Dec. 22, 2025

Federal Update: Trump Admin Unveils GLOBE, GUARD Models, Plus Nine Additional MFN Arrangements

Overview:

On Dec. 19, the Trump administration closed out a year of international pharmaceutical reference pricing announcements with the publication of CMS's proposed Global Benchmark for Efficient Drug Pricing (GLOBE) and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) models, as well as the release of nine additional Most-Favored-Nation (MFN) pricing arrangements with major pharmaceutical manufacturers. The announcements align with the Trump administration's goal of lowering the prices that American patients pay for prescription drugs to the prices paid in similarly developed countries, as well as May 12 Executive Order on delivering MFN prices to patients. Both the GLOBE and GUARD models, which would test new rebate formulas for certain Part B (GLOBE) and Part D (GUARD) drugs in randomly selected geographic areas, would require mandatory participation from manufacturers. Beneficiaries, providers, and suppliers would not be included as mandatory participants in these models. Each model would utilize the existing Medicare Inflation Rebate programs to allow manufacturers to reimburse the federal government for the difference in applicable drugs' current net price and the international reference price. As proposed rules, public comments for each model must be submitted via the Federal Register by Feb. 23, 2026. The MFN pricing announcements follow several previous deals on high-cost drugs, in-vitro fertilization therapies, and GLP-1 products.

GLOBE Model:

Part B drugs and biologics eligible for the GLOBE model must be single source, be used to treat conditions under certain U.S. Pharmacopeia Drug Classifications (including: Antigout Agents, Antineoplastics, Blood Products and Modifiers, Central Nervous System Agents, Immunological Agents, Metabolic Bone Disease Agents, Ophthalmic Agents), have a Part B fee-for-service (FFS) spend in excess of $100 million over a 12-month period, and cannot be excluded. CMS would randomly select the geographic areas for which the model would apply to balance the Medicare beneficiary population and Medicare expenditures. It would cover roughly 25% of Medicare beneficiaries nationwide. Excluded drugs would include those with a Medicare Drug Price Negotiation Program-negotiated Maximum Fair Price (MFP), as well as 340B-eligible drugs. CMS is seeking public comment on whether cell and gene therapies should be excluded.

To calculate the rebates, CMS would adjust the existing Part B formula with an international price benchmark, while maintaining the existing Inflation Reduction Act rebate floor. The rebate would be the greater of the difference between applicable drug's average sales price (ASP) and a GDP-adjusted international benchmark price, or the difference between the ASP and the inflation-adjusted payment amount currently used to calculate Part B inflation rebates. International benchmarks would be determined from a set of countries that have a real GDP per capita at least 60 percent of the U.S. real

GDP per capita based on purchasing power parity (PPP), and an annual real GDP that is at least $400 billion based on PPP. Rebates would be paid directly to the Medicare Supplementary Medical Insurance Trust Fund.

CMS estimates that the model would save $11.9 billion in Part B net spending over seven years. While the model won't directly affect beneficiaries' out-of-pocket costs, CMS believes it may have downstream effects that benefit Part B enrollees. The GLOBE model would run for seven years, with a five-year performance period beginning Oct. 1, 2026, through Sept. 30, 2031. Rebate invoicing and reconciliation would continue until Sept. 30, 2033. Public comments may be submitted via the Notice of Proposed Rulemaking by Feb. 23, 2026.

GUARD Model:

The GUARD model would operate in a similar fashion to GLOBE, applying instead to Part D drugs and the Part D inflationary rebate program. Eligible single-source drugs and biologics include those in the following therapeutic categories: Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents. Again, CMS would randomly select the geographic areas for which the model would apply to balance the Medicare beneficiary population and Medicare expenditures, covering roughly 25% of Medicare beneficiaries nationwide. Generics and biosimilars, single source drugs and biologics with total gross covered drug costs below a minimum spend threshold, drugs with a negotiated MFO, and 340B-eligible drugs would be excluded from the model.

Manufacturers would be required to pay GUARD model rebates if the Medicare net price is greater than a GUARD model international benchmark. The international benchmark would be determined from the greater price calculated by either a default or updated benchmark. Default international benchmarks would reflect the lowest average price among a set of average prices for each reference country. Pricing data would be gathered from an eligible drug's "international analog," i.e. a drug with the same active ingredient, route of administration, dosage form, and strength. An updated international benchmark would allow manufacturers to submit global net pricing data from reference countries. As with GLOBE, international reference countries must have a minimum of 60% of the U.S. PPP GDP and a minimum $400 billion PPP GDP and be a member of the Organization for Economic Cooperation and Development. Rebates owed would be reduced if the drug is under a shortage at any point in the performance year.

CMS estimates that the GUARD model would save the Part D program upwards of $14.1 billion over its seven-year period. While the model won't directly affect beneficiaries' OOP costs, CMS believes it may have downstream effects that benefit Part D enrollees. The GUARD model would run for seven years, with a five-year performance period beginning Jan. 1, 2027, through Dec. 31, 2031. Rebate invoicing and reconciliation would continue until Dec. 31, 2033. Public comments may be submitted via the Notice of Proposed Rulemaking by Feb. 23, 2026.

Additional 12/19 Most-Favored-Nation Arrangements:

In addition to the aforementioned MFN models proposed by CMS, President Trump announced agreements with nine additional pharmaceutical manufacturers to offer medications at MFN prices. The announcement follows the release of demand letters to 17 major manufacturers directing them to implement MFN prices, and brings the total number of publicly announced agreements to 14. The Dec. 19 announcement reflects agreements with Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Genentech, Gilead Sciences, GSK, Merck & Co., Novartis, and Sanofi. As with previous agreements, the manufacturers will offer MFN prices to all Medicaid recipients, not offer lower prices to other nations, offer drugs directly to consumers via the TrumpRx platform, and repatriate foreign revenue back into lowering drug prices in the U.S. The TrumpRx platform is set to launch in Jan. 2026, but details regarding its implementation remain to be seen. Collectively, the nine manufacturers also agreed to invest at least $150 billion into strengthening domestic manufacturing capabilities. In an effort to reduce reliance on foreign products, GSK, Bristol Myers Squibb, and Merck also announced intentions to contribute active pharmaceutical ingredients for key products to the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR). During the announcement, President Trump stated that agreements were reached with the remaining three manufacturers who received demand letters and will be publicly announced in early 2026. AMCP will continue to monitor these announcements.