SUBMITTED ELECTRONICALLY

February 23, 2026

Mehmet Oz, MD, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

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

Dear Administrator Oz:

The Protecting Innovation in Rare Cancers (PIRC) coalition, together with the undersigned rare disease advocacy organizations, appreciates the opportunity to comment on the Global Benchmark for Efficient Drug Pricing (GLOBE) Model proposed for implementation through the Center for Medicare and Medicaid Innovation's (CMMI) authority under Section 1115A of the Social Security Act.

PIRC is a coalition of rare cancer patient advocacy organizations representing individuals living with hematologic malignancies, sarcomas, neuro-oncologic conditions, rare gastrointestinal cancers, and other low-incidence malignancies. For our patient communities, physician-administered therapies covered under Medicare Part B are not discretionary expenditures — they are life-extending and potentially life-saving interventions.

We recognize the challenges CMS faces as it balances Medicare's mission of ensuring access to medically necessary health care for America's seniors and disabled individuals with its responsibility for the program's fiscal sustainability. PIRC acknowledges that innovations in care delivery and coordination are appropriately tested through CMMI models and offer CMS an important tool toward achieving these objectives. However, the GLOBE Model raises serious concerns regarding statutory alignment, drug price "valuation" methodologies, provider stability, behavioral uncertainties, and beneficiary protections. These concerns are compounded by the unprecedented period of drug policy transition currently underway within Medicare.

We offer our comments in the spirit of strengthening beneficiary confidence and ensuring that any Innovation Center model remains legally sound, economically coherent, and protective of vulnerable patient populations.

Given that our concerns are linked to the inherent nature of the model and its design, PIRC's participating organizations cannot support the GLOBE model. If, however, CMS determines to move forward with the GLOBE model test, we urge that it incorporate a beneficiary notice and consent protocol, maintain ethical oversight throughout implementation, and exempt individuals with a cancer diagnosis or a rare disease from the model test.

The GLOBE Model Strains the Limits of CMMI Authority - Section 1115A Prioritizes Care Quality over Savings and Favors Patient-Centered Models with Care Coordination Elements

Section 1115A authorizes the Secretary to test models that are expected "to reduce program expenditures… while preserving or enhancing the quality of care furnished to individuals." 42 U.S.C. § 1315a(a)(1).

The statute does not authorize savings-first experimentation; it requires preservation or enhancement of quality as a threshold condition. The prioritization of care quality and patient experience over Medicare savings is evident from the statute's explicit statement permitting model tests unlikely to demonstrate cost neutrality or savings during the initial year of testing. There is no similar provision enabling compromises in patient outcomes or quality of care.

The GLOBE Model introduces international reference benchmarking into Medicare Part B pricing. CMS acknowledges uncertainty on the impact this benchmarking might have on access and expects to "monitor" and potentially modify the model to respond to beneficiary complaints and access impediments. Where the agency anticipates the possibility of altered access dynamics, reliance on retrospective monitoring is an implicit failure to satisfy the statutory requirement that quality preservation or enhancement be expected within the model from its outset.

For cancer and rare disease patients, even temporary disruptions in access to physician-administered therapies can have irreversible clinical consequences. While we acknowledge that GLOBE does not remove any drug from coverage, economic factors shape manufacturer distribution channels, provider stocking decisions, site-of-care availability, and launch strategies. These mechanisms can influence access in ways that are indirect but clinically consequential. Treatment delays, forced switching, or site-of-care migration are not neutral events. They are

detriments in care quality that can place a model outside the permissible contours of CMMI's statutory authority.

