

Issue Brief

FEDERAL ISSUE BRIEF



Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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CMS Finalizes New Mandatory Drug Payment Model

The Centers for Medicare & Medicaid Services (CMS) are finalizing a

drug payment model to address the increasingly expensive cost of drugs in Original Medicare (OM) Part B while preserving or enhancing Medicare beneficiaries' quality of care. The Global Benchmark for Efficient Drug Pricing (GLOBE) Model will test whether a new rebate formula for certain drugs in the Medicare Part B Drug Inflation Rebate Program reduces costs for Original Medicare beneficiaries.

The GLOBE Model is established under section 1115A of the Social Security Act (the Act), which authorizes CMS's Center for Medicare and Medicaid Innovation (hereinafter, "the CMS Innovation Center") to test innovative payment and service delivery models. The GLOBE Model will begin on January 1, 2027 with the collection of voluntary manufacturer-submitted international drug net pricing data, and will be tested over 5 performance years, running from April 1, 2027 through March 31, 2032.

The 585-page rule is published in the October 2, 2026 **Federal Register**. A copy of the rule is ntly available at: <https://public-inspection.federalregister.gov/2026-20281.pdf>.

Comment

This rulemaking does not, as is typical with many recent CMS rules, contain a table of contents. We are providing one below.

The rule's summary of major provisions (Pages 6-14) provides a reasonable description of the rule's actions. We are adopting such below.

Next, we include a detailed table-of-contents, followed by a brief summary of the entire document.

Summary of Major Provisions

CMS is finalizing the GLOBE Model to include the following major provisions.

1. Model Performance and Test Period:

The model will includes a 7-year payment period, which will begin on April 1, 2027 and will end on March 31, 2034, during which CMS will calculate, invoice, collect, and reconcile the GLOBE Model rebates for a performance year. The model evaluation will reflect the entire GLOBE Model test period—which includes the voluntary manufacturer submission period and the 7-year payment period.

2. GLOBE Model Drugs:

The GLOBE Model will include a subset of Part B rebatable drugs that have the following United States Pharmacopeia (USP) Drug Classification (DC) categories: Antigout Agents, Antineoplastics, Blood Products and Modifiers, Central Nervous System Agents, Immunological Agents, Metabolic Bone Disease Agents, and Ophthalmic Agents.

These drugs must have a Healthcare Common Procedure Coding System (HCPCS) Level II code with OM Part B spending greater than \$100 million over a 12-month period ending 6 months prior to the start of the applicable calendar quarter (as further specified in § 513.130(b)(3) and § 513.130(d)) and must not be excluded from the GLOBE Model as set forth in § 513.130(c).

The following drugs and biological products are excluded from the GLOBE Model (§ 513.130(c)):

(1) a Part B rebatable drug for applicable calendar quarters prior to the first applicable calendar quarter for which CMS identifies a specified amount under 42 CFR 427.302(b);

(2) a Part B rebatable drug for which a maximum fair price under the Medicare Drug Price Negotiation Program is in effect;

(3) a drug or biological product which is no longer a Part B rebatable drug;

(4) a Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare disease or conditions;

(5) a Part B rebatable drug that is a product listed on the FDA Approved Cellular and Gene Therapy Products website; and

(6) a Part B rebatable drug that is a plasma-derived product as set forth in 42 CFR 427.400.

3. Defined Population and Intervention:

The model cohort will be identified by CMS from approximately 25 percent of beneficiaries who are enrolled in OM Part B, have OM Part B as their primary payer (as defined by a beneficiary being enrolled in OM), and are not enrolled in a Medicare Advantage (MA) plan, section 1876 cost plan, or section 1833 healthcare repayment plan.

Beneficiaries must not have other group health coverage that is a primary payer (such as employer-sponsored health insurance). The GLOBE Model geographic areas will be determined through a random selection of ZIP Code Tabulation Areas (ZCTAs).

Prior to the model performance period, and no more frequently than monthly thereafter, CMS will identify beneficiaries for inclusion in the model cohort by determining whether the beneficiary's address of record falls within the GLOBE Model geographic areas. Medicare beneficiaries who are in the model cohort, or "GLOBE Model beneficiaries," will not be model participants but will benefit from reduced coinsurance, as applicable, when they receive a separately payable GLOBE Model drug as described in section II.G.7. of this final rule.

