



July 16, 2018

Alex M. Azar, Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (RIN 0991-ZA49)

Dear Secretary Azar:

The Epilepsy Foundation is pleased to submit comments on the Department of Health and Human Service's request for information, published on May 16, 2018 on potential future policy development to lower drug prices and reduce out-of-pocket costs.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of the at least 3.4 million Americans living with epilepsy (chronic seizures). In consultation with medical experts on our Professional Advisory Board and through our national office, and more than 50 local chapters and affiliate offices located in 42 states across the country, we promote the wellbeing of children and adults affected by seizures through research into cures and better treatments, educational programs, advocacy, and direct community services.

Epilepsy is a medical condition that produces seizures and affects a variety of mental and physical functions. There is a high rate of co-morbidities among people with epilepsy, with mood disorders being most common. Seizures can be life threatening, particularly when frequent or poorly controlled. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime, with incidence and prevalence significantly higher among people older than 55. For the majority of people living with a seizure disorder, anti-epilepsy medications are the most common and cost-effective treatment for controlling and/or reducing seizures. People affected must have meaningful and timely access to expert physician-directed care in order to promptly identify seizure type and best treatment options. 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, resulting in breakthrough (unexpected) seizures, accidents, or death.

With at least 23 prescription drug coverage plans available in every region across the country, the Medicare Part D program plays 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 less than originally estimated when the program was first created.¹ 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.²

We are encouraged by some of the proposals put forth by the Administration that would help lift the burden of prescription drug costs and encourage the Department of Health & Human Services (HHS) to go forward with select changes that would improve the Medicare prescription drug benefit. However, we are extremely concerned about other proposals being considered that would be harmful to our patients, including proposed changes to the protected classes, limiting the number of covered medications per class, and indication-based pricing. The Epilepsy Foundation rejects these proposals which would undermine the future success of the important Medicare Part D program in promoting the health care of people affected by seizures.

Preserve the Six Protected Classes Policy

The Epilepsy Foundation strongly opposes any policies that would weaken the six protected classes within Medicare Part D. The 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, which include people affected by chronic seizures and related morbidities. The policy, intended to ensure additional protections beyond the statutory minimum of two drugs per therapeutic class for these special populations, has also been cost-effective.³

The six protected classes policy was designed to ensure Medicare Part D beneficiaries living with chronic conditions like epilepsy, HIV, mental illness, cancer, and organ transplants have meaningful and timely access to lifesaving medications necessary for controlling their conditions and maintaining their existence and quality of life. This policy has been a critical safety net for some of the most medically fragile beneficiaries by requiring plans to cover "all or substantially all drugs" for these six classes of lifesaving medications. Anti-epilepsy medications (also known as anti-convulsants or anti-seizure medications) are not interchangeable or "one size fits all" and people living with epilepsy need access to the full range of therapies available so they can find the right medication or combination of medications that most effectively treats

¹ See CBO Medicare Baselines *available at* www.cbo.gov.

² Iuga, A.O., McGuire, M.J. (2014, February 20). *Adherence and health care costs*. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/>

³ Starc, A., and Town, R.J. (August 2016). *Externalities and Benefit Design in Health Insurance*. Available at: https://kelley.iu.edu/BEPP/documents/starc_town_fall2016.pdf.



their condition. As a result, managing these serious and often life-threatening conditions requires meaningful and consistent access to the full range of therapies available. Failure to effectively manage these six protected conditions will result in decreased quality of life and health complications for individuals, as well as higher costs to the Medicare program through increased hospitalizations, deteriorating health conditions, and also adversely affects society overall by increasing the risk of accidents and the cost of care for people affected.

Clinical decisions must be made by patients' health care providers—the medical experts who have direct contact with the patients—and these clinical decisions should not be impaired by burdensome barriers to access. Medication restrictions or interruptions are harmful and ultimately are not cost-effective for the Medicare program.

