AAMC
655 K Street, NW, Suite 100
Washington, DC 20001-2399
T 202-828-0400
aamc.org

Submitted electronically via www.regulations.gov

February 20, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5545-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Global Benchmark for Efficient Drug Pricing (GLOBE) Model

Dear Administrator Oz,

The AAMC[1] welcomes this opportunity to comment on the proposed rule titled "Global Benchmark for Efficient Drug Pricing (GLOBE) Model," 90 Fed. Reg. 60244 (December 23, 2025), issued by the Centers for Medicare & Medicaid Services (CMS or the agency).

As part of the administration-wide effort to reduce drug prices, CMS proposes the GLOBE model, which would be a mandatory Centers for Medicare & Medicaid Innovation (CMMI) model that would require drug manufacturers to offer rebates to Medicare on certain Part B drugs administered to Medicare beneficiaries. The rebates would be paid through an existing mechanism that CMS uses to collect inflationary rebates under the Inflation Reduction Act, but the exact amount of the rebate would be calculated based on an international pricing benchmark. This rule comes in response to the White House's Most Favored Nation (MFN) executive order from last May.[2] The executive order called on federal agencies to explore policies to pursue "Most Favored Nation" pricing for drugs, including through rulemaking if necessary. In conjunction with the GLOBE model, CMS proposed a similar model that applies to Part D drugs, the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) model.[3] CMS references increasingly high drug prices in the US relative to other similarly situated countries as a primary

[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] White House. Delivering Most-Favored Nation Prescription Drug Pricing to American Patients. May 12, 2025.
[3] 90 FR 60338.

rationale for proposing the model. The agency notes that high drug prices limit access to care and treatment, which can lead to worse health outcomes.[4]

The AAMC firmly believes in the need to reduce drug prices, as astronomically high drug prices directly affect providers and patients. Drug costs continue to rise, with year-over-year drug expenses increasing fourteen percent in November 2025 compared to previous years. Drug costs continue to be a concern for patients and their ability to afford paying for their health care, with over half of adults expressing concerns about their ability to afford prescription drugs.[5] Additionally, drug expenses are the main driver of expense growth for hospitals.[6] Rising drug prices strain hospital budgets and ultimately limit patient access. High and rising drug prices—especially for specialty, oncology, and biologic products—are driving disproportionate cost growth in academic health systems that care for complex Medicare beneficiaries. We applaud CMS for its goal of reducing drug prices. However, as CMS itself acknowledges in the rule, the evidence on whether the GLOBE model will directly reduce drug prices and address the root causes of high U.S. drug prices is still unclear. **While we commend CMS' attempt at tackling this issue, we urge CMS to not finalize the GLOBE 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.**

CMS Should Study the Interaction of the GLOBE Model with Other Drug Pricing Policies and on Beneficiary Access

CMS expects the GLOBE model to result in savings to the Medicare program and to Medicare beneficiaries. However, as CMS notes in the preamble to the rule, there are multiple areas of uncertainty that could in fact result in higher costs to Medicare beneficiaries or higher drug prices in other contexts. We urge CMS to more fully evaluate these unintended consequences and costs, particularly whether they would serve the ultimate goal of reducing drug prices and preserving beneficiary access.

The GLOBE model would operate by requiring drug manufacturers to provide rebates to Medicare on drugs included in the model, which include certain categories of single-source (i.e., non-generic) drugs and biologics that have a minimum of $100 million in annual Part B spending and that are included in the Inflation Reduction Act's rebate program. The model would apply to drugs administered to beneficiaries residing in geographic areas to be determined by CMS using zip code tabulation areas, covering 25 percent of the Medicare Part B fee-for-service (FFS) population. The rebates would be calculated as the difference between the Medicare net price of the drug and the international pricing benchmark. The beneficiary coinsurance amount, which is typically 20 percent for Medicare Part B, would be calculated on the rebate-adjusted price of the drug instead of the usual Medicare price. Payment to providers would be adjusted upward to

[4] 90 FR 60247.
[5] KFF. Public Opinion on Prescription Drugs and Their Prices. October 4, 2024.
[6] [6] Kaufman Hall, November 2025 National Hospital Flash Report. Jan. 15, 2026

offset the lower beneficiary coinsurance and ensure that the net payment the provider receives from Medicare and from the beneficiary does not change as a result of the model.