Beneficiary selection for the model cohort and comparison group (and removal, if applicable) will be solely determined by CMS and will not be subject to appeal pursuant to section 1115A(d)(2) of the Act. Providers and suppliers who furnish GLOBE Model drugs to GLOBE Model beneficiaries who are in the model cohort will not be model participants and will continue to buy and bill for GLOBE Model drugs as usual and receive separate payment under Medicare Part B (if applicable).

These providers and suppliers include, but may not be limited to, hospital outpatient departments, physician practices, ambulatory surgical centers, pharmacies enrolled as durable medical equipment (DME) suppliers, and other pharmacies (in certain situations). When the reduced beneficiary coinsurance applies to units of GLOBE Model drugs furnished to a GLOBE Model beneficiary, the provider or supplier will reduce the amount of coinsurance charged to the beneficiary and the portion of the Medicare Part B allowed amount that will be payable by Medicare Part B will be adjusted upwards, as applicable. For example, if the Medicare Part B allowed amount for a GLOBE Model drug under the GLOBE Model is \$100 and the GLOBE Model beneficiary coinsurance percentage is reduced to 10 percent (instead of the usual 20 percent), the Medicare Part B program payment to the provider or supplier will be adjusted upward and will be \$90 (instead of the usual \$80) and the beneficiary coinsurance financial responsibility will be \$10 (instead of the usual \$20).

4. Manufacturer Participation:

The GLOBE Model will require mandatory participation for all manufacturers (as defined in 42 CFR 427.20) of Part B rebatable drugs that are GLOBE Model drugs.

5. Model Alternative Rebate Amount Calculation and Rebate Payment:

As described in section II.G.2., the GLOBE Model will incorporate two approaches for establishing a benchmark amount for the alternative rebate amount calculation, each using differently sourced international drug pricing information and distinct calculation methodologies. The model evaluation will assess the impact of testing these two approaches.

The first approach, Method I will use existing, commercially available international drug pricing information to establish a benchmark based on an estimate of the lowest country-level price among the set of reference countries, as set forth in § 513.310, at a baseline. This pricing data may represent drug-specific sales data, list prices, ex-manufacturer prices, retail prices, other prices, or a combination of such pricing information, as available to CMS in commercially available data sources.

The second approach, Method II, will use voluntary manufacturer-submitted international drug net pricing data to establish a benchmark based on an average international price among the set of countries. This benchmark will reflect net prices realized by a manufacturer. Manufacturer submission of international drug net pricing data is discussed in section II.G.6. of this final rule. CMS is finalizing that the set of reference countries for Method I and Method II benchmarks, as set forth in § 513.310(b), will include Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.

6. Model Waivers:

CMS has determined that it will be necessary to waive certain requirements of title XVIII of the Act and related program requirements codified in regulations, solely for purposes of carrying out the testing of the GLOBE Model. CMS will waive provisions of sections 1847A(i), 1833(a), and 1833(t) of the Act, as well as associated regulatory provisions at 42 CFR 410.152(m), 419.41€, 489.30(b)(1), and 489.30(b)(6), to the extent necessary to permit the testing of an alternative rebate amount calculation for certain units of GLOBE Model drugs, the collection of GLOBE Model rebate amounts, GLOBE Model reduced coinsurance, and adjusted Medicare payment.

7. Enforcement of Manufacturer Payment of Rebate:

Consistent with the enforcement framework of the Medicare Part B Drug Inflation Rebate Program, manufacturers of a GLOBE Model drug that have failed to timely pay the incremental GLOBE Model rebate amount may be subject to a civil money penalty (CMP). Further details on the enforcement of manufacturer payment of rebates are provided in section II.H.

8. Quality and Monitoring Strategy:

CMS has finalized a quality and monitoring strategy for the GLOBE Model. CMS will monitor and evaluate whether the alternative Medicare Part B drug inflation rebate calculation under the GLOBE Model reduces Medicare spending while preserving or enhancing the quality of care for beneficiaries. Consistent with section 1115A(b)(4) of the Act, CMS will conduct ongoing monitoring and evaluation activities throughout the model performance period to identify potential changes in beneficiary access to GLOBE Model drugs, utilization and prescribing patterns, beneficiary out-of-pocket costs, continuity and site of care, downstream healthcare utilization, drug availability and distribution patterns, and other unintended consequences.

