



April 24, 2017

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

Dear Administrator Verma:

The Epilepsy Foundation appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) request for information regarding Medicare Part D and to contribute the patient perspective to the conversation on the value of medications for beneficiaries. Our comments focus on maintaining and strengthening existing patient protections, and exploring ways to ensure high cost-sharing burden does not limit access to physician directed care. As the new Administration considers regulatory changes to the Medicare program, we welcome a dialogue with the agency to ensure meaningful access to prescription medications for all Medicare beneficiaries.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of nearly 3 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. For the majority of people living with epilepsy, medications are the most common and cost effective treatment for controlling or reducing seizures, and they must have meaningful, timely access to physician directed care.

Medicare provides health insurance for Americans age 65 and older, and to younger people with disabilities. More than 570,000 adults age 65 and older live with epilepsy, and that number is rising rapidly as the baby boomer generation enters retirement age. Additionally, many individuals under age 65 living with epilepsy are Medicare beneficiaries due to their disability status. Medicare Part D is a successful program that is popular among beneficiaries. Importantly, the Part D program is less costly to the federal government than initially projected.<sup>1</sup>

As CMS explores ways to enhance the Part D benefit, we urge the agency to consider meaningful access to medications the primary consideration, and to keep in mind that changes to the Part D benefit that limit access to physician directed care can and do often result in higher cost to the Medicare program and the healthcare ecosystem. Limiting access to medications often leads to decreased quality of life and health complications for beneficiaries, as well as higher costs to the Medicare program, state Medicaid programs, and to society due to increased hospitalizations and related expensive complications that impact beneficiaries and their caregivers.

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<sup>1</sup> Congressional Budget Office. Competition and the Cost of Medicare's Prescription Drug Program. July 30, 2014.  
<https://www.cbo.gov/publication/45552>.



## Six Protected Classes

The Epilepsy Foundation strongly supports Medicare Part D's Six Protected Classes policy which ensures greater protections for six classes of medications, including anticonvulsants for epilepsy. Medications in the six protected classes are not interchangeable, and beneficiaries often react quite differently to the available treatments. As a result, managing these serious, chronic, and life-threatening conditions requires meaningful access to the full range of therapies available -- and the specialists who know how to prescribe them. When people living with epilepsy are forced to switch medications, or alter their treatment plan, it can lead to breakthrough seizures, associated complications and costs, or even death. Beneficiaries living with other complex chronic conditions treated by medications in the other protected classes face equally dire consequences if they cannot access their lifesaving medications in a timely manner.

Despite the success of the Six Protected Classes policy in ensuring access to almost all medication in the classes of clinical concern, Medicare Part D beneficiaries living with epilepsy still confront barriers to care. Part D plans have the ability to use step therapy, prior authorization, tier placement and high cost-sharing, to limit access to lifesaving epilepsy medications. A 2013 [study](#) by Avalere Health found that Medicare Part D plans provide lower levels of coverage for anticonvulsants than commercial health insurance plans. As CMS evaluates beneficiary cost-sharing and the impact it can have on medication adherence and meaningful access to care, we encourage the agency to explore ways to further strengthen the protection for epilepsy medications.

## High Cost-Sharing: Specialty Tier Exemption

We urge CMS to establish a cost-sharing exception and appeal process for medications on the specialty tier. For all other plan formulary tiers, beneficiaries may file an exception for a medication to be placed on a lower cost-sharing tier, provided the medication is the only therapy available for their condition. This option is not available for specialty-tier medications, which often are also the ones with the highest cost-sharing requirements and often do not have a lower priced counterpart.

CMS should also consider the impact that the specialty-tier threshold can have on beneficiary cost-sharing for medications. Inflation will force more medications into the specialty tier as their price exceeds the current threshold, making it harder for beneficiaries to afford medications. This access barrier will be further exacerbated absent the option of an exemption to mitigate the higher cost-sharing (specialty-tier medications are increasingly subject co-insurance rather than a flat co-pay).

