The Inflation Reduction Act's Medicare Drug Price Negotiation Program

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Background

On August 16, 2022, President Biden signed into law landmark legislation aimed at curbing inflation by possibly reducing the federal government budget deficit. The law, known as the Inflation Reduction Act, includes several provisions impacting prescription drugs and, most notably, requires the Secretary of Health and Human Services to directly negotiate prices with drug manufacturers for certain drugs covered under Medicare Part D. To be eligible for negotiation, a drug must be a single source brand-name drug or biological product, without a therapeutically equivalent generic or biosimilar. Additionally, it must have been approved or licensed by the Food and Drug Administration for either seven years in the case of small molecule drugs or 11 years in the case of biologics.

For over a decade, legislators have debated whether to grant the federal government the authority to negotiate prices for drugs covered by Medicare. When Medicare Part D was originally established in 2003, Congress left Medicare drug pricing to the drug manufacturers, PBMs and insurers to determine and expressly prohibited the government from interfering in these private negotiations under the program's "noninterference clause."

A summary of the Medicare Drug Price Negotiation Program follows.

10 drugs selected for negotiation for initial price applicability in year 2026:

Eliquis for preventing strokes and blood clots, from Bristol Myers Squibb and Pfizer	**Jardiance** for diabetes and heart failure, from Boehringer Ingelheim and Eli Lilly	**Xarelto** for preventing strokes and blood clots, from Johnson & Johnson	**Januvia** for diabetes, from Merck	**Farxiga** for diabetes, heart failure and chronic kidney disease, from AstraZeneca
Entresto for heart failure, from Novartis	**Enbrel** for arthritis and other autoimmune conditions, from Amgen	**Imbruvica** for blood cancers, from AbbVie and Johnson & Johnson	**Stelara** for Crohn's disease, from Johnson & Johnson	**Fiasp and NovoLog** insulin products, for diabetes, from Novo Nordisk

FIGURE 1

Negotiation Program Details

In creating Medicare's Drug Price Negotiation Program (the Program), Congress directed the Centers for Medicare and Medicaid Services (CMS) to select the top spend drugs under Medicare and negotiate with the manufacturers of those drugs to determine a "maximum fair price." To identify drugs selected for negotiations, CMS determined a list of eligible drugs (qualifying single source drugs without a generic or biosimilar alternative) and then looked at total expenditures for each based on spending data for the 12-month period June 1, 2022 to May 31, 2023. Late last summer, CMS announced its initial list of 10 drugs that will be negotiated for price applicability in 2026, see FIGURE 1.

Together the selected 10 drugs accounted for $50.5 billion in Part D gross costs or 20% of Medicare Part D spending over the pricing reference period. In future years, CMS will select for negotiation up to 15 additional drugs covered under Part D for 2027, up to 15 additional drugs for 2028 (including drugs covered under Part B and Part D) and up to 20 additional drugs each year thereafter.

Next, CMS will determine the maximum fair price by considering a list of statutory factors including the manufacturer's research and development costs, the extent to which these costs have been recouped, current unit costs of production and distribution, etc. The Program also establishes an upper limit for the maximum fair price of a given drug. That limit is the lower of a fixed percentage discount (between 25% and 60% based on the drug's approval date) off the pre-rebate non-federal average manufacturer price, or the prior year's net price negotiated by Medicare Part D plan sponsors after rebates. A manufacturer of a drug selected for the Program may choose not to participate in the negotiation process, in which case the manufacturer should not sign the voluntary agreement to negotiate maximum fair price and must then withdraw its drugs from coverage under Medicare and Medicaid. The manufacturers of all ten drugs selected for negotiation have signed agreements to participate in the Program.

Potential Impact

The Congressional Budget Office projects that the Program will save the government $98.5 billion over the years 2022 to 2031. The savings will offset approximately $1.9 trillion in expected Part D drug spend over that same time. As the prices negotiated for selected drugs are only applicable to Medicare beneficiaries, any direct savings related to the Program will not apply to the commercial market. Some experts suggest that the published negotiated prices will provide the commercial market with benchmark pricing to leverage in drug purchasing. But, given the small number of drugs being negotiated and the fact that negotiations will occur three years in advance of the applicable pricing year, the impact is likely to be small. Another possibility is that these negotiations have the opposite effect; reducing Medicare prices could lead to cost shifting and an increase in prices for the privately insured market.

Another dynamic to keep in mind is that the 10 negotiation-eligible drugs were chosen without accounting for rebates that are already negotiated by Part D plans and/or pharmacy benefit managers. In other words, a selection of highly-rebateable drugs may skew the projected savings and CMS's negotiated prices may not ultimately end up lower than what the government currently pays after factoring in rebate payments.

Patent expirations and brand competition will also factor into the Program's impact.

Key Negotiation Deadlines:

OCT 2023

The deadline for manufacturers to sign agreements to participate in the negotiations for 2026.

FEB 2024

CMS will make its initial offer of the maximum fair price for a chosen drug.

AUG 2024

The parties must reach an agreement on a negotiated price.

SEPT 2024

Final negotiated prices for the first 10 drugs will be released to the public.

MAR 2025

CMS to release a public explanation of the negotiated prices.

JAN 2026

Maximum fair prices will go into effect for Part D plans.

For example, Merck's Januvia could lose exclusivity mid-2026 and AstraZeneca's Farxiga patent for cardiovascular risk is set to expire in 2025. Thus, it is entirely possible that we will only feel the impact of negotiations for a year before generic competition minimizes the effects of the negotiated price or even that a drug may "drop off" the negotiations list prior to 2026 due to the drug no longer technically being single source. The Program does include a mechanism to grant a delay in selecting drugs that have a high likelihood of biosimilar market entry within two years of publication of the initial drug list. To qualify for this delay, the manufacturer of the biosimilar product for a given negotiation-eligible reference product must submit a delay request to CMS prior to the drug list publication date, and there must be a high likelihood of biosimilar market entry within two years after publication of the list.

Ongoing Stakeholder Challenges

So far, drug makers and trade associations (including Merck, Bristol-Myers Squibb, PhRMA, AstraZeneca, Boehringer Ingelheim, Johnson & Johnson, the National Infusion Center Association and the U.S. Chamber of Commerce) have filed at least 10 lawsuits challenging the Program. The suits bring a variety of claims alleging that the Program violates the First, Fifth and Eighth Amendments of the Constitution for free speech, takings and excessive fines. Some suits also raise administrative law claims that the Biden administration violated the Administrative Procedure Act by trying to implement the Program via agency guidance rather than the formal regulatory process. However, these lawsuits will face an uphill battle to overcome the argument that Medicare is a voluntary program and that if manufacturers desire to participate in Medicare drug coverage, then they must agree to participate in the negotiations Program. Unsurprisingly, the lawsuits are strategically spread across six different circuits. Any split judicial opinions regarding the viability of the Program would serve as a prime vehicle for consideration by the U.S. Supreme Court.

Closing Thoughts

The Program faces substantial uncertainty in the coming months due to ongoing litigation. Even assuming that none of the lawsuits are successful at blocking the provisions or delaying the first round of negotiations, the Program's first year of price applicability is likely to have a muted impact. Generic competition may even lead to pricing for fewer than 10 drugs ultimately being negotiated. Overall, the potential for greatest savings will be when a substantial amount of high-cost drugs are phased into the Program and when the government strategically negotiates the prices of high-cost drugs with lower-rebate yields.

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