



April 8, 2019

Via electronic filing at www.regulations.gov

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

RE: Removal of Safe Harbor Protections for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees Proposed Rule (OIG-0936-P)

Dear Secretary Azar,

The Epilepsy Foundation appreciates the opportunity to comment on the proposed rule amending the safe harbor regulations to the Federal anti-kickback statute regarding rebates in Medicare and Medicaid.

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) and seizures. In consultation with medical experts on our Professional Advisory Board and through our national office, nearly 50 local chapters and affiliate offices in 40 states across the country, we promote the wellbeing of children and adults affected by seizures through research into cures and treatments, educational programs, advocacy, and direct community services.

Overall, we support the administration's efforts to reduce out-of-pocket costs. We also support the changes to the anti-kickback statute as they pertain to Medicare, in order to reduce cost-sharing and ensure all discounts are passed on to the beneficiary at the point of sale. We also strongly encourage CMS to increase its oversight of Part D and Medicare Advantage plan drug benefit designs as these changes take effect, to ensure that beneficiaries benefit from the change and do not experience unintended negative consequences, such as narrower formularies; increased deductibles, coinsurance rates, and copays; more stringent utilization management; or other limitations on access.

We would like to reiterate our opposition to the changes to the Six Protected Classes policy outlined in the proposed rule *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* released in November of 2018. We believe that the change outlined in that rule, combined with the changes to the safe harbor provision, could even



more negatively impact access as plans ratchet up utilization management and reduce coverage in order to make up for losses from rebate revenue.

Finally, we oppose the changes to the safe harbor provision as they relate to Medicaid and believe that Medicaid should be carved out from the rule. Medicaid beneficiaries face little or no cost sharing, so have no way to benefit from the change. Instead, it represents a cost shift from pharmaceutical manufacturers to the states and the federal government.

Medicare

The Epilepsy Foundation applauds the administration's efforts to reduce cost sharing at the point of sale. Access and affordability of medications is a significant challenge for people living with epilepsy. Total annual healthcare costs for the 1 in 26 Americans who develop epilepsy in their lifetimes can be up to \$47,862.¹ Twenty-one percent of adults with epilepsy reported not being able to afford prescription medications within the last year.² Within Medicare Part D, in 2016, 58% of anticonvulsants (brand and generic) were on the non-preferred tier and 15% on the specialty tier. Forty-three percent of anticonvulsants (brand and generic) had coinsurance, with an average monthly coinsurance amount of \$391.³ The proliferation of high deductibles and coinsurance in Part D and Medicare Advantage has increased exposure to high cost sharing, especially as coinsurance and payments during the deductible phase are based on the list prices of medications and do not take into account rebates or other discounts that reduce the overall price.

For this reason, we support the proposal to eliminate the safe harbor protection for rebates applied after the point of sale and establish a new safe harbor for rebates and other discounts provided at the point of sale in Medicare.

In addition to supporting the administration's proposed change regarding the rebate safe harbor, we encourage the administration to take additional action to protect beneficiaries from high cost sharing and ensure that beneficiaries have access to physician-directed and person-centered courses of treatment. These actions include:

- Supporting legislation to cap beneficiary out of pocket costs in Part D, and in Medicare more broadly, and

¹ Charles U. Begley & Tracy L. Durgin, *The Direct Cost of Epilepsy to the United States: A Systematic Review of the Estimates*, 56:9 EPILEPSIA 1376-87 (2015). Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13084>.

² David J. Thurman et al., *Health-care access among adults with epilepsy: The U.S. National Health Interview Survey, 2010 and 2013*, 55 EPILEPSY BEHAV 184-88 (2015). Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/>.

³ 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.



- Increasing CMS oversight of Part D plans, including formularies, utilization management practices, plan operations, and overall out of pocket spending.

Six Protected Classes

While we appreciate this proposal's efforts to reduce out-of-pocket costs for Medicare beneficiaries, we urge the administration to be thoughtful and consider how different proposals will work together and could create unintended consequences. To that point, we would like to take this opportunity to reiterate our significant concerns with several proposals included in a NPRM released in November of 2018 titled Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P).

The Six Protected Classes policy was created 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 November 2018 NPRM would allow plans to institute even more step therapy and utilization management including for people who are currently stable on their medications, exclude new formulations, and exclude medications with prices increases beyond certain threshold.

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).⁴ 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.⁵

⁴ Devinsky, O., *Sudden unexpected death in epilepsy*, 365 NEW ENGL J MED 1801-11 (2011). Available online <https://www.nejm.org/doi/full/10.1056/NEJMr1010481>.

⁵ 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>.



If the safe harbor for rebates is eliminated, we are concerned that Part D plans may take action to make up for the loss of rebate revenue. Plans are already not following current law with regard to the protected classes. A research study conducted by Avalere has shown that under current law, many plans already exclude a significant number of drugs that technically should be included 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.⁶

When taken together, the safe harbor and protected classes proposals could encourage plans to exclude even more drugs from their formularies and create even greater incentives to inhibit access to medications through practices like utilization management. This is particularly problematic in the protected classes, which were created specifically to address the potential for discriminatory benefit design and protect access to medications in for conditions that are so difficult to treat beneficiaries truly need access to the full range of treatments on the market. We encourage CMS and OIG to consider the effects that these two rules could have together, and take actions that protect access to medications.

CMS Oversight

We strongly support greater CMS oversight of formulary design and utilization management practices in Part D. While we think this oversight is needed regardless, we think it will be even more necessary if the rule is finalized. This should include oversight of:

- Plan operations, including timeliness and resolution of appeals;
- Rate and amount of rebates following this change, especially to ensure that rebates are passed on to consumers;
- Formulary design, including discriminatory benefit design;
- Pharmacy and Therapeutic Committee membership, including consumer representation, and process and procedural requirements; and
- Utilization management tools, including but not limited to step therapy, prior authorization, medication substitution, quantity limits, and other efforts.

