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# The Reality of Medicare Part D Drug Price Negotiations Under the Inflation Reduction Act

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## Abstract

**What is the message?**

The Drug Price Negotiations policies of the Inflation Reduction Act (IRA) promise to bring down the cost of healthcare by reducing the cost of drugs covered by Medicare. While well intended, the real-world application tells a different story.

**What is the evidence?**

Analysis of the 10 drugs selected includes the discounts negotiated, the timing, patent expirations, market conditions and the application of the policies within the current healthcare system. The evaluation considered pricing and cost implications from the patient, Medicare, and pharmaceutical perspectives.

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## Introduction

As the United States approaches the implementation phase of the Drug Price Negotiation policies of the Inflation Reduction Act (IRA) in 2026, the discourse within health policy and pharmaceutical industry circles continues to intensify. This article aims to shed light on the implications of these policies, focusing on the 10 drugs selected for price negotiations. While the legislative framework promises significant price and cost reductions, it is crucial to examine the actual impact once these measures are in effect. This review does not seek to assess the policy aspect, but rather to present an objective analysis of the consequences of the law's practical implications.

As we delve into the specifics, it becomes apparent that the law's theoretical benefits may not fully materialize in practice, resulting in minimal impact on reducing drug prices, minimal reductions to Medicare patients out-of-pocket (OOP) costs, minimal reductions to Medicare's budget, and minimal impact to pharmaceutical companies' margins and R&D investments. In fact, the unintended consequences could very well result in higher costs to Medicare patients in premiums and OOP costs. Through this analysis, we will explore the broader implications for healthcare management, industry innovation, and patient affordability. The policy sounds promising on paper, but its real-world impact falls short, leaving the stakeholders to question its overall effectiveness.

## Components of the IRA Related to Healthcare

The IRA's legislative framework focuses on five main areas of Medicare drug pricing; this analysis focuses primarily on the government's ability to negotiate drug prices for Medicare patients, which will be reviewed in the second part of this paper. The other four areas are the following:

1. Monthly insulin prices capped at $35 OOP expenditure for Medicare patients
2. Medicare patients' drug prices capped at $2,000 OOP annually
3. More vaccines fully covered by Medicare

4. The ability of the Centers for Medicare & Medicaid Services (CMS) to demand an inflation rebate from pharmaceutical companies.

**Insulin Price Cap at $35:** Starting in 2023, the cost of insulin purchased under a prescription drug plan, or a Medicare Advantage Part D plan, will not exceed $35 per month. The Trump Administration in 2021 originally introduced a voluntary $35 monthly cap, covering specific insulin types obtained via Medicare Part D drug plans. The Biden administration rescinded the Trump Administration's pricing rule, after which insulin reverted to the previous average OOP of $54. The IRA policy then made the voluntary $35 monthly cap mandatory, encompassing all insulin users on Part B and Part D plans. Approximately 5% to 7% of Medicare patients use insulin. Of those patients, 85% use Part D, which covers traditional insulin pens, and less than 15% of Medicare insulin users fall under Part B, which covers insulin pump users. Finally, not all insulin is priced above or even at $35 for a monthly supply. Many insulin offerings are currently less than $33/month OOP for patients (Lilly has a $25 Wholesale Acquisition Cost (WAC) price and California will provide $30 insulin), with some as low as $16 per month. Patients can also receive necessary insulin for less than $35/month through drug company-sponsored patient assistance programs.

**$2,000 OOP Cap:** Starting in 2025, Medicare enrollees will pay no more than $2,000 OOP for prescription drugs covered under Part D, and this will be indexed annually to the rate of change in Part D costs. This effectively lowers the catastrophic coverage from $3,300 OOP for those enrolled in Medicare to $2,000. In 2021, roughly 1,537,000, or 2.2% of Medicare enrollees, spent more than $2,000. Thus, this new provision will save approximately 1.5 million Medicare enrollees about $1,000 annually.

**Expanded Vaccine Coverage:** Effective January 1, 2023, the IRA eliminated cost sharing and deductibles for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Medicare Part D. This saved Part D enrollees an average $38.84 on both RSV and Shingles shots if they elected to receive those vaccines. There was no impact on the vaccines already covered by Part B or by the public health programs that provide vaccines at no cost to adults who wanted, but could not afford, vaccinations.

**Inflation Rebate:** The Medicaid inflation rebate has been in place since 2019; it requires manufacturers to pay a rebate to the government if their drug prices for the program rise faster

than inflation. The IRA expands this policy to Medicare. The primary expected result is that new drugs will have higher list prices at launch, which could end up costing Medicare Part B even more as drug price negotiations won't be possible under the IRA until the selection criteria have been met.

