PhRMA, BIO Allege GLOBE, GUARD Models Illegal

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The top pharmaceutical and biotechnology lobbies allege the Trump administration's proposed Medicare models to tie drug inflation rebates to prices charged in other wealthy countries are illegal and should be scrapped, signaling they could sue if the models are finalized.

They wrote to CMS Monday (Feb. 23) that the proposed innovation center models to base Part B and Part D inflation rebates off the prices charged in other countries exceed the agency's statutory authority while providing no meaningful benefit to patients. The models would erode the ecosystem for innovation that has secured the United States early access to quality medicines, according to the Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO).

The two lobby groups ask CMS to rescind both the proposed Global Benchmark for Efficient Drug Pricing (GLOBE) model and the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) model. They say neither model would test a legitimate research question about the efficacy of tying U.S. drug pricing and payment decisions to pricing achieved in foreign countries, nor do they have a defined patient population in mind to address alleged "deficits of care."

The lobbies also say the models are not appropriately designed, alleging improper use of both waiver authority and authorization for CMMI to impose civil monetary penalties on drug companies that decline to pay certain rebates.

PhRMA and BIO say both models would violate principles of federal appropriations law set forth in the Constitution and fiscal statutes because they would require drug companies to transfer funds to the Medicare Supplementary Medical Insurance (SMI) Trust Fund without statutory authorization.

The models also would also violate the Constitution's separation-of-powers and non-delegation clauses, the Presentment Clause that forbids the executive branch from "unilaterally amending, repealing, or nullifying duly enacted statutes," and the Patent Clause that assigns to Congress the responsibility to design and calibrate the balance between innovation incentives and access to patented inventions, including innovative medicines, the lobbies allege.

They also say finalizing the GLOBE and GUARD models would introduce flawed pricing methodologies to the United States that would impede the country's lead in innovation -- specifically, Quality Adjusted Life Years, or QALYs, which are a common metric used in health technology assessment to determine the benefit of medical interventions by combining the quality and quantity of life in one composite measure of value.

"GLOBE/GUARD presumes that foreign government drug prices are appropriate reference points, but these governments artificially suppress prices through controls and discriminatory valuation methods like QALYs, which devalue the lives of seniors, persons with disabilities, and the chronically ill. Whether relying on the QALY or other standards of comparative- and cost-effectiveness analysis, these systems result in restricted access to medicines compared to the U.S., where patients enjoy broader and faster access to innovative treatments," PhRMA says in its comment letters.

PhRMA told reporters Monday that it's one thing for some of its member companies -- 16 specifically -- to voluntarily enter agreements with the Trump administration to make their products available directly to patients at heavily discounted prices comparable to what's paid in other wealthy countries.

It's another thing, however, for the government to mandate that all drug companies adhere to the GLOBE and GUARD models -- including the companies that have already made deals to offer "most favored nation" pricing for certain drugs, the lobby says. The deals say the companies are exempt from future drug pricing policy changes, but nothing indicates so far that this would be the case regarding the GLOBE and GUARD models.

Both PhRMA and BIO are urging the administration to place its attention back onto efforts to address the role pharmacy benefit managers play in keeping drug costs high for patients and payers -- and to improve the 340B drug discount program, which the administration hopes to do by testing the use of post-purchase rebate payments to covered entities instead of traditional upfront discounts on 340B drugs.

"The U.S. is the only country in the world that allows entities like PBMs, insurers, and other intermediary entities to capture 50 percent of every dollar that patients spend on medicines.16 PBM fees and rebates can exceed ex-U.S. drug prices by as much as 900 percent. The 340B hospital markup program is also unique to the U.S., and allows tax- exempt hospitals and clinics to buy certain medicines for as little as a penny before substantially marking up the price, often by thousands of dollars; 340B markups can exceed drug prices abroad by as much as 700 percent. In both the 340B program and discounts achieved by PBMs, savings are often not shared with patients," PhRMA says in its letters.

The proposed GLOBE Model would focus on tying Part B drug inflation rebates to prices paid in 19 other countries. It would run for five years starting in October if finalized, plus two additional years for rebate reconciliation. CMS says it intends to monitor the model for its impact on beneficiary out-of-pocket costs, drug access, overall health care utilization and total traditional Medicare spending across Part A and Part B.

The GUARD Model would tie inflation rebates for certain Part D drugs to international prices, as well, testing the impact of doing so on overall Medicare spending and the quality of care for seniors.

CMS expects the GLOBE model to save nearly $12 billion over seven years and the GUARD model to save $14.1 billion over six years.

Recent analysis from Avalere Health Advisory found that only 0.3% of Medicare beneficiaries are likely to see lower out-of-pocket costs under the GLOBE model. PhRMA also notes the CMS Office of the Actuary has said it expects some Medicare Advantage plans may limit supplemental benefits and increase OOP spending for seniors as a result of the GLOBE model, specifically.

"This is the kind of spillover effect that we're sort of expecting to see and that, apparently, CMS is expecting to see as a result of these policies," PhRMA told reporters. "The bottom line is, it's not about saving beneficiaries money. It's about saving the federal government money, and it's not doing anything to remove any of the insurance barriers that Medicare patients see every day in terms of having trouble getting through step therapy, or any other barriers insurance companies put up in order to get their drugs."