

Here is a **three-page summary** of the proposed rule **RIN 0938-AV66 — Global Benchmark for Efficient Drug Pricing (GLOBE) Model** from the Centers for Medicare & Medicaid Services (CMS), scheduled for publication in the Federal Register. [Public Inspection Federal Register+1](#)

I. Introduction & Policy Context

The **Global Benchmark for Efficient Drug Pricing (GLOBE) Model** is a CMS proposal to establish a new Medicare payment model under **section 1115A of the Social Security Act** designed to address the rapid growth of **Medicare Part B drug costs**, particularly for expensive physician-administered medications like cancer therapies, immunologics, and biologics. The proposed rule seeks to test an alternative methodology for calculating **inflation rebate amounts** for certain Part B drugs by tying them to **international price benchmarks**— i.e., what comparable developed countries pay — with the expectation that aligning U.S. prices more closely with global norms will reduce spending for Medicare and beneficiaries while preserving or enhancing quality of care. [Public Inspection Federal Register+1](#)

Medicare Part B currently reimburses providers for outpatient drugs using Average Sales Price (ASP) plus a fixed add-on percentage, with limited mechanisms to curb high or rising prices. This model has contributed to disproportionately higher U.S. drug spending than in many other economically similar nations, burdening beneficiaries with higher co-insurance and taxpayers with elevated program costs. GLOBE intends to leverage **international drug pricing data** as a benchmark to determine **rebates** owed by manufacturers when U.S. prices exceed the benchmark, thereby effectively lowering net costs within Part B. [Centers for Medicare & Medicaid Services](#)

The proposed rule would implement GLOBE as a **mandatory model test** over several years, allowing CMS to evaluate impacts on program expenditures, beneficiary cost sharing, drug utilization, and quality outcomes. CMS opened the regulation for public comment, typically a 60-day window after publication, inviting stakeholders — including manufacturers, providers, patient groups, and economists — to provide input on model design, operational details, and potential effects. [Federal Register](#)

II. Detailed Model Design & Payment Framework

A. Model Scope & Applicable Drugs

The GLOBE Model would focus on a defined set of “**GLOBE Model drugs**”, primarily **Part B rebatable, single source drugs and sole source biological products** that meet specified eligibility criteria. These are drugs typically administered in outpatient or clinical settings, such as physician offices and hospital outpatient departments. Drugs selected for the Medicare Price Negotiation Program under the Inflation Reduction Act are excluded, reducing duplication and focusing the model on prices not yet subject to negotiated payment limits. [Public Inspection Federal Register+1](#)

B. Beneficiary Population & Geographic Areas

CMS proposes to **limit the initial testing of the model to approximately 25 % of Medicare Fee-for-Service (FFS) beneficiaries** based on geographic areas predetermined by CMS. Included beneficiaries must be enrolled in traditional Medicare Part B (not Medicare Advantage or other plans) and identified through their address of record. Providers furnishing included drugs continue to be paid under existing Medicare Part B systems but with adjusted calculations to reflect GLOBE provisions. [Public Inspection Federal Register](#)

C. Alternative Rebate Calculation Using International Benchmarks

Under the proposed model, **manufacturers of GLOBE Model drugs would be required to pay rebates to Medicare** if the specified inflation-adjusted U.S. reimbursement amount exceeds a **benchmark drawn from international drug pricing data**. CMS proposes two approaches to establish benchmarks:

- **Method I:** Use publicly available international drug price data to estimate the **lowest price** among a set of economically comparable countries.
- **Method II:** Use **voluntary manufacturer-submitted net international price data** to estimate an **average international price** across the same set of countries.

