



February 23, 2025

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: Global Benchmark for Efficient Drug Pricing (GLOBE) Model [CMS-5545-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 “Global Benchmark for Efficient Drug Pricing (GLOBE) Model [CMS-5545-P]” (Proposed Rule).

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.

AMCP appreciates CMS’s efforts to explore alternative payment approaches to address rising Medicare Part B drug spending and recognizes the importance of testing innovative models through CMMI. At the same time, effective model testing requires designs that are operationally feasible, analytically sound, and aligned with beneficiary protection objectives. As proposed, the GLOBE Model raises concerns regarding administrative complexity, benchmark reliability, beneficiary affordability, and cross-program impacts that warrant further refinement prior to finalization.

Administrative and Operational Burden

The GLOBE Model introduces significant operational complexity by establishing rebate and coinsurance methodologies that diverge from existing Medicare Part B inflation rebate processes and rely on international pricing benchmarks. These changes would require substantial updates to rebate reporting, invoicing, reconciliation workflows, claims systems, and data exchange protocols. Managed care organizations, providers, and vendors that administer or support Part B drug benefits would face increased administrative costs and coordination challenges, potentially diverting resources from patient care and benefit management.

CMS should consider leveraging established reporting and reconciliation infrastructure. Phased or voluntary participation with clearly defined transition flexibilities would reduce implementation burden, promote consistent stakeholder participation, and enhance the scalability and policy relevance of evaluation findings.

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.

Access and Affordability

CMS acknowledges that CMMI models frequently include beneficiary protections, such as opt-out mechanisms, to mitigate access and affordability risks. Despite recognizing that the GLOBE Model may affect beneficiary access to drugs, CMS proposes no beneficiary opt-out, citing concerns about test integrity. This design choice prioritizes evaluation considerations over beneficiary choice and leaves patients exposed to potential adverse effects without a meaningful mechanism to avoid them. Retrospective monitoring does not function as a protection once access disruptions or cost increases have occurred.

Although the GLOBE Model is intended to reduce Medicare spending and beneficiary coinsurance, it does not establish a clear or reliable mechanism to reduce patients' costs. Because beneficiaries experience affordability holistically—through premiums, benefits, coverage stability, and access—reductions in coinsurance alone do not ensure improved affordability when offsetting costs or benefit reductions are plausible.

To address uncertainty in beneficiary affordability outcomes, CMS should more clearly specify how model-generated savings are expected to translate into beneficiary-level affordability improvements, consistent with CMMI's beneficiary protection objectives. Establishing prospective monitoring and CMS-directed mitigation mechanisms would help ensure that affordability gains are realized at the beneficiary level while preserving plans' flexibility to manage overall financial risk.

Medicaid and Dual-Eligible Implications

Although the Model applies to Medicare, it may have meaningful spillover effects on Medicaid programs and dual-eligible beneficiaries. Changes in Part B allowed amounts and manufacturer pricing behavior could affect Medicaid rebate dynamics, wraparound payments, provider participation, and utilization patterns for drugs disproportionately used by duals. Given the heightened access sensitivity of this population, reductions in provider participation or service

availability could have disproportionate equity impacts absent explicit safeguards or reinvestment in care coordination and pharmacy services.

To address potential spillover effects on Medicaid and dual-eligible beneficiaries, CMS should incorporate explicit assessment of cross-program interactions and access impacts into the model's monitoring and evaluation framework. Proactively accounting for these dynamics would help mitigate unintended effects on provider participation and beneficiary access while strengthening the policy relevance of evaluation findings.

Conclusion

While AMCP supports CMS's goal of improving prescription drug affordability for Medicare beneficiaries, the GLOBE Model, as proposed, introduces significant uncertainty and risk without clearly demonstrating how model design will produce predictable, beneficiary-centered outcomes. Addressing these concerns through greater alignment with existing infrastructure, clearer affordability pathways, and explicit consideration of cross-program impacts would strengthen model fidelity and evaluation validity. Absent such modifications, the Model risks imposing substantial burden and unintended consequences that may undermine its policy relevance and scalability.

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
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