Medicaid patients, making it increasingly difficult for them to access the right treatment at the right time. We thank the Commonwealth for the opportunity to register our opposition to the Waiver Amendment Request Draft and look forward to working with you in advancing waiver proposals that test novel approaches for delivering healthcare to the state's most vulnerable population.

Sincerely,

/s/

John A. Murphy, III
Deputy General Counsel
Biotechnology Innovation Organization
202-962-6673 | JMurphy@bio.org

health law advocates
Lawyers Fighting for Health Care Justice

HLA

One Federal Street, 5th Floor
Boston, MA 02110

T 617-338-5241
888-211-6168 (toll free)
F 617-338-5242
W www.healthlawadvocates.org

August 21, 2017

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

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

Re: Request to Amend the MassHealth 1115 Demonstration Waiver

Dear Assistant Secretary Tsai,

Health Law Advocates (HLA) respectfully submits the following comments to the Massachusetts Executive Office of Health and Human Services (EOHHS) regarding the proposed changes to the MassHealth 1115 Demonstration Waiver.

HLA is a non-profit, public interest law firm that provides free legal assistance to low-income Massachusetts residents who face barriers to accessing health care and coverage. We appreciate the agency's willingness to work with advocates and listen to feedback as it begins to investigate possible changes to the MassHealth program. The financial strength of this program is a goal that we can all come together on, that we all agree is vital to the long-term stability of MassHealth. We also believe maintaining consumers' current level of access to health care is equally vital to preserve the strength of our Commonwealth and health of our residents.

We are concerned that the current proposed changes will impose considerable new obstacles for low-income Massachusetts residents' *access* to health care. If individuals are unable to access health care services – either due to the financial burden imposed by new cost-sharing and deductible amounts, or administrative hurdles described below – their health and wellbeing will inevitably suffer. Coverage without access is tantamount to no coverage at all.

Below, HLA highlights the three proposed changes by the Amendment request that we believe most threaten the ability of low-income Massachusetts residents to access health care: 1) Shifting non-disabled adults with incomes over 100% of the Federal Poverty Level (FPL) from MassHealth to the Health Connector; 2) Changing the MassHealth's Premium Assistance program and implementing a so-called "eligibility gate;"; and 3) Implementation of a closed prescription drug formulary and restricted availability of specialty pharmacies

While we strongly urge EOHHS against pursuing these policy proposals further, we have also included suggestions for implementation that may mitigate some of the possible negative outcomes. Finally, we have also included a list of other aspects of the proposed amendment that concern HLA, as well as areas where we tentatively support the changes put forward.

I. The proposed shift of non-disabled adults with incomes over 100% of the FPL into Health Connector plans endangers health care access for the affected members, particularly parents and caretakers, and their MassHealth-eligible children

EOHHS proposes five reforms to "align coverage for non-disabled adults with commercial plans."[1] This includes moving roughly 140,000 people with incomes between 100% FPL and 138% FPL from MassHealth to the Health Connector, and shifting roughly 230,000 individuals from MassHealth Standard into MassHealth CarePlus. We understand that the rationale behind this change is that this group is the most "economically mobile"[2] and does not require the "unique services" that Medicaid offers."[3] Many of HLA's clients fall into this category of non-disabled adults and we feel the proposals fail to account for numerous factors that distinguish this group and therefore justifies their access additional support from the MassHealth progam in regards to health insurance coverage.

We are especially concerned about those moving from MassHealth to the Health Connector. This group is still very poor even though many have employment income. At their income level, they are more likely to be working in part-time or seasonal positons in which employers do not offer health benefits. As you know, an individual at 138% FPL earns $16,656 a year, or $1,388 a month, and a family of four earns $33,960 a year or $2,830 a month. These amounts do not go very far in Massachusetts where essentials such as housing, food, transportation, and medical care are very expensive. Additional cost-sharing for health care would be a monumental impediment to meeting daily necessities for many of HLA's clients.

Under the current proposal, increased cost-sharing in terms of monthly premiums could reach up to 17% of income for individuals and 24% of income for couples. Higher cost-sharing in the form of out-of-pocket co-pay increases could represent 10% of income for an individual and 15% of income for couples at 100% FPL, or up to 7.7% of income for an individual and 11.5% of income for couples at 133% FPL. Certain essential services, such as primary care visits, mental and behavioral health services, and emergency room visits, will have co-pays where there are currently none under MassHealth. These costs could be devastating for an individual or a family on an already limited budget. HLA currently has clients for whom co-pays, no matter how small the amount, are unsurmountable barriers to accessing care. Additionally, there are certain services – such as dental and vision – which will not be covered at all. We are extremely concerned about the impact this increased cost-sharing will have on the ability of this population to access medically necessary health care. Massachusetts is one of the only states which has proposed going this far in increasing cost-sharing, which runs counter to the "culture of coverage" in the Commonwealth, and our historic commitment to provide coverage to all residents.

One population of particular concern to HLA are parents and caregivers of children who are eligible for MassHealth coverage. Under the current proposal, 100,000 parents and caretakers

---

[1] *MassHealth Section 1115 Demonstration Amendment Request (Waiver Amendment),* July 20, 2017, 3.
[2] *Id.* at 4.
[3] *Id.*

will be moved from MassHealth to the Health Connector. This means they will be on an entirely different health insurance system then their MassHealth-eligible children. We are concerned about the implications of this move on both the parents' and the children's ability to access health care. Even with abundant attempts at notice and messaging, and an extended transition period, it is likely that many parents will not take the necessary steps to enroll in a qualified health plan (QHP) through the Health Connector. Other states that have attempted this type of population shift have seen significant coverage reductions among parents who were moved from the state Medicaid system to the exchange.

In 2015, Connecticut eliminated eligibility for parents and relative caregivers of children in the HUSKY program.[4] The state undertook an extensive notice and marketing campaign, emphasizing that affordable health insurance was still available under the Access Health CT exchange, and even provided many parents with a year of transitional medical assistance (TMA).[5] Nonetheless, among the parents disenrolled from Husky Care, just one in four enrolled in a QHP through Access Health CT, including some who experienced gaps in coverage during the transition.[6] Most parents in the group (73.5%) did not enroll or have since dropped coverage and may be uninsured.[7]

In 2012, Maine reduced the Medicaid income eligibility level for parents from 133% FPL to 105% FPL, and about 28,500 working Maine parents lost regular Medicaid coverage in the following two years.[8] In Rhode Island, out of 6,574 parents affected when Medicaid eligibility was rolled back in 2014, roughly 20% never submitted an application to enroll in a QHP and likely became uninsured, while roughly 10% signed up for a plan but never made a payment and likely became uninsured.[9] These states had a high percentage of drop-off with a relative small population of parents; the outcome for the 100,000 parents and caretakers affected by the MassHealth proposal could be much worse, but even a loss of 20-30% of currently covered parents could be devastating. It could represent the first dramatic increase of the uninsured in Massachusetts in recent times.

HLA is particularly concerned about the impact on MassHealth-eligible children whose parents are moved to the Health Connector. Continuous coverage for low-income parents is likely to result in uninterrupted coverage for their children and more effective use of that coverage for addressing health care needs.[10] Conversely, children in low-income families are three times more likely to be uninsured if their parents are uninsured.[11] Data shows that children with uninsured

---

[4] Connecticut Voices for Children, *HUSKY Program Coverage for Parents: Most Families Will Feel the Full Impact of Income Eligibility Cut Later in 2016 (Connecticut Voices)*, April 2016, 1.

[5] *Id.* at 1 – 2.

[6] *Id.* at 1.

[7] *Id.*

[8] *Ensuring Health Coverage for Maine Families with Children in 2014: A Health Policy Brief by the Maine Children's Alliance (Maine Health Policy Brief)*, 1.

[9] These numbers don't take into account 36% of parents who were unaccounted for at the time the date was collected, and likely became uninsured. Community Catalyst, *Parent Eligibility Roll-Back in Rhode Island: Causes, Effects and Lessons Learned (Roll-Back in Rhode Island)*, September 2015, 5.

[10] *Connecticut Voices*, 3; *quoting* Rosenbaum S, Whittington RPT, *Parental health insurance coverage as child health policy: Evidence from the literature*, Washington DC: George Washington University School of Public Health and Health Services, June 2007. Available at: http://publichealth.gwu.edu/departments/healthpolicy/CHPR/downloads/Parental_Health_Insurance_Report.pdf.

[11] *Id.*; *quoting* Schwartz K, *Spotlight on uninsured parents: How a lack of coverage affects parents and their families*, Washingington DC: Kaiser Commission on Medicaid and the Uninsured, June 2007; *see also* DeVoe JE, Krois L, Edlund C, Smith J, Carlson NE, *Uninsured but eligible children: are their parents insured? Recent findings from Oregon*, Medical Care, January 2008, 46(1): 3-8.

parents have a greater risk of gaps in coverage, and are less likely to receive check-ups, preventative care and other health services.[12] Particularly at risk are children with complex medical or behavioral health needs. In Maine, when the change in parent's eligibility occurred, 6,000 children who were eligible for Medicaid became unenrolled. This represents roughly 13% of children who lost coverage for which they were otherwise eligible.[13] Advocates hypothesized that some parents who received notice of their own termination from Medicaid believed, erroneously, that their children were also being terminated.[14] This is a probable outcome in Massachusetts, as well. Compounding this confusion is the prevalence of MassHealth MCOs and Health Connector plans with the same or similar names. Massachusetts has long been a champion of children's health care access, and this proposal threatens our commitment to maintaining quality health care coverage for vulnerable young people.

A subset of the parent population who are especially at risk are mothers of newborn children above 100% of the FPL. Shortly after they give birth, these women must navigate setting up their own health insurance while also ensuring they enroll in health coverage for their newborn child. Maintaining health coverage during the postpartum period is vital to maintain population health.[15]

HLA is strongly against shifting parents and caretakers from MassHealth to the Health Connector. However, if this change were to take place, there are several measures that have been used in other states that could mitigate potential harm. First, the Commonwealth could implement a redetermination process for any member who would lose MassHealth eligibility to identify those who may still be eligible under another coverage category (for example, pregnancy or disability). In Rhode Island, 24% of the affected parent population remained on Medicaid after an eligibility review.[16] Once people enroll in coverage through the Health Connector, a streamlined process for determining medical frailty, which confers access to MassHealth would be imperative to ensure individuals have access to the appropriate level of coverage for their circumstances. A long and vigorous notice period, as well as the availability of benefits during the transition and access to a robust network of assistors, will be imperative.

We recognize that Massachusetts has a "culture of coverage" not seen in many other states, but Massachusetts will likely suffer the same coverage drop-offs if residents do not have knowledge of and access to the resources to maintain coverage. Additionally, a plan made available on the Health Connector that closely resembles and mimics MassHealth (and the old Commonwealth Care coverage) – including $0 premiums and minimal cost-sharing – would greatly reduce disruptions in care. Automatic enrollment into a $0 premium Health Connector plan would greatly reduce barriers to access, although HLA recognizes that conversations would need to happen with the Health Connector, and possibly the legislature, to determine if such a change would be possible.

HLA is also concerned with the proposed shift of approximately 230,000 parents and caretakers from MassHealth Standard to MassHealth CarePlus due to the availability of CommonHealth and the medical frailty program. However, we emphasize the importance of a redetermination process to ensure that members are in the appropriate level of coverage, and the necessity of a

---

[12] *Maine Health Policy Brief*, 1; *quoting* Rosenbaum and Whittington, 5-6.
[13] *Maine Health Policy Brief*, 1, 3.
[14] *Id.* 3.
[15] *Id.* 4.
[16] *Roll-Back in Rhode Island*, 3.

streamlined exceptions and waiver process, so that members can easily move to more comprehensive coverage should their health care needs change.

II. Proposed changes to the Premium Assistance program, including introduction of an "ESI gate" and narrowing of the Medicaid wrap, endanger access to health care for MassHealth members

HLA is very supportive of the Premium Assistance program, and has been engaged with MassHealth over the past year to help improve the efficacy and visibility of Premium Assistance benefits. HLA supports some of the measures that MassHealth has suggested to improve the program, such as the reintroduction of the HIRD form. However, we are concerned that two proposed changes to the Premium Assistance program – the implementation of an "employer-sponsored insurance (ESI) gate" and the potential reduction of the MassHealth benefit wrap – may impose unneeded barriers to accessing health services.

HLA opposes the implementation of a gate that would bar access to MassHealth for individuals with access to "affordable" ESI. In the August 4th hearing on this proposal, MassHealth revealed that ESI would be considered "affordable" if the ESI premium plus deductibles totaled less than 5% of income.[17] The inclusion of deductibles in this calculation is new, though it is unclear what exactly is meant by "deductible" Is this the out-of-pocket maximum cost? Are co-pays included? How is this calculated when an individual notifies MassHealth that they have access to ESI? MassHealth estimates that with the new calculation, roughly 5,000 members would be affected. We believe that affected individuals will be among the poorest and most vulnerable in the state. The example that MassHealth included in the presentation exemplifies the dangers of this proposal: a single non-disabled adult earning $12,000 a year with ESI that costs less than $50 per month.[18] This member would likely be taking home less than $1,000/month – after rent, food, and other essentials, any new costs associated with health care, even at an amount of less than $50 a month, would be devastating. HLA has clients who are unable to go to scheduled medical appointments or have necessary tests done because of the associated costs, even where co-payments are as small as 10 or 20 dollars. This population needs the protections of Premium Assistance and MassHealth to allow them to access necessary and affordable health care. HLA urges MassHealth not to impose the gate, and to allow these members into the Premium Assistance program).

