PATIENTS FOR AFFORDABLE DRUGS™

August 17, 2026

The Honorable Mehmet Oz
Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program Proposed Rule (CMS-4215-P)

Dear Administrator Oz,

Patients For Affordable Drugs (P4AD) appreciates the opportunity to offer comments on the latest draft guidance for the Medicare Drug Price Negotiation Program.

P4AD is the only national patient advocacy organization focused exclusively on policies that lower prescription drug prices. We are bipartisan and do not accept funding from any organizations that profit from the development or distribution of prescription drugs. Since we launched nearly ten years ago, we have collected over 40,000 stories from patients from every state and every congressional district who are struggling to afford their prescription drugs because of high prices.[1] Recent polling shows that nearly nine in ten Americans — across party lines — believe prescription drugs are priced too high, and Americans overwhelmingly hold pharmaceutical manufacturers responsible for those high prices.[2,3]

The United States is experiencing a drug affordability crisis. One in three people in the U.S. cannot afford their prescription drugs. Americans unfairly pay between four and eight times more for brand-name drugs than people in other wealthy nations.[4] Older Americans are particularly vulnerable and are more likely to skip doses or forgo prescription refills due to cost, at more than double the rate of seniors in other countries.[5] In 2022, about one in five adults ages 65 and older skipped, delayed, or rationed their prescribed medicines due to cost, and 20 percent were concerned about being able to afford the prescriptions they needed.[6,7] Studies have estimated that over 1.1 million people on Medicare could die in the next decade because they are unable to afford their prescriptions.[8]

We applaud the Trump administration's continued commitment to addressing this affordability crisis through the Medicare Drug Price Negotiation Program. The historic reform allows Medicare, for the first time, to negotiate lower prices directly with pharmaceutical manufacturers for some of the highest-cost

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[1](2024, June 20). *Patients For Affordable Drugs Map*. Patients For Affordable Drugs. https://map.patientsforaffordabledrugs.org/
[2](2025, April 22). *Majority of Americans Support Lower Drug Prices, Demand Congress Act*, Fabrizio Ward. https://www.arnoldventures.org/newsroom/new-poll-majority-of-americans-support-lower-drug-prices-demand-congress-act
[3] (2026, March 31). *Public Opinion on Prescription Drugs and Their Prices,* KFF, https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/#9c8e3834-7c6d-497e-a1ea-ea26c7145100
[4](2024, February 1) *International Prescription Drug Price Comparisons*. RAND Corporation. https://www.rand.org/pubs/research_reports/RRA788-3.html
[5](2024, December 5). *Healthcare Affordability for Older Adults: How the U.S. Compares to Other Countries*. The Commonwealth Fund. https://www.commonwealthfund.org/publications/issue-briefs/2024/dec/health-care-affordability-older-adults-how-us-compares-other-countries
[6](2023, May 18). Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022. Journal of the American Medical Association. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012
[7](2022). *Healthcare in America Report*. Gallup. https://www.gallup.com/analytics/401972/healthcare-in-america-2022.aspx
[8](2020, November 18). *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost*. Council for Informed Drug Spending Analysis. https://www.cidsa.org/publications/xcenda-summary

drugs in the program. This year, nine million people on Medicare will benefit from lower negotiated prices, with millions more expected to benefit when the second round of negotiated prices takes effect on January 1, 2027. More than 85 percent of Americans support the federal government negotiating lower prescription drug prices for Medicare enrollees.[9]

We are already hearing from patients in our community who are experiencing meaningful financial relief. Evelyn from Missouri, for example, previously paid $249 a month for Eliquis — an unaffordable expense on her fixed income. Today, she pays $74 a month. Her experience demonstrates the meaningful difference lower negotiated prices can make for patients. But millions of Americans are still struggling to afford the medicines they need, and many high-cost drugs remain outside the negotiation program.

We applaud CMS's tireless efforts to implement the Medicare Negotiation Program and urge the agency to build on this historic progress. The proposed rule provides important opportunities to strengthen the program, close loopholes that would allow pharmaceutical manufacturers to delay or avoid negotiation, and ensure lower negotiated prices reach more patients as quickly as possible.

