MFN MODELS

GLOBE AND GUARD REGULATORY ANALYSIS

CALIFORNIA LIFE SCIENCES

OVERVIEW

On December 23, 2025, CMS's Center for Medicare and Medicaid Innovation (CMMI) proposed two new payment models, the Global Benchmark for Efficient Drug Pricing (GLOBE) model for Medicare Part B[1] and the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) model for Medicare Part D.[2] These two mandatory CMMI models are intended to implement Most Favored Nation (MFN) pricing for Medicare drugs by replacing the existing method for calculating manufacturer rebate benchmarks under Parts B and D with a new international benchmark test. These models are still in the proposed rulemaking stage.

Each model applies to a defined set of single-source drugs and sole-source biological products that meet certain eligibility criteria and spending thresholds and would only apply to units dispensed or administered to beneficiaries selected for participation in the models. CMS proposes to test each model in geographic areas comprising approximately 25% of Medicare Part B fee-for-service (FFS) beneficiaries for GLOBE and 25% of Medicare Part D beneficiaries for GUARD. These geographic limitations are intended to test these models (25% "test group" with the rest of the nation as a "comparator group"), and the results of these tests could help CMS determine whether these models merit eventual nationwide expansion.

Instead of asking whether a drug's price has increased faster than inflation and rebating back the difference (as is the case under current law), these new models would ask whether US prices are higher than what comparable countries pay and rebate back that difference.[3] Manufacturers must pay the rebate amount owed or be subject to monetary penalties.

CMS estimates that the GLOBE model could encompass 55 percent of annual Part B FFS drug spending and could save the government $13 billion and seniors $4 billion over the course of the model. CMS separately estimates that the GUARD model could save the government $14 billion over the model's duration.

GLOBE AND GUARD SIMILARITIES

Same MFN Calculations (2 Options): Manufacturers are given the choice to either rely on CMS's default methodology or submit their own international drug price data. CMS would set the international benchmark as the larger number reached between these two methods.

- **Method I – Lowest Peer-Country Average Price (Default Benchmark):** The lowest average price[4] among reference nations based on available data obtained by CMS.
- **Method II – Across Country Average Price (Voluntary Manufacturer-Submitted Data):** The average price in the chosen subset of nations from data provided voluntarily by the drug manufacturer. A manufacturer may choose to adopt this method, but does not have to, in which case the international benchmark would be determined by the "default" method I. Should CMS find the data submission to be acceptable, then this pricing data would serve as an alternative international benchmark.
- **Total Rebate Owed = (US Price Per Unit – International Benchmark Per Unit) x Number of Units Dispensed to Model Beneficiaries:** If the US price[5] is higher than the international price, the manufacturer owes a rebate. Since international prices are generally lower than US prices, a rebate will likely be owed for most drugs that fall under these two models, with higher rebates being owed the greater the price disparity.
- **Same Reference Country Basket (Reference Nations):** The reference nations include Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.
- **Both Models are Mandatory:** All manufacturers supplying qualifying drugs that meet the inclusion criteria must comply with these models.
- **Geographic Scope – Both Models Only Apply to 25% of Medicare Beneficiaries Based on Zip Code:** GLOBE[6] applies only to approximately 25% of Medicare Part B fee-for-service beneficiaries in randomly selected geographic areas. GUARD[7] applies to approximately 25% of Part D beneficiaries in randomly selected geographic areas, including both standalone Prescription Drug Plans and Medicare Advantage with Part D coverage.

COMPARISON CHART

The chart below provides a side-by-side comparison of GLOBE and GUARD.

