NATIONAL HEALTH COUNCIL

February 23, 2026

Mehmet Oz, MD, MBA
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]**

*Submitted electronically via regulations.gov*

Dear Administrator Oz:

The National Health Council (NHC) 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).

Created by and for patient organizations more than 100 years ago, the NHC convenes organizations from across the health ecosystem to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, comprehensive, accessible, and sustainable health care. Made up of nearly 200 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

The NHC appreciates CMS' efforts to examine approaches to prescription drug affordability in Medicare and recognizes the complexity of designing models intended to balance fiscal sustainability with beneficiary access. At the same time, the NHC recognizes that certain model design choices can introduce foreseeable risks for patients, particularly with respect to affordability as it is experienced through out-of-pocket costs, supplemental benefits, and stability of access to care. After a review with these factors in mind, the NHC cannot support the GLOBE Model as proposed.

Unlike some CMMI models that test delivery system reforms with more indirect or delayed effects on beneficiaries, the GLOBE Model operates through pricing and participation mechanisms that CMS acknowledges may directly affect beneficiary cost-sharing, supplemental benefits, and access to drugs. As a result, the Model has implications for beneficiaries that are closely tied to coverage behavior and plan responses. The concerns described below relate to the fundamental structure of the GLOBE Model as proposed and are not amenable to resolution through technical refinement, supplemental safeguards, or post hoc monitoring once the Model is underway.

**Affordability Pathway and Patient Experience**

CMS describes the GLOBE Model as an approach intended to reduce Medicare expenditures and beneficiary coinsurance for certain Part B drugs by modifying inflation rebate calculations using international pricing benchmarks. At the same time, CMS' own impact analysis reflects uncertainty regarding patient-facing affordability effects and acknowledges that potential reductions in coinsurance may be offset by other cost impacts experienced by beneficiaries. Moreover, the Model's selection of therapeutic categories is based on aggregate Medicare spending rather than on measures of beneficiary out-of-pocket burden, which further underscores the gap between program-level expenditure targets and the way affordability is actually experienced by patients.

In particular, CMS acknowledges that Medicare Advantage plans may respond to the Model by reducing supplemental benefits and increasing beneficiary out-of-pocket costs. CMS' estimates reflect negative supplemental benefit impacts for beneficiaries in multiple years. From a patient perspective, affordability is not experienced solely through coinsurance on an individual claim. It is reflected in premiums, supplemental benefits, predictable coverage rules, and stability in access to care. A model that contemplates cost relief in one dimension while acknowledging the potential for cost increases or benefit reductions in others does not establish a clear or reliable patient-facing affordability pathway, because patients experience affordability in the aggregate rather than through isolated cost components.

These dynamics are not incidental. They flow directly from the Model's reliance on pricing adjustments that do not directly constrain how plans manage downstream financial pressure. As a result, any program-level savings generated under the Model may not translate into improved affordability for patients in practice.

The GLOBE Model relies on CMS' authority to waive statutory provisions, including sections 1833 and 1847A of the Social Security Act, to test alternative approaches to pricing and beneficiary coinsurance. While this authority allows CMS to adjust how coinsurance is calculated for certain drugs, the proposed rule does not establish a corresponding obligation or mechanism to ensure that such adjustments result in net affordability improvements for beneficiaries. CMS' own impact analysis acknowledges the potential for reductions in supplemental benefits and other downstream cost effects that may offset any coinsurance changes. As a result, the Model's use of waiver authority underscores a fundamental gap between program-level savings and patient-level affordability, rather than a clear pathway by which beneficiaries reliably experience financial relief.

**Beneficiary Protections and Exposure to Access Risk**

CMS recognizes that CMMI models frequently include beneficiary protections to mitigate the risk of adverse consequences and notes that opt-out mechanisms are among the most common of these protections. CMS further acknowledges that the GLOBE Model may affect beneficiary access to drugs, yet elects not to include a beneficiary opt-out, citing concerns related to test integrity and generalizability.

From a patient perspective, this reflects a design that prioritizes evaluation considerations over beneficiary choice in the face of acknowledged access risk. While CMS proposes monitoring beneficiary experience through reporting mechanisms, retrospective monitoring does not function as a protection where beneficiaries lack a meaningful ability to avoid exposure to adverse effects before they occur.

