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Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5546-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model

Dear Administrator Oz,

The AAMC[1] welcomes this opportunity to comment on the proposed rule entitled "**Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model**," 90 FR 60338 (December 23, 2025), issued by the Centers for Medicare & Medicaid Services (CMS or the agency).

CMS and the administration have recently taken multiple approaches to lowering drug costs following an executive order issued April 2025.[2] Through the Center for Medicare and Medicaid Innovation (CMMI), the agency is proposing a new mandatory model, the GUARD Model, targeting the cost of certain drugs paid under Medicare Part D if their prices exceed those paid in economically comparable countries. The model seeks to reduce the costs of these drugs by requiring drug manufacturers to provide a rebate for Part D drugs to the Medicare Supplementary Medical Insurance Trust Fund for drugs subject to the model whose prices are greater than the international drug pricing benchmark. The agency plans to use the existing mechanism for the

[1] The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 162 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 Canadian medical schools accredited by the Committee on Accreditation of Canadian Medical Schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

[2] Executive Order: Lowering Drug Prices By Once Again Putting Americans First (April 15, 2025)

Medicare Part D Inflation Rebate Program by using a benchmark based on international pricing information rather than the current domestic benchmark.[3]

The AAMC commends the administration for its work towards lowering U.S. drug prices. Drug costs continue to rise with year-over-year drug expenses increasing fourteen percent in November 2025 compared to previous years, making drug expenses the main driver of expense growth for hospitals.[4] As drug costs rise, patients may experience increased costs to purchase drugs, creating additional challenges for medication adherence as well as increasing costs for providers and further straining already scarce resources. We agree with the administration's goal of lowering prescription drug costs; however, we have a few concerns with the proposed GUARD Model, including creating burden and confusion for providers and other stakeholders on the implementation and interaction with other drug pricing policies, negatively impacting patient safety and other drug discount programs, and failing to address affordability concerns for patients directly. Adequately addressing drug costs is imperative to the success of the administration's goals of making health care more affordable and will increase patients' access, leading to improved patient outcomes. **While we commend CMS' attempt at tackling this issue, we urge CMS to not finalize the GUARD model until it has conducted a thorough analysis of any unintended consequences of the model, evaluates how the model would interact with other drug pricing policies, and has addressed how to implement the model in a way that minimizes imposing administrative burden on providers.**

Limit Regulatory Burden and Confusion

Over the past year, CMS has implemented and proposed several changes to drug pricing through changes to existing programs and policies and the creation of new ones. However, all of these changes have been implemented or proposed independent of each other, leaving room for unintended consequences and confusion on how these changes may interact with one another. This lack of understanding of how these may interact leaves unanswered questions around how prices, access, and administrative and infrastructure needs will be impacted. This creates a challenge for stakeholders to properly evaluate the impact of these changes on patients, providers, drug manufacturers, and other drug pricing as a whole. **As the agency moves through the rule making process for drug pricing CMMI models, we urge CMS to review these changes holistically and weigh any interactions or negative unintended consequences that may occur. CMS should not move forward with finalizing these proposals until these interactions have been fully vetted.** Further, we've supported CMS' interest in deregulation and removing administrative burden and confusion in healthcare.[5] We ask that CMS review these policies through this lens while evaluating for interactions between the models, agreements, and price negotiations.

[3] 90 FR 60338
[4] Kaufman Hall, November 2025 National Hospital Flash Report. Jan. 15, 2026
[5] AAMC, Comment Letter in Response to RFI on Deregulation (May 12, 2025)

In addition to GUARD, CMMI is pursuing three other drug pricing models. The first is a similar mandatory model for Part B drugs, referred to as the GLOBE Model.[6] The second is a voluntary model, the GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model, focused on enabling state Medicaid programs to purchase drugs at prices aligned with those paid in economically similar countries to the U.S..[7] Lastly, CMMI announced a voluntary model, BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) Model, to allow CMS to negotiate the pricing of GLP-1 medications with drug manufacturers for state Medicaid agencies and Medicare Part D plans.[8]