The six protected classes policy within Medicare Part D is crucial for individuals living with epilepsy, and indeed, Medicare Part D overall has served as a model for best practice in medication management and treatment for private sector programs to ensure optimal patient outcomes. To the contrary, since the Medicare Part D program was put in place, it has unfortunately become more common place in private sector plans to control costs through increasing formulary restrictions and utilization management techniques that limit access to all medications. Every day, the Foundation and its local offices hear from patients and their treating physicians who are not able to secure their medications without heavy cost, or have to go through a lengthy process to obtain the medications that their doctor thinks is best for them. For example, a step therapy or “fail first” policy in place in some markets requires that beneficiaries prescribed a new, and therefore more expensive, medication must first use a less expensive or plan-preferred medication and experience that medication failure before the plan will pay for the original prescription. In other circumstances, the specialty drugs for rare or hard to treat seizures are placed on the highest tier in the formulary, so that the sickest individuals must go through needless expense and delay to secure their chance for seizure control with the fewest side effects. People living with epilepsy who have their medication switched, or who experience a delay in accessing their medications due to onerous formulary changes or fail first policies, are at a much higher risk for developing breakthrough seizures and related complications including death. Another terrible example of the potentially disastrous results of limiting access to anti-seizure medications occurred recently in Massachusetts, where a patient was denied access to her prescribed medication by the pharmacy because of pre-authorization requirements and died as a result of the delay in access.⁴ Limits to physician-directed care can also significantly increase medical costs related to preventable seizures because each seizure raises the risk of injury and death, and requires medical intervention and care.

⁴ Christensen, J. (2018, June 8). *Family can sue Walgreens over woman's death after insurance denial, court says*. Retrieved from <https://www.cnn.com/2018/06/08/health/massachusetts-walgreens-lawsuit-bn/index.html>



Better Negotiation

Demonstration Projects

The Epilepsy Foundation is concerned about the proposed demonstration project to test value-based care and pricing. Demonstration tests, while useful in establishing the impact of policies for the average person, may accurately reflect the impact policies would have on individuals with chronic conditions who will be the population most impacted by any potential changes in policy. The sector of the Medicare population which has the greatest costs and needs are those with multiple chronic conditions, and any project would have to ensure it includes a significant representation of those most needy and expensive patients. We recognize that the proposals in the blueprint are exploratory and lack detail to thoroughly vet their productivity at this point, but we are invested in ensuring that the rights guaranteed to beneficiaries in Part D are not diminished as a result of policies intended to lower the cost of prescription medication. **Given the possible adverse impact on people with multiple chronic needs, we urge that any proposed widespread changes to Medicare Part D as a result of a demonstration project happen through a formal rule-making process as the agency explores options to lower drug prices.**

Formulary Flexibility

In addition to strongly opposing any changes to the six protected classes policy, we firmly oppose allowing plans to cover only one medication per category and class. The long-standing protection under Medicare Part D of requiring two therapeutic options in each category and class is an absolute minimum for people with chronic life-threatening and multiple disabilities, and in practice has helped ensure patient access to the treatments they need. Reducing the number down to one has serious implications for individuals with epilepsy to access any additional medications they need for seizure control, to treat comorbidities, or to combat the side effects of their anticonvulsant medication.

For the majority of people living with epilepsy, prescription medications are the most common and cost-effective treatment for controlling and/or reducing seizures. If it would be possible to control the seizures of all people with epilepsy with one, two, or even five available medications today, there would not still be a critical need for research to identify better treatments and cures. Unfortunately, approximately 25 percent of people with epilepsy cannot have their seizures completely controlled with any current medication or treatments today. About 50 to 60 percent of people with epilepsy are able to achieve seizure control (no seizures for a year or longer) after the first, second or third medication they try. Another 10 percent may never achieve control with the addition of multiple anti-seizure and related medications to their treatment regimen; indeed, recent data shows that for these patients with difficult to control seizures, the more medications they are on, the less likely they are to experience SUDEP



(sudden unexpected death in epilepsy).⁵ Other recent treatments that are used when medications cannot control seizures adequately include devices such as VNS (vagus nerve stimulator) or brain implants, such as the RNS (responsive neurostimulation). The most successful new treatment that has developed over the last few decades, available to some who meet the criteria for it, is surgery which can effectively remove a small area in the brain that is the focus of an individual's seizures. Some medications lead to unacceptable side effects in some individuals, or are contraindicated for a particular type of epilepsy, and/or for those with co-morbidities where there may be drug interactions. There are more than 20 medications for epilepsy and each one has its place in the panoply of treatment options for epilepsy.⁶