We are particularly concerned that the changes to the rebate system actually result in lower out of pocket cost sharing. We recommend that CMS also increase its monitoring and oversight of trends in deductibles, coinsurance, and copays to ensure that the rule results in lower costs at the point of sale and lower overall out of pocket costs. According to analysis that accompanied the rule, premiums for Part D beneficiaries will rise as part of this change. For many Part D beneficiaries, especially those living on Social Security alone, increases as low as \$5-10 per month may break already stretched budgets. We believe that for people with serious chronic conditions like epilepsy, the reduction in out-of-pocket spending will outweigh the rise in

⁶ 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.



premiums, but strongly suggest increased CMS oversight of premium increases and that CMS take action to ensure premium increases are kept at a minimum.

We are also concerned that there are no requirements or incentives other than market forces to force manufactures to lower list prices and/or continue to provide discounts and rebates that will be passed on to the consumer at the point of sale. We believe that CMS should closely monitor the actions of drug manufacturers and plans, including list prices of drugs, cost sharing faced by beneficiaries, and the rebates passed on to consumers. Especially in light of the recent announcement by CMS that the plans should submit bids under the current safe harbor structure, we encourage CMS to monitor plan premiums to ensure plans do not pre-emptively raise premiums in 2020 while also not yet passing rebates on to consumers.

Medicaid

While we support the administration's proposals for Medicare, we are concerned about the extension of the proposal into Medicaid. The pre-Affordable Care Act implementation data showed that 33% of people with active epilepsy rely on Medicaid for their health insurance and that number has likely since grown due to Medicaid expansion.⁷

Consumers have little to gain from the inclusion of Medicaid in the rule. Medicaid beneficiaries have low cost sharing amounts. According to the Kaiser Family Foundation, cost sharing amounts are typically between \$1-3, with the highest amount in the country has a cap of \$20 and only one state, Kentucky, imposes such high cost sharing.⁸ While \$20 cost sharing for a prescription is not a nominal sum for a Medicaid beneficiary, Medicaid-only and dually eligible beneficiaries do not face the deductibles and co-insurance common in Medicare Advantage and stand-alone Part D plans for Medicare-only beneficiaries. As such, they have little to gain from the inclusion of Medicaid in the rule as there is no way for rebates to be passed on to them.

While beneficiaries' cost sharing may not change, the proposal may have a negative impact on beneficiaries. The rule would eliminate the supplemental rebates that Medicaid managed care organizations (MCOs) negotiate with pharmaceutical manufacturers. While these rebates are modest compared to the statutory rebates required by the Medicaid Drug Rebate Program, they help reduce state and federal Medicaid prescription drug costs.

By eliminating supplemental rebates, Medicaid managed care plans will lose a source of revenue that is assumed when they negotiate capitation rates with the state. The analysis provided by the

⁷ David J. Thurman et al., *Health-care access among adults with epilepsy: The U.S. National Health Interview Survey, 2010 and 2013*, 55 *EPILEPSY BEHAV* 184-88 (2015). Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/>.

⁸ Kaiser Family Foundation, "Premium and Cost-Sharing Requirements for Selected Services for Medicaid Adults" Retrieved from: <https://www.kff.org/health-reform/state-indicator/premium-and-cost-sharing-requirements-for-selected-services-for-medicaid-expansion-adults/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>



Office of the Actuary (OACT) estimate that the proposed rule would increase total Medicaid spending by \$1.9 billion over the next 10 years, with \$1.7 billion in increased federal Medicaid spending at \$200 million in increased state Medicaid spending.⁹ OACT expects that 85% of the current Medicaid managed care drug rebates would no longer be negotiated between manufacturers and PBMs on behalf of Medicaid managed care plans. As a result, Medicaid managed care plans would see higher net pharmacy costs under the proposed rule.

This raises two concerns. First, we are concerned that states will not have time to re-negotiate their capitation rates and amend their state Medicaid managed care contracts by January 1, 2020. Such changes may require the actions of state legislatures, most of which will wrap up their 2019 sessions by spring or early summer, likely before the rule is finalized. This will significantly disrupt the Medicaid program in 2020 as plans may cut value added or other benefits in order to make up for lost revenue and remain solvent under a capitation rate that assumed rebate revenue.

Second, we are concerned that states will not be able to adapt to the change and negotiate directly with manufacturers for rebates that flow to the state. OACT expects only half of the existing rebates that would no longer be provided to Medicaid managed care plans would be replaced by directly negotiated supplemental rebates. After 2020, states may raise MCO capitation rates but not be able to collect rebate revenue from manufacturers. This will result in increased Medicaid costs to the states and federal government, with no advantage to beneficiaries. Instead, it is simply a cost shift from pharmaceutical manufactures to the states.

The Epilepsy Foundation urges the administration to exclude Medicaid and Medicaid managed care from the proposed rule, and instead focus on efforts to reduce cost sharing in Medicare.

We appreciate this opportunity to comment on such a historic change to the prescription drug system in our country. Please do not hesitate to reach out with any questions by contacting me at lweidner@efa.org or 301-918-3766.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura Weidner", with a long horizontal line extending to the right.

Laura Weidner
Vice President, Government Relations & Advocacy
Epilepsy Foundation

⁹ Office of the Actuary, Centers for Medicare and Medicaid Services, "Proposed Safe Harbor Regulation," August 30, 2018, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>.