The absence of beneficiary-level protections is therefore not a discrete design omission. It is a structural feature of the Model that shapes how access risks are borne by patients during the test period.

**Coverage Behavior and Access Dynamics**

CMS anticipates that stakeholders may respond to the GLOBE Model in ways that affect beneficiary cost-sharing, coverage, and access, and proposes to evaluate whether unintended consequences occur over time. CMS also acknowledges uncertainty related to market behavior and policy interactions.

In the Medicare context, cost pressures introduced through pricing changes are commonly managed through adjustments to coverage policies, including changes to utilization controls, site-of-care incentives, and benefit structures. For patients, these responses can manifest as delayed access, increased administrative burden, or changes in where and how care is delivered, even where nominal coverage remains in place.

The GLOBE Model relies on these stakeholder responses to generate savings while offering limited prospective constraints on how those responses may affect beneficiaries. CMS' emphasis on post hoc evaluation rather than upfront patient protections increases the likelihood that adverse access impacts would be identified only after beneficiaries have already encountered new barriers to care.

**Geographic Participation Design and Patient Impact**

CMS proposes selecting a cohort of beneficiaries for participation in the GLOBE Model based on geographic criteria tied to address of record. The proposed rule does not demonstrate that selected geographic areas correspond to populations most affected by affordability challenges or access barriers.

For patients, geographic selection can result in uneven exposure to changes in coverage conditions, cost-sharing, and access. Beneficiaries with similar clinical needs may experience materially different outcomes based solely on place of residence. The absence of an opt-out mechanism further embeds this variation into the Model's design, limiting beneficiaries' ability to avoid exposure even where participation results in higher costs or reduced access.

**Interaction with the Inflation Reduction Act and Policy Coherence**

Congress recently enacted the Inflation Reduction Act (IRA), establishing a comprehensive framework for addressing drug affordability in Medicare. That framework reflects deliberate policy choices regarding how savings are generated, how patient protections are maintained, and how incentives for innovation, including in rare disease research, are preserved.

The NHC has previously emphasized the importance of maintaining this balance, including preserving incentives for rare disease research and avoiding policy approaches that could reduce investment in areas of unmet medical need. The GLOBE Model introduces a parallel pricing structure that relies on international benchmarks and was not contemplated as part of the IRA framework.

Layered onto recently enacted reforms, the GLOBE Model risks altering how those statutory choices operate in practice. From a patient perspective, the concern is not simply policy overlap, but the cumulative effect of multiple, rapidly implemented reforms that interact in complex ways and introduce uncertainty into coverage, access, and continuity of care.

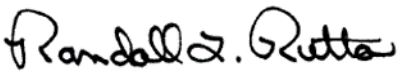
**Conclusion**

The NHC supports efforts to improve prescription drug affordability for Medicare beneficiaries and recognizes CMS' responsibility to test models intended to reduce program spending while preserving quality of care. However, the GLOBE Model, as proposed, does not establish a clear and consistent pathway by which program-level savings translate into predictable, patient-centered affordability improvements.

CMS' own analysis acknowledges uncertainty in beneficiary impacts, identifies plausible scenarios in which beneficiaries experience reduced supplemental benefits or higher out-of-pocket costs, and recognizes potential access risks without adopting standard beneficiary protections. These concerns arise from the Model's core structure and are not readily addressed through incremental adjustment or monitoring once the Model is underway.

For these reasons, the NHC cannot support the GLOBE Model as proposed. The NHC appreciates the opportunity to provide comments and remains committed to engaging with CMS on approaches that more directly and transparently improve beneficiary affordability while preserving timely access to clinically appropriate therapies and maintaining the policy balance Congress has recently established. Please do not hesitate to contact Kimberly Beer, Senior Vice President, Policy & External Affairs at kbeer@nhcouncil.org or Shion Chang, Senior Director, Policy & Regulatory Affairs at schang@nhcouncil.org, if you or your staff would like to discuss these comments in greater detail.

Sincerely,



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