CBO: Window Into IRA Rx Price Assumptions

50% Drop In Net Price for Negotiated Drugs (1/5 Total Spend)

CBO quietly released a presentation here on how it estimated the budgetary impact of three key prescription drug provisions in the *Inflation Reduction Act* (IRA). In total, Medicare negotiations, inflationary rebates, and Part D restructuring are expected to generate savings of $31 B in 2031.

Medicare Part B&D Negotiation

- **Net prices for selected drugs are estimated to decrease by ~50%, on average, from negotiations, but will only make up 20% of total spend.** Despite the steep decrease in net prices, negotiated drugs are only expected to make up less than 1/5 of total spending, which significantly reduces the impact on Medicare spending. Recall, negotiated prices for both Part B and Part D drugs are capped at between 40% and 75% of the previous nonfederal average manufacturer price, depending on how long the drug has been on the market. This 40-75% is per the IRA (not new in CBO report).

- **Because of negotiation in 2026+, CBO estimates that average drug prices in 2031 will be 9% lower in Part B and 8% lower in Part D.** Other salient findings from CBO.

    - 1- Drug manufacturers will comply with the negotiation process because the costs of not doing so are greater than the revenue loss from lower, negotiated prices
    - 2 - The Secretary's leverage in negotiations will be sufficient to attain prices below the upper limit established in the act in some cases.
    - 3 - Price negotiation will lower average drug prices paid by Medicare and reduce the budget deficit by $25 B in 2031: Part D spending will be $14 B lower than it would have been, Part B drug spending will be $9 B lower, and other federal spending will be $1 B lower on net.

- **CBO expects that drug manufacturers will comply with the negotiation process because the costs of not doing so are greater than the revenue loss from lower, negotiated prices**. The IRA allows HHS to wield significant enforcement authority over manufacturers that refuse to comply with the negotiation process in the form of excise taxes.

    - The excise tax (penalty) starts at 65% of a product's sales in the U.S. and increases by 10% every quarter to a maximum of 95%.
    - The other alternative for manufacturers is to withdraw all drugs from coverage under Medicare and Medicaid if they choose to not pay the excise tax.
    - Both options are financially burdensome, and manufacturers are expected to participate in the negotiations process if selected.

- **Negotiated (lower) prices are expected to drive up drug usage among Medicare beneficiaries.** Medicare drug usage is expected to increase as beneficiaries use more prescription drugs due to lower costs sharing from lower net prices. However, spending for medical services under Medicare Parts A and B are expected to decrease from better prescription adherence.

- **Recall that starting 2026, Medicare will start negotiating prices for 10 Part D drugs with top Medicare spend (Part B is subject to negotiations starting in 2028)**. Drugs that can be selected for negotiation must have either been on the market for 7 years (small molecule drugs) or 11 years for biologics. They cannot be selected if they face competition from one or more approved generic equivalents or biosimilars or if they are not among the 50 drugs with the largest expenditures under Part D or Part B.

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Inflationary Rebates

- **Some manufacturers may initially avoid inflation rebates and maintain net prices by adjusting their Part D rebates**. Under the IRA, if the reference price of a drug covered by Part B or Part D exceeds its inflation adjusted benchmark, manufacturers must pay an inflation rebate for each unit sold to a Medicare beneficiary. For Part D drugs, the reference price is the average manufacturer price (AMP) and not the net price which determines what is actually paid for the drugs. The gap between the AMP and net prices means that manufacturers could avoid paying the inflation rebate without reducing net prices by reducing rebates so that the AMP remains below the benchmark without affecting net prices. Other manufacturers are expected to pay inflationary rebates to avoid constraining the net price.

- **Inflationary rebates are expected to lower retail prices and manufacturer rebates for Part D drugs on the market in 2022.** However, higher retail prices and rebates are expected for drugs launched in 2023 and later to allow for slower price growth over time.

- **Average net drug prices in Part B and Part D are both expected to be 2% lower in 2031 due to inflationary rebates**. In Part D, overall price decline is expected to be driven by brand-name drugs whose prices have not been negotiated and that were already on the market by 2022.The average net prices of these Part D drugs will be about 6% lower in 2031 (compared to no inflationary rebate policy).

- **Inflationary rebates are expected to have a ripple effect on commercial premiums**. CBO projects commercial drug prices, and therefore health insurance premiums, will be lower due to inflationary rebates.

- **However, Medicaid drug spending is expected to increase under inflationary rebates**. Smaller rebates under Medicaid's statutory drug rebate formula and higher prices for newly launched drugs is expected to increase Medicaid net prices. Under Medicaid's statutory formula, rebates are based on the sum of the greater of 23.1% of AMP or the difference between AMP and the Best Price, and the inflation-based rebate. Both will be reduced from lower AMPs, reducing the amount rebates that Medicaid can receive.

