



January 25, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Administrator Verma:

The Epilepsy Foundation appreciates the opportunity to provide input on the Centers for Medicare and Medicaid Services (CMS)'s proposed rule entitled Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P). The Foundation's comments focus on two components of the proposal: support for the prohibition against gag clauses in pharmacy contracts and opposition to the proposed changes to a policy that is of utmost importance to people living with epilepsy and seizures—Medicare's Six Protected Classes.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of the at least 3.4 million Americans, including the approximately 570,000 individuals aged 65 years or older, living 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—which are sudden surges of electrical activity in the brain that affect a variety of mental and physical functions. Epilepsy is a spectrum condition with a wide range of seizure types and control varying from person-to-person. Anti-epilepsy medications or anticonvulsants are the most common and cost-effective treatment for controlling and/or reducing seizures. To change, deny, or limit access to anticonvulsants can be extremely dangerous.

Support for Prohibiting Pharmacy Gag Clauses

The Epilepsy Foundation believes that individuals deserve affordable access to the treatment their providers have determined they need, and access should not be dependent on the type of insurance they carry, and applauds the Administration for this part of the proposed rule. Occasionally, for some individuals or some therapies, it can be less expensive for a person to purchase the medication outside of their healthcare plan. Certain insurance practices prevent pharmacists from passing information to their customers about the lower price option – these policies are known as pharmacy gag clauses. However, with enactment of the Know the Lowest Price Act and effective January 1, 2020, Part D plan sponsors will no longer be able to restrict pharmacies from informing beneficiaries of a lower cost option.

We supported passage of this bill and now support implementation of the policy through this proposed rule. The Foundation believes that pharmacists should be free to speak to consumers about all available options, particularly if an individual is inquiring about alternative ways to afford a therapy or to save money on their



treatment regimen. Along with this, we believe that individuals should be educated about the impact of paying for a prescription outside of their health plan and understand the implications for meeting deductibles and out-of-pocket caps. If there are alternative, and cheaper, means of purchasing a prescription medication, individuals should be entitled to that information and allowed to make the purchasing decision that works for them and we are grateful this will soon become a reality for Part D beneficiaries.

Importance of Medicare Part D and the Six Protected Classes for People with Epilepsy

With at least 23 prescription drug coverage plans available in every region across the country, the Medicare Part D program and the Six Protected Classes policy play a vital role in improving patient access to quality medications and treatment. Part D plans have successfully negotiated substantial discounts and rebates with manufacturers, which have kept total program costs down. Overall, Part D costs are \$349 billion—or 45%—less than originally estimated when the program was first created.ⁱ This program has been critical in controlling overall federal spending in Medicare thanks to the program’s success in expanding coverage and increasing adherence to treatment among beneficiaries. Increasing adherence keeps costly hospitalizations and other complications to a minimum, resulting in lower long-term costs occurred in other Medicare plans.ⁱⁱ

While the Foundation recognizes the need to cut healthcare and medication spending costs, it should not be done at the detriment of vulnerable populations who have a clear clinical, life-saving need to accessing medications. This absolute need to access the full range of certain medications is, after all, why CMS created, and Congress has since confirmed, the Six Protected Classes policy. CMS established the Six Protected Classes policy to ensure that Medicare Part D beneficiaries living with chronic conditions like epilepsy, HIV, mental illness, cancer, and organ transplants have meaningful and timely access to the full range of approved lifesaving medications necessary for controlling their conditions and maintaining their existence and quality of life. Rather than the statutory minimum of two drugs per therapeutic class, Medicare Part D plans must cover “all or substantially all” drugs for these six classes of medications.

The Epilepsy Foundation strongly opposes any policies that would weaken the Six Protected Classes within Medicare Part D. The Six Protected Classes policy has enjoyed strong, bipartisan support since its inception in 2006 and both CMS and Congress have affirmed it as a critical mechanism for the most vulnerable and medically fragile Medicare beneficiaries including people affected by chronic seizures and related morbidities. The policy has also been cost-effective.ⁱⁱⁱ Weakening the Six Protected Classes policy will result in decreased quality of life and health complications for people with epilepsy, as well as higher costs to the Medicare program through increased hospitalizations and deteriorating health conditions.