9. Beneficiary Protections:

CMS has finalized beneficiary protections activities for the GLOBE Model. CMS will not require direct beneficiary notification or establish a beneficiary opt-out because inclusion in the model does not require beneficiaries to enroll or take any action and does not change Medicare coverage or provider choice.

10. Interaction and Coordination with Other Models and Programs:

CMS reviewed potential interactions between the GLOBE Model and other models and programs to ensure that the evaluation of model impact is not compromised by issues of model overlap. The GLOBE Model has been designed to function alongside and in addition to the Medicare Part B Drug Inflation Rebate Program.

11. Evaluation Methods:

The GLOBE Model evaluation will employ a design to provide evidence that the proposed intervention would reduce Medicare expenditures and would preserve or enhance the quality of care for Medicare beneficiaries.

Summary of Costs and Benefits

CMS estimates that the GLOBE Model will result in overall savings of \$440 million in Medicare Part B net spending during the 7-year payment period, inclusive of \$298 million in OM Part B benefit savings, \$288 million in MA payment savings, and \$147 million in premium offset impacts.

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Summary of the GLOBE Model Final Rule

Document: RIN 0938-AV66. The rule runs 585 pages, was approved September 23, 2026, and is scheduled for ***Federal Register*** publication on October 2, 2026. It is effective **November 30, 2026**.

1. Purpose and rationale:

The rule creates a **mandatory** CMS Innovation Center model under Section 1115A. It tests an alternative way to calculate **Medicare Part B drug inflation rebates** for certain separately payable drugs, using international net-price benchmarks. The stated aim is to lower spending and beneficiary cost-sharing while preserving or improving quality.

The background section relies on several themes:

- Affordability and cost-related non-adherence among seniors.
- Growth in Part B drug spending and premiums.
- ASPE and RAND findings that U.S. prices exceed those in peer OECD countries.

2. Timeline:

Date	Milestone
Jan 1, 2027	Voluntary manufacturer submission of international net-price data begins.
Apr 1, 2027 – Mar 31, 2032	Five performance years, when beneficiary coinsurance changes and adjusted provider payments apply.
Apr 1, 2027 – Mar 31, 2034	Seven-year payment period for calculating, invoicing, collecting and reconciling rebates.

Geographic areas are randomly selected at least **90 days** before April 1, 2027. The proposed rule said 60 days, and CMS lengthened it after comments on operational complexity.

3. Which drugs are covered:

A drug is in the model if it meets all of these:

- It is a Part B rebatable single-source drug or sole-source biologic.
- It falls in one of seven USP classes: antigout agents, antineoplastics, blood products and modifiers, CNS agents, immunological agents, metabolic bone disease agents, or ophthalmic agents.
- It has a HCPCS Level II code with **more than \$100M** in OM Part B spending over a 12-month lookback ending 6 months before the quarter.

Exclusions:

- Drugs with a Negotiation Program maximum fair price in effect.
- Drugs no longer Part B rebatable.
- Drugs for quarters before a "specified amount" exists.
- Three exclusions **added in response to comments**: orphan-only drugs, FDA-listed cell and gene therapies, and plasma-derived products.
- Drug selection and removal are not appealable.

4. Who is in the model:

- **Manufacturers** of GLOBE Model drugs participate mandatorily.
- **Beneficiaries** are the model cohort, about **25% of OM Part B enrollees**, identified through randomly selected ZIP Code Tabulation Areas.
 - Medicare Advantage, cost plan and prepayment plan enrollees are excluded, as is anyone whose primary payer is other group coverage.
 - There is no beneficiary opt-out. CMS reasoned that assignment is geographic, and it kept this provision as proposed.
 - Cohort selection is not appealable.
- **Providers and suppliers** are not participants. They continue to buy and bill as usual.