We recognize that CMS identifies reduced costs as the primary benefit/improvement anticipated for Medicare beneficiaries. Even that is tenuous at best. CMS' discussion on financial toxicities related to treatment costs relied fully on studies examining the impact of high cost-sharing within the Part D benefit and surveys conducted before Part D redesign created a more affordable out-of-pocket cap and an opportunity to "smooth" costs over the plan year. Although the 20% Part B cost-sharing is significant, most beneficiaries are protected from high Part B cost-sharing through MediGap, other "supplemental" coverage, or Medicaid, Less than 1% of fee-for-service beneficiaries are without supplemental coverage and likely to receive a GLOBE model drug[1] The GLOBE model's benefits would, therefore, accrue to the subset of this 1% of beneficiaries for whom the incremental GLOBE cost reduction makes a previously unaffordable 20% cost-sharing affordable. We believe it is safe to say that the financial benefits of the GLOBE model would accrue primarily to the Medicare program.

Moreover, Section 1115A(b)(2)(B) lists "priority" model types and directs CMS to focus on models that improve care coordination, advance patient-centered delivery reform, and address high-need populations through delivery system innovation. The GLOBE Model would apply broadly to any patient receiving one or more of the Part B drugs CMS identifies over time as subject to the model. It primarily recalibrates manufacturer rebate obligations by benchmarking against international prices. It does not identify a high-need patient population that might benefit from the model, alter care coordination, provider incentives for quality improvement, or care delivery structures. Other than the theoretical beneficiary cost savings identified above, the anticipated real-world model impact is potential constricted access to GLOBE model drugs.

A model that functions principally as a pricing mechanism risks falling outside the statute's prioritization directive. While drug spending is an important policy concern, Section 1115A was not enacted as a generalized price control authority. It was enacted to enable CMS to test delivery system reforms that maintain care quality and offer the potential to improve value.

We urge CMS to re-evaluate the GLOBE model's fit within CMMI's innovation authority and consider alternative approaches such as voluntary manufacturer-participant models that provide "carrots" for pricing behaviors aligning US prices with relevant international markets. We similarly urge CMS to ensure that proposed CMMI models incorporate guardrails to protect beneficiary access in real time.

[1] How MFN Pricing in Part B May Affect Beneficiary OOP Costs | Avalere Health Advisory

GLOBE Injects QALY-Based Value Analyses into Medicare Pricing Despite Repeated Congressional Rejection of the Framework in Medicare

Congress has repeatedly rejected use of QALY-based valuation frameworks in federal health programs. The Affordable Care Act prohibits the Secretary from using cost-per-QALY thresholds in Medicare coverage and payment determinations.[2] The Inflation Reduction Act's Medicare Drug Price Negotiation Program explicitly prohibits CMS from using QALY-based methodologies or evidence that relies on QALY thresholds in setting maximum fair prices[3].

Many of the nations included in GLOBE's benchmarking framework employ and rely on centralized health technology assessment systems that incorporate QALY-based cost-effectiveness thresholds in determining national prices. Where benchmark prices are the product of QALY-constrained negotiation frameworks, adoption of those prices, even in aggregating prices across nations, functions as a mechanism for importing the consequences of QALY-based valuation into Medicare reimbursement.

Given that Congress has clearly signaled that QALY-based frameworks are inappropriate for establishing coverage or setting drug prices in federal programs, GLOBE's reliance on international prices warrants careful examination as well as transparency on how QALY-driven prices are excluded from any international benchmark.

Provider Economics, including ASP Compression, Creates Uncertainties and Potential Model-Related Harms Impacting Cancer and Rare Disease Patients and their Access to Treatment

Medicare beneficiaries receiving medications for a rare disease or cancer often receive their prescribed treatments within independent community practices and specialty centers, even if their treatment plan is developed by a specialist at a teaching hospital, center of excellence, or comprehensive cancer center. These providers operate under the ASP + add-on framework and have experienced structural pressures that threaten practice viability and stability.

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[2] **Social Security Act § 1182(e):** This section, added by the ACA, states that the Secretary "shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs" under Medicare (Title XVIII).

[3] Social Security Act Section 1194(e)(2)(C): "The Secretary **shall not use quality-adjusted life years (or such a similar measure** that discounts the value of a life because of an individual's disability) as a threshold to determine what type of health care is cost effective or recommended."

