National Alliance on Mental Illness

October 20, 2017

Seema Verma
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the National Alliance on Mental Illness (NAMI), I am pleased to submit the following comments on the State of Massachusetts' request to amend the Massachusetts Section 1115 Demonstration Project. As the nation's largest organization representing people living with mental illness and their families, NAMI urges you to seek substantial changes to this proposal or reject it entirely.

Massachusetts argues that the amendment is needed to build on the state's demonstration project approved in November 2016. However, the amendment fails to explain why these changes are needed to implement the state's current demonstration project. Instead, the state justifies this amendment with claims that it will ensure "the long-term financial sustainability of the MassHealth program and reduce the shift in enrollment from commercial health insurance to MassHealth through the alignment of coverage for non-disabled adults with commercial plans, adoption of widely-used commercial tools for prescription drugs, and changes to cost sharing requirements for higher income members." Under federal Medicaid law, this is not an appropriate justification for an 1115 waiver. Massachusetts has a statutory obligation to provide mandatory benefits to all individuals who are eligible.

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

Unprecedented Closed Drug Formulary Would Severely Restrict Access to Needed Medications
Massachusetts' amendment proposes an unprecedented change to Medicaid coverage of prescription drugs by waiving the requirement that the state comply with Section 1927 of the Social Security Act, which requires Medicaid to cover Food and Drug Administration (FDA) approved drugs (subject to certain conditions and exclusions) if the manufacturer of such drugs has signed an agreement to pay rebates under section 1927. Under current law, states can impose preferred drug lists (PDLs) that require prior authorization before a prescription drug may be covered under Medicaid. But, except for certain classes drugs that states may exclude under section 1927, states are barred from imposing a fully

'closed' formulary under which drugs cannot be covered under any circumstance. Massachusetts' waiver proposes to exclude FDA-approved drugs entirely if it determines the drugs are not supported by adequate evidence of clinical efficacy. The state would then only need to offer just one drug per therapeutic class.

Under current law, Section 1927 is not waivable as part of an 1115 waiver demonstration project. Moreover, as described above, Section 1115 gives the Secretary authority to waive sections of the statute for demonstration projects that are "likely to assist in promoting the objectives of [Medicaid]." The goal of the proposed policy is to reduce MassHealth's expenditures by leveraging the threat of a closed formulary to obtain additional rebates from manufacturers. This objective simply does not meet the criteria of an 1115 waiver. Furthermore, the proposal does not appear to be testing a specific hypothesis, which is the stated purpose of an 1115 demonstration project.

The proposed closed formulary would dramatically restrict Medicaid beneficiaries' access to needed prescription drugs. While the proposal states that "members would continue to have access to the latest drugs that provide additional clinical benefits," it fails to define or describe any process for demonstrating "clinical benefit," or any specific consumer protections that would ensure access to needed treatments. Under the proposal, the state's formulary could include as few as one prescription drug per therapeutic class – without ever defining the term "therapeutic class." Under Title XIX, there is no statutory standard and such classes could be defined very broadly.

Massachusetts claims that some FDA-approved drugs may have "limited evidence of clinical quality." However, the FDA is the sole agency under federal law responsible for ensuring that all prescription drugs marketed in the United States are safe and effective. The state is claiming that the FDA approves drugs that have not clearly demonstrated clinical benefit. If this were the case, it would put the agency in direct violation of its own statutory mandate to ensure manufacturers conduct studies that confirm clinical benefit prior to approval. Further, the proposal fails to cite any evidence to support these claims. It also ignores the fact that the state can already limit utilization of certain drugs based on clinical criteria through a preferred drug list, prior authorization requirements or review by a Pharmacy and Therapeutics (P&T) Committee.

Allowing a state to employ a PDL that is limited to one drug per therapeutic class would be an unprecedented step as part of an 1115 waiver. It overlooks the fact that states already have significant tools to limit prescription drug costs in their Medicaid programs. These tools—including generic substitution, step therapy, prior authorization and "fail first" requirements—are routinely used by state Medicaid agencies as cost containment measures. It is likely that Massachusetts already employs these tools, as Medicaid retail drug spending is only 4% of total spending.

Massachusetts cites the need to impose a "rigorous clinical review process" as justification for a closed formulary. However, the proposal does not describe this process, its clinical criteria or beneficiary appeals rights. It does imply that cost will be a key factor in these decisions—and not only clinical considerations—stating, "The state could avoid exorbitant spending on high-cost drugs that are not medically necessary."

Eliminating the requirement that Medicaid cover all drugs subject to a rebate agreement under section 1927 (subject to certain exclusions and limitations, as mentioned above) threatens to undermine the entire structure of the Medicaid drug rebate program. The rebates allow the federal government and the states to achieve savings of about 50 percent, according to analysis from the HHS Office of Inspector General (OIG). But the key reason that Medicaid is able to achieve rebates of this magnitude is because manufacturers, in exchange for these considerable rebates, can generally have their drugs covered under Medicaid. Beyond these rebates, states can still impose restrictions or conditions on such coverage.

