WHITE PAPER

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# PAYERS AND THE INFLATION REDUCTION ACT:

## Initial Perspectives and Forecast Implications

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The Inflation Reduction Act of 2022 includes substantial changes to our healthcare system and was signed into law by President Joe Biden on August 16, 2022. With an aim to address issues related to healthcare affordability for Medicare beneficiaries, the Act requires that drug manufacturers negotiate prices with US Health and Human Services (HHS) for selected drugs with high budget impact, and includes a significant redesign of cost-sharing provisions under Medicare Part D. Price negotiations are currently ongoing for the first 10 drugs (selected in August 2023), with results to be finalized in 2024 and implemented in 2026. Negotiations for additional groups of Part D and B drugs will follow, with implementation in later years, and provisions for the Part D redesign will be finalized in 2025.

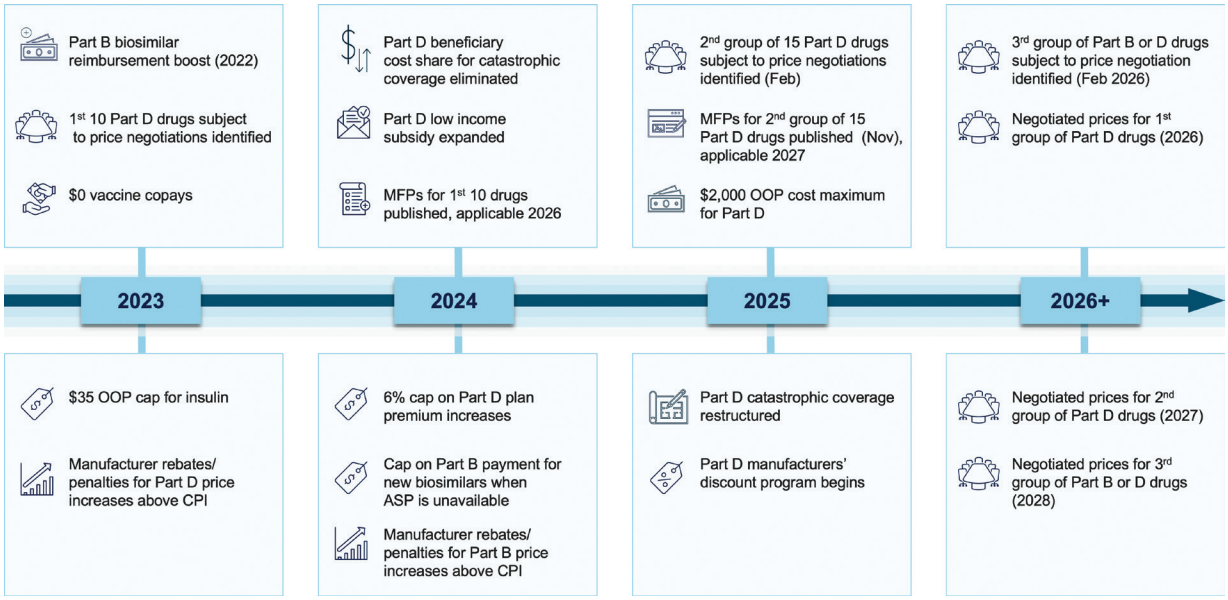
The legislation has potentially far-reaching implications for patients, manufacturers, and payers but there is also significant uncertainty regarding how things will eventually play out over time. Manufacturers have initiated legal challenges to the legislation, and many of the Act's key provisions are yet to be implemented. Nevertheless, there has been great interest in forecasting the potential impacts of the IRA on both pipeline and in-market assets and evaluating alternative commercial strategies for both payers and manufacturers. In this paper we review some of our recent research investigating payer perceptions of the IRA and discuss implications for pharmaceutical forecasts and forecasting practice.

