Getty Images

Bloomberg Law

Trump's Plan for Medicare Drug Talks Offers Pharma Fresh Fight

June 22, 2026, 2:00 AM PDT
Nyah Phengsitthy, Reporter

The Trump administration's proposal for the fourth cycle of the Biden-initiated Medicare drug price negotiations includes provisions that have drawn skepticism from pharmaceutical giants, opening a new path for legal challenges.

The Centers for Medicare & Medicaid Services last week released a proposed rule for implementing another round of drug price negotiations—the government's first move to codify the program through rulemaking, rather than the guidance approach from previous cycles. The fourth round seeks to slash the costs for 20 drugs, to be selected later in the process, that are covered under Medicare. Those prices will take effect in 2029.

The plan includes policies to widen the selection of drugs for negotiations, which if finalized as proposed, would pave the way for additional product-specific lawsuits from pharmaceutical companies. Drugmakers have opposed the program since its inception under the Biden administration.

"The initial batch of lawsuits were all focused on just constitutional claims and the law itself before anybody had been arguably harmed," said Christopher Schott, a partner at Latham & Watkins, representing pharmaceutical companies. "Now, we're at this turning point where people are actually experiencing the impacts of the laws, where particular individual companies are being harmed or impacted."

The rule creates a new pathway for challenges after the US Supreme Court in May declined to hear a series of drugmaker lawsuits fighting constitutional and procedural aspects of negotiations.

There is still one pending case led by a top drug lobby, the Pharmaceutical Research and Manufacturers of America, that provides a silver lining for drugmakers, if a federal appeals court sides with industry for the first time.

Meanwhile, more-recent challenges from Teva Pharmaceuticals Inc., AbbVie Inc., and AstraZeneca PLC have started the latest wave for product-specific suits disputing Medicare's standards for selecting drugs.

"What I anticipate seeing is more discreet challenges under the rule," said Andrew Twinamatsiko, director of the Center for Health Policy and the Law at Georgetown University's O'Neill Institute.

New Harms

The 434-page proposal released June 12 notably includes a provision for how the CMS will select drugs that have a fixed-dose combination treatment.

Fixed-dose combination drugs contain multiple medications in a single dosage form to help simplify treatment for patients. They can be delivered subcutaneously, meaning beneath the skin, to reduce treatment time compared with long intravenous infusions.

If finalized, the CMS could slash the prices of negotiation-eligible drugs, along with their fixed-dose combination versions, if the agency determines there's no clinically meaningful difference between the products.

The move is expected to face pushback from drugmakers such as Merck & Co., Johnson & Johnson, and Bristol-Myers Squibb Co. that have newer hyaluronidase-based subcutaneous formulations, over concerns their newer treatments are at risk for earlier price cuts if the CMS aggregates them with older drugs.

"The impact it can have will be great," said Constance Wilkinson, a member of Epstein Becker & Green P.C. focused on pricing policy. "You're taking a whole new subset of drugs and combining them so that you're getting more drugs into the pipeline in terms of being negotiated. It's like a multiplier effect."

Proponents of the policy argue this could prevent drugmakers from resetting the negotiation clock by introducing modified versions of existing drugs, and closes what advocates call a loophole that allows industry to dodge price cuts.

The drugmakers did not respond to requests for comment, but PhRMA pushed back on the program's advancement.

"As more medicines, including complex drugs administered by physicians, are pulled into government price setting, these harms will only grow, restricting patient access and weakening incentives for innovation," Chanse Jones, PhRMA spokesperson, said in an email.

The rule could also raise issues for pharmacy benefit managers and insurance companies because the proposal states that any medication with a negotiated price has to be on Medicare Part D plans' formularies, said Jonathan Swichar, chair of Duane Morris LLP's pharmacy litigation group. Drugs being on a formulary, or the list of treatments that plans cover, would help ensure access to negotiated drug prices, according to the CMS.

"Companies and PBMs are likely going to say that they are in a much better position than CMS to determine to what extent certain products are appropriately on their Medicare Part D network formulary," Swichar said.

Others are also eyeing whether the CMS will take comments into full account under the rulemaking process.

"It makes a big difference that the proposed rule is now beginning the process of becoming part of the Code of Federal Regulations," said John Shu, a lawyer and legal commentator focused on constitutional law who worked in both Bush White Houses. "I still think the pharmaceutical companies are going to challenge certain aspects of the Inflation Reduction Act. As a matter of policy, price controls generally are just not a good idea."

Firmer Grounds

The government's rulemaking, however, could make it harder for drugmakers to be successful in challenges.

Federal courts have largely sided with the program's standing, shutting down claims that range from due process and takings, to compelled speech and nondelegation.

"Those arguments did not even fly during the time when the program was being implemented via guidance," Twinamatsiko said. "By codifying the process, it will later rest on those arguments that reverberate in the future."

Additionally, almost all of the policies in the proposed rule are not new, potentially limiting the types of challenges a drugmaker could bring.

"There's no reason to think that we couldn't see manufacturer challenges to some of the new elements of the program," said Rachel Sachs, a law professor at Washington University in St. Louis School of Law. "But again, there's very few of those."