Identification of a Single-Source Drug

P4AD strongly supports the CMS-proposed changes to the identification of single-source drugs to prevent pharmaceutical manufacturers from using fixed-combination drugs to delay or evade negotiation. CMS should urgently finalize this policy to ensure the negotiation program rewards genuine innovation for patients, not industry product-hopping tactics designed to extend monopolies and keep prices high.

Without this change, a manufacturer could combine a negotiation-eligible drug with an additional ingredient that provides no significant clinical benefit and is not biologically active against the disease, then market the combination as a "new" product that resets the clock on negotiation eligibility. Pharmaceutical manufacturers already use similar product-hopping tactics in the commercial market to extend monopolies and delay lower-cost generic and biosimilar competition. The cancer drug Keytruda demonstrates why closing this loophole is important. As Keytruda approaches negotiation eligibility, its manufacturer, Merck, launched QLEX, a new subcutaneous formulation that adds hyaluronidase, an ingredient that is not biologically active against the disease. Without the proposed change from CMS, this formulation could allow Keytruda to delay negotiation for even longer without offering meaningful clinical value for patients. Without clear protections against this type of gamesmanship, manufacturers could launch new formulations shortly before their drugs become eligible for negotiation, allowing them to keep prices higher for patients for longer.

We urge CMS to finalize its proposal to more narrowly define eligibility for single-source fixed-combination drugs based on active moiety rather than route of administration. Drug manufacturers should not be able to reset the negotiation clock through minor changes that provide no significant additional clinical benefit to patients.

Preventing Reclassification From Delaying Negotiation

Existing guidance creates another potential pathway for high-cost drugs to remain outside the negotiation program for years longer than the program intended. In 2020, the definition of a biologic drug under the Biologic Price Competition and Innovation Act (BPCIA) changed. The FDA accordingly reclassified some drugs formerly approved as small molecule drugs as biologic drugs. Certain drugs such as AbbVie's Creon were filed initially as new drug applications (NDAs) and later deemed to be a biologics license application (BLA)–without the product itself changing. Under current guidance, the negotiation eligibility timeline restarts at the date of biologic reclassification rather than with the drug's initial FDA approval,

[9](2026, March 31). *Public Opinion on Prescription Drugs and Their Prices,* KFF, https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/#9c8e3834-7c6d-497e-a1ea-ea26c7145100

delaying when these drugs become eligible for lower negotiated prices. Creon demonstrates the real consequences of this policy for patients. If Creon's initial FDA approval date had been used to determine eligibility, the drug would have been eligible for the program's second round of negotiation, potentially delivering lower prices to more than 185,000 patients who rely on it.[10] Instead, patients like Heather from Texas–who pays $500 every month for her Creon prescription until she reaches the out-of-pocket cap–will have to wait an additional seven years for the drug to become eligible for negotiation.[11] We urge CMS to close this loophole and ensure that reclassification does not reset the negotiation eligibility timeline for other drugs. Patients should not have to wait years longer for lower negotiated prices simply because an existing drug is later reclassified.

Calculation of Total Expenditures

P4AD strongly supports the inclusion of Part B covered drugs in the Medicare Drug Price Negotiation Program. Spending on Part B drugs has grown significantly over the past decade, in line with growth in Part D spending and driven in large part by rising drug prices. Many high-cost treatments for conditions such as cancer and autoimmune diseases are covered under Part B, and it is critical that the expenditure data used to determine eligibility accurately capture the full amount Medicare spends on these drugs.[12] In previous guidance, P4AD raised concerns that incomplete Medicare Advantage (MA) claims data could understate total expenditures for certain Part B drugs and potentially allow high-spend drugs to escape negotiation eligibility. With more than half of Medicare enrollees now receiving coverage through MA plans, accurate accounting for this spending is essential to ensuring that drugs are appropriately identified for negotiation.[13]

We applaud CMS for working to address these concerns by explicitly including MA expenditures for Part B drugs in the definition of "total expenditures under Part B of Title XVIII". We also recognize that MA expenditure data may not always be readily available and support CMS's proposed framework for estimating these expenditures using MA encounter data when necessary. We urge CMS to continue refining this methodology to ensure that MA expenditures are fully and accurately accounted for when determining drugs' eligibility for negotiation.