As an organization representing one of these vulnerable populations who relies on a protected class of medicine—people with epilepsy and seizure disorders relying on anticonvulsants—we sincerely hope that the Administration listens to our concerns. As described in more detail below, because the proposal would impose additional barriers for people with epilepsy in accessing their anticonvulsants, restrict access to less than the full range of anticonvulsants and is contrary to the policy’s original intent, the Foundation respectfully asks the Administration to rescind all components of its Six Protected Classes proposal.

Imposing Additional Barriers to Life-saving Medications is Burdensome and Dangerous for People with Epilepsy and Seizures

Part D plans already have the ability and often employ tools like utilization management to steer beneficiaries to lower cost medications. A 2018 Avalere Health report using CMS claims data reveals that people taking



brand anticonvulsants already have to go through utilization management protocols thirty-three percent of the time and people taking generic anticonvulsants have to go through utilization management seven percent of the time.^{iv} While these percentages may objectively sound small, they must be looked at through the lens and experience of someone living with a complex, chronic, unpredictable condition like epilepsy where access to your anticonvulsants is life-changing and life-saving.

The Epilepsy Foundation opposes step therapy and similar policies intended to restrict access to physician-directed care that unnecessarily prolong ineffective treatment and prevent individuals from immediately starting the treatment their physicians think is best. 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. Delaying access to the anticonvulsant(s) that work(s) for a particular person puts him/her at risk for breakthrough seizures and related complications including injury, disability, loss of mobility or employment, and even death. Mortality rates among people with epilepsy are three times higher and sudden death rates are twenty times higher than rates for the general population. Each year, about 1 out of 1,000 adults and 1 out of 4,500 children with epilepsy die from Sudden Unexpected Death in Epilepsy (SUDEP).^v In addition to these serious and potentially life-ending consequences, when people with epilepsy are not on the anticonvulsant that works for them, it causes higher healthcare costs for the system—in this instance, the government. A review of studies has shown that direct, epilepsy-related medical costs associated with uncontrolled epilepsy are 2 to 10 times higher than costs associated with controlled epilepsy.^{vi}

In essence, the Foundation opposes step therapy and believes that just because some people already have to jump through burdensome hoops is not a reason to offer plans additional flexibility that force more people to face these barriers. The Foundation is particularly troubled by and absolutely opposes the proposal that would require people who are already stable on a medication to go through utilization management if they are newly joining a Part D plan or switching between Part D plans. As discussed, patient response to an anticonvulsant is highly individualized. People with epilepsy may respond to only one of a number of anticonvulsant drug options, or may experience side effects when on some, but not all anticonvulsants. Most anticonvulsants need to be titrated to an individualized dose, and that dose needs to be determined to be effective in a specific individual. This process can take months. Once an appropriate regimen has been determined, it can be very destabilizing to switch to any alternative regimen. Studies have demonstrated that people with epilepsy are at greater risk of seizure after a switch. In one study, seizure-free individuals who switched their drug had a 16.7% rate of seizure recurrence at 6 months, compared to 2.8% among people remaining on the same drug.^{vii} These people could be driving or performing job functions in which a single seizure could be catastrophic.

A thorough literature search focusing on step therapy found little evidence that formulary controls and restrictive benefit designs achieve the intended goal of reducing total costs while maintaining quality care.^{viii} Patients subjected to step therapy do not fill prescriptions, underutilize medications and have lower therapy adherence. Several of its studies revealed that while drug costs may go down, total healthcare costs remained the same or increased—with, not surprisingly, disproportionate negative financial impact for the poor and elderly. Nearly thirty-eight percent of patients who were forced to switch to a covered medication had to wait five or more days from the step edit to receiving their medication. Healthcare providers and pharmacists similarly reported increased time and related increased administrative costs navigating various plans and submitting required documentation.



CMS alleges that these vulnerable populations have grown accustomed to and are skilled at navigating utilization management techniques and appeals processes, but this oversimplifies circumstances and ignores cognitive challenges that many of the populations relying on protected class medications experience. A March 2018 Medicare Payment Advisory Commission (MedPAC) report to Congress noted patients' frustrations with Part D determinations, exceptions and appeals processes and hence recommended that CMS continue to improve the appeals process.^{ix} Many people with epilepsy for instance experience problems with thinking and memory as a result of seizures, medications or underlying brain problems. A whole host of subpopulations also face challenges. People transitioning from private insurance to Medicare may have already faced step therapy and other utilization management, only to face such hurdles again and be forced to try a medication that they and their doctor already know doesn't work for them. People transitioning from Medicaid to Medicare also – such as Disabled Adult Children who have intellectual and developmental disabilities– who likely have *not* faced utilization management before would newly have to navigate these difficult processes. Also, it is not accurate that all people can simply switch their plans when faced with these obstacles. Medicare Part D Low-Income Subsidy (LIS) in particular already have limited plan choices. In all cases, patients have likely spent years finding appropriate medications and should not be destabilized in a short-sighted attempt to save money.

