



February 23, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via regulations.gov

Re: Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model [CMS-5546-P]

Dear Administrator Oz:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model [CMS-5546-P]

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

The Academy of Managed Care Pharmacy (AMCP) appreciates CMS's efforts to address rising drug costs through the proposed GUARD Model. While the model reflects an important policy objective, several aspects raise concerns for managed care pharmacy related to operational feasibility, pricing dynamics, and the extent to which anticipated savings will translate into meaningful benefits for plans and beneficiaries. The following comments highlight key areas where additional clarity and refinement are needed.

Administrative and Operational Burden

The proposed GUARD Model introduces operational complexity through its reliance on international reference pricing benchmarks and multi-step rebate calculations tied to Medicare net prices. While the rebate obligation is imposed on manufacturers, the data inputs and reconciliation processes underlying the model are inextricably linked to Part D plan operations, including direct and indirect remuneration (DIR) reporting, claims adjudication, and multi-year reconciliation. These processes would require substantial systems changes, auditing, and ongoing coordination among stakeholders.

This complexity creates material compliance risk and administrative burden without clear alignment to existing Part D operational workflows. Plans would need to account for rebate mechanisms largely outside their control, yet with implications for bid development, actuarial assumptions, and financial reconciliation. CMS should consider whether these burdens are proportionate to the expected savings and consider additional simplification or alignment with existing Part D reporting frameworks to reduce unnecessary operational strain.

International Price Benchmarking

The Model's reliance on international pricing data raises concerns about the accuracy and reliability of the benchmarks used to calculate rebates and payment adjustments. Publicly available international prices often do not reflect confidential discounts, managed entry agreements, or other market-specific factors. Misaligned benchmarks could result in over- or under-estimated rebates, undermining plan financial modeling, actuarial forecasting, and budgeting for Part B drug spending.

To improve the reliability of international price benchmarks, CMS could consider incorporating validation or sensitivity-testing mechanisms and providing greater transparency around data sources and assumptions. Allowing for periodic recalibration would help ensure that payment adjustments better reflect real-world pricing conditions and support more interpretable, policy-relevant evaluation findings.

Interaction With Existing Rebate Structures and Incentives

The proposal to waive the standard Part D inflation rebate when the GUARD rebate is greater raises concerns about overlapping or conflicting incentive structures. Managed care pharmacy relies on predictable and transparent pricing and rebate dynamics to support formulary development, utilization management strategies, and beneficiary cost-sharing design. Introducing an international benchmark-based rebate on top of existing rebate frameworks risks distorting manufacturer pricing strategies and undermining the stability of current negotiations.

Manufacturers may respond to the GUARD Model by adjusting list prices, reducing or reallocating commercial and Part D rebates, or altering launch and lifecycle pricing strategies, complicating formulary competition. These responses could erode the effectiveness of existing market-based tools that managed care pharmacy uses to secure value and manage utilization. CMS should clarify how the GUARD rebate is expected to interact with existing Part D rebate structures and consider safeguards to avoid unintended pricing behavior that increases net costs or reduces plans' competitive leverage.

Limited Direct Benefit Realization for Plans and Patients

Although the GUARD Model is intended to generate Medicare program savings, it is unclear whether these savings will translate into lower premiums, reduced beneficiary out-of-pocket costs, or enhanced benefit offerings. Reforms that increase administrative complexity or disrupt pricing dynamics should be closely evaluated against their ability to deliver tangible beneficiary and plan-level benefits.

If GUARD rebates primarily accrue to the federal government and are not reflected in plan-level net costs, plans may be unable to pass savings through to beneficiaries. This disconnect could undermine stakeholder support and limit its real-world impact on affordability. CMS should

provide greater transparency regarding how GUARD-related savings will flow through Part D and consider mechanisms to ensure that any savings achieved benefit beneficiaries at the point of sale or through reduced premiums.

Access

The GUARD Model raises important questions about how international reference pricing–based rebate incentives may affect formulary design, utilization management, and patient access. AMCP supports the use of evidence-based tools to promote appropriate utilization and value-based coverage decisions. However, abrupt or poorly aligned pricing incentives can unintentionally restrict access to clinically appropriate therapies or shift costs to other parts of the benefit.

While CMS proposes beneficiary protections and monitoring, additional clarity is needed regarding how access safeguards will be implemented and enforced in practice. CMS should ensure that the model does not incentivize manufacturers to limit distribution, delay launches, or otherwise restrict availability of therapies in GUARD regions. Moreover, CMS should explicitly recognize the role of managed care pharmacy in using formulary and utilization management tools to protect access while maintaining affordability and avoid policies that inadvertently constrain these tools or undermine clinically nuanced decision-making.

Conclusion

AMCP encourages CMS to address these concerns by aligning the GUARD Model more closely with existing Part D operations, ensuring transparency and predictability in pricing and rebate structures, and establishing clear pathways for savings to benefit beneficiaries. Thoughtful refinements in these areas would help mitigate unintended consequences while preserving managed care pharmacy’s ability to support affordability, access, and high-quality care.

AMCP appreciates your consideration of AMCP’s concerns and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP’s comments or would like further information, please contact Vicky Jucelin, AMCP’s Manager of Regulatory Affairs, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,



Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer