The Honorable Richard E. Neal, Chairman
Committee on Ways & Mean
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Kevin Brady, Ranking Member
Committee on Ways and Means
1139 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr., Chairman
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Greg Walden, Ranking Member
Committee on Energy and Congress
2322 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Neal, Ranking Member Brady, Chairman Pallone, and Ranking Member Walden:

The Epilepsy Foundation appreciates the opportunity to provide input on this discussion draft to improve prescription drug coverage under Medicare Part D.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than three million Americans 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 the majority of people living with epilepsy, epilepsy medications are the most common and most cost-effective treatment for controlling and/or reducing seizures. For people living with epilepsy and seizures, there is no "one size fits all" anticonvulsant, and the response to anticonvulsants can differ between seizure type and be different from person to person. Maintaining seizure control with minimal side effects on the correct anticonvulsant(s) requires careful evaluation and monitoring by healthcare providers and patient. Because it is such an individualized and complex condition, having more treatment options and having access to the full range of approved treatment options so that each individual with direction from his/her healthcare provider can identify and remain on the anticonvulsant(s) that works is vital.

The Epilepsy Foundation strongly supports a cap on out-of-pocket costs in Part D. In recent years, premiums, deductibles, and overall cost-sharing have increased, placing more of a burden on beneficiaries. The increasing use of of specialty tiers, which are subject to significant coinsurance and excluded from cost-sharing exceptions, forces beneficiaries to pay a significant percentage of their medication cost. For medications placed on specialty tiers, like anticonvulsants for epilepsy, the coinsurance amounts can range anywhere from 25% to 33%, leaving beneficiaries paying thousands of dollars for their medication. As a result, many beneficiaries are denied access to the most clinically appropriate medication because it is out of reach financially. We have heard of this hardship firsthand, including from a 65-year-old woman in Massachusetts with a difficult-to-control epilepsy. Working with her physician, she tried more than 10 different medications before she finally became seizure free on a new brand-name seizure medication. After changing her insurance plan, she was unable to afford the more than

$250 a month payment required for her seizure medication. Unable to afford this monthly cost, she switched to a different, less expensive medication. Unfortunately, this switch led to her experiencing her first seizure in more than four years. This is not an isolated event and to combat this issue, and to help ensure that beneficiaries do not face insurmountable financial hurdles to access the more clinically appropriate and effective medication, we believe an out-of-pocket cap would better enable beneficiaries to anticipate and meet their financial obligations.

Compounding these issues is the fact that after non-Low-Income Subsidy (LIS) beneficiaries get through the coverage gap and into catastrophic coverage, they must pay 5% coinsurance until the next calendar year, when the cycle starts anew. Given the high cost of specialty products per year, the catastrophic coverage phase 5% cost-share requirement can impose a material financial burden on beneficiaries.

The Epilepsy Foundation is extremely grateful that the Administration declined to proceed with its proposal to change and effectively weaken Medicare's Six Protected Classes. However, additional barriers remain and the Epilepsy Foundation encourages the committees to examine these. We are also concerned about the erosion of access through barriers other than out-of-pocket costs. Challenges to access in Part D include narrowing formularies, an erosion of beneficiary protections, increased utilization management, use of preferred pharmacy networks, and a confusing and difficult to navigate exceptions and appeals processes. We urge you to consider these issues as you work to strengthen Part D. We encourage the committees to call for increased CMS oversight of plan benefit design.

Question 1: How the Part D program is addressing the problem of high cost drugs and how the program could better address the costs of these drugs. Specifically, whether or not Congress should consider changing or eliminating the distinction between the initial coverage phase and the coverage gap discount program.

In addition to supporting an out-of-pocket cap, the Foundation encourages the committees to consider simplifying the benefit design. The current structure – including deductible, initial coverage period, coverage gap discount program, and catastrophic coverage – is a result of legislative history, not a benefit designed with beneficiary ease of access and predictability and consistency of access in mind. We support simplifying the benefit design, but want to emphasize that any change should not result in higher overall cost sharing or reduced access to medications.

In addition to the complicated design of the program, the design of Part D plans has become increasingly complex, making it more and more difficult for patients to understand, anticipate, and compare costs and plan designs. An increasing number of tiers charge a percentage co-insurance based on the drug's retail price, rather than a set copay amount. Further, there are pricing tiers for preferred and non-preferred retail pharmacies and for preferred and non-preferred mail order pharmacies. Particularly problematic is the fact that plans are not required to maintain a drug's retail price throughout the year. They can adjust prices based on changed agreements with manufacturers. The result is that prices can rise mid-year, sometimes quite dramatically.

We encourage the committee to explore simplifying the Part D benefit and Part D plan designs in ways that benefit consumers through lower cost sharing overall and make it easier to choose plans, navigate their benefits and have consistently affordable access. In addition to improving prospective and real-time price transparency, plans should be required to provide clarity and transparency on coverage and consumers' out-of-pocket costs. A mix of copayments and coinsurance can cause significant confusion, especially for individuals on multiple and/or expensive medications who are trying to navigate the system and compare plans.

Question 2: What share of costs should be attributed to the beneficiary, Part D plans, and manufacturers under the current system and how this share should change if the liability were shifted for the manufacturer from the current coverage gap discount program to the catastrophic phase of the Part D benefit.

Any proposed change to the program must be made with the beneficiary in mind. For example, the draft legislation would lower the federal reinsurance rate in the catastrophic phase of the benefit. While we appreciate the intent, we are concerned that this would result in increased use of utilization management and other tactics on the part of plans to recoup their costs. However, this could be mitigated with increased protections against utilization management in Part D and oversight from CMS to ensure compliance. Similarly, the committee may explore other alternatives to re-shaping the Part D benefit. While examining the shifting liability of manufacturers in a simplified benefit package, the committee may want to consider a simple, off-the-top rebate or discount as used in the Medicaid program.

Question 3: What improvements the Committees should consider with respect to low-to-moderate income Part D beneficiaries and out-of-pocket costs below the catastrophic level.

We appreciate the committees' interest in protecting low-and-moderate income beneficiaries. We are also concerned about the LIS program, including low-income beneficiaries who are still not eligible for full LIS protections, and LIS beneficiaries who still face cost sharing. Beneficiaries with incomes of as low as $16,860 to $18,735 (135% to 150% FPL in 2019) who also meet the program's asset test are still exposed to premiums, deductibles and high coinsurance rates (15%). We encourage the committees to expand the Part D Low Income Subsidy by:

1. eliminating the asset test,
2. extending the full benefit to beneficiaries with incomes under 200% FPL, and
3. eliminating cost sharing for generics for LIS beneficiaries.

On behalf of the 3.4 million Americans living with epilepsy, including approximately 1.1 million with Medicare, we appreciate the opportunity to comment on the draft legislation and questions posed by the committees. Please do not hesitate to contact me at lweidner@efa.org or 301-918-3766 with any questions.

Sincerely,

Laura Weidner, Esq.
Vice President, Government Relations & Advocacy