



February 23, 2026

The Honorable Mehmet Oz, M.D.  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
PO Box 8016  
Baltimore, MD 21244-8016.

*Submitted electronically via regulations.gov*

### **CMS-5546-P: Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model**

Dear Administrator Dr. Oz,

As a leading national, non-partisan voice for health care consumers, Families USA appreciates the opportunity to respond to the proposed *Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model*. Based on our analysis and commitment to ensuring that Medicare beneficiaries have access to affordable, lifesaving and sustaining medications and protecting the long-term sustainability of the Medicare program, we have key concerns about the model and must oppose without the significant changes we outline

The high costs of prescription drugs are a core driver of the nation's current affordability crisis, with escalating consequences for beneficiaries and the federal government alike. In 2022, U.S. brand name drug prices were more than 3 times higher than those in comparable countries, even after rebates.<sup>i</sup> Skyrocketing drug prices drove \$146 billion in Medicare Part D spending for 53.1 million enrollees in 2024, accounting for roughly 31% of total U.S. prescription drug spending.<sup>ii</sup> Too often, these unaffordable prescription drug prices force American seniors and aging adults to skip taking their medications or filling prescriptions due to the cost, underscoring the urgent need to improve prescription drug affordability and access.<sup>iii</sup>

The proposed *GUARD Model*, along with the proposed *Global Benchmark for Efficient Drug Pricing (GLOBE) Model* pertaining to Medicare Part B drugs, are part of this Administration's broader policy agenda to use international benchmarking as a tool to lower Medicare drug spending and beneficiary costs. At their core, these proposed mandatory models seek to test whether rebates tied to international prices will lower prescription drug spending rather than the direct negotiation of maximum fair prices. Specifically, the Centers for Medicare & Medicaid Services (CMS) proposes to exercise its authority under Section 1115A of the Social Security Act to waive requirements related to the inflation rebate calculations set forth in the Inflation Reduction Act that require rebates for Medicare Part B and D drugs when prices for rebatable drugs exceed the rate of inflation. These models propose to replace the current domestic benchmark used to calculate manufacturer rebates with a benchmark derived from international pricing information.

**While we support broader efforts to test new payment approaches to reduce the cost of prescription drugs and increase Medicare sustainability, we have significant concerns that the GUARD model as proposed would increase cost-sharing for Medicare beneficiaries and**

**introduce a layer of administrative complexity which is inconsistent with the stated goals of the model, ultimately undermining access to Part D benefits. As a result, we oppose the proposed model in its current form and offer comments below to highlight and address our major concerns.**

### **Section G. Determination of the GUARD Model Applicable International Benchmark**

#### ***Cost-Sharing and Out-of-Pocket Costs: Patients Need Relief, Not Potential Increases in Costs***

CMS proposes tying mandatory rebates to international benchmarks when U.S. drug prices exceed those benchmarks. However, evidence, including CMS's own regulatory analysis, suggests that manufacturer rebate obligations can create incentives for companies to increase list prices to offset rebate exposure.<sup>iv</sup> As CMS acknowledges, changes in list prices may shift the balance between GUARD rebate liability and other rebate obligations, thereby creating incentives for manufacturers to raise prices across payers to counteract lost revenue. Higher list prices may directly increase beneficiary cost-sharing for drugs, subject to coinsurance, causing Medicare beneficiaries to face higher out-of-pocket expenses and potentially forgo life-saving treatment. Such cost increases would be particularly problematic for those with chronic conditions.

To that end, Families USA is deeply concerned that Center for Medicare and Medicaid Innovation's (CMMI) own "cost-savings projections" for the GUARD model show it is unlikely to reduce out-of-pocket costs for Medicare Part D beneficiaries and, in fact, may *increase* beneficiary costs during the model period. Specifically, CMMI estimates that the model would reduce Medicare spending by approximately \$14.1 billion over its five-year test period but does not project that any of those savings will be directly passed through to beneficiaries at the point of sale.<sup>v</sup>

We agree about the importance of reducing Medicare spending and improving the program's long-term sustainability. However, such efforts must be paired with meaningful cost-sharing reductions for health care consumers, particularly given the ongoing healthcare affordability crisis.<sup>vi</sup> Cost-sharing reductions are most meaningful when they occur at the point of sale through lower copayments or coinsurance when beneficiaries fill a prescription.<sup>vii</sup> Importantly, rebates that accrue to Medicare or to plan sponsors often do not translate into lower out-of-pocket costs for beneficiaries unless there are explicit mechanisms requiring those savings to be passed through at the pharmacy counter.<sup>viii</sup> Without such requirements, savings generated at the federal level may only be absorbed into premium stabilization, plan margins, or federal budget offsets, leaving out the need to directly reduce financial barriers to prescription drug access for Medicare beneficiaries.