Also, HLA is concerned about the health care access implications of reducing the Medicaid "wrap" of commercial plans for MassHealth-eligible people. It is unclear based on available materials which benefits would potentially be reduced. We are heartened to see a commitment to cover programs not usually covered by commercial insurance. For many members with Premium Assistance, the wrap covers medically necessary services such as behavioral health services, and long-term services and supports. We would be very concerned if there were any effort to reduce access to any of these services, or to reduce the wrap-around coverage for co-payments and deductible that allows many in the Premium Assistance program to access crucial benefits. HLA requests additional information regarding which benefits EOHHS is requesting to reduce as part of the Premium Assistance MassHealth wrap. We oppose any changes and reductions to the program which would reduce access for low-income MassHealth members who rely on these benefits to access their health care.

---

[17] *MassHealth August Presentation*, Slide 14.
[18] *Id.*

III. Proposed changes to pharmacy benefits may reduce access to medically-necessary drugs for MassHealth members

HLA recognizes the need to manage the rapid growth of prescription drug costs to ensure the overall financial strength of the MassHealth program. We believe that an increase in MassHealth's bargaining power in relation to prescription drug companies is a tool that would have a positive impact on the pharmacy program. However, we are concerned by the proposals to implement a closed formulary and narrow the specialty pharmacy networks. HLA recognizes that there are a number of positive and reasonable outcomes that will be achieved by establishing a closed formulary, especially given the historical context where Medicaid programs have been forced to cover some low-value, high cost drugs if the manufacturer participates in the federal drug rebate program. A closed formulary that gives MassHealth the ability to exclude brand-name drugs from coverage in certain therapeutic categories – such as high cholesterol, high blood pressure, etc. - is very reasonable given available generic equivalents. Also, it would be helpful to protect financial resources where the cost of a drug spikes. HLA hopes that any savings generated would be put back into the pharmacy program to ensure greater access for members.

We are concerned about a closed formulary when it comes to specialty drugs, such as treatments for hepatitis-C and other chronic illnesses. While HLA supports the agency's ability to negotiate for rebates that allows MassHealth to lower the costs associated with these high-priced drugs, there must be a **truly expedited** exceptions process to permit access to drugs outside of the formulary. Such a process is necessary for affected individuals who have a negative indication or reaction to a MassHealth-preferred drug. HLA is also concerned about the rise of "fail first" policies introduced as part of the closed formulary, which may pose an undue obstacle to certain drugs and may undermine the stability of a member's condition that has been well-managed under a certain medication regime. Currently, our clients find it extremely difficult and cumbersome to navigate the MassHealth exceptions process for prescription drugs, particularly when an MCO is involved. We believe MassHealth should ensure access to an exceptions process that is streamlined and accessible if it plans to further restrict access to prescription drugs.

Additionally, HLA is concerned about overly restrictive language related to drugs that were "fast-tracked" under the 21st Century CURES Act. While it is true that many of the drugs that are coming to market through the FDA's accelerated approval pathway have not yet proven their efficacy on primary endpoints in clinical trials,[19] many of these drugs treat cancer and other chronic terminal illnesses and the affected members may not have time to wait. While we are encouraged by the language that would support coverage of "breakthrough" drugs,[20] we are concerned that the exclusion included in the waiver amendment is too broad and will prohibit MassHealth members from accessing potential life-saving treatments that their privately insured peers will be able to obtain.

Finally, we are troubled by the proposal to establish a more selective specialty pharmacy network. Language in the waiver refers to "selected pharmacy locations."[21] If MassHealth chooses only one pharmacy to manage and provide specialty drugs, then MassHealth members who do not live in a geographic area that houses one of the selected pharmacies may be unable to

---

[19] *Waiver Amendment*, 10.
[20] *Id.*
[21] *Id.*

access the medication they need. Many MassHealth members do not have reliable access to public transportation, particularly in the Western part of the state, and limiting where they can access medications may pose an insurmountable access barrier. Furthermore, "mail order or home delivery"[22] of drugs is not workable for many MassHealth members. Often, specialty drugs are delivered during the day and members may need to take time off from work to insure the medication is not stolen or does not go bad because it is not adequately refrigerated in time. Additionally, MassHealth members who face housing instability may not be able to access their medications at all through a mail order or home delivery system. HLA believes that restricting where and how MassHealth members can access specialty medication is not an effective way to manage pharmacy costs in the MassHealth program.

IV. Miscellaneous Comments and Concerns

- HLA supports EOHHS's request to waive federal payment restrictions on care provided in Institutions of Mental Disease (IMDs), as we believe this step will increase access to behavioral health services, including treatment for substance use disorders (SUD). However, the agency must clearly state that the waiver applies to *private hospitals only* -- not public institutions -- to avoid an overwhelming and unmanageable reliance on state institutions to provide behavioral health care.

- HLA cautiously supports the elimination of MassHealth Limited coverage for Health Connector-eligible individuals. Currently, many members are confused by the dual notices informing them that they are eligible for both MassHealth Limited and the Health Connector. Many of our clients do not understand that they must take action to choose and enroll in a plan after receiving the eligibility determination. However, if MassHealth Limited coverage were to be terminated for this population, MassHealth must engage in a comprehensive notice period and education effort to inform individuals how to access coverage from the Health Connector. Eligibility for the Health Safety Net (HSN) should be available to this population during the time between filing the application and enrolling in Connector Care. Additionally, HSN eligibility should be extended for this group once they are terminated from MassHealth Limited for a period of at least 6 months. This extension would minimize coverage gaps during the transition period, resulting in the accrual of unmanageable medical debt.

- HLA is concerned with MassHealth's proposal to limit and narrow MassHealth's Primary Care Clinician (PCC) plan, especially because it is unclear exactly how narrow the network would become. While we recognize the importance of coordinated, integrated care, and support MassHealth's move to the accountable care (ACO) model, many of our members are in the PCC plan for very specific reasons. Often, due to their medical needs, they require access to very specific and varied specialists, and none of the MCOs have provider networks adequate to meet their needs. We think that even after the move to the ACO model, there will still be MassHealth members who cannot access key specialists and who will need to enroll in the PCC plan to access medically appropriate care. In regards to network adequacy, especially in the face of a shrinking PCC plan, HLA is also concerned with MassHealth's proposal to waive the requirements for multiple managed care options in certain areas of the state.[23] We feel this could severely restrict access, particularly in western Massachusetts, Cape Cod, and the Islands.

---

[22] *Id.*

[23] *Waiver Amendment*, 12.

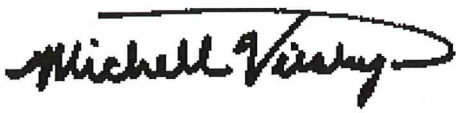
- HLA does not support the proposal to implement cost sharing greater than five percent of income for members over 300% FPL.[24] MassHealth members above 300% FPL are members who have disabilities or families with children with disabilities who are covered under the MassHealth CommonHealth program. While these members may have higher incomes, their cost of living is also much higher. Their housing and transportation costs, as well as many other aspects of everyday life, must be modified in relation to their disability. For example, families of children with complex medical or behavioral health needs face significant costs to keep them safely in the home. We have clients who are CommonHealth members who struggle to pay the 5% deductible and we have some clients who end up paying more than 5% income for their medical costs, regardless of the restriction. Increased cost sharing for this population could pose an insurmountable obstacle to accessing medical care and may have a detrimental impact on the wellbeing of vulnerable people with disabilities. We are especially concerned because MassHealth did not include the amount of the cost-sharing increase in the waiver amendment.

V. Conclusion

HLA would like to thank EOHHS for your willingness to engage in an open dialogue regarding MassHealth reforms and the agency's diligent efforts to ensure the ongoing strength of MassHealth. We share your goal of ensuring a MassHealth program that is financially strong in the long term. However, we believe that some of the Waiver proposals – in particular the population shift from MassHealth to the Health Connector, the changes to Premium Assistance program, and changes to the MassHealth pharmacy benefit – go too far by limiting access to health care for vulnerable residents of the CommonHealth. We look forward to working with EOHHS ensure the sustainability of MassHealth without endangering access for the thousands of low-income Massachusetts residents who rely on the program to access medically necessary health services.

Thank you again for the opportunity to comment on MassHealth's proposed 1115 Waiver Amendment. If you have any questions or need additional information, please do not hesitate to contact Andrew Cohen at 617-275-2891 or acohen@hla-inc.org.

Sincerely,



Michelle Virshup
Staff Attorney

Andrew P. Cohen
Staff Attorney

[24] *Id.* at 13.

AARP® Real Possibilities
Massachusetts

August 21, 2017

The Honorable Marylou Sudders, Secretary
Executive Office of Health and Human Services
Commonwealth of Massachusetts
Office of Medicaid
Attn: 1115 Demonstration Amendment Request Comments
One Ashburton Place, 11th Floor
Boston, MA 02108

RE: MassHealth Section 1115 Demonstration Amendment Request

Dear Secretary Sudders:

AARP Massachusetts would like to thank the Executive Office of Health and Human Services' Office (EOHHS) of Medicaid for the opportunity to submit our comments to your MassHealth Section 1115 Demonstration Amendment Request. AARP is a nonprofit, non-partisan membership organization for people 50 and over. We have nearly 38 million members nationwide and 783,000 members in the Commonwealth. We know the Commonwealth provides essential services for the older population – services that keep people healthy and living with dignity. It is critical that adequate funding remain for these programs and services.

As we pointed out in the comments we submitted one year ago in response to the EOHHS Section 1115 waiver demonstration project extension request, AARP is encouraged by the goals for this demonstration project. These goals include the adoption of alternative payment methodologies, improvement in the services provided to MassHealth participants and movement towards a more integrated and coordinated system of care. We noted our appreciation for the year-long process you established to engage and receive input from stakeholders. This demonstration project represents an ambitious and innovative undertaking and one that merits close attention. We have endeavored to provide meaningful comments and participation during this process, including our June 2017 letter addressing non-emergency medical transportation and presumptive eligibility.

While the current demonstration amendment request includes some provisions that will have either a positive or minimal impact on consumers, AARP believes that a number of the

proposed policies could result in harm to low-income individuals and families. Our concerns are as follows:

Aligning coverage for non-disabled adults with commercial plans

Proposed amendment:
This demonstration amendment request outlines a plan to move 40,000 childless adults and 100,000 parents and caretakers, namely individuals and families with incomes above 100% of the Federal Poverty level (FPL), off of MassHealth and into subsidized commercial plans through ConnectorCare.

We have serious concerns with this proposed change and how it may adversely affect individuals with incomes over 100% FPL. This elimination of MassHealth coverage will require those who want to continue to receive health care coverage to enroll in ConnectorCare qualified health plans (QHPs), which will require new premiums and copays for this low-income population.

It is our understanding that coverage available through ConnectorCare would offer fewer benefits (e.g., no dental, eyeglasses) and would also impose co-pays almost five times higher than co-pays in MassHealth. It is also our understanding that coverage for home-based health care is very limited in commercial plans and this lack of coverage would be of great concern for AARP members and other individuals in need of home-based health care.

If implemented, AARP believes that this proposal would likely create significant financial hardship for many MassHealth beneficiaries, individuals who are already having trouble making ends meet, thereby making it difficult for these "transitional" enrollees to maintain health coverage while affording other everyday essentials.

AARP believes this proposal would worsen health outcomes, increase administrative costs to the state, and result in increased uncompensated care costs for Massachusetts' health providers. In addition to being subject to higher out-of-pocket expenditures, beneficiaries within this enrollee group are also likely to be limited to less robust healthcare coverage than is available under standard Medicaid.

We note that the demonstration amendment does not indicate whether EOHHS intends to seek enhanced federal matching funds for this group of beneficiaries. It is important to highlight that, to date, the Centers for Medicare & Medicaid Services (CMS) has required states to cover all expansion adults up to 138% FPL in order to receive enhanced federal matching funds.

Proposed amendment:
This demonstration amendment seeks to align MassHealth benefits for all non-disabled adults in a single plan that mirrors commercial coverage by enrolling non-disabled parents and caretakers with incomes up to 100% FPL in MassHealth's CarePlus Alternative Benefit Plan.

Again, we are concerned that this amendment would result in less robust healthcare coverage for this population and would not include important benefits that beneficiaries are currently receiving.

Proposed amendment:
The amendment seeks to modify the premium assistance program for non-disabled adults with access to commercial insurance to reduce Medicaid "wraps" on top of the commercial plan while ensuring continued affordability for members.

There appear to be two different types of premium assistance coverage proposed in the amendment: "affordable" employer-sponsored insurance (ESI) where the Commonwealth is proposing to provide no cost-sharing wrap (except if the enrollee seeks a "hardship" waiver if the ESI premium is affordable but the other cost-sharing is not); and other ESI coverage where the Commonwealth's cost-sharing wrap will continue.

We do not quite understand how changes to the premium assistance program will be operationalized. We would appreciate additional details on how the program will be modified and the steps the Commonwealth will take to ensure that non-disabled adults will continue to have access to health plans they can afford.

For ESI where cost-sharing wrap will continue to be provided, we are also concerned that the Commonwealth is not responsible to cover cost-sharing when an enrollee accesses a provider that is not enrolled in Medicaid. If an enrollee is going to be mandatorily required to access the ESI coverage, we urge the Commonwealth to assure that the plan includes adequate Medicaid-enrolled providers in-network.

