February 23, 2026

Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Global Benchmark for Efficient Drug Pricing (GLOBE) Model [CMS-5545-P]

Dear Administrator Oz:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising nearly 200 institutions from across the health care spectrum, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed Global Benchmark for Efficient Drug Pricing (GLOBE) Model issued through the Center for Medicare and Medicaid Innovation (CMMI).[i] PMC and CMS share the goal of achieving better health outcomes and lowering costs for patients. However, the GLOBE Model would dictate foreign price setting in Medicare, bringing with it negative consequences that pricing setting policies have had in other nations. These include reduced incentives for innovation and slower, narrower access to new treatments that could disrupt care for many American patients. PMC does not support the GLOBE Model moving forward because of the impact it may have on access to personalized medicines to treat serious, rare, and chronic conditions. We strongly urge CMS to withdraw the notice of proposed rulemaking for the GLOBE Model.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests and individual details about a person's health to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which leads to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC and its members are leading the way in personalized medicine and in developing evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Statement of Neutrality

Many of PMC's members will present their own responses to the Global Benchmark for Efficient Drug Pricing (GLOBE) Model proposed rule and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance and are not intended to adversely impact the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the GLOBE Model.

Impeding Clinical Decision Making

The transformation of health care from one-size-fits-all, trial-and-error medicine to targeted treatment utilizing each patient's molecular information continues to progress as the U.S. Food and Drug Administration (FDA) approves new personalized medicines. Since 2020, personalized medicines have accounted for at least a third of newly approved therapies each year.[ii] In 2025 alone, 15 of the 46 new molecular entities approved by the FDA were personalized medicines to treat individuals with certain cancers, rare, and chronic diseases.

The GLOBE Model relies in part on international price benchmarking methodologies, including Method I, which references prices in economically comparable countries. CMS describes this approach as a means of identifying lower-cost benchmarks. However, reliance on external price references will likely have downstream effects that are not closely aligned with individual patient needs or clinical circumstances.

Personalized medicine depends on the consideration of a patient's molecular and biological characteristics and also on individual values, clinical and economic circumstances, and the potential impact of a therapy for that patient over the long term. Fundamental patient values and preferences, including the impact of treatment on quality of life, quantity vs. quality of time, functional ability related to illness or treatments, cost of supportive care, and other patient costs of treatment are weighed by patients and their caregivers. Access to appropriate therapy depends on this type of individualized clinical decision making between patients and their providers.

Advances in pharmaceutical innovation over the past two decades have influenced how American patients perceive their health care. Today, patients in the United States expect not only access to cutting-edge therapies but also meaningful involvement in decisions about their care. American patients consistently report valuing access to pharmaceuticals and the autonomy to choose, alongside their providers, from available treatment options that improve their lives and the lives of their loved ones. These perspectives highlight that patients in this country prioritize both faster access to effective treatment options and the long-term health benefits those medicines deliver. This combination of expectations for innovation and preferences for personal agency in treatment decisions is part of the American context.[iii] In stark contrast to what American patients want, pricing benchmarks like those proposed in the GLOBE Model will interfere with achieving treatment value that matters to patients.

Some patients will experience more or less benefit from a treatment than suggested by the averages reported within clinical trials and population-based data. Health care policies based on averages tend to undervalue personalized medicines because they fail to consider the full range of individual patient outcomes and benefits. Personalized medicine treatment strategies create considerable benefits for patients and society since they are used in a manner that directs them toward patients who are most likely to benefit and away from those who are not.

Interrupting Innovation

Congress enacted the *Inflation Reduction Act (IRA)*, which established a framework for addressing some aspects of drug affordability in Medicare. That framework reflects policy choices aimed at generating savings and introduced a discussion of timelines that are necessary to preserve innovation, like incentives to support the development of rare disease treatments. PMC is concerned that layering additional pricing models like GLOBE onto the *IRA* framework may have unintended consequences for patients.

Research conducted after approval of a new drug is important for advancing personalized medicine. After initial approval of a drug by FDA, further research provides greater understanding of patients' responses to treatment based on results from molecular diagnostics. This research may lead to new or improved treatment indications that contribute to progress in personalized medicine. But smaller patient subpopulations can make it difficult to recoup investment in this research, which can require additional clinical trials. The *IRA* anticipated that the clinical and economic value of a drug could evolve over time—due to factors such as new FDA-approved indications, biosimilar entry, or shifts in real-world utilization.

The GLOBE Model introduces a parallel pricing and participation structure that was not contemplated as part of the *IRA* framework and that may alter how statutory policy choices operate in practice, effectively revisiting policy tradeoffs that Congress confronted during consideration of the *IRA*. The cumulative effect of multiple, rapidly implemented reforms that interact in complex ways may result in policy overlap that reduces investment in areas of unmet medical need.