#### ***Premium Stability and Benefit Design: Guardrails Needed to Prevent Destabilization of Part D***

Beyond beneficiary cost sharing, the proposed GUARD model raises substantial concerns regarding premium stability and benefit design volatility within Medicare Part D. Part D premiums are established through a competitive bidding process in which plan sponsors must project expected drug costs, rebate flows, federal reinsurance payments, and enrollee liability.<sup>ix</sup> The GUARD model introduces significant new sources of actuarial uncertainty, including: 1) the application of international reference-based benchmarks; 2) the interaction between GUARD rebates and existing Inflation Reduction Act manufacturer discount obligations; and 3)

unpredictable manufacturer behavioral responses to benchmark pricing. When plans cannot reliably project net drug costs, they typically build in risk margins to protect against financial exposure.<sup>x</sup> This dynamic could result in higher premiums for all enrollees, including for those who do not use the prescription drugs included in the model, as plans potentially guard against some level of volatility introduced by the model.

Further, because GUARD would be tested in a randomized 25 percent sampling of geographic areas, multi-state Part D sponsors may face region-specific pricing exposure. In other words, geographic variability could complicate the bidding process and could create enrollment shifts among beneficiaries with high drug spending, potentially distorting risk pools and increasing the risk of adverse selection. Without appropriate guardrails to address premium stabilization and shifting risk, this uncertainty could translate into premium increases rather than premium reductions.

### ***Administrative Complexity and Prescription Drug Formulary Placement: Instability Could Lead to Medications Moving to Higher-Cost Tiers***

The proposed model also raises significant concerns regarding administrative complexity and formulary placement. CMMI proposes two approaches for calculating the alternative international price benchmark under GUARD and applies them to a broad set of drugs across multiple therapeutic classes. Under Method I, CMMI would identify the lowest country-level average price among 19 non-U.S. OECD countries that meet specified purchasing power parity and gross domestic product (GDP) criteria. CMS proposes using three different data sources including IQVIA MIDAS data – a pharmaceutical industry standard database including sales, volume and patient level-data across 95 countries and more than 600 diseases - to determine the lowest average country-level price and to establish that figure as the international benchmark.<sup>xi</sup> Under Method II, manufacturers may voluntarily submit international net price data, after which CMMI would calculate an “across-country” average net price. CMS proposes selecting the higher of the two benchmark prices derived from Method I or Method II. If manufacturers do not submit data, CMS would default to Method I.

Administering these methodologies across Part D plans introduces significant operational complexity. Current rebate calculations rely on domestic statutory formulas tied to average manufacturer price (AMP) and inflationary benchmarks.<sup>xii</sup> By contrast, GUARD requires integration of international pricing datasets, optional manufacturer submissions, reconciliation across two methodologies, and interaction with existing rebate and discount programs. Plan sponsors would need to update claims adjudication systems, actuarial projections, formulary tiering models, and compliance reporting infrastructure. These added layers of pricing calculation further complicate an already highly complex Medicare program.

From a formulary perspective, uncertainty regarding net pricing and potential list price increases could incentivize plans to mitigate exposure by re-tiering affected drugs, increasing coinsurance percentages, or imposing additional utilization management tools such as prior authorization or step therapy. Even if aggregate Medicare spending declines, beneficiaries could experience higher out-of-pocket exposure if drugs move to specialty tiers or face more restrictive coverage conditions. Moreover, because GUARD excludes certain drugs subject to separate drug negotiation processes, plans may face unbalanced pricing signals within therapeutic classes, potentially undermining existing evidence-based formulary placement decisions.

**As a result, we oppose the GUARD model in its current form and offer the following recommendations for CMS to address our concerns and incorporate guardrails to protect beneficiaries and preserve market stability, including:**

- Require a significant portion of the model savings be passed through to lower out-of-pocket consumer costs at the point of sale;
- Develop concrete premium stabilization protections during the initial implementation period to help create more predictability for Part D plans on net drug costs under the model and shield consumers from higher premiums;
- Create specific performance metrics that assess the impact of any changes to beneficiary cost-sharing to better understand how the model addresses Medicare sustainability as well as beneficiary affordability;
- Establish safeguards against mid-year formulary changes driven by benchmark recalculations.

Without these additional protections, the GUARD model risks increasing premium volatility, exacerbating formulary complexity, and shifting financial burden onto Medicare beneficiaries. These outcomes that would be inconsistent with the model's stated goals of improving affordability and access and would undermine the promise of Medicare coverage to our nation's seniors.

