Rotten to the Core: Inflation Reduction Act Undermines Medicare Part D, Pill Penalty Drug Costs Increase Up to 76%

As a result of a flawed Inflation Reduction Act (IRA), CMS is authorized to set a maximum fair price (MFP) that takes effect as early as nine years post-approval for certain small molecule drugs with high Medicare expenditures. This price-setting timeline is four years earlier than when certain biologics can be subject to MFP. This difference is referred to as the small molecule "pill penalty". The pill penalty has far-reaching effects; if the IRA had established equivalent timelines for price-setting small molecule drugs and biologics at the same timeframe—13 years—half of the drugs chosen for price controls in 2026 would not have been selected.

Policy changes are needed to grant small molecule drugs the same timelines as biologics, allowing beneficiaries to maintain more affordable, consistent access to necessary treatments for longer.

How do IRA Price Controls and the Pill Penalty Affect Part D Plans and Beneficiaries?

While the IRA aims to lower the cost of prescription drugs, a previous Magnolia Market Access (MMA) survey found that it could increase access barriers for medicines selected for 'negotiation'.[i] Based on a new analysis of plan cost sharing for these medicines conducted by MMA, it appears that plans have already responded to CMS price-setting and other IRA disruption. Patients taking widely used medicines impacted by the pill penalty could experience:

- **Restricted coverage -** According to a survey of payers representing nearly 300M covered US lives, over half of Medicare Part D plans intend to increase the use of utilization management for selected drugs in 2026 on both their Medicare Part D and commercial formularies.[i]

- **Increased patient cost-sharing at the pharmacy counter -** Cost-sharing comparisons between 2024 and 2025 show that seniors and individuals with disabilities are already being affected by CMS price-setting, which goes into effect in 2026. Plans are shifting away from flat copayments to coinsurance for price-controlled drugs, generally resulting in a higher out-of-pocket (OOP) cost per prescription at the point of sale for patients. For the nearly 7.5M Part D beneficiaries taking any of four pill-penalty medicines —

Eliquis®, Entresto®, Farxiga®, and Jardiance® — monthly OOP costs could increase between 10.6% to 75.8%.[a]

MFP Drugs[b]	Estimated Part D Beneficiaries Affected[c]	Estimated Change in Monthly OOP (2024-2025)
Eliquis	3.9M	10.6%
Entresto	664K	21.8%
Farxiga	994K	75.8%
Jardiance	1.8M	69.7%

Other IRA Price Controls and Pill Penalty Considerations

Beyond the direct impact of the IRA on Part D plans, PBMs, and patients at the pharmacy counter, the small molecule pill penalty could also present broad, industry-wide challenges that could affect treatment access and availability.

- **Product Availability –** IRA price control policies pose a financial risk for pharmacies, which will be required to provide discounts to patients at the pharmacy counter and wait weeks for manufacturers of dispensed MFP drugs to reimburse them for these discounts. A survey by the National Community Pharmacists Association suggests that approximately one-third of independent pharmacies have said they will not stock MFP drugs on their shelves.[ii] This will affect the nearly 10.5 million beneficiaries who use one or more MFP drug.[c]

- **Research and Development (R&D)** - The timeline discrepancy for drugs selected for price controls has led to concerns manufacturers may shift R&D efforts away from small molecule drugs (which are often oral) to biologics (which are commonly physician-administered). This could limit access to convenient at-home treatments and increase other healthcare costs for office or facility drug administration. One study estimated that Part D price controls could reduce overall R&D investments by over 12%, resulting in 188 fewer small molecule treatments approved and marketed over 20 years, including 79 new small molecule drugs and 109 fewer post-approval indications. Fewer post-approval indications are particularly concerning, as approximately one-third of FDA-approved drugs receive at least one subsequent indication following initial approval.[iii,iv] R&D reductions related to the IRA are anticipated to result in 116 million life years lost due to missed opportunities to improve health.[v]

[a] Analysis conducted by Magnolia Market Access. See Cost Analysis Methodology for data sources and approach.
[b] The list of drugs subject to the pill penalty was developed by including medicines used annually by 500K or more Part D beneficiaries and had been on the market for fewer than 11 years at the time of selection on September 1, 2023. Each drugs' approval date found on their FDA Approval Letters was used as the date of market entry (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm).
[c] Based on Part D enrollees who used the drug of interest in CY 2023. (https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026)

Despite the improvements the IRA provides to Part D beneficiaries, such as establishing a maximum out-of-pocket cap and prescription payment plan, CMS price-setting and the pill penalty will contribute to disruptions in patient access and increased costs at the pharmacy. Additionally, it could pose challenges for pharmacies and reduce R&D efforts for future treatments. Revising the timelines to align all products subject to price controls could at least level the playing field for small molecule products and provide equitable access to a provider's treatment of choice for Medicare patients.

Cost Analysis Methodology: CMS Part D formulary files were used to determine plan coverage for each drug of interest in 2024 and 2025. Plans from 2024 were mapped to 2025 plans using the 2025 Part C & D Plan Crosswalk file. Medicare enrollment by plan was used to weight beneficiary copayment and coinsurance costs across all Part D plans in each year, with enrollees assumed to remain in the same plan in 2025 since enrollment data for 2025 was not yet available at the time this analysis was conducted. Calendar year 2023 list prices for a 30-day supply of each MFP drug (less a 4% wholesaler discount) was used for coinsurance estimates and provided in "CMS' Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026" fact sheet.

[i] Magnolia Market Access. Inflation Reduction Act Payer Insights Report. Summer 2024. Accessed February 18, 2025. www.magnoliamarketaccess.com/wp-content/uploads/MMA_IRA-Payer-Insights-Survey-4.0_Chartbook_2024.07.31.pdf

[ii] National Community Pharmacists Association. Report for January 2025 Survey of Independent Pharmacy Owners/Managers. January 2025. Accessed February 18, 2025. https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf

[iii] Philipson TJ, Ling Y, Chang R. The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act. October 2023. Accessed February 18, 2025. https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf

[iv] Sahragardjoonegani B, Beall RF, Kesselheim AS, Hollis A. Repurposing existing drugs for new uses: a cohort study of the frequency of FDA-granted new indication exclusivities since 1997. *J Pharm Policy Pract*. 2021;14(1):3. Accessed February 18, 2025. https://doi.org/10.1186/s40545-020-00282-8

[v] Philipson TJ, Ling Y, Chang R., as cited previously.