US Congress lets Medicare negotiate lower drug prices

A new law also targets climate change in a major victory for Democrats and President Joe Biden. Susan Jaffe reports from Washington, DC.

Shattering decades of opposition from the pharmaceutical industry and its allies, slim Democratic majorities in the US House of Representatives and Senate have passed landmark legislation to begin to control runaway drug prices for almost 50 million older Americans with Medicare's pharmaceutical benefit. The bill also provides the largest federal investment in US history—US$370 billion—to slash greenhouse gases by 40% below 2005 emissions and respond to the devastating effects of climate change.

President Joe Biden signed the bill into law at the White House on Aug 16, fulfilling campaign pledges to lower Medicare drug prices and address climate change. The achievement emerges from a deeply divided Congress that nearly buried the legislation several times. Hawaii Democrat Senator Brian Schatz called the outcome "a political miracle".

In addition to requiring that Medicare negotiate some prescription drug prices directly with manufacturers, other health-care provisions restrict price increases to the rate of inflation, limit patients' co-pays for insulin to $35 a month, and expand premium subsidies for people on low-incomes covered by Medicare and the Affordable Care Act martketplace health insurance. Ending the subsidies for 13 million marketplace enrollees would have increased their premiums by about 53% in 2024 or an average of $700 for the year.

"These measures are a big blow to Pharma, which has had a stranglehold for decades preventing us from making this move", House Speaker Nancy Pelosi told members before they passed the bill Aug 12, 2022. "It is a resounding victory for America's families."

The legislation also ensures that no Medicare beneficiary pays more than $2000 a year for drugs. "That means you will have more money in your pocket", said Tatiana Fassieux, education and training specialist at California Health Advocates. "You won't have to worry about having enough money to pay for food or your power bills", she said.

The legislation also makes some tax changes, including imposing a new 15% minimum tax on large companies and providing additional funds for the Internal Revenue Service to crack down on corporate tax cheats.

The law is expected to save more money (about $737 billion) than the $437 billion it spends. According to the Senate Democratic leadership, prescription drug pricing reform would generate most of the savings, about $265 billion by 2030. Expenditures under the law include $64 billion for a 3-year extension of subsidies for people with Affordable Care Act health insurance, the Congressional Budget Office reported. However, despite its name, the Inflation Reduction Act would have a negligible impact on inflation this year and next, according to the Congressional Budget Office. It would, however, save money for Medicare patients and others. The provisions take effect over the next few years (panel).

Not a single Republican voted for the law, which passed in the Senate on Aug 7 only after Vice President Kamala Harris cast the deciding 51st vote to break a 50:50 tie. Democrats used a procedural strategy called budget reconciliation, requiring only a majority for approval.

"This legislation will do the exact opposite of what Democrats intend", said Michael Burgess, a Texas Republican and physician, shortly before voting against the bill. "It is going to kill research and development. It is going to reduce the quality of care and it is going to threaten patient access to life saving drugs."

Senator Bernie Sanders, the Vermont Democrat who chairs the Senate Budget Committee, criticised the law for cutting most of the social programmes from the massive $2 trillion House version of the bill passed in November, 2021. Missing from the final package was funding for universal preschool, home health care, and affordable housing. Adding Medicare coverage for hearing care was also gone. "It falls far short of what the

A future article will analyse the climate change and environmental health provisions in the Inflation Reduction Act

Panel: Inflation Reduction Act timeline for major health-care provisions

2023
- Drug companies must pay rebates to Medicare if their Part D drug prices increase faster than inflation
- Monthly co-payments for any type of insulin are limited to $35 for Medicare drug plan enrollees
- Affordable Care Act premium subsidies will be extended through 2026

2024
- Medicare drug plan members with very high drug costs will no longer pay 5% for catastrophic coverage
- Eligibility for Part D premium subsidies is expanded
- Insurers cannot raise Medicare Part D premium by more than 6% a year through 2030

2025
- Part D enrollees' out-of-pocket costs are limited to $2000 a year

2026
- Negotiated prices for first ten Medicare Part D drugs take effect

2027
- Negotiated prices for 15 more Medicare Part D drugs take effect

2028
- Negotiated prices for a combination of 15 more Medicare Part D and Part B (doctor-administered) drugs take effect

2029
- Negotiated prices for 20 more Medicare Part B and Part D drugs take effect this and every year after

Source: Kaiser Family Foundation, Inflation Reduction Act of 2022.

American people want, what they need, and what they are begging us to do", he said, before voting for it.