In addition to CMMI models, the administration secured negotiated agreements with several drug manufacturers directly to lower U.S. drug prices. [9] While the exact terms of these agreements are not public, it is understood that these agreements aim to lower drug prices to similar levels as those in other economically similar countries. These agreements also aim to allow patients to purchase drugs directly from manufacturers and provide a discount when drugs are purchased in this manner through a government hosted direct-to-consumer platform.[10]

Meanwhile, CMS is continuing with negotiations with manufacturers for the maximum fair price (MFP) on selected drugs in the Medicare program through Inflation Reduction Act (IRA) negotiations. The first round of negotiations began in 2023 for Part D drugs in order to take effect in 2026 and expanded to include Part B drugs in drug price negotiations beginning in 2026. Each year CMS identifies an additional list of drugs that will be subject to negotiation. As negotiations have progressed, CMS has been increasingly more successful with negotiating lower prices.[11] In addition to moving these negotiations forward, CMS continues to work through regulations related to IRA negotiations and MFP to avoid duplicate discounts and ensure stakeholders receive sufficient guidance on the program.[12,13]

Finally, the 340B Program, which is overseen by the Health Resources and Services Administration (HRSA), requires drug manufacturers to provide discounts on covered outpatient drugs to safety net institutions that meet thresholds demonstrating their commitment to low-income patients. Due to the way that the 340B discount is calculated. changes in drug pricing on GUARD model drugs could result in smaller 340B discounts. Specifically, 340B discounts are calculated using a drug's best price and average manufacturer price (AMP). The best price represents the lowest price available to any wholesaler, retailer, or provider in the U.S. drug market, while the AMP is calculated as the average price paid to manufacturers by retail

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[6] 90 FR 60244
[7] CMS, GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model
[8] CMS, BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) Model
[9] The White House, Fact Sheet: President Donald J. Trump Announces Largest Developments to Date in Bringing Most-Favored-Nation Pricing to American Patients (Dec. 19, 2025)
[10] https://trumprx.gov/
[11] CMS Newsroom, CMS Delivers Savings for Seniors on 15 Major Drugs for Cancer and Chronic Disease (November 25, 2025)
[12] CMS, Medicare Drug Price Negotiation Program (May 2025)
[13] 90 FR 49266

pharmacies and wholesalers.[14] For most brand name drugs, the 340B discount is calculated as the greater of: 1) 23.1% of AMP; or 2) AMP minus the best price. Depending on how much the price for a given drug decreases, the AMP and best price could be affected as well, which could ultimately result in changes to the 340B discount. For example, a lower AMP would result in a smaller 340B discount, which would increase the 340B ceiling price. Therefore, 340B hospitals could end up paying more for these drugs, both diminishing their savings and affecting their patients' access to the drugs. **The AAMC supports lowering drug prices and the administration's commitment to addressing high drug prices. However, if CMS determines that the GUARD model could negatively impact 340B hospitals, we ask that CMS explore ways to insulate 340B price calculations from being affected by the GUARD model.**

GUARD May Not Adequately Address Prescription Drug Affordability for Patients

In addition to regulatory complexity, the AAMC is uncertain the proposed drug pricing model will have a significant effect on health care affordability for patients. The design of the GUARD program does not include a mechanism to address cost sharing for beneficiaries, meaning drug prices will only go down for patients based on potential manufacturer response to the model of lowering prices to avoid paying the rebate. (P. 60352). In addition to a lack of policy addressing cost sharing for patients, CMS predicts that under this model manufacturers may actually raise the price for other drugs not subject to these rebates to counter the effects. Specifically, CMS believes that drug manufacturers may choose to negotiate the prices more aggressively for drugs that are subject to price negotiations under the IRA. This would mean CMS expects the MFP for drugs selected for negotiation to land closer to the ceiling price required under the IRA rather than the lower rates they have been able to achieve recently. (P.60411). As a result, this would shrink estimated savings for CMS from IRA drug price negotiations and would keep the cost sharing requirements for these drugs higher than they would be without the rebate models in place. CMS also notes that the change in these negotiations will impact beneficiary premiums after the end of the IRA premium stabilization provisions, resulting in higher costs. (P.60412).