While CMS expects the model to result in $1.4 billion in lower beneficiary cost sharing over the course of the model,[7] CMS notes other factors could result in price increases to beneficiaries, including higher cost sharing in Medicare Advantage (MA) or the reduction in supplemental benefits to MA beneficiaries.[8] This could happen as a result of lower FFS spending translating to reduced benchmarks and payments to MA Plans. Furthermore, behavioral responses from manufacturers could negate any benefits of the model through price increases more broadly and outside of the GLOBE model. For example, manufacturers could seek to offset financial losses stemming from the GLOBE rebates by increasing prices on drugs covered by other payers and by seeking more favorable prices for drugs covered under the Medicare Drug Price Negotiation Program through more aggressive negotiations with CMS. Additionally, manufacturers are likely to increase international drug prices to increase the international pricing benchmark that is used to determine the rebate and thus reduce the rebate owed to Medicare. These are just some examples of the ways in which requiring rebates under Part B could result in higher spending to Medicare beneficiaries in other contexts (such as MA) or to patients covered by other payers. **CMS should carefully evaluate the design of the GLOBE model to ensure it minimizes these consequences and that it truly addresses the high manufacturer list prices that drive up costs for Medicare and its beneficiaries.**

In addition, it is unclear how the GLOBE model would overlap with other key drug pricing policies, and CMS does not thoroughly address these in the rule. For example, there are multiple other policy levers and drug pricing policies that could affect or be affected by the GLOBE model:

- The Medicare Drug Price Negotiation Program, through which CMS and manufacturers negotiate a Maximum Fair Price for selected drugs (10 drugs in 2026, with 15 to be added in 2027).
- The 340B Drug Pricing Program, through which safety net providers are guaranteed discounted drugs that can be used to stretch their scarce federal resources and reach more eligible patients.
- The GUARD Model, which is similar in structure to the GLOBE model, requiring manufacturers to provide rebates on Part D drugs.
- The Generating Cost Reductions For U.S. Medicaid (GENEROUS) Model, a voluntary model focused on enabling state Medicaid programs to purchase drugs at prices aligned with those paid in economically similar countries to the U.S.[9]
- Other CMMI models, such as the voluntary Better Approaches to Lifestyle and Nutrition for Comprehensive Health (BALANCE) Model, which allows CMS to negotiate the

[7] Table 14, 90 FR 60314.
[8] 90 FR 60313.
[9] CMS, GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model

pricing of GLP-1 medications with drug manufacturers for state Medicaid agencies and Medicare Part D plans.[10]

- Direct MFN agreements between the administration and drug manufacturers. The White House has announced at least 16 such agreements that require drug manufacturers to provide most favored nation pricing on some of their drugs.[11]

In the case of Medicare Drug Price Negotiation Program, the negotiation-eligible drugs are excluded from rebates under the GLOBE model. However, as noted above, the GLOBE model could lead to perverse incentives whereby manufacturers could more aggressively negotiate Medicare drug prices under the Medicare Drug Price Negotiation Program to offset rebates they provide on other drugs as a result of the GLOBE model rebates. CMS also believes manufacturers could seek to have more drugs covered under the Medicare Drug Price Negotiation Program to avoid paying GLOBE rebates if they think the negotiated drug price will end up being higher than the post-rebate price. These potential interactions merit further analysis to ensure that the GLOBE model is structured in a way that does not interfere with the operation of the Medicare Drug Price Negotiation Program, through which CMS has been increasingly more successful in negotiating lower prices.[12]

CMS does not address how the GLOBE model could interact with the other CMMI models, such as the BALANCE and GENEROUS models, as well as individual agreements with drug manufacturers. Many key questions remain unanswered, such as whether drugs covered by those models or for which an MFN price agreement was reached through direct negotiations with the administration would be excluded from the GLOBE model.

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 GLOBE 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 pharmacies and wholesalers.[13] 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

[10] CMS, BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) Model
[11] NPR. Trump Struck Deals with 16 Drug Companies. But They're Still Raising Drug Prices This Year. January 16, 2026.
[12] CMS Newsroom, CMS Delivers Savings for Seniors on 15 Major Drugs for Cancer and Chronic Disease (November 25, 2025)
[13] KFF. Understanding the Medicaid Prescription Drug Rebate Program. November 12, 2019.