If CMS were to allow states to waive Section 1927, it will likely create enormous pressure to undo the entire Medicaid drug rebate program legislatively. Ultimately, that could result in states receiving less in rebates than they do today and incurring higher prescription drug costs. In turn, that would likely lead to states severely limiting access to needed medications for beneficiaries, particularly those with chronic conditions such as serious mental illness.

Finally, NAMI would note that decades of research have established that severely restricting access to prescription medicines leads to poor adherence and negative health outcomes, ultimately causing increased Medicaid costs—precisely the opposite of what the state is seeking to do. Without access to multiple drugs within a therapeutic class (including innovative formulations), beneficiaries cannot effectively treat or manage their conditions. Medications used to treat mental health conditions are not interchangeable, even in the same therapeutic class, as the effect of psychiatric medications is highly individualized. A May 2017 New England Journal of 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. Allowing Massachusetts' proposal for a highly restrictive formulary as part of an 1115 waiver would be an unprecedented step for CMS and ultimately result in higher expenditures and poor health outcomes for the Medicaid population.

Waiver of the IMD Exclusion Should Ensure Expanded Access to Acute Inpatient Psychiatric Care
Massachusetts' proposal requests a full waiver of Section 1905(a)(29)(B), the statutory prohibition against medical assistance payments to Institutions of Mental Disease (IMD). NAMI has long supported repeal of the IMD exclusion, a longstanding vestige of discrimination against people living with serious mental illness. Efforts to scale back the IMD exclusion have gained momentum in Congress. In addition, a number of states, including this proposal from Massachusetts, have sought to use 1115 waivers to roll back restrictions in the IMD Exclusion to expand access to mental health and substance abuse treatment.

NAMI recommends that CMS grant Massachusetts the IMD exclusion waiver and press the state to provide additional assurances that resources will be directed toward addressing the current shortage of acute inpatient beds across the state.

Ending Medicaid Eligibility for Adults with Incomes Above the Poverty Line Would Lead to Loss of Coverage for Medicaid Beneficiaries
This waiver proposal would lower Medicaid eligibility for non-disabled adults ages 21 to 64 with incomes above 100 percent of the federal poverty line. This change would apply to both adults newly eligible for

Medicaid under the Affordable Care Act (ACA), as well as parents and caretaker relatives with longstanding Medicaid eligibility under Massachusetts' waiver. The proposal projects that approximately 140,000 adults would be affected by this change, which would take effect in January 2019.

Massachusetts wants to continue receiving the enhanced Medicaid expansion federal match for eligible adults with income below the poverty line — a policy that CMS has said is not permissible and has never been approved. In 2012, CMS issued guidance stating that, while it would consider partial expansion proposals, the enhanced Medicaid expansion match rate would not be available for a partial expansion. In effect, this would mean that a state's regular Medicaid match rate would apply, as is the case in Wisconsin's partial expansion waiver.

Regardless of the federal match rate that would be available, CMS should reject this request. It would not promote the objectives of the Medicaid program because it would likely result in loss of coverage. The experience of other states that have lowered Medicaid eligibility, including Wisconsin, Connecticut and Rhode Island, shows that even when efforts are made to assure a smooth transition to marketplace coverage, people get lost in the transition.

Here, the state is asserting that its proposed rollback in Medicaid eligibility would "improve continuity and reduce churn as long their income remains above 100 percent of the federal poverty line." However, the state could better address churn by requesting expenditure authority to provide 12 months of continuous Medicaid eligibility for adults or by testing innovative delivery system reform efforts to improve continuity of care, such as encouraging Medicaid managed care plans to participate in the state's marketplace or vice versa (i.e., encouraging QHPs to participate in MassHealth). These alternative approaches align with existing criteria for Medicaid waivers by increasing and strengthening overall coverage, improving health outcomes and increasing the efficiency and quality of care for Medicaid beneficiaries and other low-income populations rather than causing people to lose coverage, as the state's proposal would likely do.

The state also notes that its proposal would support efforts to maintain universal coverage in the state through improved enrollment procedures. Lowering Medicaid eligibility for non-disabled adults with incomes above 100 percent of the poverty line is *not* an improved enrollment procedure—it simply cuts Medicaid coverage and leads to higher numbers of uninsured. Further, the express goal of ensuring the "long-term financial sustainability" of MassHealth through this proposal does not further the objectives of the Medicaid program, as cost savings have been found to *not* be a permissible purpose for a section 1115 demonstration.

Eliminating the Non-Emergency Medical Transportation Benefit Would Restrict Access to Care

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

If approved, Massachusetts would become the third state to waive the NEMT benefit for the expansion population (Indiana and Iowa are the other states). CMS granted short-term waivers to Indiana and Iowa so the impact on beneficiaries could be evaluated. NAMI is concerned that the evidence thus far suggests that the lack of transportation is an obstacle to getting needed care, and it is an even bigger obstacle for people with low income. Although this may be viewed as a cost-saving measure, it could shift costs to more intensive and expensive forms of care as individuals with mental illness experience disruptions in care. NAMI recommends that CMS reject Massachusetts' waiver of NEMT until more is known about the impact on low-income beneficiaries in states where NEMT has been waived.

Thank you for your consideration of these comments.

Sincerely,

Angela Kimball
National Director, Advocacy & Public Policy