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October 20, 2017

VIA ELECTRONIC SUBMISSION

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

Re: Amendment Request for MassHealth 1115 Demonstration

Dear Secretary Hargan:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and under-served people. We appreciate the opportunity to offer comments on Massachusetts' request to amend its § 1115 MassHealth Medicaid demonstration. We support Massachusetts' decision to accept federal funds to cover low-income adults through Medicaid.

However, this amendment includes various waiver requests that we believe do not satisfy the approval requirements for § 1115 demonstrations and would set dangerous precedents for the program. NHeLP recommends that HHS not approve the Massachusetts demonstration with these waivers that would in many cases undermine access to care and are not likely to promote the objectives of the Medicaid Act.

Constraints on HHS Authority to Approve § 1115 Demonstrations

To be approved pursuant to § 1115, Massachusetts' demonstration amendment must:

- propose an "experiment[], pilot or demonstration;"
- waive only provisions of 42 U.S.C. § 1396a;

- be likely to promote the objectives of the Medicaid Act; and
- be approved only “to the extent and for the period necessary” to carry out the experiment.¹

The purpose of Medicaid is to enable states to furnish medical assistance to individuals who are too poor to meet the costs of necessary medical care and to furnish such assistance and services to help these individuals attain or retain the capacity for independence and self-care.² As explained below, a number of Massachusetts’ proposals cannot be approved because, separately and together, they are inconsistent with the provisions of § 1115, including:

- phasing down adult eligibility to 100% FPL,
- establishing a closed formulary and limited pharmacy networks,
- waiving entirely the prohibition on payments to Institutions for Mental Disease (IMDs),
- eliminating Emergency Medicaid for certain immigrants,
- reducing choice of providers and competition among managed care organizations in some areas,
- waiving some important cost sharing protections,
- curtailing important services like nonemergency medical transportation (NEMT), and
- requiring parents and caretakers to enroll in a more limited benefit package.

The state claims these provisions are necessary to reduce costs and seeks to “align coverage” with commercial insurance and shore up employer sponsored insurance. But in both cases, the process seems to reflect a race to the bottom. Rather than entertaining policies that would make ESI more attractive and affordable, the State seeks to make Medicaid coverage *worse* to achieve its goals. Using alignment as a demonstration goal also has questionable validity. Congress has specifically tailored Medicaid to serve the unique needs of the low-income populations it serves. It is not *intended* to function like commercial insurance. Many of the proposed changes would likely make coverage less affordable for some current MassHealth enrollees and reduce access to NEMT and emergency care for others, but would not likely reduce the overall cost of care. An estimated 140,000 MassHealth enrollees would shift to more expensive subsidized private Market coverage.³ This move would save the State enormous amounts of money, but would shift care costs onto the federal government and, to some extent, to beneficiaries. This is neither likely to promote Medicaid objectives nor clearly showing an experimental purpose or budget neutrality for the federal government.

¹ 42 U.S.C. § 1315(a).

² 42 U.S.C. § 1396.

³ MassHealth § 1115 Amendment Application, Sept. 20. 2017 at 5 (hereinafter “Application.”).

Lowering Medicaid Expansion Eligibility Threshold

Massachusetts proposes to reduce its adult Medicaid eligibility threshold from 133% Federal Poverty Level (FPL) to 100% FPL and shift the affected populations – an estimated 40,000 expansion adults and 100,000 parents and caretakers – into the private marketplace coverage.

The State suggests that this change will reduce churn without dramatically affecting the affordability of coverage for most of these adults, but this claim is unsupported by evidence. Lowering the eligibility threshold to 100% FPL simply creates a new “churn point” at that threshold, and the state has provided no evidence to suggest that income fluctuations are more common around 133% FPL than they are around 100% FPL. A more plausible motivation for this change is that the state wants to shift costs for the affected population to the federal government. Currently, the state pays regular match - Federal Medical Assistance percentage (FMAP) – for parents and caretakers in the 100-133% FPL group and has a small state match for expansion adults. Shifting these individuals to ConnectorCare would eliminate the need for this state match and instead leave the federal government and, to a lesser extent, beneficiaries, to make up the difference. The increases in federal costs would mostly stem from increased Advanced Premium Tax Credits (APTCs) and Cost Sharing Reductions (CSRs), with some increases to Medicaid in the form of increased extra cost sharing subsidies for ConnectorCare. Moreover, because commercial coverage is typically more expensive than Medicaid, the overall costs of coverage for this population would likely increase under this proposal, and the cost to the federal government would increase significantly.