The GLOBE Model's implementation of international benchmarking may also result in the United States forfeiting breakthroughs patients are waiting for. Experiences in many European systems shows that price setting policies can be accompanied by delayed drug launches or decisions not to launch at all.[iv] This dynamic is especially problematic for rare disease therapies and targeted therapies, where small patient populations, high development costs, and complex manufacturing already make investments in such areas especially risky. Estimates suggest just 10 to 12 percent of drugs that reach human clinical trials become commercially available medicines.[v] In 2019, the Congressional Budget Office (CBO) evaluated a mandatory drug pricing proposal that relied on international benchmarking, capping drug reimbursement for certain products at 120 percent of other "wealthy nations' pricing." The CBO estimated that such a proposal would lead to approximately 8–15 fewer new drugs over the first decade after implementation and about 30 fewer drugs over roughly 20 years, reflecting how reduced reimbursement is understood to reduce the number of new medicines brought to market.[vi]

The GLOBE Model could introduce practices to the United States that have resulted in slower and more limited access to innovative therapies abroad. A RAND study comparing drug availability and launch timing found that new medicines are more likely to be launched first in the United States than peer wealthy nations and that the United States has a higher share of globally available new drugs than peer countries. More than half of new drugs studied were launched first in the United States, with an average lag of about one year before launch in other major markets including Australia, Canada, France, Germany, Italy, Japan, and the United Kingdom.[vii]

Rare disease is an area where the federal government has previously implemented multiple policies to support treatment innovation. In the last five years, an increasing number of these

treatments have been personalized medicines affecting small patient populations for whom the expected market return would otherwise be insufficient to justify development. CMS did not substantively address how treatments that meet the criteria of orphan drugs will be considered under the GLOBE Model. Failing to account for orphan drug exclusivity periods and other incentives in the GLOBE Model risks undermining the policy framework that has supported rare-disease research and development for nearly four decades.

Cancer is known to be a complex disease in which the same cancer type can behave differently in different patients. The consequence of these individual responses is that within a population of patients suffering from the same cancer, the mainstay therapy fails to achieve efficacy in many patients.[viii] Personalized medicine has driven significant improvements in survival rates in recent decades, but oncology has pronounced cross-country variability in the availability and timelines of patient access. Of the 74 cancer drugs launched between 2011 and 2018, 95 percent are available in the United States, compared with 74 percent in the United Kingdom and 49 percent in Japan.[ix] A recent multi-country study of hospital access to innovative oncology medicines in Europe found average delays of roughly two years between European Medicines Agency authorization and real-world patient access.[x]

Finally, the GLOBE Model framework is poorly suited to the complex operational and economic realities posed by cell and gene therapies. Cell and gene therapies are highly personalized interventions that often function more like individualized medical procedures than conventional therapies manufactured for larger patient populations. For example, chimeric antigen receptor T-cell (CAR T-cell) treatments for certain cancers and a growing number of other diseases, are manufactured using a patient's own cells, which are collected, modified, and then returned to the same patient with days of administration. As of 2025, there are 30 cell and gene therapies available for patients in the United States.[xi] Reduced uncertainty in countries whose pricing is referenced in the GLOBE Model proposal has resulted in significant differences in the availability and timing of cell and gene therapies than observed in the United States.[xii] If pricing uncertainty and international pricing benchmarks seen globally are put in place in the United States, access to existing cell and gene therapies and future innovation in this promising space could be undermined.

Conclusion

Thank you for considering these comments. PMC strongly urges CMS to withdraw the GLOBE Model proposal. We look forward to serving as a resource to you and your colleagues on alternative paths that ensure sustainability of the Medicare program while maintaining an ecosystem for innovation and patient access to personalized medicine. If you have any questions about the contents of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

[i] Centers for Medicare and Medicaid Services. *Global Benchmark for Efficient Drug Pricing (GLOBE) Model; Proposed Rule. [Docket No. CMS-5545-P].* December 23, 2025. https://www.govinfo.gov/content/pkg/FR-2025-12-23/pdf/2025-23702.pdf (accessed February 12, 2026).

[ii] Personalized Medicine Coalition. *Personalized Medicine at the FDA: The Scope and Significance of Progress in 2004.* https://www.personalizedmedicinecoalition.org/wp-content/uploads/2025/06/PMC_PM_at_FDA_The_Scope__Significance_of_Progress_2024_1.pdf (accessed February 12, 2026).

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[vi] Congressional Budget Office. *Re: Effects of Drug Price Negotiation Stemming from Title I of H.R. 3.* October 11, 2019. https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf (accessed February 12, 2026).

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