

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 community, we, the undersigned organizations collectively representing 3.4 million Americans living with epilepsy and seizure disorders, write in opposition to proposals in the Massachusetts 1115 Demonstration (“Waiver”) Amendment that would limit access to new and innovative therapies by creating a closed formulary and requiring that medications approved by the Food and Drug Administration (FDA) via expedited pathways undergo a secondary review process to determine if coverage would be available in the Massachusetts Medicaid program.

Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. More than one third of people living with epilepsy rely on Medicaid for their health coverage, including many children and individuals with the most severe forms of epilepsy who cannot reach seizure control with current FDA-approved therapies.

Epilepsy medications are not interchangeable and access to new and innovative therapies is particularly important for the more than one million people living with intractable or uncontrolled seizures and severe forms of epilepsy. There currently are no FDA-approved therapies for many rare epilepsies, which is precisely why new therapies targeting the rare epilepsies enjoy expedited review at FDA. News of a newly approved epilepsy therapies brings hope for our community, and we need timely and meaningful access to these promising treatments approved by FDA without unnecessary delays.

We commend 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, but we have significant concerns about the proposals to limit access to lifesaving medications.

We are opposed to the creation of a closed drug formulary that requires coverage of 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. The treatment of epilepsy is highly individualized, and epilepsy medications are not interchangeable. Epilepsy medications are lifesaving, they help avoid unnecessary hospitalizations, and they 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

of developing breakthrough seizures and related complications including death. We oppose policies intended to restrict timely access to physician-directed care. Health care providers, based on their expert knowledge, experience, and interactions with patients, are in the best position to make care decisions.

Further, we are extremely disappointed that Massachusetts wants to subject innovative new therapies approved by the FDA via expedited pathways to an additional review process intended to allow 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. 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 how the process would be transparent, timely, and guided by medical considerations rather than financial motives to avoid coverage for innovative and lifesaving medications and cures.

The Medicaid program serves the most vulnerable Americans, including more than a third of people living with epilepsy and many children living with rare epilepsies. As Massachusetts looks to limit costs in the Medicaid program, we caution against shortsighted cost cutting proposals that limit access to medications and result in higher medical costs associated with uncontrolled seizures and related medical complications.

We appreciate the opportunity to comment on the pending MassHealth 1115 Demonstration 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 or 301-918-3766.

Sincerely,

Bridge the Gap SYNGAP Education and Research Foundation
Danny Did Foundation
Dravet Syndrome Foundation
Dup15q Alliance
Epilepsy Foundation Epilepsy Foundation New England
Hope for Hypothalamic Hamartomas
Lennox-Gastaut Syndrome Foundation
Phelan-McDermid Syndrome Foundation
RASopathies Network
Ring 14 USA Outreach
Tuberous Sclerosis Alliance