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 GLOBE model could negatively impact 340B hospitals, we ask that the agency explore ways to insulate 340B price calculations from being affected by the GLOBE model.**

CMS Should Minimize Administrative Burden and Clarify how Providers Should Identify Beneficiaries and Drugs for Which to Reduce Cost-Sharing

The GLOBE model would provide lower coinsurance on model drugs to beneficiaries in the geographic areas identified by CMS for inclusion in the model. Providers would be responsible for billing beneficiaries the lower coinsurance amount, which will be based on the rebate-adjusted Medicare price instead of the otherwise-applicable Medicare payment amount that is based on average sales price. Based on the limited information provided in the rule, it is evident that the process of determining coinsurance rates for a providers' beneficiaries could be burdensome and impractical. The GLOBE model applies to beneficiaries in 25 percent of geographic areas, so providers would administer drugs to patients both included and not included in the model. Furthermore, not all drugs are model-eligible, such as generic drugs and those that don't meet the minimum spending threshold. Finally, both the GLOBE rebate amounts and the beneficiaries included in the model are subject to change, with the rebate amounts recalculated on a quarterly basis and the beneficiary list updated up to weekly. Therefore, the coinsurance calculation is not as simple as adjusting coinsurance amounts for all of a provider's patients for affected drugs—instead, this would be a beneficiary and drug-specific determination that would fluctuate as additional beneficiaries are added into the cohort and as the drug rebate amounts change. Compounding the issues related to identifying beneficiaries and their reduced coinsurance amounts is that 87 percent of Medicare FFS beneficiaries have supplemental coverage that would likely cover part or all of their coinsurance liability.[14] It is unclear how supplemental sources of coverage, such as Medigap plans, would account for the reduced coinsurance amounts associated with GLOBE model drugs and what system changes would be necessary. **We ask that CMS provide more information on how providers will be given the necessary information to calculate their beneficiaries' coinsurance amounts and encourage CMS to streamline processes for billing coinsurance as efficiently as possible.**

CMS Must Ensure the Model Does Not Result in Practices that Will Diminish Patient Safety

Lastly, the agency must consider the effects of the model on patient safety if the model results in changes to drug procurement processes. CMS notes one of the potential consequences of the rule could be an increase in white bagging, which CMS maintains could result in drugs being reimbursed under the Part D benefit but still administered in an office or facility setting.[15] 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.[16] The provider is responsible for storing the drug until the patient receives the treatment at the hospital or clinic. The white bagging process circumvents the provider as the party responsible for purchasing, billing for, and

[14] KFF. A Snapshot of Sources of Coverage Among Medicare Beneficiaries. December 19, 2025.
[15] 90 FR 60313.
[16] McKesson. Benefits and Challenges of White, Brown, Clear, and Gold Bagging. April 17, 2023.

storing the drug. White bagging is particularly concerning for physician-administered drugs, which are the vast majority of Part B drugs. When white bagging occurs, a beneficiary would have to pay the cost-sharing amount up front as a copay, instead of after the drug is administered, as is the case under the Part B benefit. This would result in the patient having financial liability earlier in the process than is currently the case.

Moreover, we are concerned about the adverse effects of white bagging on patient safety. Because the hospital is not maintaining its own supply of medication, white bagging removes the hospital's ability to ensure there is an adequate supply of medications available for their patients' treatment. White bagging can result in delays in treatment, errors in medication orders, inability to ensure product safety standards, and conflicts with federal and state regulations.[17] **CMS must consider how these unintended consequences could affect affordability (due to changes in patient cost-sharing responsibilities) and patient safety and identify ways to remove incentives for manufacturers and health plans to engage in white-bagging.**

Thank you for the opportunity to comment on this proposed rule. We would be happy to work with CMS on any of the issues discussed. If you have questions regarding our comments, please feel free to contact my colleague Shahid Zaman (szaman@aamc.org).

Sincerely,

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.
Chief Health Care Officer
AAMC

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

[17] American Hospital Association. White Bagging Infographic.; ASHP. White Bagging Jeopardizes Patient Care.