CMS should pursue greater efforts to educate beneficiaries and other stakeholders on the entire exceptions and appeals process. Given the complex process for seeking determinations and redeterminations or a tiering exception, it is worthwhile to explore ways to enhance education on this issue. For example, CMS could require easy-to-understand information at the point-of-sale at pharmacies. If a beneficiary has been prescribed a non-preferred brand and the cost-sharing amount is more than the beneficiary can afford, the pharmacist could provide standard information for the beneficiary to initiate the tiering exception process. Absent this easy-to-understand information, beneficiaries abandon their prescription at the pharmacy



counter and walk away without an understanding of why the cost-sharing is so high or what recourse they may have to obtain the medication at a lower price.

We support CMS effort to implement an appeals-tracking system in Part D and encourage CMS to release annually data on denials at the pharmacy counter, as well as plan-level appeal and exceptions. This would help us better understand the magnitude of the problem so we can then formulate policy solutions and educational approaches that lead to greater medication adherence and meaningful access to care.

### **High Cost-Sharing: Out-of-Pocket Costs**

The Epilepsy Foundation is concerned about higher cost-sharing burdens for beneficiaries in the form of higher out-of-pocket costs, which are driven in great part by the proliferation of specialty tiers. Medications on specialty-tiers are subject to significant co-insurance that can range from 25 to 33 percent. Beneficiaries may have to pay thousands of dollars out-of-pocket for expensive, lifesaving medications. High out-of-pocket costs can effectively result in denied access when a beneficiary simply can afford the medication. Some beneficiaries may stretch their budgets to pay high sums out-of-pocket to obtain the medication, to the detriment of other expenses, including other medications necessary for managing their multiple co-morbidities

Another potential factor driving out-of-pocket costs for Part D beneficiaries is the actual drug price beneficiaries must pay at the point of sale, particularly in instances where a beneficiary faces co-insurance. In Part D, the price at the point of sale (during the deductible phase or a co-insurance for the drug) is based on the list price and does not account for any rebates or discounts that might reduce the overall price.

A recent Milliman [report](#) concluded that higher rebates may lead to higher cost-sharing by beneficiaries and the government. Part D plans have a financial incentive to cover medications with higher list prices and higher rebates as a means of driving down the premium, as opposed to covering lower priced medications with lower rebates. This can translate into a higher cost-sharing burden for beneficiaries who rely on brand medications with high rebates and do not enjoy the savings from higher rebates but instead pay co-insurance on the higher list price before the rebate. CMS should consider how rebates impact beneficiaries' cost-sharing burden in unexpected ways and explore alternatives to ensure higher rebates translate into lower cost-sharing for beneficiaries and the government, greater medication adherence and meaningful access to care.

### **Formulary Oversight**

The Epilepsy Foundation supports greater formulary oversight by CMS to ensure meaningful access to medications for all beneficiaries. This is especially important for low-income subsidy recipients, who often face limitations on physician directed care, as well as for beneficiaries living with very complex chronic conditions that need a carefully calibrated medication regimen.

While epilepsy medications enjoy some protections via the Six Protected Classes policy, beneficiaries living with epilepsy need meaningful access to other medications to manage co-morbidities. Managing medication



interactions and treating other conditions, while maintaining seizure control with minimal side effects, requires careful evaluation by the treating physician and access to the full range of therapies.

Greater oversight can also help CMS determine if Part D plans are engaging in discriminatory coverage practices that would not be identified by CMS' standard formulary review process. As more medications find their way to the specialty tier, with high cost-sharing and no exemption recourse, it is especially important that CMS ensure Part D plans cannot design formularies in a way that makes it nearly impossible to afford the critical and often lifesaving medications beneficiaries need.

The Epilepsy Foundation appreciates the opportunity to bring the patient perspective to the conversation on the value of medications for beneficiaries and how CMS can play a role to ensure high cost-sharing does not limit access to physician directed care. As CMS evaluates proposals related to the Medicare program, we look forward to working with CMS to ensure timely, affordable access to prescription medications for all Medicare beneficiaries.

The Epilepsy Foundation Please do not hesitate to contact Angela Ostrom, Chief Legal Office & Vice President Public Policy, at 301-918-3766 or [aostrom@efa.org](mailto:aostrom@efa.org) with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Philip M. Gattone".

Philip M. Gattone, M. Ed.  
President & CEO  
Epilepsy Foundation