The response to epilepsy medications can be different for each person depending on a number of factors like age, gender, type of seizure, and daily routine. Maintaining seizure control with minimal side effects requires careful evaluation and monitoring by physicians and their patients. Because anti-convulsant medications act on different parts of the brain, and in different ways within the brain, they are variably effective for the multiple types of epilepsy that exist. It would be highly medically irregular and bad medical care to limit medications available in each therapeutic class. This issue is particularly important to the epilepsy community because people living with epilepsy who have had their medications switched without being under the careful control and monitoring of a health care expert in epilepsy, or who experience a delay in accessing their anti-seizure medications, are at a high risk for experiencing seizures and related complications including death. Annual death from epilepsy, while rare, occurs at the same level of frequency as all death by drownings and by fire in the US. It has been recognized that a critical factor in predicting the likelihood of SUDEP is a lack of seizure control and seizure frequency.⁷

Limits to physician-directed care can also significantly increase medical costs related to preventable seizures, along with lost wages and productivity, not just for the individuals living with epilepsy, but also for their families and communities. Gina from Massachusetts illustrates this point. Gina's college-aged daughter has epilepsy. Her epileptologist felt it was best for her condition if she switched from a chewable variation of one medication to the extended release version of the same drug. Unfortunately, the insurance company refused to fill this new prescription and informed Gina that the appeals process could take up to two weeks. While the appeal was taking place, Gina and her family were left with an impossible choice: pay out of

⁵ Ryvlin, P. (2011, September 20). *Risk of sudden unexpected death in epilepsy in patients given adjunctive antiepileptic treatment for refractory seizures: a meta-analysis of placebo-controlled randomized trials*. Retrieved from [https://www.thelancet.com/journals/lanneur/article/PIIS1474-4422\(11\)70193-4/abstract?code=lancet-site](https://www.thelancet.com/journals/lanneur/article/PIIS1474-4422(11)70193-4/abstract?code=lancet-site)

⁶ See Shafer, P. & Sirven, J. (2014, March 19). *Seizure Medication List*. Retrieved from <https://www.epilepsy.com/learn/treating-seizures-and-epilepsy/seizure-medication-list>

⁷ Buchhalter, J., Cross, J.H., Donner, E., French, J.A., Gil-Nagel, A., Gloss, D., Walczak, T.S. (2017, April 24). *Practive guideline summary: Sudden unexpected death in epilepsy incidence rates and risk factors*. Retrieved from <http://n.neurology.org/content/88/17/1674>



pocket for the medication without coverage or forego the best possible seizure medication for her condition. In the end, Gina's family incurred \$500 in prescription medication costs by choosing to pay the \$50/day price for the drug outside of insurance coverage. This situation repeated itself for Gina's family earlier this year. This time, Gina had to take several days without pay from her job to work with her daughter's doctors and the insurance company to ensure her daughter received the medication she needed. In the end, this situation was solved, but not before Gina and her family lost part of their wages and paid several hundred dollars out of pocket.

The Epilepsy Foundation urges CMS to analyze formularies, both prior to **and** during the plan year, to determine whether appropriate access is being given to needed drugs and classes of drugs. In general, we would like CMS to conduct greater oversight to ensure robust formularies exist within Medicare Part D. We would welcome a dialogue with the agency to help ensure that its approach to formulary oversight results in meaningful access for all Medicare beneficiaries without chipping away at key protections for vulnerable beneficiaries. Access to physician-directed care should be based on independent clinical judgment, and Medicare Part D should generally cover all prescribed medications. Rather than saving costs, we are concerned that limiting access to the most appropriate medications will lead to higher overall costs to the Medicare program, including higher out of pocket costs for beneficiaries and increased costs in Medicare Part A and Part B, as well as Medicaid.

Indication-Based Pricing

The Epilepsy Foundation opposes implementing widespread payment models based on the value of each indication because this would impede access to medication for conditions, like epilepsy and the various disease syndromes that include seizures, in which treatment is highly personal and seizures are often extremely difficult to control.⁸ While most value-based contract agreements rely on some mix of objective, measurable patient outcomes and a comparative cost of treatment, those measures may not accurately reflect the reality of treating epilepsy. Value in any context should be looked at, to at least some degree, subjectively as treatments and success of those treatments vary from one person's perspective to the next. In the context of treating chronic conditions, it is critical to consider what each individual values in order to truly assess a product's price on an individual basis. For some conditions, such as epilepsy, these answers will not be uniform across the community which limits the ability to either develop payment models based on value or to best treat epilepsy on an individual basis.