The inflation rebate impacts the cost of the Part D benefit, but it may not impact the product prices individuals pay given the different formulary structures under Part D, as well as the OOP payment cap.

## The Drug Price Negotiation Program

The centerpiece of the IRA is the provision allowing the government to negotiate drug prices for Medicare Part D (starting in 2026) and eventually, Part B (starting in 2028), a policy shift that has been heralded as a significant step toward controlling pharmaceutical costs. However, a closer examination reveals that the practical implications of this policy may be limited as many of the drugs selected already face strong competition from other branded medications, are currently sold to Medicare at heavily discounted prices from the List Price, and will experience patent expirations in coming years that will open the market to generics. Under the IRA, the Centers for Medicare & Medicaid Services (CMS) negotiates the list prices of the drugs (the list, or WAC, prices are the basis of prices paid by distributors for inventory but do not reflect drug rebates that are later paid by the manufacturer for each product sale), and not the net price (the prices booked as revenue by the manufacturer after the rebate is paid). Six of the 10 drugs selected in the 2026 negotiation are in classes with a rebates of more than 60%, so the list price is not the price paid by CMS. Further, at least eight, and potentially all 10 of the drugs, will be off patent by the time the policy is implemented in 2026*.  The 10 drugs selected, medications from the same or overlapping therapeutics areas, as well as the timing of the implementation, means that these drugs would face both therapeutic and generic competition regardless of the new negotiation provisions, leading to substantial price reductions independent of the IRA's influence. In fact, the reduction in prices from the impact of the brands going generic will be much more substantial than the newly negotiated price reductions, with prices naturally decreasing as much as 90% once generics are on the market.

| Company | Drug | Percent of Discount Negotiated | Patent Expiration |
|---|---|---|---|
| Johnson & Johnson | Imbruvica (Ibrutinib) | 38% | March 30, 2032 |
| Bristol Myers Squibb | Eliquis (Apixaban) | 45% | February 28, 2025 |
| Merck & Co. | Januvia (Sitagliptin) | 50% | April 16, 2025 |
| Novartis | Entresto (Sacubitril/valsartan) | 55% | March 1, 2025 |
| Eli Lilly | Jardiance (Empagliflozin) | 60% | May 15, 2025 |
| AstraZeneca | Farxiga (Dapagliflozin) | 65% | June 30, 2025 |
| Novo Nordisk | Fiasp (Insulin aspart) | 70% | July 20, 2025 |
| Amgen | Enbrel (Etanercept) | 75% | February 28, 2029 |
| Johnson & Johnson | Stelara (Ustekinumab) | 78% | August 15, 2025 |
| Bristol Myers Squibb | Xarelto (Rivaroxaban) | 79% | February 28, 2025 |

**Patent expiration dates for the selected drugs are complex with various extensions, formulations and ongoing litigation. Reliable sources like the FDA's Orange Book and other patent databases were used. The sources for the patent expiration dates and other dates that have been found in our research are noted below.*

1. ***Imbruvica (Ibrutinib)**: March 30, 2032 – GreyB, additional sources indicate a 2026 patent expiration date.*
2. ***Eliquis (Apixaban)**: February 28, 2025 – GreyB, additional sources indicate April 21, 2026, as the expiration date.*

3. ***Januvia (Sitagliptin)****: April 16, 2025 – GreyB, additional sources indicate November 24, 2026, as the expiration date.*
4. ***Entresto (Sacubitril/Valsartan)****: March 1, 2025 – GreyB, additional sources indicate May 27, 2027, as the expiration date.*
5. ***Jardiance (Empagliflozin)****: May 15, 2025 – GreyB, additional sources indicate April 15, 2027, as the expiration date.*
6. ***Farxiga (Dapagliflozin)****: June 30, 2025 – GreyB,*
7. ***Fiasp (Insulin Aspart)****: July 20, 2025 – GreyB*
8. ***Enbrel (Etanercept)****: February 28, 2029 – GreyB, sources show an expiration in 2023, pending legal disputes.*
9. ***Stelara (Ustekinumab)****: August 15, 2025 – GreyB*
10. ***Xarelto (Rivaroxaban)****: February 28, 2025 – GreyB*

*Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*

The impact on the pharmaceutical industry appears to be minimal. The initial price cuts seem manageable as the first 10 drugs under IRA price negotiation were already facing near-term headwinds due to competition, newer medications, and anticipated patent expiry. Stock prices have also not shown any considerable change as a result of the legislation (with January 1, 2023 as a basis), indicating no real impact on sales or profits for the industry. The stock prices for all eight companies facing the first round of drug price negotiations have either gone up (5) or declined modestly, except for a decline in Bristol-Myers Squibb stock that is due to the steep “patent cliff,” i.e. the expiration of drug patents, and other challenges faced by the company.

