

5 Things to Know About the New Drug Pricing Negotiations

The Biden initiative marks a turning point in a long-fought battle to control ever-rising drug prices.

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The Biden administration has picked the first 10 high-priced prescription drugs subject to federal price negotiations, taking a swipe at the powerful pharmaceutical industry. It marks a major turning point in a long-fought battle to control ever-rising drug prices for seniors and, eventually, other Americans.

Under the 2022 Inflation Reduction Act, Congress gave the federal government the power to negotiate prices for certain high-cost drugs under Medicare. The list of drugs selected by the Centers for Medicare & Medicaid Services will grow over time.

The first eligible drugs treat diabetes, blood clots, blood cancers, arthritis, and heart disease — and accounted for about \$50 billion in spending from June 2022 to May 2023.

The United States is clearly an outlier on drug costs, with drugmakers charging Americans many times more than residents of other countries “simply because they could,” Biden said Tuesday at the White House. “I think it’s outrageous. That’s why these negotiations matter.”

He added, “We’re going to keep standing up to Big Pharma and we’re not going to back down.”

Democratic lawmakers cheered the announcement, and the pharmaceutical industry, which has filed a raft of lawsuits against the law, condemned it.

The companies have until Oct. 2 to present data on their drugs to CMS, which will make initial price offers in February, setting off negotiations set to end next August. The prices would go into effect in January 2026.

Here are five things to know about the impact:

1. How important is this step?

Medicare has long been in control of the prices for its services, setting physician payments and hospital payments for about 65 million Medicare beneficiaries. But it was previously prohibited from involvement in pricing prescription drugs, which it started covering in 2006.

Until now the drug industry has successfully fought off price negotiations with Washington, although in most of the rest of the world governments set prices for medicines. While the first 10 drugs selected for negotiations are used by a minority of patients — 9 million — CMS plans by 2029 to have negotiated prices for 50 drugs on the market.

“There’s a symbolic impact, but also Medicare spent \$50 billion on these 10 drugs in a 12-month period. That’s a lot of money,” said Juliette Cubanski, deputy director of KFF’s analysis of Medicare policy.

The long-term consequences of the new policy are unknown, said Alice Chen, vice dean for research at University of Southern California’s Sol Price School of Public Policy. The drug industry says the negotiations are essentially price controls that will stifle drug development, but the Congressional Budget Office estimated only a few drugs would not be developed each year as a result of the policy.

Biden administration officials say reining in drug prices is key to slowing the skyrocketing costs of U.S. health care.

2. How will the negotiations affect Medicare patients?

In some cases, patients may save a lot of money, but the main thrust of Medicare price negotiation policy is to provide savings to the Medicare program — and taxpayers — by lowering its overall costs.

The drugs selected by CMS range from specialized, hyper-expensive drugs like the cancer pill Imbruvica (used by about 26,000 patients in 2021 at an annual price of \$121,000 per patient) to extremely common medications such as Eliquis (a blood thinner for which Medicare paid about \$4,000 each for 3.1 million patients).

While the negotiations could help patients whose Medicare drug plans require them to make large copayments for drugs, the relief for patients will come from another segment of the Inflation Reduction Act that caps drug spending by Medicare recipients at \$2,000 per year starting in 2025.

3. What do the Medicare price negotiations mean for those not on Medicare?

One theory is that reducing the prices drug companies can charge in Medicare will lead them to increase prices for the privately insured.

But that would be true only if companies aren’t already pricing their drugs as high as the private market will bear, said Tricia Neuman, executive director of KFF’s program on Medicare policy.

Another theory is that Medicare price negotiations will equip private health plans to drive a harder bargain. David Mitchell, president of the advocacy group Patients for Affordable Drugs, predicted that disclosure of negotiated Medicare prices “will embolden and arm private sector negotiators to seek that lower price for those they cover.”

Stacie B. Dusetzina, a professor of health policy at Vanderbilt University, said the effect on pricing outside Medicare isn't clear.

"I'd hedge my bet that it doesn't change," she said.

Nonetheless, Dusetzina described one way it could: Because the government will be selecting drugs for Medicare negotiations based partly on the listed gross prices for the drugs — distinct from the net cost after rebates are taken into account — the process could give drug companies an incentive to lower the list prices and narrow the gap between gross and net. That could benefit people outside Medicare whose out-of-pocket payments are pegged to the list prices, she said.

4. What are drug companies doing to stop this?

Even though negotiated prices won't take effect until 2026, drug companies haven't wasted time turning to the courts to try to stop the new program in its tracks.

At least six drug companies have filed lawsuits to halt the Medicare drug negotiation program, as have the U.S. Chamber of Commerce and the Pharmaceutical Research and Manufacturers of America, known as PhRMA.

The lawsuits include a variety of legal arguments. Merck & Co., Johnson & Johnson, and Bristol

Myers Squibb are among the companies arguing their First Amendment rights are being violated because the program would force them to make statements on negotiated prices they believe are untrue. Lawsuits also say the program unconstitutionally coerces drugmakers into selling their products at inadequate prices.

“It is akin to the Government taking your car on terms that you would never voluntarily accept and threatening to also take your house if you do not ‘agree’ that the taking was ‘fair,’” Janssen, part of Johnson & Johnson, [wrote in its lawsuit](#).

Nicholas Bagley, a law professor at the University of Michigan, predicted the lawsuits would fail because Medicare is a voluntary program for drug companies, and those wishing to participate must abide by its rules.

5. What if a drug suddenly gets cheaper by 2026?

In theory, it could happen. Under guidelines CMS issued this year, the agency will cancel or adjourn negotiations on any drug on its list if a cheaper copycat version enters the market and finds substantial buyers.

According to company statements this year, two biosimilar versions of Stelara, a Johnson & Johnson drug on the list, are prepared to launch in early 2025. If they succeed, it would presumably scotch CMS’ plan to demand a lower price for Stelara.

Other drugs on the list have managed to maintain exclusive rights for decades. For example, Enbrel, which the FDA first approved in 1998 and cost Medicare \$1.5 billion in 2021, will not face competition until 2029 at the earliest.

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