



February 23, 2026

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

**RE: CMS-5545-P — Global Benchmark for Efficient Drug Pricing (GLOBE) Model;  
Proposed Rule (90 FR 60244)**

Dear Administrator Oz:

The National Association of Specialty Pharmacy (NASP) appreciates the opportunity to submit comments on the proposed rules establishing the Global Benchmark for Efficient Drug Pricing (GLOBE) Model. NASP represents the specialty pharmacy industry, including pharmacies, manufacturers, distributors, some PBMs, GPOs, patient advocacy organizations, and technology companies that collectively serve Medicare beneficiaries with the most complex, chronic, and life-sustaining conditions in America. NASP represents specialty pharmacies that provide comprehensive patient care services for individuals with complex, chronic and rare medical conditions requiring high-touch specialty medications covered under Medicare Part B.

NASP shares the Administration's commitment to reducing prescription drug costs for all Medicare beneficiaries. We commend the Administration for working to pursue new ideas to ensure all prescription drugs are affordable and accessible, especially as new therapies come to market. However, after careful review of the proposed GLOBE model rule, NASP has concerns regarding the proposed methodology, its potential to disrupt patient access and specialty pharmacy operations, and the lack of transparency surrounding manufacturer exemptions. We respectfully urge CMS to consider the following comments and recommendations before proceeding with the GLOBE model.

## I. Qualification Criteria for Reference Countries and Their Exposure to Sole-Source Drugs

CMS proposes to identify 19 reference countries. While GDP-based thresholds provide a reasonable starting point for economic comparability, NASP is concerned that these criteria alone are insufficient to account for the fundamental structural differences in how each reference country manages pharmaceutical benefits, negotiates drug prices, and delivers specialty drugs to patients. Specifically, we urge CMS to consider the following:

- **Benefit Structure Variability.** The 19 reference countries operate under vastly different pharmaceutical benefit structures — ranging from single-payer national health systems (e.g., the United Kingdom's NHS) to social insurance models (e.g., Germany, France) to hybrid public-private systems (e.g., Australia, Canada). These systems employ different formulary management approaches, cost-sharing requirements, and reimbursement methodologies that directly affect the prices at which sole-source drugs are available. A direct comparison of list or ex-manufacturer prices across these disparate systems without adjusting for structural differences produces benchmarks that are inherently unreliable as proxies for what the U.S. Medicare program should pay.
- **PBM Involvement and Decision-Making.** Unlike the U.S. system, where Pharmacy Benefit Managers (PBMs) play a central role in formulary construction, rebate negotiation, and utilization management for Part D drugs — and where buy-and-bill dynamics govern Part B drug reimbursement — most reference countries rely on government-led health technology assessment (HTA) bodies and centralized procurement to set or negotiate drug prices. The absence of PBM-like intermediaries in these countries means that international prices reflect entirely different negotiation dynamics, cost structures, and distribution overhead. CMS must account for these differences to ensure the international benchmark does not produce artificially low price targets that fail to reflect the legitimate costs embedded in the U.S. supply chain.
- **Sole-Source Drug Exposure.** Many reference countries use international reference pricing, therapeutic substitution policies, and volume-based procurement agreements that the U.S. does not employ for sole-source drugs under Medicare Part B. Additionally, several reference countries limit or delay access to certain sole-source therapies through HTA gatekeeping that restricts patient access in ways that would be unacceptable under the Medicare program. CMS should assess and disclose how each reference country's regulatory approval timeline, formulary

access policies, and pricing mechanisms for sole-source drugs compare to the U.S. before using those countries' prices as benchmarks.

- **Overhead and Distribution Cost Differentials.** The U.S. pharmaceutical supply chain — including specialty pharmacy clinical services, cold-chain logistics, REMS compliance, and adherence monitoring — involves significantly higher overhead and operational costs than distribution systems in most reference countries. International benchmarks that do not account for these cost differentials will systematically undervalue the true cost of delivering sole-source specialty drugs to Medicare beneficiaries.