We would also be remiss if we did not echo the widespread concern that certain pharmaceutical manufacturers could be exempted from participating in both the GLOBE and GUARD Models, pursuant to alternative drug pricing agreements they struck directly with the White House over the last several months. While that approach is not explicitly articulated within the proposed model, such an exemption would have significant and detrimental impact on meaningful drug pricing reform. Such exemptions could mean that certain companies could be released from requirements to participate in these mandatory models, leaving consumers who rely on their medications having to foot higher costs at the pharmacy counter. We urge CMMI to clarify that no such exemptions exist and would not be allowed under this proposal.

Thank you again for the opportunity to share our feedback on the proposed GUARD Model. Please don't hesitate to reach out to Hazel Law, Policy Analyst at [hlaw@familiesusa.org](mailto:hlaw@familiesusa.org) with any questions or concerns.

Sincerely,



Sophia Tripoli  
Senior Director of Health Policy

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- <sup>i</sup> ASPE, “Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability,” HHS, January 31, 2024. <https://aspe.hhs.gov/reports/comparing-prescription-drugs>.
- <sup>ii</sup> “How much does Medicare cost the federal government,” USAFacts. <https://usafacts.org/answers/how-much-does-medicare-cost-the-federal-government/>; Juliette Cubanski and Anthony Damico, “Key Facts About Medicare Part D Enrollment, Premiums, and Cost Sharing in 2024,” KFF, July 2, 2024. <https://www.kff.org/medicare/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2024/>; CMS, “National Health Expenditures 2024 Highlights,” HHS. <https://www.cms.gov/files/document/highlights.pdf>
- <sup>iii</sup> Grace Sparks, Ashley Kirzinger, Alex Montero, et al, “Public Opinion on Prescription Drugs and Their Prices,” KFF, October 4, 2024. <https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/>; See also, Stacie B. Dusetzina, Robert J. Besaw, and Christine C. Whitmore, “Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022,” JAMA, May 18, 2023. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012>.
- <sup>iv</sup> 90 FR 60338, “CMS Proposed Rule, Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model,” Federal Register, 2025. <https://www.federalregister.gov/documents/2025/12/23/2025-23705/guarding-us-medicare-against-rising-drug-costs-guard-model#h-108>
- <sup>v</sup> 90 FR 60338, Table C4, <https://www.federalregister.gov/documents/2025/12/23/2025-23705/guarding-us-medicare-against-rising-drug-costs-guard-model#h-133>.; see also, 90 FR 60338, “CMS Proposed Rule, Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model,” Federal Register, 2025. <https://www.federalregister.gov/d/2025-23705/p-74>
- <sup>vi</sup> Grace Sparks, Lunna Lopes, Alex Montero, et al, “Americans’ Challenges with Health Care Costs,” KFF, January 29, 2026. <https://www.kff.org/health-costs/americans-challenges-with-health-care-costs/>.; See also, “Lowering Prescription Drug Costs,” National Conference of State Legislatures, December 1, 2022. <https://www.ncsl.org/health/lowering-prescription-drug-costs>.
- <sup>vii</sup> Yao Ding and G. Edward Miller, “The Impact of Sharing Drug Rebates at the Point of Sale on Out-of-Pocket Payments for Enrollees in Employer Sponsored Insurance,” Value in Health, February 2023. <https://www.sciencedirect.com/science/article/pii/S1098301522021416#:~:text=Across%204%20simulations%20with%20different,drugs%20that%20face%20significant%20competition>; See also, “Lowering Prescription Drug Costs,” National Conference of State Legislatures, December 2022. <https://www.ncsl.org/health/lowering-prescription-drug-costs>.
- <sup>viii</sup> CMS, “Medicare Part D- Direct and Indirect Remuneration (DIR),” CMS, January 19, 2017. <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>
- <sup>ix</sup> Medicare Payment Advisory Commission, Part D Payment System, MedPAC, 2024.
- <sup>x</sup> “Issue Brief: Drivers of 2026 Premium Changes,” American Academy of Actuaries, July 2025, <https://actuary.org/wp-content/uploads/2025/07/brief-Drivers-2026-Premium.pdf>; See also, “Issue Brief: Drivers of 2018 Health Insurance Premium Changes,” American Academy of Actuaries, July 2017, <https://actuary.org/drivers-of-2018-health-insurance-premium-changes/#:~:text=However%2C%20the%20extent%20of%20the,the%20risk%20pool%20is%20undetermined.&text=Potential%20changes%20to%20the%20ACA,withdraw%20from%20the%20individual%20market>.
- <sup>xi</sup> 90 FR 60338, “CMS Proposed Rule, Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model,” Federal Register, 2025. <https://www.federalregister.gov/documents/2025/12/23/2025-23705/guarding-us-medicare-against-rising-drug-costs-guard-model#h-108>
- <sup>xii</sup> Medicare Payment Advisory Commission, Part D Payment System, MedPAC, 2024.