

CMS Significantly Scales Back GLOBE MFN Demo

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CMS significantly scaled back its controversial “most favored nation” drug-pricing demonstration in Medicare Part B, issuing a final rule Wednesday (Sept. 30) that will save \$440 million over seven years, down from the \$11.9 billion projected in the proposed rule, and appears to only apply to four pharmaceutical companies, according to consumer advocacy group Public Citizen.

The model, which begins Jan. 1, 2027, excludes orphan-only drugs, cell and gene therapies, plasma-derived products and drugs with an Inflation Reduction Act maximum fair price. CMS will also waive mandatory participation for manufacturers in the GENERating cost Reductions fOr U.S. Medicaid (GENEROUS) model.

“The carve-outs sharply reduce industry exposure while preserving international reference pricing as a Medicare policy tool,” according to a note Bloomberg Intelligence Senior Health Policy Analyst Duane Wright sent to clients Wednesday evening.

Despite the scaling back, Wright predicted litigation seeking to block implementation remains “highly likely.”

The final rule sets in motion the Global Benchmark for Efficient Drug Pricing (GLOBE) model, which will require the drug companies involved pay rebates when prices for certain Part B drugs are above the lowest average prices charged for the same drugs in other wealthy countries.

The final rule for the model also excludes biosimilars and the biologic treatments they reference.

The drug industry had hoped to sway CMS away from finalizing the GLOBE model. Drug makers were among stakeholders that submitted comments over the summer arguing the model would exceed the authority granted to CMMI by Congress and would violate key facets of the Constitution, including the separation of powers and the nondelegation clause. CMS notes in the final rule that it disagrees with those arguments, but the comments could foreshadow a lawsuit.

The GLOBE model will run for five years from Jan. 1, 2027, through March 31, 2032, and rebate invoicing and reconciliation from drug companies will continue through two more years, ending March 31, 2034. CMS says the model will apply to beneficiaries that reside in a “randomly selected subset of geographic areas,” covering approximately 25% of the total of beneficiaries with traditional Medicare -- Part A and Part B -- as their primary coverage.

The aim of the GLOBE model is to test whether the new rebate formula, which stems from the Trump administration’s “most favored nation” pricing framework, will help to reduce drug costs in Medicare and for traditional Medicare enrollees without hindering quality of care for seniors.

The GLOBE model was one of two models announced last year by the Trump administration intended to test the application of the MFN policy to Medicare’s inflation rebate programs. The Guarding U.S. Medicare Against Rising Drug Costs (GUARD) model will apply a similar rebate formula to affect certain Part D drugs when prices exceed the lowest average prices charged in peer nations, and this model is still under review at the Office of Management and Budget. -- *Gabrielle Wanneh* (gwanneh@iwpnews.com)