

GIBSON DUNN

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The GLOBE Final Rule: A Narrow Model that May Be a Bellwether for Most Favored Nation Pricing

This update summarizes the Global Benchmark for Efficient Drug Pricing Model, addresses key considerations for industry, and assesses what may come next.

On September 30, 2026, the Centers for Medicare & Medicaid Services (CMS) released the [final rule](#) for the Global Benchmark for Efficient Drug Pricing Model (the GLOBE Model or GLOBE), a mandatory Medicare Part B model that ties rebates on certain drugs to prices paid in other high-income countries. The rule was published in the Federal Register on October 2 (91 Fed. Reg. 62936) and takes effect on November 30, 2026, with a January 1, 2027 GLOBE MODEL start date.

1. Executive Summary

As finalized, GLOBE will reach far fewer manufacturers than the December 2025 [proposed rule](#) contemplated. CMS expects to exempt manufacturers that participate in the voluntary Medicaid GENEROUS Model – as well as orphan-only drugs, plasma-derived products, and certain cell and gene therapies. By the agency's own estimates, only four manufacturers of in-scope drugs will remain in the GLOBE Model.

It remains uncertain whether the rule will go into effect January 1, 2027. The Pharmaceutical Research and Manufacturers of America (PhRMA) recently filed a [complaint](#) challenging the GLOBE Model as unlawful, beyond the agency's statutory authority, and unconstitutional—and seeking injunctive relief. Among other arguments, PhRMA asserts that the GLOBE Model is not

an appropriate “test” of a “payment [or] service delivery model” (and, as such, CMS lacks authority to implement the model) and that the Model effectively rewrites the Medicare statute.

If the GLOBE Model takes effect, most companies will not be impacted directly given the Model’s narrowed scope. But even absent immediate impacts, the rule matters nevertheless for three other reasons. First, the rule puts in place a mechanism for international reference pricing in Medicare through what CMS has described as a first-phase test. Second, the rule reflects how the threat of a mandatory “model” may have driven participation in a voluntary one (i.e., the Medicaid GENEROUS model). Third, the rule reinforces that Most Favored Nation (MFN) and international reference pricing remain durable policy priorities, even if the legal modalities of implementation remain highly uncertain.

The GUARD final rule, which – based on the proposed rule – would apply a similar MFN rebating approach to Part D, remains under review at the Office of Management and Budget. It remains uncertain whether GUARD will track GLOBE’s approach, including whether GUARD also will exempt GENEROUS participants.

In the meantime, this alert summarizes the GLOBE Model, addresses key considerations for industry, and assesses what may come next.

2. Overview of the Final Rule; Key Changes from the Proposed Rule

- **Mechanism.** For selected single-source drugs furnished in randomly selected areas covering roughly 25 percent of Original Medicare Part B enrollees, GLOBE replaces the existing Part B inflation rebate calculation with a rebate based on an international benchmark, based off of pricing in 19 reference countries.^[1] The benchmark is the greater of the lowest economically adjusted price among nineteen reference countries, drawn from commercial data (Method I), and a volume-weighted average of the manufacturer’s own net prices in those countries, if the manufacturer chooses to submit this pricing information (Method II).
- **Scope.** In-scope drugs remain single-source Part B rebatable drugs above the \$100 million annual spending threshold in the following seven United States Pharmacopeia (USP) classes: antineoplastic agents, antineoplastic agents, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, and ophthalmic agents. The Globe Model excludes drugs with a maximum fair price in effect under the Medicare Drug Price Negotiation Program. In response to comments, CMS added GLOBE Model exclusions for orphan-designated drugs whose only approved indications are for rare diseases or conditions, products on FDA’s list of approved cellular and gene therapy products, and plasma-derived products.
- **The GENEROUS waiver.** CMS declined to “codify manufacturer exemptions.” Instead, the preamble states that CMS “intends to use its authority under section 1115A(d)(1) of the [Social Security] Act to waive the requirements for mandatory participation” for any calendar quarter in which a manufacturer participates in [GENEROUS](#). CMS ties the waiver to evaluation design, explaining that overlapping participation would make it harder to isolate the effects of either model.