The State has modified its original proposal to reduce cost sharing for all targeted populations by increasing the income threshold for ConnectorCare Plan 1 (nominal copayments for some services) from 100% FPL up to 133% FPL.⁴ We support the proposal to improve the affordability of ConnectorCare by increasing this threshold, but this amendment does not cure all the potential harm. Thousands of current MassHealth enrollees would likely face higher out-of-pocket costs. For example, individuals with “affordable” employer-sponsored insurance (ESI) offers may not qualify for ConnectorCare subsidies or APTCs, and be left without health coverage options. The threshold for “affordable” ESI coverage (9.69% of income for self-only coverage) is far above what a poverty-level family can actually pay.⁵ Today, those individuals may qualify for coverage under MassHealth. Other MassHealth enrollees shifted to Connector Care may not opt for the \$0 premium plan option if their current providers are only in network

⁴ MASS. EXEC. OFF. HEALTH & HUMAN SERVS., FY18 MASSHEALTH AND COMMERCIAL MARKET REFORM PACKAGE UPDATE, 1 (Sept. 8, 2017), <http://www.mass.gov/eohhs/docs/eohhs/healthcare-reform/masshealth-innovations/fy18-masshealth-and-commercial-market-reform-package-updates-09-08-2017.pdf>.

⁵ Healthcare.gov, Affordable Coverage, <https://www.healthcare.gov/glossary/affordable-coverage/>, (last visited Oct 19, 2017).

on other available plans. Staying with their current provider would then necessitate paying a substantial premium. Still others may have trouble navigating the enrollment process and end up uninsured.

The State has also modified its proposal to exclude people with disabilities and the Medically Frail from the MassHealth eligibility phasedown. However, it has not provided any detail on how it could successfully identify all the categories of individuals that federal regulations include as “medically frail” and flag them to stay in Medicaid.⁶

Moreover, granting a partial expansion waiver would set a very dangerous precedent for other states that would subsequently seek to shift their costs to the federal government. Wisconsin, for example, has already received approval for a partial expansion to 100% FPL, but HHS rejected the State’s request for enhanced match. Nothing has changed in the statutory structure since HHS established that precedent. HHS has previously made it 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.”⁷ Massachusetts’ proposal will likely reduce coverage for some and shift massive costs onto the federal government. Approving a partial expansion with enhanced match would likely open the floodgates as other states look to save money by shifting costs to the federal government.

Eliminating Emergency Coverage for Some Immigrants

Massachusetts proposes to eliminate coverage for emergency services for certain immigrants. This eligibility category allows hospitals to get Medicaid payment for non-qualified low-income immigrants without insurance, and protects immigrants from large medical bills in the event of an emergency. HHS has never waived this important Medicaid category. The State claims that non-qualified immigrants can enroll in ConnectorCare instead. While this may be true, many non-qualified immigrants likely do not know this coverage is available and would be negatively impacted if this coverage were no longer available.

The State acknowledges that actually enrolling non-qualified immigrants is challenging and proposes a dedicated outreach program. We support such efforts, but there is no need to waive emergency Medicaid to conduct this outreach, improve enrollment in ConnectorCare, and reduce the need for emergency Medicaid. It makes much more sense, and presents far less risk

⁶ 42 C.F.R. § 440.315(f).

⁷ 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).

to potentially eligible residents, to conduct this outreach and evaluate its impact on ConnectorCare enrollment prior to an unprecedented step like waiving emergency Medicaid.

The State provides no evidence that emergency Medicaid is causing any kind of moral hazard for these immigrant populations that might discourage them from enrolling in ConnectorCare. Rather, most probably do not even know emergency Medicaid exists. Instead, there may be reluctance to enroll due to distrust of the government in the current political environment. In any case, even a successful outreach campaign will not reach all potentially eligible immigrants. In short, this waiver proposal, if approved, is likely to cause increased medical debt for some immigrants and raise uncompensated care costs for hospitals. Without a clear experimental purpose describing the necessity for this waiver, HHS should not approve it.