Proposed amendment:
The amendment seeks to implement an eligibility "gate" that would not allow non-disabled adults with access to affordable employer-sponsored or student health insurance to enroll in MassHealth.

AARP is concerned that requiring this subset of MassHealth enrollees to obtain coverage through their employer or through student health plans will subject these individuals to higher out-of-pocket expenditures. They are also likely to be limited to less robust healthcare coverage than is available under standard Medicaid. We would appreciate an understanding of how access to coverage will be determined as well as MassHealth's process for how affordability is defined and determined.

In addition, the time and resources needed for MassHealth staff to make enrollment determinations and redeterminations for these enrollees, and the likelihood of churning that will occur between MassHealth and employer coverage will predictably add administrative costs to MassHealth's budget.

Adopting widely-used commercial tools to obtain lower drug prices and enhanced rebates

Proposed amendment:

The amendment seeks to allow MassHealth to use "commercial plan"-type mechanisms to control drug costs, including selecting preferred and covered drugs through a closed formulary.

AARP supports the use of well-designed drug formularies or preferred drug lists as they can enhance quality and conserve resources. AARP also believes that cost should not be the sole determinant of a prescription drug's value. Efforts to guide consumer utilization should encourage the appropriate use of high-value prescription drugs that is based on the clinical benefits achieved.

AARP urges MassHealth to consider developing formulary standards that are more in line with Medicare Part D (i.e., at least two drugs per therapeutic class). We also believe that the formulary should be reviewed at least annually by an independent, objective third party to help ensure formulary adequacy. Finally, we strongly urge the Commonwealth to ensure that a clinically sound and well-communicated exceptions and appeals process is in place to help ensure that consumers maintain access to medically necessary prescription drugs.

Further, AARP encourages the Commonwealth to collect data at least annually to evaluate whether the closed formulary and related processes have increased clinician and consumer burden, as well as any effects on patient health outcomes.

Proposed amendment:
The amendment seeks to procure a selective and more cost-effective specialty pharmacy network.

Given the recent proliferation of specialty prescription drugs, AARP appreciates the Commonwealth's interest in developing a more cost-effective specialty pharmacy network. However, AARP strongly urges the Commonwealth to establish convenient access standards similar to what is found under Medicare Part D to help ensure that consumer access to medically necessary specialty prescription drugs is not unduly limited. Specialty pharmacies should be used to supplement network pharmacy access when necessary and not otherwise restrict it.

AARP also encourages the Commonwealth to collect data at least annually to evaluate whether the specialty pharmacy network has increased clinician and consumer burden, as well as any effects on patient health outcomes.

Improving care, reducing costs and achieving administrative efficiencies

Proposed amendment:
The amendment seeks to implement narrower networks in MassHealth's Primary Care Clinician (PCC) Plan to encourage enrollment in Accountable Care Organizations (ACOs) and Managed Care Organizations (MCOs).

While we acknowledge that implementing narrower plan networks could be helpful in controlling healthcare costs, we nevertheless urge the Commonwealth to ensure that

the quality and adequacy of the network is not compromised or rendered insufficient to meet the needs of the state's consumers.

Proposed amendment:
The amendment seeks to waive requirements for multiple managed care options in certain area(s) of the state in which a majority of primary care providers are participating in a single MassHealth ACO.

The proposal goes on to request a freedom of choice waiver to not provide two or more managed care enrollment options in areas that do not have a large enough pool of primary care providers (PCPs) to meet network adequacy requirements for PCPs within MassHealth's time and distance standards. The proposal also points out that MassHealth will not auto-assign members to the PCC plan if these adequacy standards are not met.

It appears that the Commonwealth is proposing this change to accommodate its recent ACO initiative which requires PCPs to have an exclusive contract with an ACO or MCO in a service. To maintain consumer choice, the state will allow the enrollee to select a PCP in the PCC Plan instead of enrolling in the ACO. We would appreciate some additional details on how this proposal will be operationalized and how a consumer's choice of plan and providers will be maintained.

Proposed amendment:
The amendment seeks to implement the cost-sharing limit of five percent of income on an annual basis rather than a quarterly or monthly basis.

We do not support the request to change the cost-sharing calculation on an annual basis. We urge MassHealth to continue the cost-sharing calculations on a monthly or quarterly basis as is required under Medicaid regulations. Changes in enrollee's income can happen at any time during a 12-month period and if such changes are not accurately reflected in a timely fashion, this has the potential to be unfairly harmful to an enrollee's cost-sharing obligations.

Proposed amendment:
The amendment seeks to implement cost-sharing greater than five percent of income for members over 300% FPL eligible exclusively through the demonstration.

This amendment is seeking the flexibility to require premiums and cost-sharing that may exceed five percent of these individuals' income. It is MassHealth's belief that at higher income levels, it is reasonable and fair for members to contribute more toward the cost of their care.

We would appreciate knowing the details of how this increase in cost-sharing for consumers whose income is above 300% FPL will work in order for us to evaluate the potential for its impact on affordability and access for this population. With respect to the phrase "greater than five percent of income," is MassHealth proposing a sliding scale? Will there be an upper limit on the cost-sharing requirements?

We look forward to working with you as this demonstration progresses and would be happy to assist you in any way possible. Please do not hesitate to contact Jessica Costantino, Director of Advocacy, at (617) 305-0538 or jcostantino@aarp.org, if you have questions or concerns or need additional information.

Very truly yours,

Michael E. Festa
State Director

Sandy Albright
State President

Steward Health Care System LLC
111 Huntington Ave. Suite 1800 Boston, MA 02199
T: 617-419-4700 F: 617-419-4800 www.steward.org

August 21, 2017

Marylou Sudders, Secretary
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

Re: Comments on the Amendments to the MassHealth Section 1115 Demonstration

Dear Secretary Sudders:

Steward Health Care ("Steward") is a fully integrated national health care services organization committed to providing the highest quality of care in the communities where our patients live. Steward owns and operates 18 community hospitals across four states, serves over 800 communities, and has more than 23,000 employees. In addition to our hospitals, the Steward provider network includes more than 25 urgent care centers, 42 preferred skilled nursing facilities, substantial behavioral health offerings and more than 3,700 hospital beds under management.

The majority of Steward's community hospitals are located in Massachusetts and we have invested significant resources to build what is now New England's largest community-based accountable care organization, encompassing ten hospital campuses, over 2,700 physicians and specialists, as well as nurses, home health, behavioral health and allied services professionals. Nearly all of Steward's acute care hospitals are classified as Medicaid disproportionate share hospitals (DSH) and we operate nearly 400 inpatient acute behavioral health beds. These resources are a testament to our commitment to providing care to low-income and vulnerable populations in the communities where our patients reside and work.

Steward commends the Baker Administration for moving toward value-based models, such as accountable care organizations (ACOs). We also strongly support your efforts to reform the MassHealth program while maintaining high quality care and access for its members. We have long advocated for a movement away from fee-for-service payments and consider the ACO program a significant step to achieving that goal. Through this letter we offer suggestions to strengthen your amendments to the 1115 Medicaid waiver, supplement your efforts, and put MassHealth on a path toward long-term financial sustainability and exceptional patient care:

1. Align incentives among all providers to achieve optimal population health and lower costs: Require **all** participating MassHealth providers (e.g. hospitals, nursing homes, urgent care centers, specialists, etc.) to assume downside risk under the ACO program by 1/1/2019.

   By requiring all MassHealth providers to assume downside risk under an ACO, providers will be incentivized to coordinate patient care in an efficient manner that reduces costs, improves care outcomes, and achieves optimal population health. Under the current ACO program, only the ACO (i.e. doctors and hospitals participating in the MassHealth ACO program) is held accountable ("at-risk") for a patient's population health care needs. Additional providers that are not at-risk under the MassHealth ACO program are not incentivized to participate in an ACO's care management program, or to be more specific, are not accountable for achieving and coordinating a patient's population health needs.

   In addition, MassHealth should accelerate the timeline for including long-term services and supports in risk programs and should ensure that ACOs that are at risk for behavioral health services are given the authority to make the appropriate utilization decisions for their patients. In addition, MassHealth should integrate the risk structure between ACOs and community partners, such that clinical and financial incentives for community partners align with clinical and financial incentives for the ACO. Without this integration, the silos that exist between and among providers will be perpetuated, leading to gaps in care and ultimately higher costs and sub-optimal care outcomes for patients.

   Enhancing the ACO program to require all providers to assume downside risk will hold providers accountable for their patients' total population health needs, as well as align providers to mitigate the total cost of care of the MassHealth program.

2. Reimbursement parity for behavioral health and substance use:

   The federal Mental Health Parity and Addiction Equity Act (MHPAEA) prevents group health plans and health insurance plans that provide mental health or substance use disorder (MH/SUD) benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical benefits. Unfortunately, this legislation did not address parity in reimbursement for such services. Chronically low levels of reimbursement by Medicaid, relative to cost, lead to a lack of service availability for this vulnerable population and worse, result in significant gaps in care and inappropriate use of certain services such as emergency department use to treat these conditions.

   As the largest provider of inpatient acute behavioral health in Eastern Massachusetts, Steward has made significant investments to expand our capacity to provide care to patients with behavioral health and substance use issues. We are committed to providing effective, efficient and coordinated care to such patients, but are concerned by the growing underpayment for these services. When substance use reimbursement rates are far below the actual cost of providing care to such patients, even for cost-efficient provider systems like Steward, these chronically low levels of reimbursement result in a model that fails patients needing such intensive services.

We strongly recommend that MassHealth engage CMS to implement a reimbursement parity strategy for behavioral health and substance use services. While this initiative could take several years to take effect, nothing precludes MassHealth from requiring its contracted payers to reimburse behavioral health and substance use services at equivalent rates that are not below 100% of the Medicare inpatient acute behavioral health fee schedule for Suffolk County as a first step.

3. Integrate physical, behavioral and long-term support services:

   As stated previously, MassHealth should accelerate the timeline for including long-term services and supports in risk programs and should ensure that ACOs that are at risk for behavioral health services are given the authority to make the appropriate utilization decisions for their patients.

   If ACOs are allowed to contract for these services without limitations from MassHealth (i.e. restrictions on the number of providers and network configuration, etc.), providers will be held accountable for the totality of patient care and their costs, thereby increasing integration and care coordination among these providers, as well as across inpatient and outpatient care settings.

4. Eliminate outdated supplemental payments to hospitals:

   Of MassHealth's $15.7 billion in spending in fiscal year 2016, nearly $1 billion was in the form of supplemental payments to hospitals. Three of these payments included in the MassHealth Waiver, the Public Service Hospital Payment, the Public Hospital Transformation Initiative, and the MassHealth Essential Hospital Payment, are outdated payments to specific hospitals totaling over $550M in 2016. In order to mitigate growing costs, MassHealth should eliminate these arrangements and allocate such funding based on a patient attribution model, i.e. "dollars follow the patients". This will provide significant savings to the Commonwealth, while improving the quality of care for MassHealth members. This could be achieved by shifting such funding to the Medicaid ACO program.

   We also recommend that Safety Net Care Payments / Delivery System Transformation Initiative (DSTI) payments be redistributed based on patient attribution, not based on hospital specific appropriation. Under the existing 1115 Waiver, the original 7 DSTI hospitals receive 78% of SFY17 funding, while the new DSTI hospitals receive a proportional share of the funding "cut" from the original 7 DSTI hospitals. The result of the existing methodology is a disproportionate subsidy for hospitals that have been historically subsidized by the state under an arcane methodology, not based on patient care need. These hospital supplemental funds should be re-directed to support the care of patients, not to subsidize hospitals.

   Below are two suggestions that redistribute supplemental payments based on patient need and hospital efficiency:

a. Adopt a "dollars follow the patient" model by redistributing all hospital supplemental payments to ACOs that own DSTI hospitals based on the ACO's share of MassHealth discharges.
b. Institute a clawback for hospitals whose weighted average payer rate is 20% above the median and redistribute those funds to Medicaid ACOs who are cost efficient in order to reward high quality, cost-efficient providers that are assuming significant downside risk for their Medicaid patients.

Thank you for your leadership in reforming the state's Medicaid program. We appreciate your consideration of our suggestions and look forward to continuing our partnership as we collaboratively work to reform the MassHealth program and achieve the best care possible for our patients.

Sincerely,

David Morales
Chief Strategy Officer

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

AMERICAN ACADEMY of DERMATOLOGY | ASSOCIATION

1445 New York Ave., NW, Suite 800
Washington, DC 20005-2134

MAIN: (202) 842-3555
FAX: (202) 842-4355
www.aad.org

August 21, 2017

Kaela Konefal
EOHHS Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108

RE: Comments for Demonstration Amendment

Dear Ms. Konefal:

On behalf of the nearly 13,500 U.S.-based members of the American Academy of Dermatology Association (Academy), we are writing to express our opposition to Massachusetts' proposed amendment to the state's 1115 Medicaid waiver. This proposal will significantly impede access to medicine for those enrolled in MassHealth.

The Academy's guiding position on access to effective and affordable drugs is set forth in *the Position Statement on Patient Access to Affordable Treatments:*

> "Physicians should have the entire compendium of pharmaceutical therapies available to them and the freedom to work with their patients to determine the appropriate course of treatment based on each patient's unique circumstances.
>
> "Each formulary must be developed based on scientifically valid evidence that the selected pharmaceuticals sufficiently provide the most effective therapies for any given condition and that options are available should patients not be able to utilize a given agent due to lack of response, side effects, allergy, etc.".

