

Publications

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CMS Proposes GLOBE and GUARD Drug Pricing Models to Reduce Medicare Costs

Key Takeaways:

- CMS has proposed two mandatory Medicare drug pricing models: the GLOBE Model (for Part B drugs) and the GUARD Model (for Part D drugs).
- Both models would link Medicare drug rebate calculations to international pricing benchmarks from “economically comparable” countries.
- If finalized, the GLOBE and GUARD Models would create new and potentially significant rebate obligations for drug manufacturers.

Background:

In December, the Centers for Medicare & Medicaid Services (CMS) proposed two new drug pricing models designed to address sustained growth in prescription drug spending across Medicare, driven in part by U.S. drug prices that remain substantially higher than prices paid in other developed countries.

According to CMS:

- Medicare Part B drug spending increased at nearly four times the rate of overall drug spending across all payors between 2008 and 2021; and
- Medicare Part D spending increased from approximately \$121 billion in 2014 to \$276 billion in 2023 — a nearly 10% average annual growth rate.

In announcing these new pricing models, CMS explained that higher drug costs can create affordability challenges for Medicare beneficiaries which may result in delayed care, reduced adherence to prescribed therapies or forgone treatment. The agency also noted that cost-related nonadherence may contribute to poorer health outcomes and increased downstream health care utilization, including emergency department visits and hospitalizations, ultimately increasing Medicare spending.

In response to these trends and the Trump Administration’s broader drug pricing initiatives, on December 19, 2025, CMS issued proposed rules to implement two new mandatory models that would link Medicare drug rebates, beneficiary out-of-pocket costs

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and Medicare program spending to prices paid in economically comparable countries.¹ The proposals include the Global Benchmark for Efficient Drug Pricing (GLOBE) Model for certain Medicare Part B drugs and the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model for certain Medicare Part D drugs. If finalized as proposed, these models would create new rebate obligations for manufacturers of selected Part B and Part D drugs in defined geographic areas. These new pricing models arrive against a backdrop of other significant drug pricing efforts by the Trump Administration, including an executive order on May 12, 2025 that directed federal agencies to pursue most-favored-nation (MFN) pricing and related actions to promote international price alignment for prescription drugs. The GLOBE and GUARD Models also coincide with the Administration's broader drug pricing initiatives with the anticipated January 2026 launch of TrumpRx, a planned direct-to-consumer platform aimed at expanding access to prescription drugs at MFN aligned prices. (CMS also announced in late 2026 a model dubbed "GENEROUS," which is a voluntary rebate program for Medicaid drugs.) Collectively, these proposals signal the Trump Administration's focus on addressing prescription drug affordability by aligning U.S. drug prices more closely with those paid in other developed countries.

The GLOBE and GUARD Models

The Inflation Reduction Act of 2022 (IRA) established inflation-based rebate programs for both Medicare Part B and Medicare Part D to discourage drug manufacturers from increasing prices faster than inflation and to improve the affordability of prescription drugs for Medicare beneficiaries. Under these programs, manufacturers are required to pay rebates to the Medicare Trust Funds when prices for certain drugs exceed inflation-adjusted benchmarks.

Despite these reforms, CMS has observed continued growth in Medicare drug spending and beneficiary cost sharing. In response, CMS has proposed the GLOBE Model for Part B drugs and the GUARD Model for Part D drugs to test alternative rebate calculations that incorporate international drug pricing benchmarks. CMS aims to test whether replacing inflation-based benchmarks with international reference pricing for selected single-source drugs and biological products can reduce Medicare spending and beneficiary out-of-pocket costs while maintaining or enhancing quality of care. Under both models, manufacturers would be required to pay model-specific rebates when Medicare prices exceed international benchmarks based on prices in economically comparable countries.

The GLOBE Model would apply to a limited subset of Medicare Part B drugs that meet the statutory definition of a Part B rebatable drug, specifically single-source drugs and sole-source biological products within the following therapeutic categories:

- Anticancer agents
- Antineoplastics
- Blood products and modifiers
- Central nervous system agents
- Immunological agents
- Metabolic bone disease agents
- Ophthalmic agents

To be included, a drug also would need to have a HCPCS Level II code with Medicare Part B fee-for-service spending exceeding \$100 million over a 12-month period. CMS estimates the model could generate approximately \$11.9 billion in Medicare Part B net spending savings over the seven-year test period.

The GUARD Model would apply to a subset of Part D rebatable drugs, specifically sole-

source drugs and sole-source biological products within specified therapeutic categories:

- Anticonvulsants
- Antidepressants
- Antimigraine agents
- Antineoplastics
- Antipsychotics
- Antivirals
- Blood glucose regulators
- Cardiovascular agents
- Central nervous system agents
- Immunological agents
- Metabolic bone disease agents
- Ophthalmic agents
- Respiratory tract or pulmonary agents

CMS proposes implementing the models in randomly selected geographic areas representing approximately 25% of Medicare Part B or Part D beneficiaries. Participation would be mandatory for manufacturers of drugs included within the scope of each model. Drugs subject to a negotiated maximum fair price under the Medicare Drug Price Negotiation Program would be excluded.

CMS proposes a five-year GLOBE Model performance period beginning October 1, 2026, with post-performance rebate invoicing and reconciliation continuing through 2033. The GUARD Model would operate for a five-year performance period beginning January 1, 2027, with rebate reconciliation likewise continuing through 2033.

CMS is accepting public comments on both proposed GLOBE and GUARD models until February 23, 2026.

[1] The proposed rules identify 19 countries that CMS considers “economically comparable” to the United States based on per capita GDP and aggregate GDP.