

PATIENTS FOR AFFORDABLE DRUGS™

February 23rd, 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: Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (CMS-5546-P)

Dear Administrator Oz:

Patients For Affordable Drugs (P4AD) appreciates the opportunity to comment on the Center for Medicare & Medicaid Services' (CMS) in support of the notice of proposed rule making entitled "Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model".

P4AD is the only national patient advocacy organization focused exclusively on system-changing policies that lower prescription drug prices. We are bipartisan and do not accept funding from any entities that profit from the development or distribution of prescription drugs. Since we launched nine years ago, we have collected almost 40,000 stories from patients from all 50 states who are struggling to afford their prescription drugs because of high prices.¹ Recent polling shows that nearly nine in ten voters — across party lines — say prescription drugs are priced too high.²

The United States is experiencing a drug affordability crisis. One in three people in the U.S. cannot afford to pay for their prescription drugs. We agree with the administration that it is completely unfair for Americans to pay at least four times more for brand-name drugs than people in comparable wealthy nations.³ 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 in other countries.⁴ About one in five adults ages 65 and older either skipped, delayed, or rationed their prescribed medicines in 2022 due to cost.⁵ In that same year, 20 percent of adults 65 and older were concerned about being able to afford their needed prescriptions.⁶

We support the administration's continued dedication to addressing the drug price affordability crisis and strongly encourage the use of mandatory models to lower the price of prescription drugs and hold

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(2024, February 1) *International Prescription Drug Price Comparisons*. RAND Corporation. https://www.rand.org/pubs/research_reports/RRA788-3.html

⁴(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>

⁵(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>

⁶(2022). *Healthcare in America Report*. Gallup. <https://www.gallup.com/analytics/401972/healthcare-in-america-2022.aspx>

pharmaceutical corporations accountable. P4AD applauds the administration's continued efforts to reduce drug prices for America's seniors, especially in utilizing Medicare's statutory powers to negotiate lower drug prices. The selected drugs in the Medicare Drug Price Negotiation Program (MDPNP) make up \$27 billion in total Medicare Part B and Part D expenditures and negotiated prices will deliver savings to more than 1.7 million Americans on Medicare.⁷ We are especially heartened to see that negotiated prices for the second round were 44 percent lower than the prices previously paid by Medicare.⁸ We also support the administration's continued efforts to protect the historic law in the courts.

Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model has the potential to reduce costs for patients on Medicare who take Part D eligible drugs. Medicare Part D spending has more than doubled in the last decade, heavily driven by increasing drug prices and increased utilization. This spending is concentrated among top-selling specialty drugs that make up 5.6 percent of prescriptions but 34.6 percent of spending.⁹ We support the administration's continued efforts to reign in prices under Part D and deliver financial relief to the 58.4 million Americans who enrolled in Medicare Part D and lower program costs for taxpayers and the federal government.¹⁰ In particular, we commend CMS for including the reduced beneficiary coinsurance, ensuring that Medicare beneficiaries directly share in the savings generated by lower drug prices. Additionally, structuring the GLOBE model parameters to place financial accountability on manufacturers rather than providers mitigates the risk of the model interfering with clinically appropriate prescribing decisions. We have also identified some opportunities for improvement or clarification with elements of the model design to ensure the model's success.

International Pricing Benchmark Design

In the notice of proposed rule making CMS outlined that the Most Favored Nation (MFN) price would be calculated using either a benchmark of international pricing data available to CMS or through optional manufacturer submitted pricing data. P4AD understands the difficulties with accessing and verifying the international pricing data necessary to create MFN benchmarks and appreciates the administration's efforts toward minimizing potential industry influence. We are concerned that reliance on industry-submitted pricing data creates an opportunity for pharmaceutical manufacturers to game the system. Unless information is independently verified there is a real risk of manufacturers selectively reporting or manipulating data to evade lower pricing benchmarks. We encourage CMS to prioritize the pricing benchmark pathway that utilizes existing international drug pricing data to best ensure the benchmark accurately reflects international pricing in a timely manner. We also urge CMS to develop strategies for minimizing manufacturer influence on data used to establish drug pricing benchmarks such as utilizing multiple sources to develop a singular benchmark or utilizing pricing data prior to the announcement of the GUARD model.

Proposed Model Exclusion Criteria

⁷(2026, January 27). *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028*, Centers for Medicare and Medicaid Services. <https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf>

⁸ (2026, February 4). *The Growing Success of Medicare Drug-Price Negotiation*, New England Journal of Medicine. <https://www.nejm.org/doi/full/10.1056/NEJMp2517584>

⁹(2024, December 30). *Concentration of spending and share of specialty drug spending in Medicare Part D over a 10-year period*, National Institute of Health. <https://pmc.ncbi.nlm.nih.gov/articles/PMC11607209/>

¹⁰(2025, October 7). *A Current Snapshot of the Medicare Part D Prescription Drug Benefit*, KFF. <https://www.kff.org/medicare/a-current-snapshot-of-the-medicare-part-d-prescription-drug-benefit/>

The proposed model outlines several criteria for a drug being excluded from the model so as to not interfere with other CMS Innovation Center models or drug pricing programs such as the MDPNP. The proposed rule does have a very broad exclusionary criteria of “...interactions with other CMS Innovation Center models or for any other reason...” While not explicitly mentioned in the outline, pharmaceutical manufacturers have made public statements that companies involved in pricing agreements with the administration “will not be subject to further pricing mandates”, which suggests that these companies will not be required to participate in this model.¹¹