While the Academy understands the Executive Office's need to control drug spending, there is concern that a closed formulary severely limits a physician's ability to effectively manage a patient's condition, leading to an increase in encounters and patient cost while decreasing patient satisfaction. When a dermatologist sees a patient, the dermatologist evaluates a number of the patient's individual characteristics to determine which drug is best for that patient. A formulary with only one drug per class is a one–size-fits-all solution that will lead to barriers or delays to necessary care. As a result of this policy change, several commonly used topical dermatologic drugs will likely be excluded from the MassHealth formulary. Therefore, this policy change risks both harming the patient and saddling them with undue economic burden.

Additionally, we are concerned that the proposal will increase the number of utilization management tools available for MassHealth formularies. Physicians and patients already cite experiencing difficulties with the appeals process and by enabling the use of additional utilization management tools, such as prior authorization, step therapy and tiering of formularies, patients will see increased delays in accessing their prescription drugs. If a patient with a chronic condition is stable on a drug and loses access due to utilization management tools, it can cause a flaring of the disease and diminish the effects of the very same treatment in the future. This loss of access can also contribute to increased medical costs when the condition is not stabilized with prescription drugs.

As physicians, our number one priority is the health and welfare of our patients. The Academy appreciates the opportunity to provide written comments on this important issue. We respectfully urge you to carefully consider the ramifications of moving to a closed formulary, which moves away from the goal of ensuring patients' access to affordable and effective medications. Please contact Lisa Albany, Associate Director, State Policy, at LAlbany@aad.org if you require clarification on any of the points above or would like further information.

Sincerely,

Henry W. Lim, MD, FAAD

President, American Academy of Dermatology Association

DLC Disability Law Center, Inc.

11 Beacon Street, Suite 925
Boston, Massachusetts 02108
(617) 723-8455 *Voice*
(800) 872-9992 *Voice*
(617) 723-9125 *Fax*
http://www.dlc-ma.org

Western Mass. Office
32 Industrial Drive East
Northampton, MA 01060
(413) 584-6337 *Voice*
(800) 222-5619 *Voice*
email: mail@dlc-ma.org

August 21, 2017

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

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

Re: Comments for Demonstration Amendment

Dear Assistant Secretary Tsai,

The undersigned concur in the comments submitted by Health Care For All and Massachusetts Law Reform Institute. We submit these additional comments to further highlight the issues for people with disabilities raised by the proposed amendments.

Transferring "Non-Disabled" Adults Ages 21-64 to Connector Care

The waiver proposes to transfer the adult "non-disabled' population between 100% and 133% FPL from MassHealth to Connector Care. In limiting this transfer to the "non-disabled" population, MassHealth is correctly recognizing that people with disabilities have a particular need for reliable access to affordable health care. However, MassHealth is apparently overlooking the fact that there will be many people with disabilities in the non-disabled category because they have not yet been determined disabled by the Social Security Administration (SSA) or by the Disability Evaluation Service (DES) for a variety of reasons. We are concerned that they may be unable to get the coverage they need to live and work in the community through ConnectorCare, either because of coverage limitations, e.g., formulary limits, limits on behavioral health care, no LTSS coverage, the added costs involved with ConnectorCare for this very low income group (100-133% FPL), or because the requirement of affirmatively enrolling in a health plan may leave them without coverage. You have indicated that you will

provide opportunities for people to self-identify as people with disabilities and go through some process. We need more information on what this process will be and how effectively you will reach people about it to ensure that people with disabilities will not be harmed by this proposal.

We are also concerned about access to coverage for people newly applying for subsidized health care. A cancer or other diagnosis or a catastrophic injury can lead to an application for subsidized health coverage before an official determination of disability has been made. How will new applicants who allege disability be treated? Will someone between 100% and 133% FPL be directed to ConnectorCare, leaving them with a future start date for coverage with possible consequences such as the inability to access prescription medication?

In addition, there will likely be people with disabilities who will not be found disabled by either SSA or DES. Some will not be found disabled due to findings that drug abuse or alcoholism are "material" to their disability-related functional limitations. Others will not be found disabled because they receive affordable treatment that is effective for them and that ameliorates their disability related functional limitations. These individuals will be at risk of losing access to care and experiencing exacerbations and costly health crises. And, the design of the Social Security disability standard makes it more difficult to meet for people under age 50, putting younger people at risk of non-disability status that may prevent them getting or keeping the care they need.

We also believe that this proposal is likely to increase the volume of cases referred to DES for evaluation, creating potential delays and the need to increase DES staffing.

We ask that you reconsider shifting "non-disabled" adults with income over 100% FPL from MassHealth to ConnectorCare. If you go forward with this change, members should retain MassHealth coverage pending disability evaluations and applicants alleging disability should be given some form of presumptive eligibility for MassHealth.

ESI "Gate"

MassHealth is proposing to implement an eligibility "gate" that would prevent "non-disabled adults" with access to affordable employer-sponsored insurance (ESI) from enrolling in Medicaid. The concerns raised above about individuals with disabilities who do not have a disability determination apply equally here. Moreover, the consequences of denying access to MassHealth due to so-called affordable ESI are even more dire, as most commercial insurance has high copays and does not have coverage for many services needed by people with disabilities.

More details about this proposal are needed. Will an individual who has turned down ESI and cannot access it for another 11 months be denied MassHealth coverage? While Premium Assistance enables individuals to enroll in ESI outside of normal open enrollment periods, denial of MassHealth coverage does not appear to have the same

effect. The result of this proposal is not increased use of commercial insurance, but rather an increase in the number of uninsured.

Closed Drug Formulary and Selective Specialty Pharmacy network

We are all for your having the ability to negotiate for better prescription drug prices. However, we are very concerned about the potential effect of the proposed limits on access to prescription drugs for people with disabilities. Many people with disabilities rely on carefully balanced combinations of medications that have taken time to achieve. Great care must be taken so that the balance and continuity of care are not disrupted due to rote adherence to new rules. Many also take medications for a combination of physical and mental health conditions, which may make it more difficult to successfully adapt to a new medication regimen. A streamlined and effective exceptions process, as well as outreach about the changes and exceptions process to consumers, medical practitioners, and pharmacists will be critical to avoid health crises for people with disabilities and higher care costs for MassHealth.

Narrower Primary Care Clinician Plan Networks

The PCC option has been important for people with severe, complex disabilities to be able to see the type of medical provider they need, including those with whom they have worked for years and who have come to understand their health care needs. They should not have to lose access to coverage to make this choice.

CommonHealth Premiums and Cost-Sharing

We need more information on this cost sharing proposal. 300% FPL, or even 400% FPL, is not a lot of money for people with disabilities to be self-supporting, given the local cost of living and especially with the cost of maintaining private health insurance when working.

Thank you for this opportunity to comment.

Respectfully submitted,

Linda Landry
Senior Attorney

Nancy Lorenz
Managing Attorney
Greater Boston Legal Services

LEUKEMIA &
LYMPHOMA
SOCIETY®
fighting blood cancers

WWW.LLS.ORG

August 21, 2017

Secretary Marylou Sudders
Executive Office of Health and Human Services
Commonwealth of Massachusetts
One Ashburton Place, 11th Floor
Boston, MA 02108

Dear Secretary Sudders:

On behalf of The Leukemia & Lymphoma Society (LLS) and the 27,000 blood cancer survivors residing in the Commonwealth, I am writing to express concern regarding certain proposals in the MassHealth Section 1115 Demonstration Amendment Request. LLS urges the state to address these concerns, outlined below, to assure continued access to care for all residents of the Commonwealth.

The LLS mission is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families. In Massachusetts, delivering on this mission currently funds over 7 million dollars in research conducted at thirteen institutions, including Dana-Farber Cancer Institute, Brigham and Women's Hospital, and the Beth Israel Deaconess Medical Center. From its location in Natick, LLS's Massachusetts Chapter provides a range of support services to patients and families across the Commonwealth, which includes over $460,000 in direct assistance to help over 200 patients meet the financial burden of treating their cancer. To be sure, the Commonwealth's statistics on blood cancer are sobering: over 1,200 Massachusetts residents will die from blood cancer this year, and nearly 4,000 will face a new diagnosis of blood cancer.

LLS strongly commends Massachusetts for taking the leading role over the last decade in expanding access to healthcare coverage for its residents. However, LLS is concerned that certain components of the MassHealth amendment request will erode such gains – specifically, the proposal to adopt a commercial-style closed formulary and exclude from that formulary drugs "with limited or inadequate evidence of clinical efficacy," and the proposal to shift coverage of non-disabled adults with incomes over 100% of the FPL to subsidized Connector plans. LLS believes that both proposals could bring harm to patients, in particular those living with complex medical needs.

LLS Recognizes Increasing Cost of Care

To be clear, LLS recognizes the serious challenges facing Massachusetts and other states regarding the cost of care. In fact, earlier this year, LLS's national Board of Directors issued position statements addressing several aspects of the issue, alarmed at the growing portion of treatment costs being shifted onto patients who

already face tremendous medical and financial burdens.[1] Indeed, patients increasingly find themselves unable to afford care, choosing at times to delay or even forego treatment due entirely to cost. 'Financial toxicity' has become as threatening to patient quality of life as the actual diseases and conditions that patients are battling on the clinical front. This cost-shift is due in large part to the rapid increases in systems-wide treatment costs that will eventually strain the healthcare delivery system such that patients' access to high-quality care will be severely impacted.

LLS is committed to taking bold steps to protect and promote the interests of blood cancer patients by helping to address the unsustainable cost of cancer care. To be sure, LLS can't singlehandedly address the financial weight of our healthcare system. But LLS feels strongly that it can and must be a voice for change, pushing toward high-value healthcare for people living with blood cancer.

With that responsibility in mind, LLS calls upon all stakeholders in the oncology ecosystem – patient organizations, drug makers, payers, providers and policymakers – to similarly embrace their duty to help serve patients by reducing the cost of cancer care. It is in this spirit of collaboration that LLS asks Massachusetts to consider how provisions of its Demonstration Amendment Request will impact cancer patients who rely on MassHealth for access to care.

Proposals 6a & 6B: Adopting Commercial Tools to Obtain Lower Drug Prices/Drug Exclusions

LLS is concerned that the proposal to adopt a commercial-style closed formulary and to exclude from that formulary drugs with "limited or inadequate clinical efficacy" will reduce access for certain cancer patients to the only appropriate treatment available. To be sure, this proposal may negatively impact access to care for patients living with a range of serious diseases and conditions. But for patients living with cancer, this proposal is especially grave, as there is very little interchangeability among the drug therapies used to treat most cancers, including the vast majority of blood cancers. Typically, treating cancer is a profoundly complex undertaking; even among patients with the same diagnosis, the same treatment may be insufficient or altogether inappropriate.

Therefore, LLS requests the Massachusetts Executive Office of Health and Human Services to consider other options for cost containment. If, however, the department chooses to proceed with this proposal, LLS strongly urges that a clear and transparent exceptions process be conveyed to all MassHealth enrollees and the healthcare providers who treat them. To be meaningful, MassHealth must articulate and abide by specific timeframes within which the department will respond to all exceptions requests, including highly time-sensitive requests.

On a related note, LLS must take exception to language on page 9 of the Demonstration Amendment Request stating that "Many drugs coming to market through the FDA's accelerated approval pathway have not yet proven their efficacy on primary endpoints in clinical trials."[2] It's troubling that the Commonwealth seems to

[1] Full Statement available at https://www.lls.org/cancercost

[2] http://www.mass.gov/eohhs/docs/eohhs/cms-waiver/11115-demonstration-amendment-request-draft-07-20-17.pdf; pg. 9

be implying that the FDA is approving therapies of such questionable value that a state must take matters into its own hands by establishing secondary review processes. LLS believes it is inappropriate to exclude a particular therapy from the MassHealth formulary purely on the grounds that such therapy received accelerated approval. While LLS certainly appreciates the need for MassHealth resources to be spent on benefits and services of high value, adopting this as a blanket approach will no doubt prevent or delay some cancer patients from accessing medically appropriate—and potentially life-saving—therapies. Further, LLS is alarmed at the prospect of a secondary, state-level review process; if adopted in multiple states, this process would result in dramatic variation in access to new cancer therapies across the country. Given the small population of cancer patients relying on these new medications and the importance of timely adherence to treatment regimen, LLS believes the creation of a closed formulary, without a clear and robust exception process would be harmful to blood cancer patients.

Proposal 1: Aligning Coverage for Non-Disabled Adults with Commercial Plans

LLS urges the department to carefully consider the impact of moving non-disabled adults with incomes over 100% FPL to subsidized Connector plans, as it relates to potentially increased financial burden for patients and changes in their provider networks. As with changes to drug coverage for MassHealth enrollees, a fully transparent, easily understandable process that is communicated to both patients and providers is essential in assuring that patients to not suffer delays in treatment as a result of this shift.

In closing, LLS wishes to again express support for the Commonwealth's goal of ensuring the long-term sustainability of the MassHealth program and stands ready to work with policymakers on both sides of the aisle to protect and promote access to this critical source of coverage. Thank you again for the opportunity to offer these comments, and please don't hesitate to contact me if LLS can offer any further information.

Sincerely,

Martha M. Auster
Regional Director, Government Affairs
(914) 584-0450
martha.auster@lls.org

August 21, 2017

Secretary Mary Lou Sudders
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108
Re: Comments for Demonstration Amendment

Dear Ms. Sudders,

On behalf of the American Society of Addiction Medicine (ASAM), the nation's oldest and largest medical specialty organization representing more than 4,900 physicians and other clinicians who specialize in the treatment of addiction, and the Massachusetts Society of Addiction Medicine (MASAM), we would like to take this opportunity to comment on the request from the Massachusetts Executive Office of Health and Human Services (EOHHS) to amend the MassHealth Section 1115 Demonstration. With the opioid addiction and overdose epidemic significantly impacting the country and Massachusetts, MASAM and ASAM are concerned that the proposed changes will severely limit patients' access to medications critical to the treatment of opioid addiction and other addictions.