Changes to Medicaid Cost Sharing

The State proposes a number of changes to its Medicaid cost sharing structure. In addition to all the normal requirements of § 1115 demonstrations outlined above, any waiver of cost sharing must also meet the experimental conditions laid out in § 1916(f). These include: additional assurances that minimize risk to beneficiaries, a shorter time limit, a methodologically sound research design that includes control groups, and a new and previously untested use of cost sharing. The State's proposal has not satisfied these requirements, and cannot be approved.

Annual Five Percent Medicaid Out-of-Pocket Maximum

Massachusetts is not the first state to propose loosening Medicaid's out-of-pocket spending maximum by applying it annually instead of quarterly or monthly. CMS has never approved such a waiver. First, no state has ever presented a valid experimental purpose and design, let alone a controlled study meeting the requirements at §1916(f). Second, the monthly/quarterly limit is an important shield to excessively high out-of-pocket costs. Medical bills tend to cluster into a single month or quarter. For families with children on public insurance, the average peak month accounts for 43% of annual out-of-pocket spending, while the average peak quarter accounts for 58% of annual spending.⁸

For example, suppose Jane makes \$1,005/month (100% FPL). In January she has an asthma attack and lands in the emergency room with a subsequent hospital stay. The total Medicaid bill comes to \$5,000. The state Medicaid agency has decided to impose cost sharing that requires enrollees with her income to pay 10% of the cost of the service. Jane's out-of-pocket cost would come to \$500. If the state calculates the 5% aggregate cap on a monthly basis, Jane hits the cap after \$50 (5% of her \$1,000 monthly income). If the state calculates quarterly, she pays only

⁸ Thomas M. Selden et al., *Cost sharing in Medicaid and CHIP: How Does It Affect Out-of-Pocket Spending?* 28 HEALTH AFF. w607, w614 (online ed. 2009), <http://content.healthaffairs.org/content/28/4/w607>.

\$150 of the charge (3 x \$50). But if the state applies the cap annually, Jane’s cost sharing cap will be \$600 (12 x \$50), and she will be responsible for the full \$500 charge. Cost sharing in Massachusetts is considerably lower than these levels, but some individuals could still hit the cap if they have high care needs and/or low income. The State has not established a valid experimental purpose for waiving this important protection.

Limiting premium assistance cost-sharing wrap to Mass Health enrolled providers

Another cost sharing related provision involves the State’s proposal to implement mandatory premium assistance for MassHealth enrollees with “cost-effective” ESI offers.⁹ Medicaid requires that states provide cost sharing and benefit wraps to maintain access to affordable coverage for enrollees required to enroll in this type of program.¹⁰ Often, these wraps are administratively challenging to implement, which is one reason several recent attempts to establish ESI premium assistance programs have been discontinued for lack of interest (e.g. Indiana and Arkansas).

However, Massachusetts proposes here make coverage mandatory while at the same time limiting its liability by only allowing cost sharing wraps if the enrollee uses a provider who contracts with MassHealth. The State’s proposal provides no information on how an enrollee will be able to know or find out if his in-network ESI provider also accepts Medicaid. Moreover, if the ESI network has a limited number of providers who also take MassHealth, this limited wrap policy could also create major network adequacy barriers that make it impossible for the enrollee to access affordable care.

Again, the State has failed to establish a clear experimental purpose for this waiver of cost-sharing wraps. It appears the State is simply attempting to save money and administrative hassle. Instead the state should factor in the potential cost of cost-sharing wraps to its calculation of whether a given ESI offer is actually cost-effective for the State Medicaid program before requiring enrollees to enroll in their employer’s plan. Without meeting the conditions of § 1115 and § 1916(f), HHS cannot approve this waiver.

Unprecedented Changes to Prescription Drug Coverage

Massachusetts has proposed sweeping and unprecedented changes to prescription drug coverage that could create serious barriers to necessary care for MassHealth enrollees.

⁹ 42 U.S.C. § 1396e(e)(2).

¹⁰ 42 U.S.C. § 1396e(a)(3).

