



January 16, 2018

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

Re: Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (file code CMS-4182-P)

Dear Administrator Verma,

The Epilepsy Foundation appreciates this opportunity to offer comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed policy and technical changes for Part D for contract year 2019.

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, and people living with epilepsy must have meaningful and timely access to physician-directed care and specialists to avoid breakthrough seizures and related complications and costs.

We want to contribute the patient perspective to the conversation on the value of medications for beneficiaries and our comments focus on maintaining and strengthening existing patient protections, and exploring ways to ensure a high cost-sharing burden does not limit access to physician-directed care. As the Administration considers regulatory changes, we welcome a dialogue with the agency to ensure meaningful access to prescription medication for all Medicare beneficiaries.

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.¹

The Epilepsy Foundation applauds the centers for Medicare & Medicaid Services for efforts to continually review and refine the Medicare Prescription Drug Benefit (Part D). While we generally support this initiative by the agency to provide plan sponsors appropriate flexibility in plan operations, we believe it is critically important for the agency to balance the goals of plan flexibility with ensuring

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



beneficiary protections. In some of the proposals, the proposed solution is seeking to solve an issue that is generally not perceived as a problem. Some of these proposed solutions could jeopardize beneficiary safeguards and protections that are critical to ensuring beneficiary access to vital medications and therapies.

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. These medications are often 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 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 to co-insurance rather than flat co-pay).

High Cost-Sharing: Out-of-Pocket Costs and Rebates and Point of Sale

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.

We also applaud the movement to incorporate rebates at the point of sale and allow Medicare beneficiaries to directly benefit from the discounts and rebates provided by manufacturers. We look forward to additional guidance from CMS on this matter. The Epilepsy Foundation also applauds CMS' work on considering passing pharmacy direct and indirect remuneration (DIR) to point-of-sale. We look forward to more guidance on this move to the extent pharmacy DIR at point-of-sale ultimately saves money for beneficiaries.

Special Enrollment Periods (SEP) for Dual-Eligible Beneficiaries

While SEP is not widely used by the overall Low-Income Subsidy (LIS) population, it does provide an important avenue to access for those LIS beneficiaries who do elect to use the SEP. The Epilepsy Foundation is concerned that this policy becomes even more dangerous when combined with the proposed policy revisions to midyear formulary changes. Some LIS beneficiaries may be unable to maintain a treatment regimen to a branded drug when a generic equivalent enters the market as the branded drug may be removed from the formulary.

Under the current policy, in this scenario, the LIS beneficiary may switch to a plan still covering the product. This is an important and strong protection from low-income beneficiaries and we strongly suggest CMS consider expanding the limit to 2 to 3 SEPs during a plan year. This is an example of CMS



fixing a problem that, through its own admission, does not exist but could cause access issues for some beneficiaries.

Mid-Year Formulary Changes

We urge CMS to not allow mid-year formulary changes to prescription drug coverage. For the majority of people living with epilepsy, epilepsy medications are the most common and cost-effective treatment for controlling and/or reducing seizures. Epilepsy medications are not interchangeable and 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. Maintaining seizure control with minimal side effects requires careful evaluation and monitoring by physicians and their patients. To change, limit, or deny access to medications could be extremely dangerous. 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. Limits to physician-directed care can significantly increase medical costs related to preventable seizures.

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. Please do not hesitate to contact Angela Ostrum, Chief Legal Officer & Vice president of Public Policy at 301-918-3766 or aostrum@efa.org with any questions or concerns.

Sincerely,

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

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