Specifically, ASAM and MASAM are concerned about the EOHHS proposal to modify the Mass Health Demonstration by selecting preferred and covered drugs through a closed formulary. We are also concerned by the application to procure a selective and more cost-effective specialty pharmacy network. We note that both changes could ultimately jeopardize the health of patients who depend on access to medications to treat addiction.

As ASAM noted in our letter to the US Pharmacopeia Convention on the Medicare Model Guidelines, grouping short-acting and long-acting addiction treatments into the same respective classes could result in a de facto exclusion of one class over another.[1] Ultimately, modifying the MassHealth Demonstration to create a closed formulary and a more selective specialty pharmacy network would have the same effect by potentially limiting patients to one drug per therapeutic class, as specified in the waiver change application. However, while some anti-addiction agents are often a part of the same therapeutic class, they treat addiction differently. Thus, arbitrarily limiting patients to one drug per therapeutic class would severely limit the ability of addiction specialists to effectively treat addiction.

It is essential that patients suffering from addiction have access to the full continuum of addiction treatment therapies, including all evidence-based, effective medications approved by the FDA for the treatment of alcohol,

11400 Rockville Pike Suite 200 Rockville, MD 20852
Phone: 301-656-3920 | Fax: 301.656.3815
www.ASAM.org

tobacco, and opioid use disorder. However, all medications for the treatment of addiction may not be equally effective for all patients, so it is important that access to addiction treatment with any FDA-approved medication is supported and covered by all public and private payers. ASAM's Public Policy Statement on Pharmacological Therapies for Opioid Use Disorder further recommends that "decisions about the appropriate type, modality, and duration of treatment should remain the purview of the treatment provider and the patient, working in collaboration to achieve shared treatment goals."[2] Thus, MASAM and ASAM urge EOHHS to reconsider this proposal which could interfere with individualized treatment decisions between patients and their health care providers.

MASAM and ASAM are dedicated to increasing access to and improving the quality of addiction treatment for patients in Massachusetts and across the country. To that end, we are committed to advocating for a state addiction treatment system that provides and expands access to all FDA-approved medications to treat addiction. Ensuring addiction treatment services are not subject to restrictive formularies or unfair utilization controls in comparison to health care services for other chronic medical illnesses is a critical part of our efforts to improve access to care.

Given the recent report from the Massachusetts Department of Public Health that detailed the impact of the opioid epidemic on the Commonwealth of Massachusetts, we strongly urge the state to reconsider this waiver change application which could have harmful consequences for individuals suffering from addiction in Massachusetts. We appreciate the opportunity to comment on this proposal and we welcome further discussion. Please do not hesitate to contact Brad Bachman, Manager of State Government Relations, at (301) 547-4107 or bbachman@asam.org, with any additional questions or concerns.

Sincerely,

Kelly J. Clark

Kelly J. Clark, MD, MBA, DFAPA, DFASAM
President, American Society of Addiction Medicine

Michael F. Bierer, MD, MPH
President, Massachusetts Society of Addiction Medicine

---

[1] American Academy of Addiction Psychiatry, American Osteopathic Academy of Addiction Medicine, & American Society of Addiction Medicine. (2013, October 31). US Pharmacopeial Convention's (USP) Medicare Model Guidelines (v6.0) [Letter to US Pharmacopeial Convention]. Rockville, Maryland.

[2] American Society of Addiction Medicine. Public Policy Statement on Pharmacological Therapies for Opioid Use Disorder. Rockville, MD: American Society of Addiction Medicine; 2013. https://www.asam.org/docs/default-source/public-policy-statements/pharmacological-therapies-for-opioid-use-disorder-2013-04-24.pdf?sfvrsn=4

August 21, 2017

Secretary Marylou Sudders
Massachusetts Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

Dear Secretary Sudders:

On behalf of all Massachusetts residents affected by Duchenne muscular dystrophy, I write today to urge the Executive Office of Health and Human Services (EOHHS) to reconsider certain sections of the proposed Amendment to the MassHealth Section 1115 Demonstration, specifically parts 6a and 6b which propose changes to current regulations that would prevent Duchenne patients from accessing current and future treatments that could greatly improve their health.

Jett Foundation is a leading patient advocacy organization dedicated to ending Duchenne, and improving the lives of families affected by the disease. As you know, Duchenne muscular dystrophy is a fatal genetic disorder that affects approximately 1 in 5,000 live male births. Duchenne is the result of a defect on the dystrophin gene which results in the body's inability to read the gene and produce dystrophin, a lubricating protein found between muscle cells critical to muscle and tissue growth. Individuals are diagnosed with this rare disease in early childhood, and steadily progress as they age. They lose the ability to walk around the age of 11, and typically succumb to cardiac and respiratory complications in their twenties and thirties. There is no cure for this devastating disorder, and until the Food and Drug Administration (FDA) granted Exondys 51 accelerated approval in September 2016, there were no treatments available in the United States.

Certain provisions within the Proposed Amendment to the MassHealth Section 1115 Demonstration would, if enacted, greatly inhibit the ability of Massachusetts residents with Duchenne to gain access to potentially life-saving therapies that could improve their quality of life. Specifically, parts 6a and 6b of the proposed amendment request a waiver to restrict coverage requirements by permitting EOHHS to *"adopt a commercial-style closed formulary with at only one drug available per therapeutic class,"* and *"exclude from the formulary drugs with limited or inadequate evidence of clinical efficacy."* This waiver if granted will dramatically hinder the ability of Duchenne patients and medical experts to execute care plans that could improve the health and quality of life of Duchenne patients.

As you know, in both common disease populations and rare one's, different patients respond differently to different drugs within the same therapeutic class. For example, while there is one therapy that treats Duchenne patients amenable to exon 51 skipping currently approved by the

FDA, there are at least 3 more exon 51 skipping drugs in development with slightly different chemical backbones. Some patients will respond better to one drug than another, and EOHHS request to limit their formulary to one drug per therapeutic class would violate the rights of physicians and patients to choose the therapy that will work best for the patient. Preventing Duchenne patients in Massachusetts and their physicians from accessing the treatments the patient needs will disrupt their treatment plan and put their health and potentially their life at risk.

As you also realize, provisions included in both the Food and Drug Safety and Innovation Act of 2012 and 21st Century Cures encourage the FDA to grant accelerated approval to a new drug or biologic in cases of severe unmet medical needs. While the proposed Amendment states that these provisions were intended to *"expedite the drug approval process by reducing the level of evidence required for drugs to reach the market and allowing doctors, patients, and payers to decide whether to purchase them,"* EOHHS interpretation of the law could not be farther from the truth. The intent of such provisions was to accelerate access of potentially life-saving treatments to patients dying of progressive or rare illnesses with a severe unmet medical need, allowing physicians and patients discretion in using all approved therapies for diseases that have no other effective treatment. These provisions do not mention payers playing a part in medical decisions that should be made by patients, families, and expert physicians, not private or public payers with financial incentives to deny patient's access to an expensive treatment. The Amendment goes on to accurately state *that "current rules do not allow Medicaid programs to exercise discretion about whether these drugs should be covered without being fully clinically proven."* This is true, importantly because under Federal Rule Vol. 57 No. 239, products granted accelerated approval meet the statutory standards for safety and effectiveness, cannot be considered or defined as investigational and are reimbursable under State Medicaid Plans and other third-party-plans[1]. Until this federal rule is altered, drugs granted accelerated approval are reimbursable and should be reimbursed regardless of how a State Medicaid Plan views the accelerated approval pathway.

Accelerated approval is market approval based on a surrogate endpoint or effect on a clinical endpoint other than survival or irreversible morbidity. Accelerated approval is often used by the FDA when a drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, and pathophysiologic evidence and understanding, to predict a clinical benefit[2]. While it reduces the amount of clinical evidence needed to approval, drugs approved under the accelerated approval pathway must show strong evidence that the drug is reasonably likely to predict a clinical benefit based surrogate and intermediate clinical endpoint data garnered

---

[1]New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, FR Vol. 57 No. 239 (Dec. 11, 1992) (to be codified at 21 C.F.R. pt. 300).

[2] 21 C.F.R. § 314.510 2017.

from an adequate and well-controlled clinical trial. For many years, it was used almost exclusively in oncology and infectious disease, but an uptick in rare disease drug development has seen this pathway used increasingly in rare diseases where there are few or no disease-modifying treatment options available. In the case of Duchenne, evidence used for accelerated approval could be any number of biomarkers or intermediate clinical endpoints, including dystrophin or utrophin production, MRI data, or pulmonary and cardiac endpoints. Given that Duchenne is such a rare and devastating disorder where the majority of the population lives without a disease modifying therapy, FDA will likely continue to use accelerated approval in an effort to treat the entire Duchenne population with drugs that are safe and appear to be efficacious. The provisions within the proposed Amendment to the MassHealth Section 1115 Demonstration would create a barrier to access for patients hoping to gain access to those future therapies.

Furthermore, EOHHS proposes in the Amendment that it will *"use its own rigorous review process, in partnership with the University of Massachusetts Medical School, to determine coverage of new drugs and to guarantee that patients access clinically proven, efficacious drugs."* Regardless of the fact that it would be inappropriate of EOHHS, which operates as a payer not an unbiased reviewer free of conflicts, to review the safety and efficacy of products already approved by the US federal regulatory agency, neither the University of Massachusetts Medical School nor it's educational partners and affiliates employee neuromuscular experts who specialize in Duchenne. Duchenne medical experts are as rare as the disease itself, and there are only a few physicians in the country who understand and appreciate the physiology of the disease and how to treat it. While the University of Massachusetts Medical School is an established and renowned teaching university, it is insensible to imply that it's physicians are capable of understanding every rare disease that has a treatment granted accelerated approval, and are appropriate co-reviewers. In the case of Duchenne products, EOHHS and MassHealth should be reaching out to the Duchenne experts that practice in Massachusetts, such as Dr. Basil Darras of Boston Children's Hospital and Dr. Fawn Leigh of Massachusetts General Hospital, when deciding on coverage policies for drugs meant to treat Duchenne.

The Duchenne patient population recognizes the rising costs of prescription drug prices, and the role that rare disease products play in the increasing cost of healthcare. However, we also recognize how difficult it is to execute studies in rare disease where little is known about the natural history, the patients are few and far between, and the health outcomes are progressive and devastating. These unusual circumstances often lead to innovative clinical trials designed in partnership with regulatory officials, medical experts, and patients and advocacy organizations. These study designs carefully balance the need to show that a product is reasonably likely to predict a clinical benefit, with allowing very sick patients access to drug as soon as possible. The Duchenne patient community realizes that this philosophy may be at odds with the views of payers, but federal statutes allow and encourage this type of flexibility when dealing with drugs that have the potential to treat rare diseases and it is the responsibility of all State Medicaid Plans to comply with national rebate agreements and to draft coverage policies reflective of FDA approved labels.

Importantly, at Jett Foundation we speak for the patients; not the pharmaceutical or the health insurance industry, and it is the Duchenne patients residing in Massachusetts who will truly suffer dire consequences of the proposed Amendment to the MassHealth Section 1115 Demonstration. It is not the role of EOHHS, or any other payer to make decisions on whether patients can access potentially life-saving FDA approved treatments treatments, it is the role the of the FDA, expert clinicians, and the patients and families to weigh the benefits and risks of trying an FDA approved treatment.

For the sake of patients residing in Massachusetts with Duchenne muscular dystrophy, please reconsider parts 6a and 6b of the proposed Amendment to the MassHealth Section 1115 Demonstration. Please do not hesitate to reach out with any questions.

Sincerely,

Christine McSherry, BSN
Jett Foundation, Founder

August 21, 2017

Tim Boyd, MPH
Director of State Policy
tboyd@rarediseases.org

Marylou Sudders
Secretary of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

Transmitted via email to kaela.konefal@state.ma.us in the EOHHS Office of Medicaid

Re: 1115 Demonstration Amendment Request (Public Comment)

Dear Secretary Sudders:

On behalf of the 1-in-10 Massachusetts residents with one of the nearly 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks the EOHHS for the opportunity to provide comments on its proposed amendment to MassHealth Section 1115 Demonstration.

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. We are committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

NORD recognizes the immense challenges facing HHS to control health care costs in order to meet the needs of Massachusetts patients, especially given uncertainty around ongoing federal efforts to reform the Medicaid program. However, after reviewing the proposed Demonstration Amendment and consulting with our member organizations, NORD is concerned that specific provisions of the Amendment will create both short and long-term disruptions in care for rare diseases patients in the state currently receiving coverage through MassHealth. Further, the proposal to adopt a closed formulary and supplement the Food and Drug Administration's (FDA) determinations about the safety and efficacy of medicines proses a specific threat to rare disease patients who are benefitting from the FDA's accelerated approval of breakthrough treatments.