	GLOBE	GUARD
Overview		
Status	Proposed Rule (Comment period ended Feb 23, 2026)	Proposed Rule (Comment period ended Feb 23, 2026)
Participation Type	Mandatory	Mandatory
Insurance Program	Medicare Part B (clinician-administered drugs) • Fee-For-Service (FFS)	Medicare Part D (pharmacy-dispensed drugs) • Prescription Drug Plan (PDP) • Medicare Advantage Prescription Drug (MA-PD)
Coverage	25% of Part B members in selected geographic regions	25% of Part D members in selected geographic regions
Start Date and Performance Period	5 Year Duration • October 1, 2026 – September 30, 2031	5 Year Duration • January 1, 2027 – December 31, 2031
Payment Reconciliation Period	October 1, 2031 – September 30, 2033	January 1, 2032 – December 31, 2035
Drugs Covered		
Spending Threshold	Over $100+ million in Medicare Part B annual spending	Over $69+ million gross Part D spending (2027, indexed by CPI-U annually)
Drug Coverage Type	Single-source drugs and sole-source biological products in specified therapeutic categories	Sole-source drugs covered under Part D Inflation Rebate Program in specified therapeutic categories
Excluded Drugs	• Drugs that have a Maximum Fair Price (MFP) imposed on them through IRA's Medicare Drug Price Negotiation Program (MDPNP) • Drug units that are subject to 340B discounts	• Drugs that have a Maximum Fair Price (MFP) imposed on them through IRA's MDPNP • Drug units that are subject to 340B discounts • Generics and biosimilars
Therapeutic Categories[8]	7 Categories: 1. Antigout agents; 2. Antineoplastics; 3. Blood products/modifiers; 4. CNS agents; 5. Immunological agents; 6. Metabolic bone disease agents; 7. Ophthalmic agents	17 categories: 1. Analgesics 2. Anticonvulsants 3. Antidepressants 4. Antimigraine 5. Antineoplastics 6. Antipsychotics 7. Antivirals 8. Bipolar agents 9. Blood glucose regulators 10. Cardiovascular agents 11. CNS agents 12. Gastrointestinal agents 13. Genetic/enzyme/protein treatments 14. Immunological agents 15. Metabolic bone disease agents 16. Ophthalmic agents 17. Respiratory tract/pulmonary agents

[1] Global Benchmark for Efficient Drug Pricing (GLOBE) Model (Part B)
[2] Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (Part D)
[3] **Inflationary Rebate < International Rebate:** Note that technically, the GLOBE and GUARD models provide that CMS will apply the larger of the two rebates, either the inflationary benchmark under existing law or the new MFN benchmark proposed by GLOBE and GUARD. However, since it is expected that in the vast majority of cases the MFN benchmark will lead to far higher rebates than that of the US domestic inflationary CPI-U benchmark, the MFN benchmark would generally supersede the inflationary benchmark for most drugs.
[4] **"Average Price" Adjusted by Each Nation's Purchasing Power:** The international benchmark would be determined by the lowest country-level average (under method I, which may be less favorable to a manufacturer) or across-country average (under method II, which will likely more favorable to a manufacturer) price among the set of average prices for each reference country, adjusted by the country-specific GDP based on purchasing power parity (PPP).
[5] **Price**: CMS compares the US price against the international price. Drugs are identified by major identifying characteristics, such as scientific/nonproprietary name, dosage form, route of administration, strength, etc. The US price would be established by:
- **GLOBE – US Price (ASP or WAC) vs International Benchmark:** The per unit GLOBE Model drug rebate amount would be the difference between the average sales price (ASP) of the drug, or when not available, its wholesale acquisition cost (WAC), and the per unit GLOBE Model benchmark amount.
- **GUARD – US Price (Medicare Net Price/WAC Minus Discounts) vs International Benchmark:** The Medicare Net Price, which is the wholesale cost minus existing rebates and discounts (the Medicare net price would be calculated by subtracting manufacturer rebates and discounts paid under the Manufacturer Discount Program/MDP from the wholesale acquisition cost/WAC of the drug).

[6] **GLOBE – Part B as Primary Payor:** To qualify as a GLOBE Model-eligible beneficiary, an individual must be enrolled in Medicare Part B as his or her primary payer (not Medicare Advantage ("MA") or a Health Care Prepayment Plan) and reside in a GLOBE geographic area based on the beneficiary's address of record with Medicare.
[7] **GUARD – Standalone PDP or MA-PDP**: To qualify as a GUARD Model beneficiary, an individual must be enrolled in a standalone Prescription Drug Plan or MA-Prescription Drug plan (not an Employer Group Waiver Plan) and reside in a GUARD geographic area based on the beneficiary's address of record with Medicare.
[8] **Therapeutic Categories Per USP-DC**: Specifically, "therapeutic categories" means categories as defined by the United States Pharmacopeia Drug Classification (USP-DC).