### Key Provisions of the IRA

- **Medicare Drug Price Negotiation:** This portion of the Act has garnered the most publicity, empowering Health and Human Services to negotiate the prices of certain drugs with high budget impact on Medicare Parts B and D. Implementation of the rule began earlier this year, with discounts taking effect for 10 Part D drugs in 2026 and for 15 additional Part D drugs in 2027. Starting in 2028, discounts will apply to eligible drugs across Part B and Part D, resulting in a total basket of 60 eligible discounted Part B and Part D drugs in 2029. Small molecule drugs are subject to negotiated drug prices 9 years after Food and Drug Administration (FDA) approval if selected, compared to 13 years after approval for biologics. Minimum discounts are determined by the duration for which the therapy has been on the market; 25% for products on the market <12 years, 35% for products on the market between 12 and 16 years, and up to 60% for products on the market >16 years. Plasma-derived therapies and orphan therapies with a single indication are excluded from the legislation, along with drugs facing "imminent" generic or biosimilar competition, and certain small biotech drugs for the 2026-2028 negotiation years.
- **Medicare Part D Plan Redesign:** Currently there is no out-of-pocket (OOP) cost ceiling for Part D - enrollees pay 5% co-insurance once they exceed $7,050 (catastrophic phase), with 80% paid by Medicare and 15% by health plans. Starting in 2025, the annual OOP cap for Part D will be set at $2,000. Once the cap is reached, 60% of cost will be picked up by the health plan, with the remainder picked up by Medicare (20% branded drugs, 40% generic drugs) and by the manufacturer (20% branded drugs). The Part D redesign will provide significant cost-savings to many Medicare beneficiaries.[1] It also significantly reorders cost sharing and incentives for manufactures, payers, and patients - particularly for patients on high-cost medications.
- **Other Provisions:** The Act also includes measures to limit copayments for insulin with an OOP cap of $35/month, eliminate out-of-pocket cost sharing for adult vaccines, and expand eligibility for low-income subsidies. In addition, pharmaceutical manufacturers are required to pay rebates to the federal government if Medicare annual prices for certain drugs increase above the rate of inflation.

Key aspects of the timeline for implementation of the IRA are described in the following figure.

**Figure 1: Inflation Reduction Act Timeline**




## Payer Perceptions of the IRA

To gain a deeper understanding of how payers are planning for the IRA, we recently surveyed medical and pharmacy directors from 12 large national and regional payers with substantial Medicare and commercial books of business.[2] Our survey focused on their perceptions, plans, and expectations regarding the price negotiations and Part D redesign.

### Impact of Price Negotiations

At this stage, most payers are adopting a "wait-and-see" approach in response to the price negotiations. While payers feel that the negotiations are of paramount importance to CMS and manufacturers, most are taking no immediate actions at this stage given that the price negotiations are being introduced gradually starting in 2026. That said, payers are more than willing to provide their conjectures on the overall impact of the price negotiations and the impact of maximum fair prices (MFPs) on other brands.

Almost all payers believe the IRA price negotiations will lower prices overall, i.e., negotiated maximum fair prices will be lower than current prices net of discounts and rebates; price negotiation will have a more limited impact in categories that are currently discounted or rebated heavily such as certain antidiabetics, anticoagulants, and respiratory agents.[3] Payers also anticipate that MFPs will act as a de-facto price reference for other brands in the same category, as manufacturers of non-MFP brands are forced to offer discounts/rebates to compete with lower priced MFP products. Finally, many payers were also quick to point out that the IRA does not impact launch prices and that manufacturers could attempt to recoup projected IRA-related revenue losses for new products in later years with higher initial prices.

**Response to Part D Redesign**

In comparison with price negotiations, payers are much more concerned with the Part D redesign, focusing primarily on the $2,000 individual OOP cap and their increased liability within the catastrophic phase of coverage. Along with responsibility for a greater portion of spending in the catastrophic phase, the lower OOP cap will increase the number of patients experiencing costs above the cap, and lower costs are also likely to spur higher patient utilization. As the IRA legislation prevents payers from increasing premiums to cover their increased cost share, most anticipate significantly increasing utilization management to control costs. Formularies are likely to become narrower with more exclusions and there will be greater use of step edits and prior authorizations. Payers may also look for additional rebates and discounts from manufacturers to offset their increased liabilities. Importantly, the degree of utilization management is likely to vary significantly by therapeutic category, with higher priced medications for chronic conditions likely to face the most restrictions. While payers are "watching and waiting" on the price negotiations, they are actively modeling and planning for increased utilization management now across their books of business.

**Spillover to Commercial Business**

Since the IRA only applies to Medicare, one open question is whether the legislation will have any impact on payers' commercial business. On this point most payers (75%) feel that commercial prices will decrease as plans seek to harmonize formularies across Medicare and commercial, and/or attempt to drive larger commercial discounts to offset increased liabilities in Medicare. A minority (25%) feel that commercial prices will increase as manufacturers try to recoup revenue losses on the Medicare business. In the latter group, several payers mentioned the "squishing Jello" phenomenon, where attempts to constrain

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prices in one arena generate price increases in another, i.e., "Manufacturers are going to find ways to make themselves whole." Regardless of direction, payers feel any changes seen in commercial will be smaller than what is seen in Medicare.