I. The importance of MassHealth Coverage for Rare Disease Patients

MassHealth has long been a lifesaving source of health care coverage for rare disease patients in the state who cannot access other forms of coverage. We believe the proposed Demonstration Amendment would threaten this coverage in several ways:

First, it will transfer non-disabled adults with incomes greater than 100% of the Federal Poverty Level (FPL) to Connector plans. While some rare disease patients may be exempt from this change as a result of their disabled status, many others would be transitioned off the program because their disease is either effectively managed or has not yet resulted in severe symptoms. This transition could result in several short and long-term disruptions in care, such as patients losing coverage for their preferred provider, losing coverage to a specialist for their specific rare disease, and experiencing an unintended increase in cost sharing or premiums that results in a drop in coverage. As written, the Amendment does not specify how to address these eventualities beyond describing that, "[i]n addition to our own direct outreach efforts, MassHealth and the Health Connector plan to provide small grants to community organizations and providers for outreach and enrollment activities for this transition."

Second, the Amendment proposes to enroll non-disabled Enroll non-disabled parents and caregivers with incomes up to 100% FPL in MassHealth's CarePlus Alternative Benefit Plan and Block non-disabled adults with access to affordable employer-sponsored insurance (ESI) from enrolling in Medicaid. In addition to the aforementioned care disruptions that such changes will cause, this proposal does not satisfactorily take into account the unique needs of certain patients populations that would see a medical benefit to enrolling in MassHealth over an employer-sponsored plan.

Finally, the Amendment seeks to narrow available physician networks in order to promote the use of Accountable Care Organizations (ACOs) and Manage Care Organizations (MCOs). While there are potential benefits for this change to ensure better care coordination and outcomes for all MassHealth enrollees, it is critical that EOHHS make accommodations for the unique situation of rare disease patients who often struggle to find a physician with knowledge of their disease. Without enhancing specific procedures to ensure rare disease specialists can participate in MassHealth's ACO and MCO structures, many patients will suffer a lapse in care.

II. A Closed Formulary in MassHealth Threatens Patient Access to Treatment

The proposed Demonstration Amendment seeks to institute a "commercial-style" closed formulary that only provides access to a single drug per therapeutic class and would exclude medicines that the state determines offer limited or inadequate efficacy. The enactment of these changes would have a devastating impact on the health and well-being of rare disease patients. NORD has seen firsthand how "commercial-style" formulary restrictions overrule the prescribing decisions of physicians thus resulting in patients being unable to access the medicines best suited to treat their condition. As a result, such restrictions inhibit quality care by causing lapses in medication adherence and delays in use of medicines that provide an enhanced clinical benefit. Over time, this will not only result in poorer health outcomes for MassHealth beneficiaries but raise health care costs for the state.

1900 Crown Colony Drive, 4th Floor • Quincy, MA 02169
T 617.249.7300 • F 617.249.7301
rarediseases.org • orphan@rarediseases.org

Further, NORD is troubled by the HHS' proposal to institute the state's discretion as to the clinical efficacy of medicines above and beyond that of the FDA, particularly for medicines that received an accelerated approval. The accelerated approval of new breakthrough medicines has enabled rare disease patients to benefit from research into diseases where no treatment currently exists. These approval decisions are made in close consultation with patients, expert advisory committees, and manufacturers to determine whether a new medicine meets the specified clinical end-points for approval. At this time we do not believe that MassHealth has the capacity or expertise to overrule FDA decision regarding the safety and efficacy of new medicines.

Thank you once again for the opportunity to provide comments on its proposed Amendment to MassHealth Section 1115 Demonstration. For questions on these comments, please contact me at tboyd@rarediseases.org.

Sincerely,

T. Boyd

Tim Boyd, MPH

Director of State Policy

1900 Crown Colony Drive, 4th Floor • Quincy, MA 02169
T 617.249.7300 • F 617.249.7301
rarediseases.org • orphan@rarediseases.org

National
Multiple Sclerosis
Society
Greater
New England
Chapter

August 21st, 2017

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

Dear Assistant Secretary Tsai:

Thank you for the opportunity to submit comments regarding the proposed Mass Health 1115 Demonstration Medicaid Waiver. The National MS Society signed onto the organizational letter last week submitted by Health Care for All. The proposed prescription drug formulary changes are of particular concern to individuals with multiple sclerosis so these comments supplement those by Health Care for All.

MS is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms range from numbness and tingling to blindness and paralysis. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS. There is no cure but at present the disease modifying treatments known as DMTs are currently the best frontline approach to slowing the progression of the disease and reducing the likelihood of disability. Ensuring access to the disease modifying treatments is a high priority for the National MS Society. In 2016, the Society issued its Recommendations to Make Medications Accessible http://www.nationalmssociety.org/Treating-MS/Medications/Make-MS-Medications-Accessible

and some of these recommendations are included below.

Opposition to a closed formulary

The National MS Society recognizes the challenges that government faces in balancing access to prescription drugs with managing growing costs. However, the proposed waiver changes represent a significant deviation in the current Mass Health formulary in which all 15 FDA- The National MS Society recognizes the challenges that government faces in balancing access to prescription drugs with managing growing costs. However, the proposed waiver changes

represent a significant deviation in the current Mass Health formulary in which all 15 FDA-approved MS DMTs are available.
The National MS Society opposes a closed prescription drug formulary and maintains that all FDA-approved MS DMTs should be made available in health plan drug formularies. Studies show that early and ongoing treatment with a DMT is the best way to modify the course of the disease, prevent the accumulation of disability and protect the brain from damage due to MS. The complexity and uncertainty of MS makes identifying an effective treatment following diagnosis and staying on that treatment essential. Physicians' clinical judgement in the treatment decision process must be upheld in the best interest of the patient's well-being. It is also recommended that MS treatments not be changed unless a medical reason necessitates a switch. Patients switching medications should only occur due to a sub-optimal treatment response, intolerable side effects, and inadequate adherence to the treatment regimen. If this waiver is approved by CMS, the National MS Society and its health care advisory committee members would welcome the opportunity to provide guidance about the class of MS DMTs at the outset as the formulary is being redesigned.

CHIA supports the availability of the DMDs

In October 2016, The Massachusetts Center for Health Information Analysis issued a report as charged by the MA legislature with reviewing the MS DMDs for commercial plans and the GIC.

They issued a report MANDATED BENEFIT REVIEW OF H.B. 800 SUBMITTED TO THE 189TH GENERAL COURT: AN ACT PROMOTING CONTINUITY OF CARE FOR MULTIPLE SCLEROSIS TREATMENT
The report's conclusion -pg 5 states as follows:

"Disease-modifying therapy is at the core of MS treatment and is administered with the goals of reducing the frequency and severity of relapses, reducing the rate of nerve damage, and slowing the progression of disability. Research supports initiation of DMT early in the course of the disease, and patients who adhere to their DMT experience better quality of life and lower risk of relapse. Since 2010, the number and use of disease-modifying therapies has grown, with new mechanisms of action and expanded options for route and frequency of administration, and therapeutic approaches to MS are expected to continue to grow and evolve as researchers gain a better understanding of the pathogenesis of MS and the influence of environmental factors.54 DMTs have numerous common side effects and carry many warnings. **Choosing the right DMT for an individual depends on balancing many factors, including chances of adherence based on lifestyle. Once a patient is being managed effectively on a DMT, clinical literature supports continuation of that DMT except in prescribed circumstances."**

The Exceptions Process

The waiver proposes an exceptions process which we anticipate may be become an administrative burden to Mass Health staff depending on the number of MS DMTs drugs excluded as well as other drugs excluded a closed formulary. The exceptions process may also be

burdensome to the consumer and their physician assisting the process. Too often, people with MS report significant delays in getting their treatment and added stress and anxiety from having to navigate a complex web of uncoordinated systems, processes and entities in the healthcare system to get their treatment. MS can also impact cognition, which can make such burdensome processes particularly challenging.

Mass Health enrollees with MS cannot afford to pay out of pocket for their treatments if they are not covered, even short-term. The average wholesale price of MS DMTs $65,000-92,000 a year. Any exception process should be simplified and expedient for the consumer. In line with the Society's Access to Medications recommendations, step therapy measures if imposed should make sense, and not result in detrimental delays in accessing appropriate medications. Individuals should not be required to fail on similar mechanisms of action, similar routes of administration or a medication

Michelle Dickson
Senior Director of Advocacy
National MS Society
Michelle.dickson@nmss.org

MASSACHUSETTS
Health & Hospital
ASSOCIATION

August 21, 2017

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

Re: Proposed MassHealth Section 1115 Demonstration Amendment Request

Dear Assistant Secretary Tsai:

On behalf of our member hospitals and health systems, the Massachusetts Health & Hospital Association (MHA) offers these comments for your consideration regarding the proposed amendment to the state's 1115 Medicaid waiver. The Executive Office of Health and Human Services (EOHHS) proposed these amendment changes in connection with MassHealth reform legislation that is under review by the legislature. MHA has offered comments to the legislature on the proposed legislation and our comments here reflect those positions. In addition, we offer further comments on proposed Medicaid waiver changes that were not included in the legislative filing.

As expressed in our recent letter to the legislature, we share Governor Baker's perspective that we are at a point in time when changes are needed to make the MassHealth program sustainable. MHA and its member hospitals and healthcare systems have considered the many points regarding the Baker Administration's proposed MassHealth reforms and we believe the governor has put forward a proposal that can serve as the basis for addressing the sustainability of the MassHealth program. We also recognize that this proposal is not the final product and that improvements must be made to it to ensure than any changes to health coverage are affordable and take into consideration low-income patients who may fall through the cracks. MHA pledges to work collectively with the administration, legislature, and all stakeholders to achieve the very best solution for all.

MHA appreciates EOHHS' significant work in crafting the proposed Medicaid amendment and supporting presentations. The extensive narrative explains the intention of the administration on

significant issues affecting affordable health coverage for low-income residents. As a general observation related to some of the proposed waiver provisions, we are concerned that the language regarding the actual waiver authority is in some instances too broad and does not fully reflect the specifics that the administration has described in its narrative. Other protections that stakeholders and the legislature are suggesting to maintain access to affordable coverage should also be considered. We believe additional language is needed in the actual waiver provisions to specifically address protections that the administration and legislature plan to include. MHA respectfully requests the opportunity to further comment on any safeguards that will be incorporated to these waivers prior to submission to the Centers for Medicare and Medicaid Services (CMS).

Waiver Proposal 1: Enroll non-disabled adults with incomes over 100% FPL in subsidized commercial plans through the state's exchange (the Health Connector)

The Administration has proposed permitting non-disabled adults with incomes above 100% of the federal poverty level (FPL) to be only eligible for subsidized insurance in the Exchange (Connector) rather than MassHealth. The administration states that transitioning these individuals will maximize federal revenue associated with this population and will make MassHealth more financially sustainable over the long term. MHA supports this recommendation but also believes added protections must be created for out-of-pocket expenses and for ensuring that enrollees can access coverage readily. It is important that adequate protections be established to ensure affordable coverage is maintained.

While there is a zero-premium option, premiums can range as high as $174 per month for this income group in the Connector. Out-of-pocket expenses would also be more than MassHealth co-pays, including $50 co-pays for hospital services, $10-18 for office visits, and $10-$40 for prescription drugs. Dental coverage would no longer be a covered benefit, requiring individuals to purchase supplementary dental coverage or receive care at a community health center where it would be reimbursable by the Health Safety Net program. There are also administrative differences between the programs, including eligibility rules relating to open enrollment and income tax filings required to receive the tax credits.

Potential protections that should be considered to ensure affordable coverage include expanding Connector Plan Type I up to 133% FPL rather than the current 100% FPL limit. Since the 140,000 people earning between 100% and 133% FPL are currently entitled to Medicaid benefits under current law, it may be more appropriate that their Connector cost-sharing be aligned with MassHealth cost-sharing requirements. An evaluation of the affordability of the premiums in Connector Plan Type I should also be performed since premiums can range from $0 to $165. Under Commonwealth Care, state law once provided certain protections for those earning up to 100% FPL but those rules were repealed in 2013 as part of the Affordable Care Act (ACA)

implementation. Changes to premiums and out-of-pocket expenses are now determined by the Connector and the administration on an annual basis.

To better protect these low-income individuals being transitioned from Medicaid over the long-term, we believe these changes should be more specific both in state law as well as in the waiver. We believe state law could be drafted that defines the premium and out-of-pocket expenses levels for those earning up to 133% FPL. The state could also review the re-establishment of eligibility provisions previously afforded to Commonwealth Care members. These included continuous enrollment as well as continuity of coverage during the premium payment so-called grace period. With regard to the waiver, we believe further mention of protections regarding premium and out-of-pocket expenses should be specified in any proposed waiver authority.

Finally, with the subsidies for low-income individuals in the Connector heavily dependent on the ACA's federal tax credits and cost-sharing reductions, there is great concern about the future of the program. A requirement in state law and the waiver for the state to perform a review if federal subsidies are negatively affected would allow the legislature, administration, and stakeholders the ability to determine any needed next steps to preserve affordable coverage for this population in a transparent and open public process. While the very threat should not be a reason for inaction on the proposal to move 140,000 individuals to the Connector, it should not be ignored entirely.

Waiver Proposal 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

MassHealth proposes to move all non-disabled adults up to 100% FPL, including parents and caretakers, from MassHealth Standard coverage to MassHealth CarePlus. This benefit plan is currently available to ACA-expansion enrollees ages 21-64 and would be extended to include non-disabled parents and caretakers ages 21-64 as well. The major difference between the current benefit plans is long-term services and supports. We note that MassHealth has in the past proposed other benefit change to the Care Plus benefit plan related to optional Medicaid services and non-emergency transportation.

