



October 20, 2017

The Honorable Eric Hargan, Acting Secretary  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Re: MassHealth Section 1115 Demonstration Amendment Request

Dear Secretary Hargan:

On behalf of the Epilepsy Foundation and our affiliate in Massachusetts, Epilepsy Foundation New England, we are writing in opposition to the pending MassHealth Section 1115 Demonstration Amendment request. We previously expressed our significant concerns with the proposal when it was pending at the state level. We commended the Massachusetts Executive Office of Health and Human Service 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 several proposals in the amendment that will significantly limit access to care for Medicaid beneficiaries, especially those with chronic conditions and rare diseases. While many of the proposed changes focus on lowering costs associated with prescription medications, these costs currently account for only a small portion of the overall Medicaid expenditures. Medications are the most cost-effective way to allow individuals to manage chronic conditions. Limiting access to certain medications is dangerous to patients, especially individuals living with epilepsy, and it leads to higher overall health care costs.

Further, despite numerous available anticonvulsant therapies already on the market, more than one third of people living with epilepsy suffer from drug resistant or intractable seizures. Many more live with significant side-effects, despite available treatments. Timely access to newly-approved, innovative medications is critical for this significant portion of the epilepsy community.

### Closed Drug Formulary

The Epilepsy Foundation is opposed to the creation of a closed drug formulary – requiring only a single drug per therapeutic class in the Massachusetts Medicaid program. Epilepsy medications are the most common and most cost-effective treatment for controlling and/or reducing seizures; however, they are not interchangeable. The treatment of epilepsy is highly individualized. 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.

Limits to physician-directed care can 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. Epilepsy medications are lifesaving, and they help avoid unnecessary hospitalizations and ensure individuals can live well with epilepsy. 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. The Epilepsy Foundation opposes policies intended to restrict timely access to physician-directed care. Health care providers, based on their expert knowledge, experience, and interaction with patients, are in the best position to make care decisions.

While proposals to limit access to medications through formularies 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 many states and 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. These same considerations should be accounted for in the waiver amendment proposal.

Additionally, while the MassHealth proposal did include mention of an exceptions process to allow access to additional medications, we are overwhelmingly concerned because the proposals did not include detail about this process and exceptions processes are generally burdensome and act as barriers for patients. Ultimately, a closed formulary, even with an exceptions process, will mean that some Medicaid beneficiaries will not be able to access a medication that his/her physician prescribes.

### Secondary Review Process for FDA-Approved Medications

The Epilepsy Foundation is opposed to the proposal to create a secondary review process for certain medications even after FDA approval. This proposal would subject therapies approved by

the FDA via expedited pathways to this additional review process with the intention of allowing the state to cut costs by limiting access to important and groundbreaking new therapies aimed at addressing significant unmet need – the very reason for expedited review in the first place.

Further, this proposal would contradict provisions in the recently-enacted 21st Century Cures Act and calls into question the rigor of FDA’s reviews and the advances that have been made in bringing the patient voice to the drug review process at the agency. It would undermine the important work of the FDA and would set a dangerous precedent allowing each state to establish a process to challenge the missions of the FDA. Additionally, the proposal provides no details for how the University of Massachusetts would undertake this secondary review; how the patient voice would be incorporated into the review process; and any indication of how the process would be transparent, timely, and guided by medical considerations and not financial motives to avoid coverage for innovative and lifesaving medications and cures.

There is still a significant unmet need in the epilepsy community – more than a third of people with epilepsy do not have seizure control, and we are hopeful for approval of new and innovative treatment options, which is why we are strongly opposed to the proposal to create a secondary review process for certain medications even after FDA approval.

#### Changes to Coverage for Non-Disabled Adult Beneficiaries

The amendment proposes to shift non-disabled adults with incomes more than 100 percent of the FPL to Health Connector commercial plans and also to consolidate coverage of non-disabled adults with incomes below 100 percent of the FPL. It is important that the level of care for these beneficiaries is not diminished and that out-of-pocket cost sharing is not a barrier to care. Further, with these changes, it is important to ensure that these beneficiaries will continue to have access to current providers and the medications that they are stable on. This stability is critical for people living with epilepsy who often struggle for years to obtain seizure control.

#### Limits to Some Long-Term Care Services and Non-Emergency Medical Transportation

The Epilepsy Foundation is opposed to proposals in the waiver amendment to limit coverage for some 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.

Non-emergency medical transportation is a critical service in Medicaid programs because of the exceptional needs of Medicaid beneficiaries. These individuals, with low incomes, often cannot access health care at all because of limited transportation options. Non-emergency medical transportation is much more cost effective compared to the alternative of no health care, which will eventually lead to more hospitalizations and compounded medical issues.

The Epilepsy Foundation and Epilepsy Foundation New England urge you to reject Massachusetts’ 1115 waiver amendment and ensure that individuals have meaningful access to

physician-directed care. We have significant concerns not only with the limits to care that could result in Massachusetts, but also with the precedent that some of these proposals could set for the Medicaid program in states across the country. The Medicaid program is unique and serves a particularly vulnerable subset of Americans, including more than a third of those living with epilepsy. We understand the need to limit costs in Medicaid, but limiting access to medications that allow individuals to live meaningfully will ultimately have the reverse effect with uncontrolled seizures and related medical complications.

We appreciate the opportunity to comment on the pending MassHealth 1115 waiver amendment. Thank you again for considering our concerns before moving forward. If you have any questions, please contact Angela Ostrom, Epilepsy Foundation Chief Legal Officer & Vice President Public Policy at [aostrom@efa.org](mailto:aostrom@efa.org) or 301-918-3766.

Sincerely,



Susan Linn  
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