5. How the benchmark and rebate work:

Two benchmark methods:

- **Method I** uses existing commercial international pricing data, applied in a hierarchy of sources. It estimates the **lowest country-level price** among the reference countries.
 - It is set **once, at baseline**, when the drug enters the model. CMS wants to prevent manipulation through list-price and rebate shifts.
 - Prices are adjusted by a **GDP (PPP) adjuster**: U.S. real GDP per capita divided by the country's, using CIA World Factbook data.
- **Method II** uses voluntarily submitted manufacturer net prices. It is a **volume-weighted average** across the reference countries.

Benchmark amount: each quarter, CMS takes the **greater** of the two benchmarks (when both are available), then adds two things:

- An **applicable threshold percentage**: 2.0 percent on Method I and 5.0 percent on Method II. The higher figure is meant to encourage voluntary submission.
- The **add-on percentage amount**, typically 6.0 percent of the Part B payment amount, so the model does not change the add-on.

If neither method yields a benchmark, the benchmark is "not available" for that quarter.

Rebate: manufacturers owe a rebate when the specified amount exceeds the benchmark amount.

- It is never less than what the standard inflation rebate would be.
- It applies only to billing units for cohort beneficiaries.
- It is invoiced on an **incremental** basis.
- CMS finalized a modification to the rebate report provisions so the report shows the amount by which the specified amount exceeds the per unit rebate amount.

Beneficiary coinsurance:

CMS compares the benchmark amount with the inflation-adjusted payment amount and uses the **lesser** in computing the coinsurance percentage, so beneficiaries never pay more than they would without the model.

Other mechanics:

- Manufacturers may file a Suggestion of Error for mathematical errors only.
- Rebate amounts are not appealable.
- Late payment can bring **civil money penalties**, aligned with the existing inflation rebate program.
- CMS removed the proposed severe-supply-chain-disruption provision (§ 513.500(e)).
- The rule includes a severability clause.

6. Interactions with other programs:

- **Medicaid best price / AMP:** GLOBE rebates are paid under § 1847A(i), so they are excluded from best price. CMS does not expect a material impact.
- **340B:** claims with a 340B modifier are excluded from billing units and rebates.
- **Medicare Advantage:** MA is outside the model, but lower OM spending flows into MA benchmarks starting with 2028 rate-setting. CMS estimates MA savings of about \$288M.
- **Other models and QPP:** CMS finalized its overlap approach as proposed.

- **Waivers:** CMS waives provisions of §§ 1847A(i), 1833(a) and 1833(t) and related regulations, to the extent needed to test the model.

7. Monitoring and evaluation:

CMS will monitor quality and access during the performance period. The evaluation will assess spending and quality, and will compare the two benchmark methods. Its design is **not in regulatory text** and will be communicated through sub-regulatory guidance. Beneficiary protections were addressed in the rule, including the decision not to allow opt-out.

8. Regulatory impact:

Item	Estimate
OM Part B net spending savings (before premium effects)	\$298M over the model
Annualized Part B savings, 2027–2032	About \$80M (3% and 7% discount rates)
Medicare Advantage savings	\$288M
Medicaid savings	\$39M (about \$23M federal, \$15M state)
Beneficiary cost-sharing savings	About \$50M
Beneficiary premium savings	\$61M
Total beneficiary out-of-pocket savings	\$111M

Key assumptions:

- GLOBE drugs would have been about **3%** of 2024 non-dual, non-340B OM Part B drug spending.
- Rebates exclude 340B units and most dual-eligible units.
- Manufacturers in the **GENEROUS Model as of Aug 17, 2026** are assumed not to participate in GLOBE. Changes in GENEROUS participation would change these estimates.

The proposed rule had projected about **\$1.4B** in beneficiary cost-sharing savings. The final estimate is far lower, partly because the exclusions narrowed the drug set. Manufacturer net-price reporting costs were treated as marginal. The rule is exempt from the E.O. 14192 offset requirements.

9. Comment themes:

- Concern that only 25 percent of beneficiaries benefit.
- Concern about the inability to opt out, especially for oncology patients.
- Questions about 340B and Medicaid effects.
- Debate over whether CMS may use international reference pricing at all, since commenters point out Congress considered and did not enact it in the IRA.