Limiting outpatient prescription drug coverage

Massachusetts seeks to limit access to outpatient prescription drugs in its Medicaid program by imposing a “closed formulary” with at least one drug available per therapeutic class.¹¹ The proposal would restrict outpatient prescription drugs access across all Medicaid eligibility categories; establish a state system to evaluate the safety and efficacy of prescription drugs separate and apart from the U.S. Food and Drug Administration (FDA); and would limit pharmacy access for so-called “specialty drugs.”¹²

Congress established broad coverage for Medicaid outpatient prescription drugs that work in conjunction with the requirement for generous manufacturers’ rebates. HHS has no authority to waive selectively these complementary provisions in § 1927 of the Social Security Act through § 1115. Moreover, HHS should reject Massachusetts’ proposal because there is nothing experimental in denying access to medically necessary outpatient prescription drugs through “commercial-style closed formularies.”

Outpatient prescription drug protections may not be waived through § 1115

HHS has no authority to waive Medicaid outpatient prescription drug coverage provisions and protections. As noted above, § 1115 may only be used to waive requirements of 42 U.S.C. § 1396a. Medicaid outpatient prescription drug requirements are established under § 1927 of the Social Security Act, codified at 42 U.S.C. § 1396r-8.

Congress established broad coverage requirements to help ensure access to outpatient prescription drugs for low income Medicaid enrollees.¹³ States that elect to provide outpatient prescription drug coverage must cover all FDA-approved drugs that are offered by any manufacturer that agrees to provide rebates.¹⁴ In exchange for providing coverage for all FDA approved medications, the manufacturers enter into rebate agreements allow Medicaid programs to purchase prescription drugs at a significantly lowered cost.¹⁵

¹¹ Application, at 7-11.

¹² Id. The proposal offers no definition of “specialty drug,” nor is there a federal statutory or regulatory definition or there a common industry standard definition. The HHS Office of the Inspector General, Evaluations and Inspections Division acknowledges the lack of a “specialty drug” definition in its recently announced work plan reviewing reimbursement and savings strategies, *Specialty Drug Coverage and Reimbursement in Medicaid*, OEI-03-17-00430, expected in 2019, <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp>.

¹³ H.R. Rep. 101-881, 101st Cong. Snd Sess. 1990, 1990 U.S.C.A.A.N. 2017

¹⁴ 42 U.S.C. § 1396r-8(k)(2)(i).

¹⁵ 42 U.S.C. § 1396r-8(a)(1).

Massachusetts proposal to waive the broad coverage requirements, while retaining manufacturers' rebates, would upend the fundamental structure of these interdependent statutory provisions. HHS has no authority to waive these key provisions of 42 U.S.C. § 1396r-8.¹⁶ In addition, such a waiver would set a dangerous precedent and would lead to a race-to-the-bottom whereby other states would seek to limit Medicaid prescription drug coverage to the detriment of low income and vulnerable enrollees.

Nothing experimental about closed formularies

Massachusetts provides no hypothesis that would be tested under its proposal to limit prescription drug access for low income Medicaid enrollees. However, the consequences of limiting prescription drug access are well-known and predictable - fewer prescriptions will be filled, resulting in increased non-adherence in the treatment of potentially serious medical conditions.¹⁷ Gaps in treatment can have deadly consequences for some, including people living with HIV/AIDS where "even short interruptions of care can threaten health and undermine prevention effects."¹⁸ Such outcomes would not promote the objectives of the Medicaid Act to provide medical assistance to low income and vulnerable beneficiaries.

Furthermore, the proposal lacks sufficient detail for stakeholders to provide meaningful comment. For example, it states that the "closed formulary" would provide at least one drug per therapeutic class, but fails to specify what drug classification system it would use.

There are a number of private companies that have developed drug classification systems, such as American Hospital Formulary Service (AHFS) and the United States Pharmacopeia (USP). However, these systems have significant shortcomings. For example, the USP was created for the Medicare Part D program and was not designed to address the health needs of Medicaid enrollees, such as women of reproductive age and children.¹⁹ In addition, USP version 6.0

¹⁶ *PhRMA .v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001).