**Recommendation:** NASP recommends that CMS publish a detailed analysis of each reference country's pharmaceutical benefit structure, pricing mechanisms for sole-source drugs, the role of intermediaries in price-setting, regulatory approval timelines, patient access restrictions, and distribution cost structures. This analysis should be made available for public comment before the GLOBE Model is finalized.

## II. Support for Method II (Updated Benchmark) and the Use of Average Net Price

CMS proposes two methods for calculating the international benchmark. Method I (Default Benchmark) uses existing international drug pricing data sources to determine the lowest country-level price among the 19 reference countries. Method II (Updated Benchmark) allows manufacturers to voluntarily submit their own net pricing data (after rebates and discounts) from the reference countries, from which CMS would calculate a volume-weighted average net price. The greater of the two methods serves as the applicable benchmark.

NASP is concerned about the accuracy in the calculation of the benchmark, but between the two approaches, recommends Method II for the following reasons:

- **Accuracy of Net Pricing.** Method I relies on existing data sources that primarily reflect list prices or ex-manufacturer prices. As CMS itself acknowledges, these sources 'do not take into account rebates or clawbacks, details of which are normally confidential, and therefore these estimated prices do not reflect net prices realized by the manufacturers. Using inflated list prices as the baseline for Method I systematically understates what manufacturers actually receive in international markets, which in turn sets an artificially low benchmark for U.S. rebate calculations. Method II, as we understand it, attempts to correct this by incorporating actual net

pricing data — the prices manufacturers realize after confidential rebates and discounts — providing a far more accurate and equitable benchmark.

- **Volume-Weighted Average Softens Distortions.** Method II's volume-weighted average net price approach appropriately accounts for the reality that drug pricing varies significantly across countries based on volume, market size, and negotiation dynamics. Unlike Method I's lowest-country-price approach — which cherry-picks the single lowest price point among 19 countries with vastly different healthcare systems — the volume-weighted average under Method II produces a benchmark that is to reflect the global pricing landscape. This approach mitigates the risk of setting a benchmark based on an outlier country with exceptionally low prices driven by unique subsidies, purchasing power, or restricted formulary access.
- **Incentivizes Manufacturer Transparency.** By providing a pathway to a potentially higher (and more accurate) benchmark, Method II may incentivize manufacturers to submit transparent net pricing data to CMS.

**Recommendation:** NASP recommends that CMS adopt Method II as the primary benchmark methodology and use Method I only as a fallback when manufacturer-submitted net pricing data is unavailable or fails completeness validation.

### III. Treatment of ASP Quarterly Updates in GLOBE Model Rebate Calculations

Under current Medicare Part B payment policy, the Average Sales Price (ASP) for a HCPCS Level II code is calculated by CMS quarterly using manufacturer-submitted data on sales to all purchasers, with rebates, discounts, and price concessions factored into the calculation. ASP data is reported two quarters in arrears — meaning that the ASP payment limit for any given calendar quarter is based on manufacturer sales data from two quarters prior.

The proposed GLOBE Model rebate calculation is structured as a per-unit amount equal to the difference between the Medicare ASP-based specified amount and the per-unit GLOBE Model benchmark amount. However, the proposed rule raises critical operational questions about how CMS intends to address the inherent lag between quarterly ASP updates and the GLOBE Model benchmark calculations:

- **Mismatch Between ASP and International Pricing Data.** ASP data updates quarterly on a two-quarter lag. CMS proposes to use international drug pricing information from two calendar quarters prior to the applicable calendar quarter wherever possible, but acknowledges that existing data sources may have update lags of up to

90 days. This means that in any given quarter, the ASP numerator and the international benchmark denominator of the rebate calculation may reflect pricing from different time periods. CMS must clarify how it will synchronize ASP quarterly updates with international pricing data to prevent mismatches that could produce inaccurate rebate calculations.

