



February 20, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on the proposed rule to implement the Guarding U.S. Medicare Against Rising Drug Costs Model [File code CMS-5546-P]

Dear Administrator Oz,

Thank you for the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to implement the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model published in the Federal Register on December 23, 2025.

Arnold Ventures (AV) is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. As a philanthropy, we do not accept funding from industry or have a financial stake in policy outcomes. Our work within the health care sector is driven by the recognition that the system costs too much and fails to adequately care for the people it serves. Our work spans a range of issues including commercial-sector prices, provider payment incentives, prescription drug prices, FDA accountability, Medicare sustainability, and Medicaid.

We applaud CMS staff for your efforts to lower prescription drug prices for patients and taxpayers. We are supportive of using inflation penalties to lower drug prices for patients and taxpayers, and understand why CMMI proposes to use that mechanism to lower spending in Medicare Part D. As conveyed in our comment letter submitted February 20, 2026 on the GLOBE Model, AV is supportive of CMMI's proposal to use the inflation penalties lower drug prices in Medicare Part B if the model is severable from the Medicare inflation penalties created by the Inflation Reduction Act (IRA). However, given the complexity of the Part D program coupled with the limitations of making administrative changes to the Part D inflation rebate established in the IRA, we are not clear whether it is possible for this approach to lower costs to the federal government without significantly raising costs to beneficiaries and to Medicare Part D plans. For this reason, **we do not support the implementation of the GUARD Model as proposed.**

The design of the demonstration increases patient out-of-pocket (OOP) costs and Part D plan premiums in several ways.

- *There would be little incentive for manufacturers to share GUARD price concessions with Medicare Part D plans.¹* The way that GUARD price concessions are structured would disincentivize manufacturers from offering larger rebates in exchange for preferred formulary placement on GUARD drugs. While manufacturers would likely prefer to give price concessions directly to Medicare Part D plans because they receive something in return, like better formulary placement, it is uncertain whether a demonstration using the GUARD Model framework (which limits participation to a small share of beneficiaries to participate) can be effectively designed and

implemented administratively to achieve this goal. The GUARD model would not demonstrate the impact that this policy would have on Part D plans and beneficiaries if it were at scale.

- ***A significant share of the demonstration's federal savings would be offset by higher negotiated prices (maximum fair prices) under the IRA for top selling Part D drugs.*** These higher maximum fair prices would lead to higher Part D plan bids, higher federal direct subsidy payments, as well as higher premiums and higher OOP costs for Part D beneficiaries. Overall, the GUARD Model would worsen the rapid increase in per capita drug costs faced by Part D plans that have caused Part D bids to increase in recent years.
- ***Manufacturers would be incentivized to increase the prices charged to wholesalers and pharmacies for GUARD Model drugs with a large Medicare market share.*** The GUARD Model rebate would be based on a list price, the Wholesale Acquisition Cost (WAC). It is not based on actual transaction costs that occur throughout the supply chain. This means that manufacturers could increase prices to pharmacies and wholesalers faster than inflation without increasing the rebate amount owed under the GUARD Model.²

Should CMS proceed with the GUARD Model, AV recommends an alternative approach for calculating and verifying an international benchmark that approximates net prices in the reference countries. The GUARD Model uses methods for calculating the international benchmark that are similar to the benchmark methods used in the GLOBE model, which rely on net pricing data voluntarily submitted by manufacturers to CMS. In our comment letter on the GLOBE Model, AV recommended an alternative approach that is also applicable to the Method II international benchmark as described in the GUARD model. The advantage of our recommended approach is that it relies on data sources that are accessible to CMS and not reliant on manufacturer submissions. For further details on this approach, see the comment letter submitted by AV to CMS on the GLOBE Model on February 20, 2026.

Additionally, should CMS finalize this model, we ask that it clarifies whether participation in other CMMI models or Most Favored Nation deals would allow manufacturers to opt out of the GUARD Model. Understanding this key detail will help stakeholders assess the impact of GUARD on patients and taxpayers.

Thank you for your consideration of our comments. Comments were prepared by Anna Anderson-Cook, PhD, Senior Fellow at Arnold Ventures with assistance from Kate Young, Director of Health Care at Arnold Ventures, Andrea Noda, MPP, Vice President of Health Care at Arnold Ventures, and Mark E. Miller, PhD, Executive Vice President of Health Care at Arnold Ventures. Please contact Mark E. Miller at mmiller@arnoldventures.org or Andrea Noda, MPP at anoda@arnoldventures.org with any questions.

Sincerely,

Andrea Noda
Vice President of Health Care
Arnold Ventures

¹ Both stand-alone Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MAPDs) would be affected.

² This is partly because the WAC price is higher than the amount that pharmacies are paid by Part D plans. See CBO. (2021) A Comparison of Brand Name Drug Prices Among Selected Federal Programs. <https://www.cbo.gov/publication/56978>