



201 Chicago Avenue  
Minneapolis, Minnesota 55415

Tel: (612) 928-6100  
Fax: (612) 454-2744

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February 20, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: Draft CY 2025 Part D Redesign Program Instructions**

Dear Administrator Brooks-LaSure,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 40,000 neurologists, clinical neuroscience professionals, and students. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a doctor with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as Alzheimer's disease, stroke, migraine, multiple sclerosis, concussion, Parkinson's disease, and epilepsy.

The AAN appreciates that the Centers for Medicare and Medicaid Services (CMS) released the Draft CY 2025 Part D Redesign Program Instructions implementing critical provisions of the Inflation Reduction Act of 2022 (IRA) aimed at reducing patient out-of-pocket spending for Part D drugs. The AAN was highly supportive of provisions in the Act that reduce prices paid by neurology patients at the pharmacy counter. High drug costs pose numerous challenges for neurology patients, primarily by potentially limiting access to treatment. The annual cost of treating neurologic disease in the United States exceeds \$800 billion, and prescription drugs for neurologic conditions are some of the most expensive on the market.<sup>1</sup> Recent data also indicates that out-of-pocket costs for neurologic drugs have increased considerably in recent years.<sup>2</sup> Drugs that treat complex, chronic conditions such as Parkinson's disease, epilepsy, and migraine, and specialty drugs which may require special handling or administration, including those used for multiple sclerosis, are particularly expensive.

Since many of these chronic conditions affect patients for years, neurology patients who require these drugs are often affected by high drug costs year

<sup>1</sup> Santoro, Jonathan D, et al. "Prescription Drug Prices: An AAN Position Statement." *Neurology*, Wolters Kluwer, 9 Feb. 2024, [www.neurology.org/doi/10.1212/WNL.0000000000207105](http://www.neurology.org/doi/10.1212/WNL.0000000000207105).

<sup>2</sup> Callaghan, Brian C, et al. "Out-of-Pocket Costs Are on the Rise for Commonly Prescribed Neurologic Medications." *Neurology*, Lippincott Williams & Wilkins, 28 May 2019, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6556089/>.

after year. This is concerning given that overall specialty medication spending reached \$301 billion in 2021, a 43 percent increase since 2016, and accounts for 50 percent of total drug spending.<sup>3</sup> These prices directly impact patients and their treating providers as they work together to treat neurologic illness.

In response to the draft redesign of the Part D program, the AAN is responding to select changes outlined below.

## **20. Detailed Description of the Redesigned Part D Benefit in 2025**

The AAN supports a redesign of the Part D program to create an out-of-pocket spending maximum of \$2,000 and to remove the coverage gap phase, noting that the proposed redesign would impact an estimated 1.2 million Medicare enrollees.<sup>4</sup> Increasingly, patients have been required to absorb more and more of the cost for their drugs. As a result, medication adherence, medication rationing, and treatment compliance issues are increasingly problematic for people living with neurologic diseases. Research shows that a \$50 increase in out-of-pocket costs for prescriptions is associated with lower medication adherence of between 9 to 18 percent for dementia, Parkinson's, and neuropathy patients.<sup>5</sup> Neurologists work hard to provide high quality care for their patients, but the complexities of the prescription drug pricing system can make it difficult for patients to access necessary treatments. The AAN believes that reducing the annual out-of-pocket cost to \$2,000 and eliminating the coverage gap phase will reduce the cost of filling prescriptions and increase medication adherence. The AAN thanks the agency for the diligent implementation of this change.

## **30. Changes in True Out-Of-Pocket Costs (TrOOP)**

The AAN appreciates the agency's interpretation under the IRA of what a patient's out-of-pocket cost should be and the inclusion of supplemental coverage costs in out-of-pocket calculations for the purpose of determining when a beneficiary has reached the Part D deductible. The AAN notes that accounting practices by some Part D sponsors offering Enhanced Alternative (EA) plans may result in patients reaching their deductible slower than they otherwise would have under the standard Part D benefit. The AAN strongly supports CMS' proposal to disregard negative value accruing to a patient's out-of-pocket costs under these plans. The AAN appreciates the agency's thoughtful consideration of Medicare beneficiaries' incurred costs and encourages the agency to continue to ensure that accounting of all third-party payments is consistent with the text and policy goals of the underlying statute.