¹⁷ Ridley D.B., Axelsen K.J., Impact of Medicaid preferred drug lists on therapeutic adherence. 24 *PharmacoEconomics* 65 (2006) <http://www.ncbi.nlm.nih.gov/pubmed/17266389>. See also Happe LE, Clark D, Holliday E, Young T, *A systematic literature review assessing the direction impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resources utilization*, J MANAG CARE SPEC PHARM; 207):67-84 (2014); Mullins CD, Shaya FT, Meng F, et al., *Persistence, switching, and discontinuation rates among patients receiving sertraline, paroxetine, and citaliopram*, Pharmacotherapy 25-660-7 (2005).

¹⁸ Dana P. Goldman, et al., *The Prospect Of A Generation Free Of HIV May Be Within Reach If The Right Policy Decisions Are Made*, 33 *Health Affairs*, 430 (2014).

¹⁹ United States Pharmacopeial Convention, USP Medicare Model Guidelines v6.0: Development of the USP Medicare Model Guidelines v6.0 (2015), <http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines/medicare-model-guidelines-v60>.

excludes methadone for treatment of opioid dependency due to federal regulations that require dispensing through accredited facilities. Methadone is one of the most common and effective medications used in the treatment of opioid use disorder and should not be excluded from Medicaid coverage.

Massachusetts also promises an exceptions process to cover medically necessary drugs not on the formulary. However, the State fails to provide sufficient detail for stakeholders to provide meaningful comment. The proposal vaguely promises that the exceptions process “will be similar to the existing clinic review process used for situations such as determining coverage of non-preferred products or off-label indications.”²⁰ This description omits key information on its exceptions process, including the standard it will use to evaluate whether a non-formulary drug is medically necessary, how enrollees will be notified of the process, whether it will provide an expedited process. Moreover, Massachusetts fails to specify how the exceptions process will comport with Medicaid due process guaranteed under the 14th Amendment to the Constitution, which may not be waived under § 1115, and current law that requires states to provide a response within 24 hours of the prior authorization request for an outpatient prescription drug, and a 72 hour supply in emergency situations.²¹

Finally, Massachusetts fails to describe how its proposed “closed formulary” and exceptions process would improve the Medicaid formularies and preferred drug lists (PDLs) already authorized by federal law.²²

A state’s Medicaid formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor or the state’s drug use review board.²³ If a state decides to exclude an outpatient prescription drug from its formulary, it may only do so after finding the drug does not have a significant, clinical therapeutic advantage over other drugs, and the state must explain the basis for the exclusion in writing.²⁴ Even if a state excludes an outpatient prescription drug from its formulary, the state must permit coverage of excluded pursuant to a prior authorization program and on a case-by-case basis.”²⁵

²⁰ Application, at 9.

²¹ 42 U.S.C. § 1396r-8(d)(5). Note, the 72 hour emergency supply does not apply to drugs listed in 42 U.S.C. § 1396r-8(d)(2).

²² 42 U.S.C. §§ 1396r-8, 1396o, 1396o-1, 1396u-7.

²³ 42 U.S.C. § 1396r-8(d)(4)(A). These are often called Pharmacy and Therapeutics (P&T) committees. *See also* National Academy for State Health Policy (NASHP), *State Experience in Creating Effective P&T Committees* (March 2006) available at http://www.nashp.org/sites/default/files/medicaid_pandt.pdf

²⁴ 42 U.S.C. § 1396r-8(d)(4)(C).

²⁵ 42 U.S.C. § 1396r-8(d)(4)(C); *see also Pharmaceutical Research and Mfrs. of America v. Meadows*, 304 F.3d 1197, 1207.1208 (11th Cir. 2006).

States can control prescription drug costs through supplemental rebates pursuant to PDLs and other medical utilization controls. Federal law allows states to designate “preferred” and “non-preferred” drugs and charge Medicaid enrollees copayments, similar to a formulary tiering structure, subject to limitations.²⁶

It is not clear from Massachusetts’ how its “closed formulary” proposal would yield larger supplemental rebates than a PDL. With no hypothesis, no experiment, no control group, and no evaluation plan, Massachusetts’ proposal is a non-starter and should be rejected by HHS.