Congress added a prescription drug benefit called Part D to Medicare in 2003, the programme's largest expansion since its creation in 1965. Under pressure from the pharmaceutical industry, lawmakers prohibited the federal government from negotiating drug prices with manufacturers. Instead, Congress allowed commercial insurance and pharmacy benefit manager companies to administer the benefit and negotiate prices using confidential rebates and other strategies that obfuscate actual drug costs. Many in Congress assumed that drug plans would keep drug prices low to attract beneficiaries.

Despite abundant Part D plan choices, drug prices have continued to soar, leaving beneficiaries with an increasing share of the cost. For example, the average monthly out-of-pocket cost per prescription for all insulin products in 2020 was $54, up 39% since 2007, according to a Kaiser Family Foundation study. In another report, Kaiser Family Foundation researchers found that 1·2 million Part D enrollees still paid more than $2000 out of pocket for prescriptions in 2019.

"Huge change"

Under the new law, Part D's complicated structure—with three levels of coverage—will be eliminated and, starting in 2025, beneficiaries will pay no more than $2000 out of pocket per year for drugs. "That is a huge change from today where you have unlimited out-of-pocket spending on Part D", said Stacie Dusetzina, Associate Professor of Health Policy at the Vanderbilt University School of Medicine in Tennessee, USA. "So if you need an expensive drug, you could find yourself spending many thousands of dollars."

Starting in 2026, the first prices negotiated by Medicare and drug makers will take effect for the ten most expensive brand-name drugs covered under Part D (typically drugs dispensed by pharmacies) that have no competition and have been on the market for at least 9 years (for small molecule drugs) and 13 years (for biologicals). Another 15 Part D drugs will be negotiated in 2027, and a combination of 15 Part D drugs and drugs covered by Medicare's Part B (typically injectable drugs) will be negotiated for 2028, with more added in subsequent years. How much money Medicare enrollees will save depends on which medications are selected for negotiation. Some of today's most expensive drugs might have cheaper alternatives by 2026, disqualifying them from price negotiations, said Dusetzina.

The law provides guidelines for negotiating a drug's "maximum fair price". Manufacturers that refuse to negotiate have a choice: withdraw all their drugs from Medicare programme or, if they want stay in the programme, pay a tax of up to 95% of their previous year's sales of that drug.

"What this bill calls negotiation is not anything resembling negotiation in the common sense of the word", said Lisa Joldersma, Senior Vice President for Policy, Research, and Membership at the Pharmaceutical Research and Manufacturers of America, an industry group representing leading brand-name drug makers and biopharmaceutical researchers. "It will do far more harm than good."

Joldersma said that the negotiation process outlined in the law will discourage manufacturers from investing in finding new indications for drugs that could then help more patients. And when that happens, the increased use of the drug could subject it to price negotiations, she said. "Ultimately, the law won't do enough to reduce the prices seniors pay at the pharmacy counter", she said. However, newly introduced drugs will not be subject to price negotiation, said Juliette Cubanski, Deputy Director of Medicare Policy at the Kaiser Family Foundation. "They will have been on the market for several years, without any competition", she said. "Manufacturers will have plenty of opportunity to reap profits from bringing new drugs to market."

Additional concerns

If payments for Medicare beneficiaries go down, there is some concern that drug companies could make up the shortfall by raising prices for private insurers. 170 million Americans who receive health insurance through their employer are not covered by the law's drug pricing reforms. Employer-sponsored drug plans are dealing with high drug costs too, but the law offers them little protection.

"This step covers Medicare drugs and leaves the private plans and other payers just to fend for themselves", said Garrett Hohimer, Vice President at the Business Group on Health, which represents large employers. "There are problems with the private market drug pricing, as it stands right now, and we suspect this isn't going to help it." However, Cubanski said that drug makers might be reluctant to raise private market prices, because those prices would be used to determine the rebate amounts required if drug prices raise faster than inflation.

The American Cancer Society Action Network is concerned that that expensive cancer drugs will be disproportionately selected for negotiation, said its president Lisa Lacasse. If manufacturers refuse to negotiate, access to their drugs could be jeopardised.

AARP, which represents nearly 38 million older Americans, lobbied strongly for the law but also has concerns that it does not go far enough. "The bill doesn't address every issue with prescription drug pricing, including patent abuses and expanding protections for the private market", said Senior Vice President of Government Affairs Bill Sweeney. AARP will seek additional changes at the state and federal levels, he said, and "will keep fighting during implementation to make sure the law does what it is intended to do".

Susan Jaffe