## **40. Policy for Drugs Not Subject to the Defined Standard Deductible**

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<sup>3</sup> Office of the Assistant Secretary for Planning and Evaluation, Office of Science & Data Policy. Trends in Prescription Drug Spending, 2016-2021. September 2022. Accessed November 4, 2022. <https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdptrends-prescription-drug-spending.pdf>.

<sup>4</sup> Cubanski, Juliette, et al. "Potential Savings for Medicare Part D Enrollees under Proposals to Add a Hard Cap on Out-of-Pocket Spending." The Kaiser Family Foundation, 10 Sept. 2021, [www.kff.org/medicare/issue-brief/potential-savings-for-medicare-part-d-enrollees-under-proposals-to-add-a-hard-cap-on-out-of-pocket-spending/](http://www.kff.org/medicare/issue-brief/potential-savings-for-medicare-part-d-enrollees-under-proposals-to-add-a-hard-cap-on-out-of-pocket-spending/).

<sup>5</sup> Reynolds, Evan L., PhD, et al. "Association of Out-of-pocket Costs on Adherence to Common Neurologic Medications." *Neurology*, 31 March, 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7274913/>.

The AAN appreciates the creation of the Discount Program in CY 2025 and the clarification the agency provides regarding when and how an individual becomes an “applicable beneficiary” and receives the benefit of reduced drug prices under the Discount Program. We believe that allowing TrOOP costs to factor into whether an individual has satisfied the defined standard plan deductible is an appropriate structure to this program and will allow individuals to benefit from manufacturer discounts, consistent with statutory intent.

Although welcomed, this change adds an additional factor to take into consideration when a beneficiary selects a Part D plan. As some EA plans offer lower deductibles than the statutory threshold for eligibility in the Discount Program, some beneficiaries, when enrolling, may not understand when they become eligible for discounted pharmaceuticals. The AAN is confident that the Prescription Drug Event (PDE) reporting instructions that the agency will publish later this year will provide clarifications that will ensure smooth implementation. We recommend that the agency include a requirement in the PDE reporting instructions that plans explain the Discount Program in plain language to ensure that beneficiaries understand the relative benefits of selecting different plan types and notify beneficiaries when they become eligible for discounted pharmaceuticals.

#### **120. Definition of Enhanced Alternative Benefit Design (§ 423.104(f))**

With the changes to Part D mandated by the IRA, the AAN supports the agency’s willingness to evaluate EA plan designs to ensure these plans can maintain value as an attractive alternative for the Medicare-eligible population. For these plans to offer additional benefit to Medicare beneficiaries, it is critical that the plan design is transparent and easily understood by beneficiaries, while offering value beyond the defined standard plan. The changes made to Part D under the IRA eliminate the need for many of the benefits that EA plans historically provided; accordingly, reconsideration of these plans and their benefits will be crucial to ensuring that beneficiaries receive appropriate value. The AAN recommends a requirement that EA plans publish in plain language guidance to prospective enrollees on the plan’s superior value with particular emphasis on the EA plan’s out-of-pocket difference from other standard benefit plans.

After the changes to EA plan designs take effect, the AAN is concerned that there is potential for complicated EA plan designs to create confusion that could lead Medicare beneficiaries to select a plan that does not offer them any additional value than the defined standard plan. The AAN supports CMS’ proposal to establish a requirement that the out-of-pocket value for an EA plan must be better than that of the out-of-pocket value resulting from running the formulary of that plan through the standard Part D benefit.

#### **Conclusion**

The AAN thanks the agency for the opportunity to provide comments on the updates to the redesign of the Part D program. Our members care for the millions of neurology patients enrolled in Medicare and are grateful for the agency’s thoughtful consideration of these programs. The AAN is committed to working with regulators to ensure the strength and stability of the Part D program. Please contact Matt Kerschner, the AAN’s Director, Regulatory Affairs and Policy at [mkerschner@aan.com](mailto:mkerschner@aan.com) or Cale Coppage, the AAN’s Senior

Government Relations Manager at [ccoppage@aan.com](mailto:ccoppage@aan.com) with any questions or requests for additional information.

Sincerely,

A handwritten signature in black ink that reads "Carlyne E. Jackson". The signature is written in a cursive, flowing style.

Carlyne E. Jackson, MD, FAAN  
President, American Academy of Neurology