- **Timing.** The proposed October 1, 2026 start date for the GLOBE Model has been replaced by a January 1, 2027 start date, and a performance period running from April 1, 2027 through March 31, 2032, with rebate invoicing and reconciliation through March 31, 2034.
- **Penalties and appeals.** Failure to timely pay the GLOBE Model rebate amount would result in the imposition of a civil money penalty equal to at least 125 percent of the incremental rebate amount due for the drug. The CMP provisions in the final rule expressly track those in the existing inflation rebate program at 42 C.F.R. § 427.600. CMS also added express language precluding administrative and judicial review of beneficiary coinsurance adjustments. CMS maintains its original position that drug selection, beneficiary assignment, and rebate amounts are not subject to appeal.
- **Outstanding legal questions.** The GLOBE Model raises various outstanding legal questions – many of which were highlighted in the notice and comment rulemaking. As noted, PhRMA filed a [complaint](#) in the U.S. District Court for the District of Columbia on October 7, asserting that the GLOBE Model is unlawful and exceeds the agency’s statutory authority. PhRMA is seeking injunctive relief, including a temporary restraining order that would prevent implementation of the GLOBE Model.

3. A Model That May Be Built to Scale

Assuming that the GLOBE Model is implemented starting January 1, 2027, the narrow footprint should not be mistaken for certainty that the eventual scope will be similarly confined. CMS states in the preamble that Section 1115A(c) of the Social Security Act “provides for later expansion of the duration and the scope of a tested model, if statutory criteria are met, which could include testing the GLOBE Model on a nationwide basis,” and describes the current design as “consistent with a Phase I test.” It adds that positive results in selected areas “could inform potential expansion of the model to all beneficiaries.” The GENEROUS waiver is framed as discretionary and quarterly-determined. However, any expansion would be subject to statutory limits under Section 1115A(c) – e.g., a necessary determination that the expanded model would reduce spending without reducing quality (or improve quality without increasing spending), and certification by the CMS Chief Actuary.

What the final rule notably does, then, is it creates infrastructure: a fixed reference-country list, two benchmark methods, a process for collecting manufacturers’ voluntarily-submitted international net prices, and a rebate and reconciliation cycle built on the existing inflation rebate program.

4. GLOBE as Harbinger of Broader, Forthcoming MFN Policy?

The final rule also shows how the administration may have used the threat of a mandatory model to drive participation in a voluntary one (i.e., Medicaid GENEROUS). Based on the publicly available timeline, CMS announced GENEROUS in November 2025 and proposed GLOBE and its Part D companion, the [GUARD Model](#), the following month. Between late 2025 and August 2026, the largest manufacturers and then a group of mid-size companies entered pricing arrangements with the administration, and many agreed to participate in the GENEROUS model. At least one company told investors that it expected, as a result, not to be subject to GLOBE or GUARD. And now CMS has confirmed that the agency intends to waive the requirements for mandatory participation for any calendar quarter in which a manufacturer participates in

[GENEROUS](#). This type of exchange has become common in recent years, with MFN manufacturer agreements that result in tariff relief as another example. Over the weeks and months to come, we may see the issuance of the GUARD final rule – which could shed further light on the terms of the bargain.

More notably for all of industry – and notwithstanding the narrow scope of the GLOBE Final Rule – the concept of MFN pricing has become increasingly durable, with bipartisan interest in a “global populist” approach to drug pricing. The implications of this shift are significant for all of industry – whether or not a company is directly subject to the GLOBE Model. These implications matter, for instance, because they may impact global dealmaking and investment decision-making, as well as the future (and location) of pharmaceutical innovation and drug launches. And we are already seeing that MFN ramifications are not contained to the United States alone, but rather have a powerful impact on the approach to licensing transactions and other deals. Those trends appear to be durable, irrespective of the shifting shape that MFN may take over the months (and years) to come.

As those ramifications continue to play out, Gibson Dunn will continue to monitor regulatory developments and implementation of the GLOBE, GUARD, and GENEROUS models and related MFN pricing developments.

[\[1\]](#) The 19 reference countries are Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.

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