It must also be noted that due to the vulnerable nature of these populations' conditions, having to go through utilization management and/or an appeals process and being without their medication even for a short timeframe can bring dire, life-ending consequences. As a real world and very unfortunate example, in 2009, an insurer in Massachusetts required a young woman living with epilepsy to get pre-authorization for an anticonvulsant she had been taking for awhile.^x The family attempted to pick up the prescription five times, but due to complications with the pharmacy getting prior authorization from the physician, pre-authorization was never received. Being left without the anticonvulsant that had kept her stable, the young woman had three seizures—the third being fatal. While not a Part D example and we acknowledge the Part D appeals process requires a short turnaround time, seizures can strike quickly and without warning regardless of insurance type. Delaying access to anticonvulsants by requiring more people to go through step therapy and prior authorization is simply dangerous.

Allowing Exclusion of More Medications from the Formulary Restricts Access and Stifles Innovation

The Foundation was surprised to learn from the Avalere Health report that the current benefit design already excludes a significant number of drugs that technically should be covered under the Six Protected Classes policy. For anticonvulsants specifically, the Avalere report shows that only sixty percent of brand and generic anticonvulsants (combined) are being covered; and only forty-six percent of brand anticonvulsants are being covered.^{xi} Since the "all or substantially all" threshold isn't currently being achieved, it begs the question why the Administration is seeking to allow medications to be excluded from the formulary in *more* instances rather than seeking ways to improve access to the full range of protected class medications.

Being able to exclude anticonvulsants from the formulary—either because there is a new formulation, or the price of the medication has increased above a specified threshold—essentially equates to instituting step therapy. If a person with epilepsy was stable on the medication that is now excluded, s/he may be forced to try other anticonvulsants that may or may not work for him/her. Therapeutic equivalence cannot be assumed across products within the same class, and this is increasingly the case as new targeted therapies are identified. In addition, the new formulation exclusion could stifle access to innovative therapies that have less debilitating side effects for some people.



The Proposal is Contrary to CMS's Original Intent and Repeated Congressional Action

The current Six Protected Classes proposal contradicts the very reason CMS established the policy and repeated bipartisan Congressional intent and action to protect the Six Protected Classes. In implementing the non-discrimination provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), CMS stated that it was “[instituting] this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in Part D plans and to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”^{xii} A Senate colloquy leading up to MMA’s enactment between Chair of the Senate Finance Committee Chuck Grassley (IA) and then-Ranking Member of the Finance Committee Max Baucus (MT) further illustrates this purpose^{xiii}:

Mr. BAUCUS, ranking member, Senate Finance Committee. . . . One of the things I am particularly proud about in this bill is the strong beneficiary protections You know, Senator Grassley, that there are certain diseases and conditions like AIDS, and epilepsy where having access to just the right medicine is especially important.

Mr. GRASSLEY, chairman, Senate Finance Committee. I did know that, and I know that certain mental illnesses also fall in that category. This bill contains a number of protections for people who need exactly the right medicine for them. ...

Mr. BAUCUS. Exactly. . . . [W]e require drug plans to offer at least two drugs in each therapeutic class. And for drugs that treat AIDS, epilepsy, or mental illness, we would expect that plans would carry *all clinically appropriate drugs*.

Mr. GRASSLEY. I agree. And I am pleased with the backup protections in this bill. ...

Mr. BAUCUS. These beneficiary protections are crucial for these vulnerable Medicare beneficiaries. . . . If a plan can’t adequately ensure all of the proper medication for beneficiaries living with HIV/AIDS, epilepsy, and certain mental illnesses, that plan should not be doing business with Medicare. ...

Through enactment of Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Congress codified the Six Protected Classes policy in the Part D statute and rejected CMS’s “substantially all” standard—strengthening the Six Protected Classes and requiring that “all” such therapies be covered.^{xiv} While allowing for exceptions including using utilization management in some instances, Congress was clear that doing so must be based on scientific evidence and medical standards of practice.^{xv} Current CMS regulations and guidance maintain these parameters.^{xvi} However, no scientific evidence or medication standards of practice are used to justify the current proposal. Quite the opposite, the proposals fly in the face of medication standards of practice and physician-directed care—particularly the concept of requiring someone who is stable on a medication to go through utilization management.