- **Frozen Method I Benchmark vs. Dynamic ASP.** CMS proposes that the per-unit Method I GLOBE Model benchmark would be established once — at the time a drug enters the model — and would remain in place for the duration of the GLOBE Model performance period. However, the ASP-based specified amount updates quarterly. This creates a structural asymmetry: as ASP fluctuates (whether increasing due to price changes or decreasing due to new rebate negotiations), the frozen Method I benchmark does not adjust accordingly.
- **Method II Quarterly Recalculation.** Under Method II, manufacturers submit net pricing data corresponding to the applicable ASP calendar quarter, and CMS recalculates the benchmark quarterly. While this approach better aligns with ASP's quarterly update, CMS has not adequately explained in the proposal how it will reconcile situations where ASP data is corrected after the initial reporting period. Given that ASP corrections are common and can materially affect payment limits, CMS must clarify the reconciliation process for GLOBE Model rebates when underlying ASP data is restated/corrected.

**Recommendation:** NASP requests that CMS publish detailed operational guidance specifying: (1) how ASP quarterly updates will be synchronized with international pricing data for each applicable calendar quarter; (2) how the frozen Method I benchmark would be reconciled against dynamic quarterly ASP updates over the five-year performance period; and (3) the process for handling ASP restatements/corrections in GLOBE Model rebate calculations and reconciliation.

#### **IV. Clarification Needed for Newly Approved Drugs Billed Under Unspecified HCPCS Codes**

Under the proposed GLOBE Model, drug selection criteria require that a drug have a HCPCS Level II code with Medicare Part B FFS spending exceeding \$100 million over a 12-month period. The proposed rule also references the exclusion of products billed under a 'not otherwise classified' (NOC) code from the definition of a Part B rebatable drug.

Under current CMS processes, it typically takes approximately six months from the time a new drug is approved by the FDA to when CMS assigns a permanent, product-specific HCPCS Level II code. During this interim period, providers and pharmacies bill for the drug using unspecified or NOC codes, which creates significant data and payment ambiguity.

The proposed rule does not adequately address how this six-month interim period will be treated for purposes of GLOBE Model drug selection and rebate calculations. NASP identifies the following concerns:

- **Spending Threshold Calculations.** If spending during the unspecified-code period is included in the \$100 million threshold calculation, it could artificially accelerate a drug's inclusion in the GLOBE Model before reliable ASP data, which requires a product-specific HCPCS code for accurate reporting be available. If spending during this period is excluded, CMS needs to clarify when the 12-month spending measurement period begins for newly approved drugs.
- **ASP Reporting Accuracy.** During the unspecified-code period, ASP data is not reported under a product-specific HCPCS code, which means that ASP payment limits may be based on WAC + 3% rather than ASP + 6%. The GLOBE Model rebate calculation relies on the specified amount derived from ASP-based payment limits. CMS must clarify how the rebate calculation will function when ASP data is not yet available.

**Recommendation:** NASP recommends that CMS explicitly exclude the six-month drug launch period — during which a newly approved drug is billed under an unspecified or NOC HCPCS code before a permanent product-specific HCPCS Level II code is assigned — from all GLOBE Model spending threshold calculations, drug selection criteria, and rebate calculations.

## V. Beneficiary Eligibility Criteria by Zip Code Tabulation Areas

Limiting GLOBE participation to roughly 25% of Medicare beneficiaries based on random zip code selection will create operational complexity and risk confusion among patients and providers because eligibility for model pricing will vary among individuals despite the fact that those individuals have identical clinical needs.

## **VI. Lack of Transparency Regarding Manufacturer Exemptions from GLOBE Model**

### **A. Reported White House Manufacturer Agreements**

Multiple stakeholder reports indicate that certain pharmaceutical manufacturers have entered into separate drug pricing agreements with the White House and may be exempt from GLOBE Model participation.

### **B. Impact on Model Scope and Specialty Pharmacy Planning**

The uncertainty regarding manufacturer exemptions makes it impossible for specialty pharmacies to accurately assess the GLOBE Model's true scope and to prepare accordingly. To provide full and accurate feedback, NASP and its specialty pharmacy members need to understand:

- Which specific manufacturers and drugs are subject to GLOBE reforms?
- What specific drugs and percentage of a manufacturer's portfolio will be affected?