MHA does not oppose the proposed change in benefit plans for this population. We are concerned, however, with related proposals that have been proposed to the legislature that would give EOHHS the ability to unilaterally restructure or eliminate covered Medicaid services that are deemed optional under federal Medicaid rules. Important services include prescription drugs, physical therapy, occupational therapy, dental, vision, hearing, and other services. MHA is opposed to permitting *any* administration the ability to change these covered services unilaterally and believe changes in key Medicaid benefits should require consent by the legislature. If the

state seeks to modify MassHealth benefits, that change must be done with stakeholder input and through a public process.

Waiver Proposal 3: Modify the premium assistance program for non-disabled adults with access to commercial insurance to reduce Medicaid benefit "wraps" on top of the commercial plan while ensuring continued affordability for members

Today, MassHealth premium assistance supports out-of-pocket expenses as well as premiums for low-income patients. Through the proposed waiver amendment, EOHHS seeks flexibility to not provide any additional benefit wrap, except for a limited number of services not typically covered by commercial insurance. In addition, EOHHS requests a waiver to not provide a Medicaid cost sharing wrap when a member in premium assistance receives services from a provider that is not enrolled as a MassHealth provider, consistent with MassHealth's current practice.

MHA is concerned that through such a waiver MassHealth would no longer provide support for co-payments, co-insurance, and deductibles for employer insurance covered services. Out-of-pocket expenses can be significant in the commercial insurance market. According to the Center for Health Information and Analysis (CHIA) Massachusetts Employer Survey for 2016, "the average annual deductible for a single coverage health plan was $1,065. Deductibles were substantially higher for small firms than large firms ($1,444 vs. $929). The average annual out-of-pocket limit for single coverage was $3,600." Reducing Premium Assistance wrap coverage therefore is the wrong direction, in our opinion. We believe the commonwealth should provide the financial support needed to ensure premiums and out-of-pocket expenses are affordable for Medicaid-eligible enrollees with access to employer coverage. We recommend this change not be included in any Medicaid waiver amendment and we also would support enhancing the Premium Assistance program so that it is easier to access.

Waiver Proposal 4: Implement a "gate" that would not allow individuals with access to affordable employer-sponsored or student health insurance to enroll in Medicaid, similar to the policy for marketplace coverage

In the waiver amendment as well as the reform legislative package, the administration has proposed a new policy that disallows MassHealth coverage for non-disabled adults with access to affordable employer health insurance. Affordability is not defined in the proposed state law change or in the waiver. In the waiver document as well as subsequent supporting presentations, the administration proposes to establish the affordability "gate" as those with access to employer coverage with premiums and deductibles that are equal or less than 5% of income.

We are encouraged and appreciate that the administration's proposed definition of affordability has been modified throughout the discussion of this proposal. We agree that it is important to include deductibles in any calculation of affordability. However, co-payments and co-insurance cannot be overlooked. These out-of-expenses can be very high in the commercial market. For example, according to the 2016 CHIA Employer Survey, hospital co-payments for employer coverage averaged $396, and emergency department co-pays averaged $165. In the Connector, Bronze health plans available to small employers have co-payments that are significant, including $1,000 for inpatient hospitalizations, high-cost imagining, and skilled nursing facilities. Co-payments for outpatient surgeries are $750 and emergency department services are $500. Co-insurance is also incorporated into some of the non-standardized plans where the patient is responsible for paying between 20% and 35% on certain high-cost services. These types of products are all available in the commercial market.

Because these significant out-of-pocket costs affect the affordability of health insurance coverage, we believe they must be factored into any determination that denies Medicaid coverage because of access to employer coverage. And to the general point we have made at the outset, we believe the proposed waiver authority request to disallow Medicaid eligibility based on access to affordable coverage is too broad. We believe the affordability definitions related to premiums and out-of-pocket expenses should be incorporated into any waiver authority. MHA also believes this proposal should be explored more to determine the efficiency of such a gate in combination with determining a fair definition of affordability.

Waiver Proposal 5: Eliminate redundant MassHealth Limited coverage for adults who are also eligible for comprehensive, affordable coverage through the Health Connector

Federal rules require MassHealth to cover emergency services for individuals who would otherwise be eligible for Medicaid except for their immigration status. In the MassHealth program, that coverage benefit is called MassHealth Limited. For those immigrants that are eligible for subsidized insurance in the Exchange, EOHHS proposes to only provide MassHealth Limited and Health Safety Net wrap coverage for up to 90 days.

MHA believes ConnectorCare is preferable to the MassHealth Limited coverage with the Health Safety Net as wrap-coverage. The latter, as its name implies, is not comprehensive health coverage. Efforts should be made to encourage enrollees to take up ConnectorCare. If there are instances where individuals are in both programs at the same time, this should be addressed so that MassHealth Limited is no longer available once a person is enrolled in ConnectorCare.

However, we remain concerned with the proposal and how it will affect those that do not ultimately enroll as they will be locked-out of any coverage benefit until the next annual Connector open enrollment period. Medical care will still be needed for these low-income

individuals, and the cost of that care will likely result in hospital uncompensated care. We do not believe a lock-out is appropriate for this population. Because these individuals are entitled to emergency services under federal Medicaid rules and hospitals are obligated to provide that care, we believe the state should maintain efforts to enroll these individuals into ConnectorCare while maintaining the emergency service protections. Additional time beyond the standard 90-day limit may be needed.

Waiver Proposal 6: Select preferred and covered drugs through a closed formulary that assures robust access to medically necessary drugs

EOHHS proposes adopting widely-used commercial tools to obtain lower drug prices and enhanced rebates from pharmaceutical companies. This includes selecting preferred and covered drugs through a closed formulary and more selective use of specialty pharmacy networks.

As the Health Policy Commission (HPC) noted in its 2016 Annual Cost Trend report, prescription drug spending has grown more rapidly than any other category of service. This substantial cost increase is not limited to just payers, but providers as well. Double digit pharmaceutical increases have been frequently cited by hospitals in recent years. These cost pressures significantly affect providers, including their ability to manage cost under new accountable care arrangements. Providers are limited in what they can do to mitigate cost escalation in this area, but they are playing an active role where they can. Providers have educated patients on treatment alternatives, monitored prescribing practices, implemented medication adherence strategies, and adopted alternative payment contracts that include pharmacy spending.

While much more attention is needed at the federal level to address this cost growth, the state also has a role, including in the MassHealth program. MHA supports greater transparency and attention to addressing prescription drug prices. We encourage MassHealth to explore ways to achieve savings in this area so that the state and healthcare providers can contribute those savings to bending the Medicaid cost trend. Protecting 340B federal discount pricing for hospitals and other qualified providers also will be essential.

While the use of formularies is now common practice in managing prescription drugs, we believe the MassHealth program must have an efficient process to address circumstances when enrollees need a non-formulary drug. Newer, more expensive drugs are being introduced to treat rare diseases. We are pleased that MassHealth will continue to provide an exceptions process to cover medically necessary drugs that are not on the formulary. Given that MassHealth indicates it will make greater use of the closed formulary approach, we respectfully encourage MassHealth to be transparent and seek clinical input from the provider community on these processes so that patient care can remain at the highest level while achieving savings for the broader program.

This is particularly needed given the population MassHealth serves, which includes many with chronic medical and mental health conditions, including children where the use of prescription drugs may be more complicated.

Waiver Proposal 8: Implement narrower networks in MassHealth's Primary Care Clinician (PCC) Plan to encourage enrollment in ACOs and MCOs

For decades, the PCC program's provider network has included most MassHealth providers. Under this proposal, EOHHS is proposing to create a narrow network including "high value network of hospitals and possibly primary care providers." EOHHS states the policy is designed to incentivize MassHealth enrollees to join ACOs and MCOs.

MHA is still in the process of evaluating this proposal with our members. We believe the creation of narrow networks in the MassHealth program is a sensitive issue and a transparent stakeholder process would be needed to implement such a change. Consideration of safety net hospitals will be needed given the large number of MassHealth patients they serve. If this policy is adopted, substantial enrollee outreach and education also will be needed.

In addition, exceptions to this rule will be needed. Similar to MassHealth's managed care rule exceptions, an exception process is needed for when an enrollee requires access services that are out-of-network. For the PCC population, hospitals are the largest provider of services to these members, including newborn deliveries and related care, which are key services provided to MassHealth members. A MassHealth member's access to a local hospital is therefore very important, especially in areas where accessing the next hospital may involve unrealistic transportation requirements. Exceptions are needed to address unique circumstances such as when specialty services are not available in a narrow PCC network. There may be provider capacity issues and unrealistic wait times in other cases requiring a patient to seek care out of the narrow network. If there is a lack of access to such providers, there should be an efficient process to allow a MassHealth patient to receive reimbursable services outside the narrow PCC network. A clear timeframe and process should be known for a member to apply and receive a decision for both urgent and non-urgent cases. MHA respectfully requests that if this proposal is included in the waiver amendment, an exception process to the general rule should be incorporated in the waiver authority request.

Waiver Proposal 10: Waive requirements for multiple managed care options in certain area(s) of the state in which a majority of primary care providers are participating in a single MassHealth ACO

Federal Medicaid rules dictate requirements concerning auto-assignment to MCOs when there are not more than two MCO choices in a service area. They also require states to have time and

distance requirements for certain types of providers, including primary care providers and hospitals. In the proposed waiver, MassHealth requests a freedom of choice waiver to not provide two or more managed care enrollment options in areas where PCPs are in a single ACO. It also requests a freedom of choice waiver to allow the PCC Plan not to have two PCPs within the time and distance standards in order to enroll someone into it. Because the MassHealth ACO program limits PCP access, MassHealth states the PCC and other managed care options in certain areas will not have a large enough pool of PCPs to meet network adequacy requirements. This waiver provision would permit an exemption from the federal requirement.

MHA understands the need for this requirement given the significant change occurring as a result of the ACO program. However, it is still important to ensure that MassHealth managed care options have a sufficient number and variety of providers to meet the needs of MassHealth beneficiaries. We are not clear on how exactly this waiver authority can be used beyond addressing the unique circumstances of certain areas of the state where there may be a single ACO given the PCP limitation. It is also not clear to us exactly what waiver authority is being sought and whether the waiver from federal rules defining managed care choices is broad or isolated to certain instances. More information on the proposed waiver authority request is needed before MHA can support this request.

Waiver Proposal 12: Implement cost sharing greater than five percent of income for members over 300% FPL eligible exclusively through the demonstration

MassHealth covers certain members with incomes above 300% of the FPL. These individuals are mainly disabled individuals in the CommonHealth program. EOHHS is seeking flexibility to require premiums and cost sharing to exceed 5% of these individuals' income.

MHA believes more information is needed on this proposal. To our understanding, CommonHealth already has sliding premiums based on income, which can be substantial for higher income individuals and families. Co-pays are the modest MassHealth co-payments. If these individuals were subject to higher co-pays, the costs could prove unaffordable for them. As this population is disabled, their life circumstances are much different than the average individual and family.

Unaffordable out-of-pocket expenses affect those patients with the greatest medical needs and can discourage people from seeking needed care. On the provider side, the administrative burden of collecting and processing these claims is costly and inefficient. Such substantial fragmentation of payment responsibility significantly raises billing costs, increases the potential for provider bad debt, and causes confusion and frustration for patients. The likelihood of increased bad debt is particularly real in the MassHealth program since current rules prohibit providers from requiring payment of a co-payment for services delivered.

MHA respectfully requests further information on the cost-sharing that is expected of these individuals and what out-of-pocket protections can be afforded. The proposed use of the Connector's affordability measures are also likely not appropriate since this population has medical costs and other living expenses that are much higher than the average person. It will also be important to factor in any increase in unpaid co-payments to providers to prevent unintended cost-shifting from the MassHealth program to providers.

Guard Against Unintended Consequences

EOHHS has stated it does not believe there will be an increase in the number of uninsured or in uncompensated care as result of these changes. While we are hopeful that would be the case, experience has shown that when there are significant changes to coverage, the outcome cannot always be predicted accurately. Once these changes are enacted, it is vital for the commonwealth to closely monitor their effects on the ranks of the uninsured. In particular, monitoring of MassHealth and ConnectorCare enrollment should be done frequently to determine any net effect on these coverage changes. MHA believes that the commonwealth should continue to be committed to addressing increases in the uninsured. A trigger mechanism should be established that would result in further legislative action if there is any unexpected uptick.

The commonwealth must also be cognizant of potential increases in uncompensated care that hospitals and community health centers provide. The administration already has acknowledged that the Health Safety Net will cover dental care for the 140,000 individuals that transition to ConnectorCare and who do not purchase dental insurance. This would be an added cost to the Health Safety Net that is currently experiencing a funding shortfall.

We are also concerned that the financial exposure to the Health Safety Net will not be limited to dental costs. While affordable access to coverage should be ensured to those transitioning to the Connector and employer coverage, it is possible that some will not take up that coverage for a variety of reasons. The Health Safety Net will be available for much of this care and when any of those individuals are precluded because of the program's eligibility rules, this cost will fall as uncompensated care directly on healthcare providers.

Funding language related to Commonwealth Care Trust Fund transfers to the Health Safety Net should be revisited and a commitment should be made that this needed funding is fulfilled. While transfers are required under state law, they have not been fulfilled in recent years. Additional funding should also be made available to address increases in uncompensated care, including additional spending authority in the Medicaid Waiver's Safety Net Care Pool.

