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The Medicare Drug Negotiation Process Has Started: What Happens Next

In August 2022, President Biden signed the [Inflation Reduction Act](#) (IRA) into law. The sprawling legislation includes a number of Democratic signature initiatives, including several provisions impacting Medicare drug pricing and affordability. Provisions of the law go into effect incrementally over several years, but the Centers for Medicare and Medicaid Services (CMS) has begun the process of negotiating the prices for the first ten drugs to qualify under the IRA. The IRA reforms have major implications for the future of Medicare drug coverage, particularly for individuals who depend on high-cost drugs. Read on to learn more.

Drug Negotiation Framework

The IRA gives the Secretary of the Department of Health and Human Services (HHS) the authority to negotiate the prices of a select number of prescription drugs for Medicare, the gargantuan federal program that serves the nation's over-65 and disabled populations. Prior to the IRA, the federal government had little control over how much it paid for the prescription drugs used by millions of Medicare beneficiaries. Instead, manufacturers set the price. Non-negotiated prices have been acutely felt by both the federal government, which has been footing the bill for [rising Medicare drug costs](#), as well as Medicare beneficiaries, whose [out-of-pocket costs](#) have steadily increased over the years.

The law allows HHS to [identify 10 drugs](#) in the first year of negotiation, with the first negotiated prices slated to go into effect in 2026. These drugs are picked because they represent significant Medicare spending and high utilization. Only drugs that have been on the market for at least nine years (13 years for biologics) and that have no generic or biosimilar equivalent are subject to negotiation. CMS published this list of 10 drugs in September 2023 (see figure 1). The number of drugs subject to negotiation will ratchet up in subsequent years, and eventually 60 drugs will have been selected for price negotiation by 2030.

Figure 1: First Ten Drugs Subject to Negotiation Starting in 2026

- Eliquis (blood thinner)
- Jardiance (diabetes)
- Xarelto (blood thinner)
- Januvia (diabetes)
- Farxiga (diabetes, heart failure and chronic kidney disease)
- Entresto (heart failure)
- Enbrel (rheumatoid arthritis)
- Imbruvica (blood cancers)
- Stelara (psoriasis and Crohn's disease)
- Fiasp and NovoLog (diabetes)

Once the drugs are identified, CMS enters into a complex negotiation process with each manufacturer. HHS is charged with developing an opening bid for the price the federal government will pay for each drug under Medicare, starting with a ceiling price and considering the following factors:

- Research and development costs
- Unit cost of production
- Patents and exclusivities
- Prior federal financial support for research and development
- Revenue generated
- Benefit relative to therapeutic alternatives and their costs
- Prescribing information for drug and alternatives
- Relative comparative effectiveness, considering specific populations
- Unmet clinical need

Following a back and forth with the manufacturer, HHS will arrive at a “take or leave” price. The manufacturer can accept the price or can instead choose to subject itself to a hefty excise tax on Medicare sales from the drug. A manufacturer’s final option is to exit the Medicare and Medicaid programs altogether.

Medicare Affordability Protections Are Also Included in the IRA

The IRA also includes several Medicare Part D affordability provisions, targeting cost sharing. Combined with the IRA’s [new penalties](#) on manufacturers that raise the price of their Medicare drugs faster than the rate of consumer inflation, the drug negotiation provisions are expected to save a significant amount of federal funding, allowing Congress to make largescale reforms to patient cost sharing while still reducing the federal deficit.

Medicare Part D affordability provision	Effective date
Cap on insulin at \$35/month	January 2023
Elimination of out-of-pocket costs for recommended adult vaccines	January 2023
Expansion of Medicare “Extra Help” program to provide full Low-Income Subsidy to anyone under 150% FPL	January 2024
Maximum out-of-pocket cap of \$2,000	January 2025
“Smoothing” mechanism for Medicare Part D allowing beneficiaries the option to smooth their out-of-pocket drug costs out evenly over their plan year	January 2025

Which Drugs Will Be Selected in the Coming Years?

The list of the 10 drugs selected for the first round of negotiation includes several diabetes and cancer medications but does not include any HIV or hepatitis C drugs. However, it may only be a matter of time before these classes make the federal list. Indeed, some drug pricing experts [estimate](#) that hepatitis C drugs could be on the list for 2027 with HIV drugs following the next year. Other drugs likely to be selected include several inhalers and more diabetes medications.

Manufacturers and patient groups alike are closely watching the negotiation process play out and are concerned about the effect a negotiated fair price for Medicare drugs may have on a manufacturer’s

willingness to develop [innovative new drugs](#). The IRA’s impact on innovation is a hotly debated point, with [some economists and pricing experts](#) arguing that the immediate impacts of the IRA on manufacturer revenue will be limited and the scale of any future impact will turn on the final negotiated price. The Congressional Budget Office projected that the IRA would have only a [modest impact](#) on future drug development.

While there are plenty of benefits to lowering the costs of drugs in the Medicare program, there are also some trade-offs given the complexity of our health care system. For example, many HIV and hepatitis C clinical providers qualify for the [340B Drug Pricing Program](#), a federal program that allows [covered entities](#) that serve indigent patients to qualify for steep discounts on drugs. For the insured patients that 340B entities serve, the program allows those clinics to purchase drugs at a low discounted price and get reimbursed by public and private payers, including Medicare Part D, at a price much closer to the drug’s list price. So, while lowering the price Medicare pays for HIV and hepatitis C drugs will lower federal spending for these drugs as well as consumer cost sharing, it will also reduce the “spread” between the 340B discount price and the reimbursement to 340B entities paid by Part D plans.

What Happens Next?

As CMS continues to implement the IRA, [public comments and input](#), particularly from individuals most impacted by Medicare drug access reforms, are critical. Over the coming months, CMS will host listening sessions for each of the 10 drugs subject to the first round of negotiation to help them accurately price these products. This input process will likely be repeated every year as more drugs become subject to negotiation. CMS is also continuing to implement the Medicare Part D plan design reforms, with anticipated continued opportunities for public comment ahead of those provisions going into effect.

Hovering in the background of these implementation efforts are an [array of lawsuits](#) filed by manufacturers challenging the negotiation provisions. These lawsuits set forth a number of legal challenges and have only just begun to make their way through lower courts. At this time, it is hard to predict how the courts will ultimately rule. For now, the IRA remains the law of the land and implementation continues.

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