In Section 3307 of the Affordable Care Act (ACA), Congress updated the relevant provisions of MIPPA and again expressed its support of the Six Protected Classes policy. After affirming that Part D plans must cover “all” drugs in a protected class, the ACA directed CMS to identify categories and classes of drugs of clinical concern.^{xvii} Despite this, it is clear that Congress did *not* intend to weaken the Six Protected Classes policy or



cut costs because the Congressional Budget Office found no savings were associated with the provision and Congress did not modify the non-discrimination requirement.

When CMS proposed some changes through its implementation of Section 3307 of the ACA, bipartisan letters from the Senate Finance Committee as well as the House Energy and Commerce Committees reminded CMS of the policy's original intent and sheer importance. The February 5, 2014 Senate Finance Committee letter which was signed by all members of the Committee, for instance, clearly iterated that "Congress and the Administration have recognized that for certain types of conditions and therapies beneficiaries should have access to all available medication." The Senate Finance Committee letter^{xviii} goes on to point out many of the concerns the Foundation has outlined in this letter, namely that:

- "By limiting the number and type of medications offered under a Part D plan, a beneficiary may be forced to rely, if only temporarily, on medication that simply does not work or results in adverse side effects";
- "We are unconvinced this change will lead to significant cost savings.... Further, we remain concerned that if beneficiaries do not have access to needed medication, costs will be incurred as a result of unnecessary and avoidable hospitalizations, physician visits, and other medical intervention that are otherwise preventable with proper adherence to medication.... We are concerned that the attempt to find cost savings in Part D could result in cost increases for the Medicare program at large.";
- "...if this limitation were to be finalized, many beneficiaries would be forced to rely on the Part D appeals process to receive coverage of a drug not provided on a Part D plan's formulary. Unfortunately, this appeals process is inadequate and confusing to beneficiaries."

The Senate Finance Committee ultimately asks CMS "to continue this important beneficiary protection *as it exists today* (emphasis added)." The Committee's words and the Administration subsequently pulling back its proposal could not be more clear: people relying on protected class medications need access to the full range of treatments and the policy is working and should not change.

The Proposal Relies on Unsubstantiated Claims that Part D Sponsors Need New Tools to Negotiate Lower Costs for Protected Class Drugs

The Foundation acknowledges the need to cut health care and prescription drug costs. However, in addition to not wanting to harm vulnerable populations relying on protected class medications, after reviewing the data that is publicly available, the Protected Classes are not the right area to target. In fact, in a 2017 report to Congress, MedPAC acknowledged that protected class status does not affect plan sponsors' ability to negotiate or drive utilization of generics and reports that, accounting for generic substitution, cumulative prices for protected class medicines *decreased* by 13 percent between 2006 and 2014, compared to an 8 percent *increase* for all Part D drugs.^{xix}

Also, the 2018 Avalere Health study shows that while thirty-five percent of covered drugs across the protected classes are generic, ninety-one percent of filled prescriptions in the protected classes are for generics.^{xx} This clearly shows that plans already have power to drive consumers to the lower cost alternative. It is hard to imagine achieving more than ninety-one percent without pushing some people with epilepsy to generics when they are not in fact the best option for a particular individual. Some people are particularly brittle, and even a small change can lead to the risk of a breakthrough seizure, which could be catastrophic. People with epilepsy are very anxious about maintaining seizure control, and the thought of being at risk for a seizure is very



distressing. It is also important to note that generic medications do not equate cheap for the beneficiary. So again, while cost should be a factor, at the end of the day, physician-directed care and ensuring that people with epilepsy are on an anticonvulsant with minimal side effects that helps them achieve seizure control is most important.