As noted above, CMS has continued to be successful in securing program and beneficiary savings year after year for the drugs selected for IRA price negotiation.[15] **We urge the agency to continue to pursue greater savings each year and not adopt policies that may jeopardize the ability to negotiate an MFP that achieves these savings.** We also encourage the agency to further consider and prioritize patient affordability as well as sustainability in the Medicare program. Increased cost sharing has been linked to worse prescription adherence, which could lead to a need for more costly, inpatient care.[16] Patients who are able to adhere to their prescription drugs may also have better health outcomes overall and lower health care costs.[17]

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[14] KFF. Understanding the Medicaid Prescription Drug Rebate Program. November 12, 2019.
[15] CMS Newsroom, CMS Delivers Savings for Seniors on 15 Major Drugs for Cancer and Chronic Disease (November 25, 2025)
[16] Fusco, N., Sils, B., Graff, J. S., Kistler, K., Ruiz, K., & Xcenda. *Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review (April 7, 2022)*
[17] Neiman AB, Ruppar T, Ho M, et al. CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities. MMWR Morb Mortal Wkly Rep 2017;66. DOI: http://dx.doi.org/10.15585/mmwr.mm6645a2

Savings from ensuring patient access to needed medications could also provide more financial stability to the Medicare program due to improved outcomes and less reliance on more costly forms of care.

Avoid Policies That Incentivize Brown Bagging to Ensure Patient Safety

Further, CMS indicates in the proposed rule they expect the model may incentivize the use of brown-bagging. (P. 60410). Brown-bagging is the practice of having a specialty pharmacy dispense non-self-administered drugs directly into the patient's custody rather than from the pharmacy to the provider. This practice shifts the responsibility of ensuring proper storage, handling, and transportation from the provider to the patient. This presents a number of challenges in ensuring patient safety as patients may not have the proper equipment or education to safely handle these prescription medications prior to administration. In the proposed rule, CMS also suggests that providers would be incentivized to work with manufacturers to shift more medications to brown-bagging to obtain reimbursement under Medicare Part B. (P. 60410). The AAMC does not believe moving towards brown-bagging would shift reimbursement towards Part B as brown-bagged drugs are typically covered under the pharmacy benefit, which falls under Part D, rather than the medical benefit under Part B. Further, we do not agree with CMS' assessment that providers could seek to engage in the practice of brown-bagging. Providers would want to be the ones to receive these drugs directly as they are well trained on how to properly handle, store, and transport these drugs, eliminating patient safety concerns. However, the AAMC agrees these kinds of perverse incentives may embolden prescription drug plans to require beneficiaries to utilize brown-bagging to avoid paying a rebate. This is further complicated by the expected increase in the similar practice of white-bagging under the GLOBE (Global Benchmark for Efficient Drug Pricing) Model.[18] White bagging is a practice that results in drugs being purchased through the pharmacy benefit, instead of the medical benefit, and being shipped to the provider directly.[19] **We urge CMS to take steps to ensure any drug pricing policies prioritize patient safety and access by including guardrails to prevent increasing the practice of white and brown-bagging.**

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. The AAMC supports the administration's efforts to lower prescription drug costs but has concerns with the proposed GUARD Model, including creating burden and confusion, negatively impacting other drug discount programs and rebates, and failing to address affordability concerns for patients, CMS should continue to look at all drug pricing programs and initiatives holistically to avoid unintended negative interactions. We would be happy to work with CMS on any of the issues discussed or other topics that involve the academic community. If you have questions regarding our comments, please feel free to contact Katie Gaynor (kgaynor@aamc.org).

[18] 90 FR 60244
[19] McKesson. Benefits and Challenges of White, Brown, Clear, and Gold Bagging. April 17, 2023.

Sincerely,

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Chief Health Care Officer

cc: David Skorton, M.D., AAMC President and Chief Executive Officer