Massachusetts may not supplant the FDA drug approval process

HHS has no authority under § 1115 to allow Massachusetts to replace the FDA drug approval process with its own system for determining whether outpatient prescription drugs are safe and effective.²⁷

Massachusetts states that “[n]ew drugs approved under the FDA’s accelerated approval pathway can be particularly costly” and proposes its own “rigorous review process” with the University of Massachusetts Medical School to decide if new medications are “efficacious.”²⁸

By definition, a “covered outpatient drug” is a drug which may be dispensed only upon prescription and which is approved for safety and effectiveness as a prescription drug under the federal Food, Drug, and Cosmetic Act.²⁹ Massachusetts’ proposal suggests that FDA is approving drugs that have not demonstrated clinical benefit — which, if true, would directly violate the agency’s own requirement that drug companies conduct studies to confirm clinical benefit prior to approval. Massachusetts’ proposal fails to cite any evidence to support these claims, and should be rejected.

HHS should reject restricted pharmacy access and mail order only

Massachusetts seeks to limit pharmacy access for enrollees receiving care through the fee-for-service and the Primary Care Clinician (PCC) plan by designating “specialty” pharmacies or

²⁶ 42 U.S.C. §§ 1396o, 1396o-1. See also David Machledt and Jane Perkins, NHeLP, *Medicaid Premiums and Cost Sharing* (March 26, 2015), available at <http://www.healthlaw.org/publications/search-publications/Medicaid-Premiums-Cost-Sharing>.

²⁷ See also *Edmonds v. Levine*, 417 F.Supp.2d 1323, 1336 (S.D. Fla. 2006), finding that Florida’s Medicaid program could not establish its own criteria for approved off-label uses.

²⁸ Application, at 9-10.

²⁹ 21 U.S.C. § 355(c); 42 U.S.C § 1396r-8(k)(2)(A). The 21st Century Cures Act, Pub. L. No. 114-255 (2016), amends the Food, Drug, and Cosmetic Act to create fast track approval.

providing mail order or home delivery for certain outpatient prescription drugs.³⁰

Massachusetts posits no hypothesis or evaluation criteria. HHS has no authority to approve this request because there is nothing experimental about limiting pharmacy access for low income enrollees.

Massachusetts provides insufficient information on what it considers “specialty drugs” and how enrollees will be expected to access “specialty pharmacies.”³¹ The proposal to limit enrollees to mail order only pharmacies is especially troubling. Enrollees may need medications immediately, such as pain medications or antibiotics, and cannot wait for medications to arrive in the mail. They may run out of a medication before it can be refilled, or medications may be lost or stolen in the mail. Individuals without a permanent mailing address may be cut off from access if limited to receiving prescription drugs via mail-order. Enrollees may want to keep their medical conditions confidential and not have prescription drugs regularly delivered to their home or work where neighbors, co-residents, or co-workers can come to know of their condition.

The proposal to limit pharmacy access for “specialty” drugs should be denied.

Shifting Parents and Caretakers to a Mandatory Alternative Benefit Plan

As part of its effort to align coverage with commercial plans, Massachusetts proposes to shift adults eligible through the traditional parents and caretakers group (up to 100% FPL) into the Careplus Alternative Benefit Package (ABP). The Careplus ABP differs from the State’s standard MassHealth state plan benefit package in that it does not include certain LTSS services. The state also seeks to eliminate ABP coverage of non-emergency medical transportation (NEMT) for most purposes under a separate waiver request.³²

It is not clear how aligning coverage is likely to promote the objectives of Medicaid, as the alignment effectively amounts to a benefit cut. Medicaid coverage is not designed to align with commercial plans precisely *because* the needs of low-income beneficiaries differ from individuals typically covered by commercial insurance. Moreover, this shift would misalign the ABP with state plan benefits, and that would require the State to screen some eligible individuals (people with LTSS needs and the medically frail) out of the new ABP. This screen would increase administrative burden on the Medicaid agency and on beneficiaries without a clear hypothesis on how it will improve care.

³⁰ Application, at 10.

³¹ See Note 9 *supra*.

³² We have previously opposed this NEMT waiver proposal in a letter submitted Aug. 24, 2017 and incorporated here.