In addition to plans already being able to use utilization management techniques as described above, Part D plans already use tier placement as a negotiating tool. The proposed rule relies on assertions from certain Part D sponsors that they receive minimal or no rebates for drugs in the protected classes and that there's little incentive for manufacturers to offer rebates for the Six Protected Classes because they do not need to compete for formulary placement. However, the Avalere Health report directly contradicts this assertion. Seventy-three percent of anticonvulsants are placed in a non-preferred or specialty category, with seventy-nine percent of branded anticonvulsants categorized as non-preferred or specialty and sixty-eight percent of generic anticonvulsants being categorized as non-preferred or specialty. Higher tier placement equates to higher cost sharing and additional authorization for coverage. For brand anticonvulsants, the Avalere Health study found the average coinsurance to be \$546 and for generic anticonvulsants, the average coinsurance to be \$102.^{xxi}

Conclusion

The Epilepsy Foundation advocates for all people with epilepsy to have access to affordable, comprehensive, physician-directed health care including access to the full range of anticonvulsants so that each person living with epilepsy can find and remain on an anticonvulsant that helps them achieve seizure control with minimal side effects. To that end, while we are supportive of the prohibition of pharmacy gag clauses in Medicare, we cannot in good conscience support weakening Medicare's Six Protected Classes by imposing more barriers, ignoring physician-directed care and restricting access to anticonvulsants. The Foundation urges the Administration to rescind its dangerous Six Protected Classes proposal and maintain the Six Protected Classes policy as is. We have requested a meeting via email and would still appreciate the opportunity to discuss this matter further. In the interim, we appreciate the opportunity to provide comments and please do not hesitate to contact me at lweidner@efa.org or 301-918-3766 with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura E. Weidner".

Laura E. Weidner, Esq.
Vice President, Government Relations & Advocacy
Epilepsy Foundation

ⁱ Centers for Medicare and Medicaid Services (CMS); Morning Consult; CMS; Congressional Budget Office (CBO) figures and initial 10-year estimate National Bureau of Economic Research, 2014.

ⁱⁱ Iuga, A.O. & McGuire, M.J. (February 20, 2014). *Adherence and health care costs*. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/>.

ⁱⁱⁱ Starc, A. & Town, R.J. (August 2016). *Externalities and Benefit Design in Health Insurance*. Retrieved from https://kelley.iu.edu/BEPP/documents/starc_town_fall2016.pdf.

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- ^{iv} Partnership for Part D Access (2018). *Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs*. Retrieved from http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.
- ^v Devinsky, Orrin. Sudden unexpected death in epilepsy (2011). *New Engl J Med*, 365:1801-11.
- ^{vi} Begley, Charles E. & Durgin, Tracy L. (2015). The Direct Cost of Epilepsy to the United States: A Systematic Review of the Estimates. *Epilepsia*, 56(9), 1376-1387. Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13084>.
- ^{vii} Finamore, Jon Marc, Sperling, Michael R., Zhan, Tingting, Nei, Maromi, Skidmore, Christopher T. & Mintzer, Scott (August 2016). Seizure outcome after switching antiepileptic drugs: A matched, prospective study. *Epilepsia*, 57(8), 1294-300. Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13435>.
- ^{viii} Carlton, Rashad I., Bramley, Thomas J., Nightengale, Brian, Conner, Therese M. & Zacker, Christopher (April 2010). Review of outcomes associated with formulary restrictions: focus on step therapy. *Am J Pharm Benefits*, 2(1), 50-58. Retrieved from https://www.ajpb.com/journals/ajpb/2010/vol2_no1/review-of-outcomes-associated-with-formulary-restrictions-focus-on-step-therapy.
- ^{ix} Medicare Payment Advisory Commission. Report to Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report (March 2018). Retrieved from http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.
- ^x <https://www.cnn.com/2018/06/08/health/massachusetts-walgreens-lawsuit-bn/index.html>
- ^{xi} Partnership for Part D Access (2018).
- ^{xii} Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.
- ^{xiii} 149 Cong. Rec. S5882-03.3.
- ^{xiv} 42 U.S.C. § 1395w-104(b)(3)(G)(ii).
- ^{xv} 42 U.S. C. § 1395w-104(b)(3)(G)(iii).
- ^{xvi} CMS Medicare Prescription Drug Benefit Manual Chapter 6, Version (Rev. 18, 01-15-16), accessed at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.
- ^{xvii} 42 U.S.C. § 1395w-104(b)(3)(G)(ii)(I).
- ^{xviii} U.S. Senate Finance Committee, Letter to Administrator Tavenner (February 5, 2014). Accessed at <https://www.grassley.senate.gov/sites/default/files/constituents/6%20protected%20classes%20letter%206.30.16.pdf>.
- ^{xix} http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf
- ^{xx} Partnership for Part D Access (2018)
- ^{xxi} *Ibid.*