Without this transparency, specialty pharmacies cannot accurately forecast revenue impacts and adjust operations accordingly and assess whether model participation creates competitive advantages or disadvantages.

### **C. Arbitrary and Anti-Competitive Concerns**

The reported exemption of certain manufacturers through opaque White House agreements may create an arbitrary, anti-competitive landscape that favors large manufacturers with White House access. This is particularly concerning given that:

- Smaller specialty and rare disease manufacturers may lack political access to negotiate exemptions.
- Innovative companies developing novel therapies face GLOBE requirements while established manufacturers may be exempt.
- If certain manufacturers and their drugs are exempt while others face significant pricing reforms, this creates differential market pressures that could benefit certain manufacturers over others.

**D. Market Stability and Distribution Continuity.** The lack of clarity regarding the scope and structure of manufacturer participation in the GLOBE Model creates uncertainty within the pharmaceutical distribution system. Specialty pharmacies rely on stable pricing frameworks, predictable reimbursement methodologies, and consistent manufacturer distribution arrangements to manage inventory, maintain access to limited-distribution therapies, and ensure continuity of care for Medicare Part B beneficiaries.

If certain manufacturers or products are treated differently under separate agreements, uneven market conditions may arise, complicating contracting, reimbursement forecasting, and long-term operational planning for specialty pharmacies. CMS should ensure that any exemption framework is clearly defined, consistently applied, and fully transparent to avoid unintended disruptions to specialty pharmacy operations and patient access.

## **E. Recommendations**

NASP strongly opposes finalizing the GLOBE Model without full transparency on manufacturer exemptions. CMS should extend the comment period for 60 days after providing complete transparency on exemptions, allowing stakeholders to submit informed comments on the model's actual scope and impact.

## **VII. Impact on Specialty Pharmacy Reimbursement and Patient Access**

NASP is deeply concerned about the GLOBE Model's potential to destabilize specialty pharmacy operations and compromise patient access to critical therapies. Specialty pharmacies face higher acquisition costs, extensive clinical management responsibilities, complex care coordination activities, and heightened regulatory requirements. The model's reimbursement assumptions do not adequately account for these operational realities.

- **Margin Compression.** Lowering Medicare Part B drug reimbursement through international benchmarking may shift cost pressures upstream. Manufacturers may tighten margins offered to specialty pharmacies, increasing acquisition costs while reimbursement declines — eroding already narrow specialty pharmacy margins, particularly for high-touch therapies.
- **Supply Chain Disruption.** Manufacturers may consolidate specialty pharmacy distribution networks, impacting patient access to their specialty pharmacy.
- **340B Impact.** While GLOBE excludes 340B drugs, manufacturers already restricting 340B contract pharmacy access could attempt to further limit arrangements to reduce combined 340B and GLOBE rebate exposure, harming patient access in underserved communities.

**Recommendation:** NASP recommends that CMS: (1) reevaluate the reimbursement methodology to ensure specialty-specific cost structures are accurately accounted for; (2) conduct impact modeling specific to specialty pharmacies; (3) engage specialty pharmacy stakeholders throughout model refinement and post-implementation monitoring; and (4) establish unintended consequence monitoring with mandatory

quarterly reporting and circuit breakers to suspend the model if patient access is threatened.

## **Conclusion**

NASP appreciates the Administration's commitment to reducing prescription drug costs for Medicare beneficiaries. However, achieving this goal must not come at the expense of patient access, specialty pharmacy sustainability, innovation incentives, or the quality-assurance framework that underpins the U.S. pharmaceutical system. NASP stands ready to work collaboratively with CMS and the Administration to support prescription drug affordability while preserving the specialty pharmacy infrastructure that millions of patients depend upon for their most complex and life-sustaining therapies.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Sheila Arquette", with a large, stylized flourish at the end.

Sheila Arquette, R.Ph.  
President & CEO