According to a February 2025 report by the Community Oncology Alliance (COA)[4]:

- From 2014 to 2023, the Medicare conversion factor decreased by a total of five percent, while the compounded increase of inflation over the same period was 28 percent.
- Physician payment for chemotherapy administration was nearly the same as 10 years ago… while the hospital rate has increased by 11 percent.
- These structural pressures have already eroded independent practice stability and driven consolidation with hospital systems.
    - Hospital-physician vertical integration is associated with increased Medicare Part B spending
    - The average spend increased 30 percent after a physician went from being independent to integrated into a hospital.

If GLOBE materially compresses effective net pricing while ASP updates lag or acquisition contracts adjust unevenly, independent practices will face:

- Continued margin erosion
- Cash-flow instability
- Reduced willingness or ability to stock high-cost therapies
- Accelerated consolidation into hospital outpatient departments.

Rare disease and cancer patients are uniquely vulnerable to site-of-care shifts. Specialized infusion protocols, clinical trial participation, and multidisciplinary care often depend on stable independent practices so patients can receive expert-driven treatment plans and get the care they need close to where they live. Without explicit modeling of Medicare Advantage plan behavior and provider-level impacts, GLOBE risks inadvertently accelerating the very consolidation dynamics associated with increased Part B spending.

GLOBE Injects an Additional Layer of Uncertainty that Could Impact Rare Disease and Cancer Innovation Risk and Launch Pricing Strategies

As noted above, GLOBE would, if implemented, be layered onto CMS' implementation of its first sets of Maximum Fair Prices (MFPs) for Part B drugs under the MDPNP. The Agency has previously expressed uncertainties regarding manufacturer launch pricing and contracting responses under MDPNP and has yet to identify a Part B MFP effectuation mechanism.

International benchmarking may introduce additional uncertainties by:

[4] COA_Prescription_Reform_FINAL.pdf

- Encouraging higher launch prices to hedge against benchmark exposure
- Accelerating pre-trigger price adjustments
- Shifting R&D investment across therapeutic areas
- Altering manufacturer distribution strategies.

For rare diseases, including rare cancers, where patient populations are small and development costs are high, even modest changes or uncertainties in expected return windows can materially influence innovation decisions. We urge CMS to re-examine its projections on potential GLOBE savings and model the potential sets of manufacturer behavioral responses rather than assume static pricing trajectories will yield Medicare program savings.

The Current Part B Landscape Would Inject Confounding Variables and Impair any CMS Model Validation/Evaluation Efforts

The GLOBE Model is presented as a "test." However, its performance period coincides with:

- MFP implementation
- Inflation rebate enforcement
- Ongoing vertical integration.

If access and/or pricing/cost patterns change, CMS will be unable to determine whether effects derive from GLOBE, MDPNP, or broader market adaptation. Testing a drug pricing reduction intervention within a policy environment that has been destabilized by a separate pricing intervention (MDPNP) substantially compromises the integrity of the model test by increasing the possibility that any results from GLOBE will be difficult to interpret and unsuitable for evaluation and scaling efforts.

CMS Should Not Randomize Beneficiaries to an Intervention Unless it Can Definitively Assert that No Change in Access or Outcomes will Result OR the Beneficiary Knowingly and Willingly Consents

Although manufacturers are the identified GLOBE participants, the model will prospectively assign beneficiaries to a model cohort without opt-out and with limited (if any) reviewability. It is not clear whether beneficiaries will be notified of their assignment with a clear explanation of the model, its goal, and potential unintended consequences for patients. For cancer patients whose therapies are life-extending and whose treatment courses are highly individualized, assignment to a cohort in which pricing mechanics may influence access dynamics is not a trivial exposure.

Although CMMI models generally fall outside formal human subjects research regulations, the totality of GLOBE's design — mandatory assignment, foreseeable access implications, post-hoc monitoring, lack of real-time remediation mechanism, and limited reviewability — places it over or near the boundary where Belmont principles and the Common Rule are implicated.

