January 31, 2014

Joseph Murphy
Commissioner
Massachusetts Division of Insurance
1000 Washington Street, Suite 810
Boston, MA 02108

Dear Mr. Murphy:

The Epilepsy Foundation is writing to ask the Massachusetts Division of Insurance to ensure access to lifesaving treatments and services for Massachusetts residents who will enroll in qualified health plans (QHPs) offered in the state’s health insurance marketplaces in 2014 and beyond by conducting a thorough review of QHPs’ benefit design and formularies.

The federal government’s methodology for determining the adequacy of formularies under the Essential Health Benefits (EHB) rule for QHPs in health insurance marketplaces will lead to inadequate access to medications due to limited formularies, prohibitive cost sharing, and restrictive utilization management rules that are likely to result in insured patients who cannot access or afford their medically necessary prescription medications.

We urge Massachusetts to pursue an intensive review of benefit design elements to ensure that people enrolled in QHPs and other health plans that must comply with the EHB rule have appropriate, affordable access to those medications. QHPs should provide robust formularies that ensure access to medically necessary, physician directed care that protects people living with serious and chronic conditions from cost-sharing and utilization management policies that may restrict access and discriminate based on their health conditions.

The Epilepsy Foundation, through its Massachusetts affiliate, Epilepsy Foundation New England, represents residents of Massachusetts living with epilepsy and seizures. 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. For people living with epilepsy, access to appropriate care and effective coverage for anti-epilepsy drugs (AEDs) is a critical concern. The Massachusetts Division of Insurance has the power to ensure access to lifesaving treatments and services for millions of people living with chronic conditions by conducting a more intensive reviews of benefit design elements to ensure that people living with chronic conditions and enrolled in QHPs and other health plans that must comply with the federal EHB rule have appropriate, affordable access to the medications they need to improve and maintain their quality of life.

The Centers for Medicare & Medicaid Services (CMS) requires health plans to cover at least the number of medicines in each United States Pharmacopeia (USP) category and class as the state’s essential health benefits (EHB) benchmark. This approach, focused on the number of drugs covered rather than the effectiveness of those drugs, can and will negatively impact care for people living with chronic conditions. The CMS counting methodology was designed to be an initial test for adequate coverage of prescription drugs. It was not intended to be the only mechanism to ensure appropriate access or nondiscrimination. Reliance on this approach will
allow some plans to limit patient access to medications and yet still be deemed adequate by simply meeting the counting requirements.

The Epilepsy Foundation believes that limited drug formularies are in effect discriminatory benefit designs in violation of Section 1557 of the Affordable Care Act (ACA), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. Millions of Americans living with one or more serious chronic conditions work closely with their physicians to identify the medications that will provide the most effective treatment for their conditions. QHPs designed to limit and restrict access to physician-directed care, through inadequate formularies, burdensome utilization management policies and high cost-sharing for expensive medications, will compromise the ability of patients to access essential medications and result in delays in treatment, increases in medication non-adherence and avoidable hospitalizations, medical complications, and even death.

Epilepsy is unique in light of the grave consequences of therapy failure and non-adherence. Lack of access to the correct physician directed therapy, through inadequate coverage, or having to “fail first” on one drug before getting the medication a patient and physician have determined is the correct one for their particular seizure type, or going off a medication because of the high cost of filling the prescription could cause a breakthrough seizure, or could cause toxic side effects if levels in the blood are too high. Seizures have the potential to be life-threatening and studies show that continuing seizures over time may cause brain damage and increase the risk of sudden death. Seizures are also costly, leading to significant medical expenses, including ambulance, emergency room, and doctor visits that far outweigh the monthly expense of physician directed treatment.

Epilepsy is not a “one-size fits all” disorder and physicians and patients need to be assured that the full array of treatment options is available. When determining the right medication for a particular person, the physician takes into account a number of variables, including type of seizure, seizure frequency, age, gender, and other relevant factors. The process may require trial-and-error and combination therapies along with close observation of blood level toxicity and side effects.

The CMS counting methodology will not protect patient access to innovative medicines and is not a useful indicator of formulary adequacy because the methodology:

- Does not distinguish between brand and generic formulations, or account for combination therapies or time-release products,
- Lacks specific guidelines on how and when to incorporate new drugs that enter the market into the plan’s formulary,
- Does not define the appeals process clearly, so that patients may gain access to clinically appropriate drugs that are off-formulary,
- Misses entire groups of medications because it is based on the USP Medicare Model Guidelines, which is a classification system designed for a different population (Medicare Part D beneficiaries), and
- Overlooks factors such as tiering, cost sharing, and utilization management (prior authorization, step therapy, medication switching and quantity limits), even though they have an enormous influence on whether patients can actually get needed medications.

The Epilepsy Foundation recommends the following action steps to begin to address the need for robust formularies and nondiscriminatory benefit design:

- Set additional QHP coverage requirements for drug types that are not adequately protected by the CMS counting methodology, such as combination products for epilepsy,
- Develop a mechanism to adjust plan drug counts to encourage the inclusion of combination and extended release products, and products that do not have a USP class,
- Require health plans to review new drugs and make coverage decisions within a set timeframe.
Define the appeals process clearly, so that patients may gain access to clinically appropriate drugs that are off-formulary, as the EHB rules require,

- Review combination of coverage, cost sharing, and utilization management when reviewing plan formularies,
- Require coverage of at least one preferred brand per class on a preferred tier, and
- Establish maximum cost-sharing levels for higher formulary tiers.

Lack of federal guidance for QHPs will lead to inadequate access to medications due to limited formularies, prohibitive cost sharing, and restrictive utilization management rules that are likely to result in insured patients who cannot access or afford their necessary prescribed medications. More intensive reviews of these elements of benefit design could ensure that people enrolled in QHPs and other health plans that must comply with the EHB rule have appropriate, affordable access to those medications. QHPs should provide robust formularies that ensure access to medically necessary, innovative treatment options and protect people living with serious and chronic conditions from cost-sharing and utilization management policies that may restrict access and discriminate based on their health conditions.

The Epilepsy Foundation urges the Division of Insurance to pursue stronger benefit requirements and conduct a more thorough review of formularies for QHPs in Massachusetts. We offer the above recommendations as concrete actions that you can take to increase the likelihood of QHPs developing formularies that meet the needs of all enrollees, including those living with serious chronic conditions and disabilities. Please do not hesitate to contact Angela Ostrom, our Vice President of Public Policy and Advocacy if you or your staff would like to discuss these issues in greater detail. She is reachable by e-mail at aostrom@efa.org.

Sincerely,

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