⁸ Rare epilepsy syndromes include Lennox-Gastaut syndrome, Dravet syndrome, Infantile Spasms, Acardi syndrome, Landau Kleffner syndrome, DUP15q syndrome, and many others, who as adults are often Medicare/Medicaid dual eligible participants in Part D.



Epilepsy medications are not “one size fits all” and a number of factors like age, gender, type of seizure, and daily routine can change the medication plan from one individual to another. For some, one medication may help control their seizures, but the side effects stand in the way of adherence and productivity by impacting cognitive ability, mood, and memory. While their seizures may be under control, they are not able to lead productive lives due to debilitating side effects. Another person on the same medication may experience seizure control with no adverse side effects while a third person may not gain seizure control with the same medication. This is why access to all available treatment options is particularly important for the 3.4 million Americans with epilepsy and seizures.

Another important factor to consider when looking at indication-based pricing is that of off-label prescribing for medications. Epilepsy is a broad term that covers chronic seizures caused by a number of specific conditions or syndromes. As such, treating an individual’s particular type of seizure, condition, or syndrome, requires specific individualized treatment and medication plan. Some medications work better for certain kinds of seizures than for others, and if one medicine fails, another may work better. Physicians and patients will sometimes turn to multiple medications in search of seizure control; at times, medications will be prescribed for off-label use. While these medications are not indicated for the patient’s specific condition/syndrome or epilepsy in general, they are still able to gain seizure control with these drugs. By instituting indication-based pricing, individuals who use off-label medication to treat their epilepsy will be left with higher out-of-pocket costs or with no access to the medication at all.

The highly individualized nature of treating epilepsy is a major obstacle for accurately assessing pricing based on average effectiveness scores. While one medication may work well for a number of people, there are still individuals who do not receive *any* benefit from that medication. By pricing medication based on impersonal numbers, many members of the epilepsy community will be subjected to higher medication prices for the sole reason that the most popular medication does not work for them. Access to physician-directed care and achieving seizure control should not be hindered by price determinations based on an unreliable statistical analysis.

Incentives for Lower List Prices

340B Program

For more than 25 years, the 340B drug discount program has allowed safety net providers to purchase discounted drugs, allowing them to enhance their services to millions of low income and vulnerable patients. The statutory intent of the program is to allow 340B providers “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” As such, the Epilepsy Foundation opposes any efforts



to diminish the 340B program’s proven ability to help serve vulnerable patients and communities.

340B is vital to the health care safety net as it enables trusted community providers to fulfill their missions. In many communities—particularly low-income rural and urban areas—safety net providers are the sole pathways to affordable health care. Safety net providers use 340B savings for direct health care services, drug adherence and management programs, and education and prevention programs to benefit their patients and the communities they serve. These services are often geared towards services such as holistic care for the disabled, care for those with serious chronic conditions, and medication management, among others.

We are troubled by the assertion that the program is contributing to the rise in prescription medication costs and previous allegations that safety net providers are not truly serving underserved patients. As a condition for accessing the \$33.4 billion safety net drug market, pharmaceutical companies must offer discounts through the 340B program.⁹ These discounts have allowed over 35,000 individual non-profit clinics and hospitals to better serve 10 million individuals in underserved populations with low-cost medications and better health outcomes.¹⁰ In 2015, the discounts offered by pharmaceutical companies totaled \$6 billion, accounting for just 1.3 percent of total US drug sales that year.¹¹ We support transparency in the program to ensure that 340B is meeting the needs of individuals, but we cannot support any proposals that would have the effect of reducing the number of safety net providers in the program and, in turn, the number of individuals served.

As you prepare to consider changes to the 340B program, the Epilepsy Foundation urges you to reject any proposals that would have the effect of:

- Limiting access to affordable, clinically appropriate pharmaceuticals for low-income, uninsured, underinsured, or other vulnerable patients;
- Reducing access to care by cutting safety net providers out of the program; or
- Curtailing the ability of providers to use 340B savings to reach more eligible patients and provide more comprehensive services.