Telemedicine

Telemedicine is a critical tool that healthcare providers, payers, patients, and employers use to improve access to care for patients, improve health outcomes for chronic illnesses, and reduce costs associated with seeking in-person medical visits with healthcare providers. Advancing access to telemedicine will improve access to care and increase the efficiency of care delivery to MassHealth patients, while decreasing the overall cost of program. We believe EOHHS should consider the savings offered through telemedicine and seek spending authority for such services.

In summary, we believe the MassHealth reform blueprint that Governor Baker and EOHHS have put forward provides an opportunity to work together to develop a proposal all can endorse in the interest of sustaining the MassHealth program and protecting health coverage access for low-income residents. With further clarification and adjustments to the specific waiver authority requests, and in alignment with the legislative process that is underway, we believe this waiver amendment can be supported by the commonwealth's key stakeholders. The hospital community is committed to working with EOHHS, the legislature, and all stakeholders to forge a solution.

Sincerely,

Timothy F. Gens
Executive Vice President & General Counsel
Massachusetts Health & Hospital Association

MASSACHUSETTS MEDICAL SOCIETY
Every physician matters, each patient counts.

COMMENT RELATIVE TO MASSHEALTH 1115 DEMONSTRATION WAIVER AMENDMENT
AUGUST 21, 2017

On behalf of more than 25,000 physicians and medical students across the Commonwealth, the Massachusetts Medical Society appreciates the opportunity to provide comment regarding the amendments proposed to the MassHealth 1115 Demonstration Waiver, as released on July 10, 2017. The Medical Society is pleased to reiterate its support of the intent of the waiver to promote health care delivery reforms that will help ensure the sustainability of the MassHealth program which provides vital coverage to so many patients in Massachusetts.

The Medical Society writes to express significant concern regarding several of the proposed amendments which we believe on balance will have detrimental effects on the care provided to MassHealth beneficiaries. **The Medical Society endorses the comments provided by Health Care for All and other co-signatories in its August 18th letter to you regarding these waiver amendments.** We believe that shifts of large patient populations from MassHealth to ConnectorCare will ultimately burden patients with reduced benefits and increased cost-sharing for these patients. Not only could this lead to poorer health outcomes, but exacerbated oral health, mental health and behavioral health issues could also lead to increases in overall health care expenditures over time.

In addition to the comments raised in the aforementioned letter, the Medical Society wishes to provide further comment regarding two provisions: proposed changes to the prescription drug formulary and the proposed further narrowing of networks in the PCC plan.

Drug Formulary
The Medical Society urges caution in moving from the current pharmacy benefit to a closed drug formulary. While the Medical Society acknowledges the unsustainable escalation of health care costs, with strong evidence of the role of pharmaceutical drugs costs in driving these cost increases, a balance must be sought in cost-saving policy proposals to ensure access of all patients to medically necessary and appropriate prescription medications.

The Medical Society therefore offers the following considerations for the MassHealth drug formulary moving forward:

- A drug formulary should have clear, consistent policies that outline inclusion criteria with opportunities for expert and public comment

- Formulary development should be continuous and transparent, with significant input by practicing physicians into all formulary development.
    - Formularies should be readily available in print and through electronic media to patients and prescribers
    - Formularies should be continuously updated to respond to newly approved drugs, and to

860 WINTER STREET, WALTHAM, MA 02451-1411
TEL (781) 893-4610 TOLL-FREE (800) 322-2303 FAX (781) 893-8009 WWW.MASSMED.ORG

ongoing feedback from patients and physicians

- Drug formularies must be flexible to acknowledge the value of multiple drugs across a drug class
    - While there may be examples of reasonable reductions in the number of drugs offered across a given drug class, there are other classes of drugs where reduction in drugs offered will impede the provision of good medical care. The drug class for the treatment of substance use disorder (SUD), for example, includes methadone, buprenorphine, and naltrexone. The elimination of any one of these drugs from a given formulary would be devastating to the treatment of SUD, as each drug represents a substantially different approach to treatment that works particularly well for certain patient populations. A closed formulary that reduces the offerings in a drug class such that for the treatment of substance use disorder would have tragic effects of the care provided to MassHealth beneficiaries. Flexibility must be emphasized to allow for all options in certain drug classes.

- Exception process to the formulary must be prompt, accessible
    - The Medical Society appreciates the reference to a critical exception process to cover medically necessary drugs that are not on the formulary. The Medical Society urges physician input on the development of this process to ensure it is does not cause undue delay in care for patients, or additional administrative burden to physician office.

The Medical Society also expresses significant concern with the proposal to establish an independent process to review drugs newly approved by the FDA. Changes to FDA processes through the 21st Century Cures Act and other routes were intended to bring drugs to patients in an expedited manner with assurances of patient safety. FDA approval should not be undermined by creating a duplicitous approval process in Massachusetts. Instead, new drugs should be evaluated through the same transparent formulary process, as addressed above, to determine inclusion into the MassHealth formulary. The process outlined in the waiver amendment would have disproportionate effects on certain disease classes and medical specialties, such as oncology and infectious disease. The Medical Society believes that all FDA approved drugs should be evaluated in the same manner, irrespective of the particular FDA pathway, pursuant to formulary policies that are created with close attention to the perspectives raised above by the Medical Society.

Narrow Networks in PCC Plan

The Medical Society is concerned about the proposed changes to narrow the networks of the traditionally open-networked PCC plan. As mentioned in comments regarding the original 1115 waiver, the Medical Society appreciates the administration's desire to see more patients elect ACO plans and managed care organizatons. However, such changes should not come at the expense of patients who choose to retain the PCC plan, often so that they can retain longstanding relationships with their primary care physician or specialists Patients should be incented to enroll in ACO plans, or managed care organizations rather than penalized for retaining an existing plan through benefit reductions and narrowing of networks. Many medically complex patients seek the PCC plan as the best way to receive optimal medical treatment. Forcing narrow networks as a way to promote ACOs is not advisable. The Medical Society extends concern about compliance with Medicaid network adequacy laws, and thus urges the retention of the current network policies for PCC plans.

The Medical Society appreciates the opportunity to provide these comments, and looks forward to continuing to partner with the administration to find strategies that promote sustainability of the program in manners consistent with the best interests of the patients of the Commonwealth.

August 21, 2017

Secretary Marylou Sudders
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

RE: Request to Amend the MassHealth Section 1115 Demonstration

Dear Secretary Sudders:

On behalf of the Massachusetts Association of Health Plans (MAHP) and our 17 member health plans, including the 6 Medicaid managed care organizations (MCOs), I am writing to provide our feedback on the Commonwealth's request to amend the MassHealth Section 1115 Demonstration, released July 20, 2017. We appreciate the opportunity to provide feedback on the state's request to amend the Section 1115 Demonstration and efforts to preserve coverage for Massachusetts residents.

MAHP and our member health plans have been ardent supporters of efforts to ensure that Massachusetts residents are able to access high quality and affordable health care coverage. MAHP member MCOs have played a central role in the state's health reform initiatives since the passage of the Massachusetts health care reform law, Chapter 58 of the Acts of 2006. MAHP member health plans worked in close partnership with the state to stand up the Commonwealth Care program and as the Commonwealth restructured its health reform programs to conform to the Affordable Care Act, and are deeply involved in the changes underway to redesign the Medicaid program.

MAHP and our member health plans support the administration's goals of containing the growth of health care costs and providing the commonwealth with flexibility to ensure that coverage is available and affordable for individuals across the Commonwealth. It is with these policy goals in mind that we offer the following comments on the proposed waiver:

Enrollment of MassHealth Members in ConnectorCare

While MAHP has not taken a formal position on MassHealth's proposal to enroll non-disabled adults with incomes over 100% FPL into subsidized commercial plans, through the Health Connector's ConnectorCare program, we have raised questions regarding the uncertainty of federal cost sharing reduction (CSR) subsidies, and how the state plans to fund this program if this population is transferred to the Connector and federal funding levels for either the CSRs or the Advanced Premium Tax Credits (APTCs) were to cease or change. We would like to work

closely with the Administration to understand options for ensuring these individuals do not become uninsured while providing the Administration with important flexibility to manage the MassHealth program. Additionally, we also would like to explore how the influx of new members into the program will impact programs aimed at market stabilization.

We have additional questions as to how this proposed change will impact the MassHealth Redesign program. MassHealth just announced the execution of agreements with 17 ACOs and is in the process of finalizing its MCO procurement. The state has estimated that approximately 240,000 lives will be transferred out of the Medicaid program. This raises a number of questions regarding the impact that the transfer of such a large number of lives will have on ACOs participating in the MassHealth redesign, including any implications for the distribution of DSRIP dollars, which are funded on a PMPM basis, as well as any measures that the administration plans to take to mitigate any adverse financial impact.

We appreciate the attention that the administration has already paid to identifying solutions and we would like to continue to work with you to understand the potential impact on health care coverage subsidies and develop creative solutions to ensure that the gains made under our state health care reform law are maintained.

MassHealth Pharmacy Benefit Change

MassHealth has identified increases in pharmacy costs as a significant factor leading to growth in MassHealth spending. In general, MAHP supports providing the state with flexibility to implement changes to its prescription drug formulary to obtain lower drug prices and enhance rebates, similar to what is employed in the commercial market today.

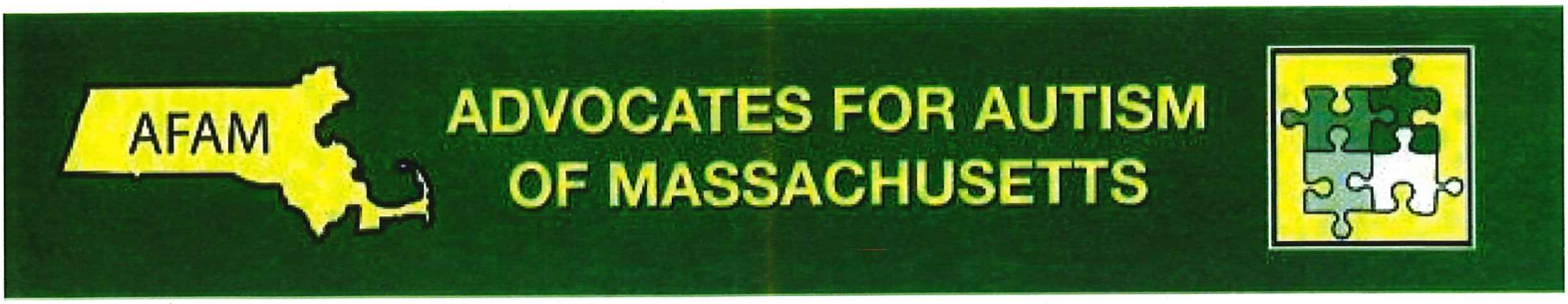
MAHP supports providing the state with flexibility to efficiently manage its pharmacy benefit and it is our understanding that MassHealth intends to make these changes to its fee-for-service (FFS) and primary care clinician (PCC) plan programs only and not to the MCO or ACO programs, however the draft Waiver Amendment is unclear as to the scope of the proposed changes. Expanding the scope of these changes to the MCOs or the SCOs could impact the NCQA accreditation of the MCOs and SCOs should they be required to implement a formulary that follows the parameters set forth in the draft Waiver amendment. NCQA accredited organizations are required to have a Pharmacy and Technology Committee (P&T). If MCOs adopted the MassHealth formulary or if MassHealth were to make coverage decisions for the MCOs, the MCOs could potentially need to delegate some of the NCQA activities to MassHealth as the P&T committees would no longer play a role in coverage decisions. Additionally, if MassHealth intends to require MCOs to mirror their formulary decisions and funnel them through the State as it does for Hepatitis C drugs, this would impact existing rebate arrangement and the ability of the MCOs to maintain current drug discounts through current agreements.

Finally, regarding the request to select preferred and covered drugs through a closed formulary that assures robust access to medically necessary drugs, MAHP supports MassHealth obtaining this flexibility. We would further like the opportunity to explore similar options for the MCO/ACO population in order to maximize savings across the program.

Again, we thank you for the opportunity to provide you with these comments. MAHP and our member health plans remain committed partners in working collaboratively with the State to ensure we retain the gains we achieved towards universal coverage and to continue to work to lower health care costs for individuals and employers. If you or your staff have any further questions regarding these comments or require any additional information, please don't hesitate to contact me or my staff.

Sincerely,

Lora Pellegrini
President & CEO
Massachusetts Association of Health Plans



August 21, 2017

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

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

RE: Comments on Demonstration Amendment

Dear Secretary Tsai:

Advocates for Autism of Massachusetts (AFAM) wishes to strongly endorse the comments sent to you on August 15, 2017 by Maura Sullivan, Director of Government Affairs of The Arc of Massachusetts regarding the MassHealth 1115 Demonstration Waiver Amendment released on July 20, 2017.

Like The Arc, AFAM supports the need and movement toward making MassHealth as sustainable as possible. We specifically applaud the proposal to maintain people with disabilities as MassHealth Standard eligible. However, AFAM is equally concerned with the changes to premium assistance coverage for caretakers who have children with disabilities, including autism, who will now be required to accept "ESI" (Employer sponsored insurance) or be forced into different products with less subsidy. In the state's posted waiver draft, premium assistance is offered for those above 100 FPL by capping out-of-pocket expenses at $1,250 and $2,500 for individuals and families respectively. This is inadequate, given that it would exceed 5% of income for those and 133% and 150% of FPL.

AFAM also endorses the other comments and recommendations outlined in Maura Sullivan's letter of August 15, 2017.

Sincerely yours,

Michael J. Borr,
Chairman

AFAM • 217 SOUTH STREET • WALTHAM MA • 02453
781-891-6270 www.afamaction.org office@afamaction.org