Excluding the sixteen manufacturers who reached private agreements with the administration from participation in this model would not only significantly decrease the projected savings of this model but would also create an additional opportunity for manufacturers to manipulate the system in their favor. These MFN agreements are private and voluntary. As a result they lack a legal mechanism for enforcing lower prices, patients and taxpayers are forced to trust the “goodwill” of an industry with a long history of price-gouging Americans. Many of the manufacturers that have entered into MFN deals produce some of the most expensive, blockbuster drugs covered by Medicare Part D. These high-cost drugs including Humira, which is manufactured by Abbvie, and Vyndamax, which is manufactured by Pfizer, would otherwise be eligible for GUARD.^{12,13}

Allowing voluntary and unenforceable deals to exempt manufacturers of the most expensive drugs to Part D would limit the potential impact and savings of the model. We strongly urge the administration not to exempt any manufacturers from the GUARD model due to existing MFN agreements with the administration. We also urge the administration in future guidance to publish transparent methodology outlining which drugs will be included in the model and which drugs will be exempt. For drugs that will be exempt we ask CMS to outline the rationale for their exclusion from the model.

Mitigating Potential Cost Increases for Patients

While the GUARD model is estimated to deliver \$14.1 billion in savings, the model is also estimated to increase potential cost-sharing and premiums by \$3.6 billion.¹⁴ We urge CMS to track any potential impacts the proposed model has on patient out-of-pocket costs, premiums, and utilization management techniques that may restrict seniors’ access to drugs included in the model. At a time where nearly half of Americans are concerned they won’t be able to afford their necessary healthcare, it is critical CMS mitigates any potential increases in senior’s healthcare costs.¹⁵ Seniors are also more likely to be taking multiple prescription drugs, with patients enrolled in Part D taking on average 4.7 prescription drugs a month.¹⁶ We also urge CMS to create opportunities for patient engagement throughout the development

¹¹ (2025, November 6). *Lilly and U.S. government agree to expand access to obesity medicines to millions of Americans*, Eli Lilly. <https://investor.lilly.com/news-releases/news-release-details/lilly-and-us-government-agree-expand-access-obesity-medicines>

¹² (2026, January 11). *Abbvie and Trump Administration Reach Agreement to Improve Access and Affordability for Americans*, Abbvie. <https://news.abbvie.com/2026-01-12-Abbvie-and-Trump-Administration-Reach-Agreement-to-Improve-Access-and-Affordability-for-Americans>

¹³ (2025, September 30). *Pfizer Reaches Landmark Agreement with U.S. Government to Lower Drug Costs for American Patients*, Pfizer. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reaches-landmark-agreement-us-government-lower-drug>

¹⁴ (2025, December 23). *Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model*, The Federal Register. <https://www.federalregister.gov/documents/2025/12/23/2025-23705/guarding-us-medicare-against-rising-drug-costs-guard-model>

¹⁵ (2025, November 18). *How Do Americans Experience Healthcare in Their State?*, Gallup. <https://news.gallup.com/poll/698042/americans-experience-healthcare-state.aspx>

¹⁶ (2025, July 1). *Health Care Spending and the Medicare Program*, The Medicare Payment Advisory Committee.. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC-1.pdf

and the duration of the model to ensure that seniors are not burdened with increased costs or barriers to accessing their prescription drugs.

Rebate Structures and Severability

Further, since this model builds upon the framework for collecting inflation rebates outlined in the Inflation Reduction Act, P4AD is concerned about the potential risk of legal challenges from manufacturers and/or injunctions relating to the proposed model that may prevent Medicare from collecting inflation rebates. Given this concern, we fully support the incremental rebate approach for rebate invoicing and urge CMS to include severability policies in further guidance. These policies would ensure that Medicare is still able to exercise its statutory power to collect inflation rebates if aspects of the proposed model are found to be unenforceable.

Potential Interference with Medicare Negotiation Program

The proposed GUARD model is temporary and would deliver savings only to 25 percent of the Medicare Part D enrollee population. After the five year period is over, the model would either need to be extended for another temporary time period or enshrined into law by Congress to ensure these savings are permanent. The 2022 prescription drug law is already delivering billions in savings to millions of patients and taxpayers and is protected by statute.¹⁷ Patients fought hard for this law and are already seeing lifesaving financial relief. Eligible drugs under the proposed GUARD model would be the same subset of high-cost and high-spend Part D drugs eligible for Medicare negotiation. As such, we are concerned that the proposed model could potentially interfere with drug eligibility for future rounds of Medicare negotiation. We urge the administration to mitigate opportunities for pharmaceutical manufacturers to game the model to prevent delay or interference with Part D drug eligibility for the Medicare negotiation program. American seniors skip doses or avoid filling their prescriptions by at least double the rate of other countries and they cannot afford to wait for financial relief.¹⁸

P4AD thanks CMS for the opportunity to provide comments and looks forward to continued engagement in the coming months.

Sincerely,



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Patients For Affordable Drugs

¹⁷ (2025, November 25). *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027*, Center for Medicare and Medicaid Services. <https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf>

¹⁸ (2024, December 4). *Health Care 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>