⁹ 42 U.S.C. Section 256(b)

¹⁰ National Conference of State Legislatures. (2017, November 13). *States and the 340B Drug Pricing Program*. Retrieved from <http://www.ncsl.org/research/health/340b-drug-pricing-program-and-states.aspx>

¹¹ DaVanzo, J.E., Dobson, A. & Murray, K. (2017, July). *Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers*. Retrieved from https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf



Lowering Out-of-Pocket Costs

Capping Out-of-Pocket (OOP) Costs for Part D Beneficiaries

In recent years, premiums, deductibles, and overall cost-sharing has increased, placing more of a burden on beneficiaries. **The Epilepsy Foundation is concerned about these increasing OOP costs for Part D beneficiaries and strongly supports an OOP cap.**

The proliferation 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 in OOP costs 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. To combat this issue, and to help ensure that beneficiaries do not face insurmountable financial hurdles just to access their medication, we believe an OOP cap would better enable beneficiaries to anticipate and meet their financial obligations.

Manufacturer Rebates Applied at the Point-of-Sale

One factor in high OOP costs is the actual drug price that beneficiaries must pay at the point of sale, particularly in instances where a beneficiary faces a coinsurance. In Part D, the price at the point of sale—during the deductible phase or a coinsurance for the medication—is based on the list price and does not account for any rebates or discounts that might reduce the overall price. Benefit designs have shifted more to coinsurance from brand name medication. This coinsurance is calculated using the list price which means beneficiaries who take medications with high rebates are not benefitting financially from them as plans are not applying the rebates to the list prices.

Given this dynamic, **we applaud the movement to incorporate rebates at the point of sale that would 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 and supports CMS' work on considering passing pharmacy direct and indirect remuneration (DIR) to the point of sale.** We look forward to



more guidance on this move to the extent that pharmacy DIR at point of sale ultimately saves money for beneficiaries.

Plan Transparency and Communication

Improving Explanation of Benefits

The Epilepsy Foundation supports providing more information in an easily accessible format to consumers. However, we believe that an end-of-year statement may not serve the needs of beneficiaries as they attempt to find a benefit package that meets their medical and financial needs. Prices change throughout the year, so unless prices are locked for the plan year, a retrospective understanding of prices may not be useful as individuals seek to determine their medical costs for the upcoming coverage year.

We urge CMS to focus on a beneficiary's ability to understand the benefits provided in a plan, along with coverage levels and OOP costs, when determining which plan best meets their needs. In addition to improve prospective and real-time price transparency, plans should be required to provide clarity and transparency on coverage and consumers' OOP 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.

CMS should work to improve beneficiaries' online shopping experience and ability to compare formularies and OOP costs across plans. As recently recommended by the National Council on Aging, Medicare Plan Finder would benefit from a comprehensive redesign and ongoing investment to remain relevant. We recommend that Medicare Plan Finder display costs with more precision, so that enrollees could view actual premium costs, coinsurance amounts in dollars, and copayments rather than percentages.

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. Occasionally, for some individuals or some therapies, it can be less expensive for a patient to purchase the medication outside of their healthcare plan. Certain insurance practices prevent pharmacists from passing information their customers about the lower price option—these policies are known as pharmacist gag clauses.

We believe pharmacists should be free to speak to customers 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 also 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.

Conclusion

The Medicare Part D program plays 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. Medicare has also been successful in expanding coverage and increasing adherence to treatment among beneficiaries, which in turn keeps costly hospitalizations and complications to a minimum.

We are encouraged by some of the proposals put forth that would help lift the burden of prescription drug costs and encourage the Department of Health & Human Services (HHS) to go forward with select changes that would improve the Medicare prescription drug benefit. However, we remain concerned about other proposals that would be harmful to patients, including changes to the protected classes, limiting the number of covered medications per class, and indication-based pricing. The Epilepsy Foundation rejects any proposal that would undermine the future success of the important Medicare Part D program.

The Epilepsy Foundation understands the monumental task ahead of balancing costs and access. If the beneficiary remains at the center of focus for proposals moving forward, we believe lasting improvements are well within reach. We appreciate your consideration of our concerns. Please do not hesitate to contact Abbey Roudebush, Government Relations Manager, at 301-918-3784 or aroudebush@efa.org with questions or follow up.

Sincerely,

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

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