HHS thus cannot approve this waiver to require adult parents and caretakers to enroll in an ABP coverage package. Approving this request would set a dangerous precedent for other states that have or might establish more limited coverage through an ABP. If Congress intended to allow such limited coverage for § 1931 parents, it would not have explicitly excluded them from mandatory enrollment in an ABP.

Blanket Waiver of Payment Prohibition on Institutes for Mental Disease (IMDs)

A number of states have proposed and received approval for a limited waiver of Medicaid's prohibition on payments to IMDs for adults from 21-64. Massachusetts' proposal describes some similar policy goals, but instead requests a blanket waiver of "all restrictions on payments" to IMDS including caps established under the State's existing Safety Net Care Pool expenditure authority and limits established in the 2016 Medicaid managed care regulations. This waiver request is not tied to specific, detailed policies the state wishes to implement, and cannot be approved in this form.

Section 1115 only authorizes the Secretary to waive provisions of section 1902 "to the extent and for the period he finds necessary to enable such State or States to carry out such project."³³ In this case, the State has not identified a specific project, only a vague goal to increase treatment availability for Substance Use Disorders (SUDs). The State's proposal does not include sufficient detail for meaningful public comment on the potential benefit or risk of what the State intends to do and why it requires such a broad waiver. While expanded access to SUD treatment is a worthy goal, we also know from past experience that treatment in IMDs can carry substantial risk in the form of long-term institutionalization.

Expanding access to IMDs may also thwart progress on improving access to community-based SUD treatment. Medicaid's IMD exclusion has provided an incentive for states and managed care plans limit use of IMDs. The trend has been to develop smaller, more community-based facilities that do not qualify as IMDs. They are often more patient-centered, and because they are likely to be spread throughout the state, and usually allow an individual to keep closer ties with their family and community supports, which, of course, are requirements of the Americans with Disabilities Act. The State's proposal contains no indication of a strategy to build access to such community-based services and shift the state away from a reliance on IMDs to provide this treatment. Moreover, while the proposal refers to increasing treatment options for people with SUD, there is nothing in the proposal that would prevent this waiver from being applied to other populations, such as individuals with serious mental illness, for IMD payments unrelated to SUD.

In summary, the State's proposal is insufficiently detailed for meaningful public comment, does not establish a clear experimental goal, and requests a broad and ill-defined waiver of an

³³ 42 U.S.C. § 1315(a)(1).

important Medicaid provision. Section 1115 circumscribes waivers to specific and limited applications. As written, the Secretary cannot approve the State's request.

Narrowing Consumer Choice

Narrow Networks for Primary Care Clinician (PCC) Plan

We understand that the state is developing an experiment to provide coverage for MassHealth enrollees through an ACO model of care. In this waiver, the State requests waivers that appear solely intended to drive enrollees toward this experimental ACO model and away from established forms of care. We are concerned about the potential impact these restrictions may have on provider choice for individuals who may wish to opt out of the ACO model. Generally, we would expect the state to provide a more attractive choice through the ACO model rather than intentionally weakening its existing product to push people into the new program. This proposal suggests a race to the bottom in terms of quality of care.

Waiver on requirement to provide choice of MCOs

The State is similarly requesting a waiver from the requirement to provide multiple managed care options for individuals in areas where the ACO model is active. Again, it is unclear how necessary this is for the successful implementation of the ACO approach. Limiting consumer choice does not appear to promote the objectives of the Medicaid program.

Conclusion

Massachusetts' MassHealth 1115 demonstration amendment contains a number of sweeping and unprecedented waiver proposals that appear intended to shift costs to the federal government and reduce benefits and access to care for critical services without a clear experimental purpose. A number of these proposals lack key details that make it impossible for the public to evaluate the state's proposed changes. Others fall outside the legal scope of 1115 authority. We recommend that HHS not approve those amendment requests unless and until the State clarifies those details, establishes a valid experimental purpose and design, and takes steps to show it has mitigated risks to beneficiaries and proposed a demonstration that is likely to promote the objectives of Medicaid.

Thank you for considering these comments. If you have questions, please contact David Machledt, Sr. Policy Analyst (machledt@healthlaw.org) or Jane Perkins, Legal Director (perkins@healthlaw.org).

Sincerely,



Jane Perkins
Legal Director