**Impact on Patients**

Payers agree that the clear winners from the IRA are patients, particularly those using higher cost drugs for managing certain chronic diseases. To get an idea of the potential benefits of price negotiation, consider the situation for Imbruvica, an oral anti-cancer therapeutic indicated for the treatment of chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL), with an average cost of $32,628 for a 30-days supply. Imbruvica was the only anti-cancer medicine included in the initial batch of 10 Part D drugs subject to price negotiation. While commercially insured patients have access to patient support programs that can reduce the out-of-pocket cost to $0, these programs are not allowed for Medicare patients. While the results of the negotiation will not be published until 2024, it is likely that the negotiated price will provide significant savings relative to the cost today. As a starting point for negotiation, the law establishes an upper limit for the negotiated MFP for each selected drug, either the current net negotiated price after rebates, or a percentage of the non-federal average manufacturer price. The specific percentage ranges from 40% to 70% depending on both, the length of time a drug has been on the market since its FDA approval and whether it is a small molecule or biologic. Rebates and discounts have historically been limited in Medicare for oncology products because oncology is one of six protected

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drug classes or categories wherein plans are required by law to cover all approved products. Forcing plans to reimburse all drugs in a category limits their ability to negotiate discounts and rebates. As a result, the published MFP percentages are likely to represent a lower bound on cost savings and are substantial.

The $2,000 cap on patient OOP costs will also provide significant cost savings for these (and other) patients. For example, standard treatments for metastatic, hormone-sensitive prostate cancer include baseline androgen deprivation therapy with traditional chemotherapy, androgen receptor inhibitors, and androgen biosynthesis inhibitors. Current OOP costs for Medicare patients for these regimens range from $464 to $11,336 per year. Under the IRA, cost savings for regimens involving branded novel hormonal therapy range from $8,480 to $9,336.[4]

Cap-related cost savings will extend to many other therapeutic areas with higher priced specialty-tier drugs where average out-of-pocket costs are often thousands of dollars. Other cost provisions in the Act – limiting insulin copays to a maximum of $35/month and eliminating out-of-pocket cost sharing for adult vaccines – will also be beneficial. Overall, cost reductions for patients are likely to reduce prescription abandonment and non-adherence to therapy and increase demand for these products.

## Forecasting Implications

The potential impacts of the IRA are complex and uncertain and will vary significantly across different therapeutic categories and in response to a host of other market characteristics. Accordingly, there has been great interest amongst our clients in revisiting forecasts for pipeline and in-line products and portfolios under the provisions of the IRA. Scenario analysis plays a key role in highlighting risks and opportunities in these situations, allowing manufacturers to pressure test alternative pricing, product development, and portfolio strategies. In other research, we have provided a detailed analysis of these strategic considerations and the impact of the IRA on corresponding forecast revenues and NPVs.[5] Here, we focus specifically on the role of payers and market access in these forecasts.

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In terms of forecast architecture, additional detail will almost certainly be required to fully capture the variations in pricing and access attributable to the IRA for both Medicare and other patients. It will be important to assess how the price negotiations progress and how payer utilization management evolves over time. There is a significant need for more in-depth research with payers to understand the trade-offs they will make between pricing and access for each unique forecasting situation in the new environment with the IRA, in order to factor in these considerations into updated forecasts. For new products in development, it has never been more important to get the launch pricing strategy right. For both new and existing products, it will also be essential to understand the extent to which additional rebates will be required to gain access, and to mitigate exclusions and restrictions. Payer research is likely to be required on an ongoing basis as strategies for the various stakeholders and competitors evolve in response to the legislation. Forecast models and platforms will need to be flexible and agile, allowing manufacturers to incorporate new research results and quickly assess opportunities and risks, and to formulate and deploy alternative strategies.

**Endnotes**

[1] The Kaiser Family Foundation estimates that 1.4 million Part D enrollees incurred annual out-of-pocket costs for their medications above $2,000 in 2020, averaging $3,355 per person. See Cubanski J, Neuman, T, Freed M. Explaining the Prescription Drug Provisions in the Inflation Reduction Act, *Kaiser Family Foundation,* 2023.

[2] Respondents were medical or pharmacy directors from large regional and national health plans and PBMs who were voting members of formulary committees and/or responsible for contracting with manufacturers. Each respondent completed a 30-minute telephone depth interview (TDI) investigating their planning and responses to specific provisions of the IRA.

[3] United States Government Accountability Office (GAO). CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending, GAO-23-105270, September 2023.

[4] Cortese BD, Dusetzina SB, Al Hussein Al Awamlh B, Penson DF, Chang SS, Barocas DA, Luckenbaugh AN, Scarpato KR, Moses KA, Talwar R. Estimating the Impact of the Inflation Reduction Act on the Out-of-Pocket Costs for Medicare Beneficiaries with Advanced Prostate Cancer. *Urol Pract*. 2023 Sep;10(5):476-483.

[5] Willson D. Navigating the Impact of the Inflation Reduction Act on Product Forecasts - What Every New Product's Leader Needs to Know and Do. Presented at: Fierce Pharma New Product Planning Summit, Oct 17, 2023; Boston, MA.