Exclusions from Qualifying Single-Source Drugs

P4AD opposed the expansion of the orphan drug exclusion enacted in the "Working Families Tax Cut" legislation because it delays or prevents negotiation for high-cost drugs, forcing patients to wait longer for lower prices. As CMS implements these changes, we urge the agency to apply exclusions as narrowly as the law allows and close any potential loopholes that could give pharmaceutical manufacturers additional opportunities to delay negotiation and keep prices high at the expense of patients and taxpayers. Many drugs that benefit from the expanded exclusion are not narrowly used treatments with limited commercial markets. Drugs with multiple orphan drug indications or additional non-orphan indications can be highly profitable blockbusters taken by large numbers of patients and responsible for significant Medicare spending.[14] Keytruda, Opdivo, and Darzalex cost the Medicare program annually $6 billion, $2 billion,

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[10] (2024). *Medicare Part D Spending by Drug: Creon*, CMS. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug/data?query=%7B%22filters%22%3A%7B%22rootConjunction%22%3A%7B%22label%22%3A%22And%22%2C%22value%22%3A%22AND%22%7D%2C%22list%22%3A%5B%5D%7D%2C%22keywords%22%3A%22Creon%22%2C%22offset%22%3A0%2C%22limit%22%3A10%2C%22sort%22%3A%7B%22sortBy%22%3Anull%2C%22sortOrder%22%3Anull%7D%2C%22columns%22%3A%5B%5D%7D

[11](2026, August 6). *Medicare Quietly Gifted AbbVie's Blockbuster Drug Seven Extra Years Before Price Negotiations*, Public Citizen. https://www.citizen.org/article/medicare-quietly-gifted-abbvies-blockbuster-drug-seven-extra-years-before-price-negotiations/

[12](2021, October 7). Addressing high prices of pharmaceutical products (and other technologies) covered under Medicare. MedPAC. https://www.medpac.gov/document/addressing-high-prices-of-pharmaceutical-products-and-other-technologies-covered-under-medicare/

[13] (2026, April). *Medicare Monthly Enrollment*, The Centers for Medicare and Medicaid Services. https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment

[14] (2023, May 9). *Five-Year Sales for Newly Marketed Prescription Drugs With and Without Initial Orphan Drug Act Designation*, JAMA. https://jamanetwork.com/journals/jama/fullarticle/2804613

and $2 billion, respectively.[15] These high-grossing blockbuster drugs illustrate why it is critical that the exclusion not extend beyond what the statute requires.

We support CMS's clarification that, for drugs with mixed orphan and non-orphan indications, the timeline until negotiation eligibility must begin with the drug's first non-orphan indication. By removing any ambiguity, this approach will help prevent unnecessary gaming of the system to delay negotiation beyond what the statute currently allows.

Conclusion

The Medicare Drug Price Negotiation Program is already delivering meaningful savings for patients, yet millions of Americans continue to struggle with high prescription drug prices and urgently need relief. As CMS implements and strengthens the program, it is critical that pharmaceutical manufacturers are not able to exploit loopholes or technicalities to delay negotiation and extend their monopolies far beyond what Congress intended.

We urge CMS to finalize the proposed policies outlined above as soon as possible — patients cannot wait.

Thank you for the opportunity to provide comments. P4AD looks forward to continuing to work with CMS to lower prescription drug prices for American patients.

Sincerely,

Merith Basey MSc
Chief Executive Officer
Patients For Affordable Drugs

[15](2025, October 10). *ORPHAN Cures Act: $8.8 Billion for the Pharmaceutical Industry and Weakened Medicare Negotiation for Patients and Taxpayers*, Arnold Ventures. https://www.arnoldventures.org/newsroom/orphan-cures-act-8-8-billion-for-the-pharmaceutical-industry-and-weakened-medicare-negotiation-for-patients-and-taxpayers