The Federal Policy for the Protection of Human Subjects (the "Common Rule"), has been codified with respect to the U.S. Department of Health and Human Resources (HHS) at subpart A of 45 CFR part 46. It requires that U.S. institutions engaged in cooperative research must rely on a single institutional review board (IRB) to review and approve the portion of the research conducted at domestic sites. See 45 CFR 46.114(b). To be exempt from this rule, research must meet one of the criteria found at 45 CFR 46.104(d). The set of "prioritized" model types delineated in the CMMI statute are exempted from the Common Rule under 45 CFR 46.104(d)(5) for Public Benefit or Service Programs.

PIRC strongly believes that even if CMS were to fully consider this issue and conclude that the Agency need not seek ethical review of the GLOBE model or provide for an informed consent or opt-out process, as steward of the Medicare program the Agency ***should*** do so. This would alleviate the Model's potential to drive beneficiary mistrust. A reasonable Medicare beneficiary living with cancer or a rare disease would expect transparency and meaningful safeguards when economic rule changes have the potential to influence access to life-sustaining therapy.

Even if GLOBE were technically exempt from IRB requirements, CMS' reliance on that exemption rather than incorporation of independent ethical oversight, informed consent mechanisms, and prospective safeguards is a policy choice that warrants careful reconsideration and an extraordinarily strong justification. CMS' summarized its assessment of the need for an informed consent/opt-out protection, noting:

> GLOBE Model beneficiaries are expected to benefit from the program through lower coinsurance costs for GLOBE Model drugs, removing the potential for downside risk for beneficiaries. Not including a beneficiary opt-out would enhance the model test integrity and improve the generalizability of results

We appreciate that CMS seeks stakeholder feedback on this decision. Our patient communities disagree with CMS' conclusion that an incremental savings on out-of-pocket costs for some beneficiaries could "remove" the downside risk associated with access hurdles that delay cancer treatment. Moreover, given the confounding variables associated with contemporaneous MDPNP implementation, denying this important beneficiary protection is unlikely to "enhance the model test integrity."

Conclusion

The GLOBE Model represents a significant intervention in Medicare drug payment policy at a time of extraordinary transition. Given the uncertainty impact on beneficiary access to care and health outcomes, we cannot support the GLOBE model. In the event CMS determines to proceed with the model test, we urge caution and proactive guardrails. CMS should:

- Mitigate any risk of irreversible and/or catastrophic patient harms by exempting cancer patients and individuals with rare diseases from the model.
- Refine GLOBE Model design to align with the requirements and priorities contained in Section 1115A.
- Address the structural tension between GLOBE benchmarking and Congressional rejection of QALY-based valuations in the Medicare program
- Model provider-level economic impacts (indirect as well as direct) and revise savings projections to account for any migration to hospital outpatient care settings
- Clarify evaluation methodology amid confounding variables, and provide an opportunity for stakeholders to weigh in on evaluation measures
- Outline a robust set of prospective beneficiary protections to address access barriers or care quality concerns in real time
- Avoid incorporating the GLOBE Model rebates into Medicare Advantage calculations until the model's impact on beneficiary access are analyzed and protections for Medicare Advantage enrollees can be implemented

Our organizations support CMS' goal of fair and rational drug pricing. However, neither rare disease patients nor cancer patients can afford policy experimentation that has potential to destabilize access to essential therapies.

PIRC appreciates the opportunity to offer these comments with the shared goal of ensuring that drug payment policy strengthens — rather than undermines — the integrity of Medicare and the trust of the patients it serves.

Respectfully submitted,

A Cure In Sight
Amyloidosis Support Groups
Association of Cancer Care Centers

Association for Creatine Deficiencies
Cancer*Care*
Cancer Support Community
Chondrosarcoma Foundation
CLL Society
Cutaneous Lymphoma Foundation
Haystack Project
International Pemphigus and Pemphigoid Foundation
MLD Foundation
National LMS Foundation
Nevus Outreach
Pheo Para Alliance
Sarcoma Foundation of America
The Life Raft Group