October 6, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: MassHealth Section 1115 Demonstration Amendment Request

Dear Administrator Verma:

I am writing today on behalf of the National Council for Behavioral Health (National Council) to express our strong opposition to the Commonwealth of Massachusetts proposal to adopt a closed formulary with only one drug available per therapeutic class. We believe that instituting a closed formulary is inconsistent with both the intent of the Medicaid program and the purpose of Section 1115 waivers (i.e., "experimental, pilot or demonstration projects" that promote the objectives of the program) and strongly urge that the Centers for Medicare & Medicaid Services (CMS) not approve this request from the Commonwealth of Massachusetts. If, however, CMS were to approve this waiver, we would advise that "protected classes," similar to those that exist for Medicare Part D, be established for medications related to the treatment of mental illness.

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 Commonwealth 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 epilepsy, mental illness, cancer, HIV-AIDS, and organ transplants. For these protected classes, Part D plans must make available all, or substantially all drugs. We believe that the Commonwealth should take a similar approach in its design of the formulary under its 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 financial 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]

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 that 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 hope you recognize the negative impact this waiver will have on those with serious mental illness and we urge you to deny it this request.

Sincerely,

Linda Rosenberg, MSW
President and CEO

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[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*.
[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.