| | | Stock Price (Adjusted Closing) | | | |
|---|---|---|---|---|---|
| **Company Name** | **Ticker** | **Prices at the start of 2023** | **IRA Selection 29th Aug 2023** | **IRA Prices Announced 15th Aug 2024** | **Price as on 30th Aug 2024** |
| AstraZeneca | AZN | $64.99 | $67.68 | $84.90 | $72.83 |
| Amgen | AMGN | $248.37 | $252.06 | $323.14 | $315.54 |
| BMS | BMY | $66.87 | $59.89 | $49.11 | $52.66 |
| Johnson & Johnson | JNJ | $167.52 | $159.27 | $157.89 | $160.61 |
| Lilly | LLY | $360.51 | $550.20 | $931.58 | $846.83 |
| Merck | MRK | $105.90 | $106.42 | $112.56 | $104.83 |
| Novo Nordisk | NVO | $66.08 | $94.15 | $137.06 | $113.24 |
| Novartis | NVS | $83.74 | $99.48 | $113.31 | $109.91 |

*Source: Yahoo Finance – Historical Data*

Historically, the patent cliff has led to significant revenue losses for pharmaceutical companies with the introduction of lower-cost generic alternatives. Between 2010 and 2015, approximately $250 billion in sales were at risk from patent expirations, prompting companies to adopt strategies such as price increases, mergers, and diversification into biologics and diagnostics to maintain profitability.

The anticipated savings from negotiated prices are thus overshadowed by current market forces. CMS's list for Medicare drug price negotiation includes drugs that accounted for $50.5 billion in gross Part D costs, affecting about 8.2 million Medicare enrollees. However, since these drugs are approaching their loss of exclusivity, the impact on actual cost savings will be limited. The Congressional Budget Office (CBO) concurs with this assessment, estimating that the IRA will have minimal impact on Part D spending.

Pharmaceutical companies are expected to adapt to the IRA program in ways that may mitigate the financial impact of this program. One likely response is the adjustment of launch prices for new drugs. Anticipating future price negotiations and inflation-based rebates, companies may set higher initial prices to “bake in” their anticipated price decreases into the launch price. This preemptive pricing strategy would allow them to maintain profit margins and continue funding robust research and development (R&D) efforts, which historically account for a significant portion of their expenditures.

The uncertainty introduced by the IRA also plays a critical role. Pharmaceutical companies face increased risk due to the unpredictability of whether their drugs will be selected for future price negotiations. This uncertainty may influence investment decisions, particularly in areas where the return on investment becomes less certain. Companies and investors generally prefer stable market conditions, and this added risk could lead to a more cautious approach in drug development pipelines.

Part D plans may respond to reduced rebates by increasing premiums and deductibles, effectively passing costs back to consumers. This result is the perverse logic of the design of the Part D program, which has those using the benefit subsidizing the premium cost for Part D coverage. Currently, consumers pay inflated drug prices at the retail pharmacy (higher list prices associated with rebates leads to higher patient cost-sharing), while the rebate dollars from these sales decreases the premiums for those purchasing Part D coverage. Lower list prices and rebates will decrease the costs at the pharmacy for individuals, but depending on the math, they could result in higher premiums for the coverage.

The policy may also inadvertently reduce patient access to certain medications. As Medicare Advantage plans adjust their formularies to control costs, they might limit the range of covered drugs, leading to fewer choices for patients. Pharmaceutical companies might deprioritize developing new indications for existing drugs if the financial incentives for drug development diminish, potentially slowing innovation and the availability of new treatments.

Furthermore, CMS has outlined a complex negotiation process involving data submissions, meetings, and offers between CMS and drug manufacturers, targeting the establishment of maximum fair prices by 2026. While the process aims to balance cost reduction with the maintenance of innovation incentives, participation by drug companies is technically voluntary,

with significant penalties for non-participation. This framework adds another layer of uncertainty and operational burden for pharmaceutical companies.

Finally, as the current policy is written, our analysis indicates that future drugs selected for price negotiation will also be those facing imminent patent expiration. The criteria set for drug selection state that medications must be on the market for nine years (small molecule) or 13 years (biologics), leaving little to no patent life in most cases after implementation of the negotiated price, as seen with the first round of drugs selected. Again, this reinforces the CBO perspective about the modest potential impact of this program.

## Conclusion

Overall, the IRA represents a significant policy development. However, based on the current analysis, its real-world impact on drug prices, patient OOP costs, Medicare spending, and pharmaceutical innovation appears limited. Stakeholders across the healthcare spectrum must consider these findings as they plan for future change, recognizing that additional efforts may be necessary to achieve meaningful progress in reducing cost while enhancing patients' access to healthcare.