In either approach, the benchmark would be no lower than what the manufacturer owes under the existing Medicare Part B Drug Inflation Rebate Program, ensuring that GLOBE rebates supplement rather than undercut the current mechanism. [Public Inspection Federal Register](#)

D. Rebate Process & Timing

CMS would modify standard rebate reporting and invoicing procedures. The GLOBE Model rebate amount — defined as the **incremental amount** above the Part B inflation rebate — would be invoiced to manufacturers after a calendar quarter ends, using timelines harmonized with existing Part B rebate operations. CMS proposes two possible approaches:

- **Combined Approach:** Incorporate GLOBE Model data within existing Part B rebate reports, with slight delays to ensure complete information.
- **Incremental Approach:** Issue separate rebate reports specific to GLOBE Model rebates, coordinated with traditional Part B rebate cycles.

Manufacturers would have opportunities to submit a **“Suggestion of Error”** if they believe CMS’s calculations contain mathematical inaccuracies, similar to existing rebate dispute processes. CMS may also use civil money penalties to enforce timely payment of rebate amounts. [Public Inspection Federal Register](#)

E. Beneficiary Coinsurance Adjustments

In addition to rebates, CMS proposes to **adjust beneficiaries’ coinsurance responsibilities** for GLOBE Model drugs. The model includes alternative calculations to reduce coinsurance percentages when international benchmark-based payment amounts are lower, thereby lowering out-of-pocket costs for beneficiaries. CMS also proposes to adjust the Medicare payment to providers accordingly so as to balance incentives and maintain access. [Public Inspection Federal Register](#)

III. Implementation Timeline, Waivers, Evaluation & Impact

A. Performance Period & Waivers

CMS proposes a **seven-year test period** for the GLOBE Model, including **five performance years** (from **October 1, 2026 to September 30, 2031**) during which adjusted payments and coinsurance would apply, followed by two additional years for reconciliation and evaluation through **September 30, 2033**. To implement the model, CMS proposes waivers of specific statutory provisions that would otherwise impede testing — including portions of the Medicare inflation rebate calculation rules and timing requirements under section 1847A of the Social Security Act, as well as certain Part B payment rules under

section 1833. These waivers are intended solely for model purposes and do not alter the underlying law outside the test. [Public Inspection Federal Register](#)

B. Regulatory & Evaluation Objectives

CMS must conduct a rigorous **evaluation** of the GLOBE Model, as required under section 1115A(b)(4), to assess both **cost and quality outcomes**. The evaluation will compare results in model regions with non-model regions, measuring effects on Medicare spending, beneficiary financial liabilities, drug utilization patterns, access to care, and clinical outcomes. CMS may collect representative data from manufacturers, providers, and beneficiaries to support this analysis. The evaluation is designed to inform whether GLOBE should be modified, expanded, or ended after the test period. [Public Inspection Federal Register](#)

C. Estimated Impacts

CMS's economic analysis in the proposed rule estimates that the GLOBE Model could generate **billions of dollars in savings** for Medicare Part B net spending over the model period, including reduced costs for Medicare FFS, Medicare Advantage, and potential premium offset impacts. Estimated savings are driven by reduced net prices through benchmark-linked rebates and lower beneficiary coinsurance, though actual results will depend on manufacturer behavior and utilization responses. [Public Inspection Federal Register](#)

D. Costs, Burden, and Stakeholder Implications

The model would introduce administrative costs for CMS, manufacturers, and providers related to new reporting, invoicing, and compliance processes. Stakeholders may raise concerns about complexity, data availability for international benchmarks, impacts on innovation incentives, and access to drugs subject to global pricing comparisons. CMS seeks public comment on these operational and policy aspects. [Partnership to Improve Patient Care](#)

IV. Conclusion & Policy Significance

The GLOBE Model represents a **major policy initiative** to integrate **international price benchmarking** into Medicare payment for Part B drugs, building on longstanding concerns about high U.S. drug costs relative to other countries. If implemented, it would mark a significant departure from traditional domestic ASP-based pricing mechanisms by tying rebate liabilities and beneficiary cost sharing to how much other developed nations pay for the same medications. The model's outcomes could inform future Medicare pricing reforms aimed at improving **affordability and sustainability** without compromising quality of care. CMS's solicitation of public comments will play a crucial role in refining the model's parameters before final rule publication and potential implementation in 2026. [Centers for Medicare & Medicaid Services](#)