Part D Redesign

- **Certain elements of the Part D redesign, including a shifting of cost sharing and required statutory discounts, is expected to generate some federal savings**. CBO predicts that manufacturers will bear a greater share of total Part D costs through statutory discounts, which reduces subsidies from the federal government. Plans, which will be responsible for a greater proportion of costs, are expected to have a stronger incentive to control costs.

- **However, growth in Part D spending from other provisions is expected to offset these savings**. Federal subsidies to plans are expected to increase as they bear higher cost sharing and premium stabilization is also expected to increase federal spending on Part D. Increase in drug utilization from other IRA provisions will also likely increase drug spending.

- **NEXT UP/OUR TAKE:** CMS is still working to implement IRA drug provisions. We are still waiting for draft guidance from CMS on the Medicare negotiation program which is expected to be released in 1H 2023. The list of selected drugs for negotiations will be released by September 1, 2023. CMS released its draft guidance for inflationary rebates earlier this month, but key questions e.g. how 340B units are addressed remain unanswered. Additionally, manufacturers are not expected to be

billed until 2025 which reduces the financial benefit to the government in the short term. Medicare negotiations, inflationary rebates, and Part D restructuring are expected to lower Part D spending by $62 B in 2031. The negotiation policy accounts for most of the overall decrease in drug spending in 2031 from lower federal spending and lower costs for enrollees. An estimated decline of $20 B in manufacturer discounts and rebates, largely from negotiations, also contributes to the decrease in Part D spending.

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Background

IRA major drug provisions. See CMS implementation timeline here.

Part D restructuring (costs $30 B over ten) starts in 2024 with beneficiaries owing $0 out-of pocket in the catastrophic phase. By 2025, beneficiary total out-of-pocket spending for Part D drugs will be capped at $2,000 per year. Drugmakers have largely embraced these changes as good for patient access.

- Expands Part D LIS. The income threshold for eligibility for the Part D low-income subsidy has been expanded from 135% to 150% of the federal poverty level.
- Stabilized premiums. Premium growth will be capped at 6% per year starting in 2024 through 2029.
- Beneficiary premium percentage adjustment. To provide beneficiary premium protection in the long run, the Secretary will be authorized make a one-time adjustment to the beneficiary Part D premium percentage in 2030.
- Part D vaccine out-of-pocket protection. $0 cost-sharing for vaccines went into effect in January 2023.
- Changes in drug benefit. Instead of 70% in the donut hole, manufacturer discounts are 10% in the initial phase and 20% in the catastrophic phase. See chart below for breakdown.

Part D Restructuring Drug Benefit Changes

2023	2025 (generics)	2025 (brand drugs)
Catastrophic Phase ($7,400 OOP threshold): 15% Plans, 5% beneficiary, 80% Medicare	$2000 OOP threshold: 60% Plans, 40% Medicare	$2000 OOP threshold: 60% Plans, 20% Medicare, 20% manufacturers
Coverage gap (starting at $4,660): 5% plans, 70% manufacturers, 25% beneficiary	Coverage gap eliminated	Coverage gap eliminated
Initial coverage: 75% Plans, 25% beneficiary	Initial coverage: 75% Plans, 25% beneficiary	Initial coverage: 65% Plans, 25% beneficiary, 10% manufacturers
Deductible: 100% beneficiary	Deductible: 100% beneficiary	Deductible: 100% beneficiary

Source: Capitol Street, IRA legislative text, CMS, 2023

Medicare negotiations start in 2026, but the list of selected drugs will be released by September 2023.

- Negotiated prices will go into effect in 2026. The first year of negotiation is 2023.
- 10 qualifying Part D drugs must be negotiated in 2026, 15 additional drugs in 2027-28, and 20 each year in 2029 and beyond. Part B drugs will not be negotiated until 2028.
- Small biotech protections will go into effect in 2026 and end after 2028. For 2029 and 2030, there would be a maximum fair price protection of a maximum 34% discount for small biotech drugs.

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- For drugs subject to Medicare negotiation, there will be minimum discount of 25% in years 9-11, 35% for years 12-15, and 60% for year 16+ based on a 'maximum fair price' while there is no cap on the negotiated discount.
- Manufacturers not participating in negotiation will be subject to an exercise tax beginning at 65% and increasing 10% quarterly up to 95%.

Inflationary Rebates for Part D started in October 2022, Part B started in January 2023. Manufacturers that raise prices above inflation (CPI-U) will have to "rebate" the difference back to the government for Part B &D drugs The civil monetary penalty is equal to units sold to Medicare using the Part B&D billing and payment code multiplied either by the amount by which the Part B payment rate exceeds the inflation-adjusted Part B payment rate or by the amount the volume-weighted average annualized AMP exceeds the inflation-adjusted volume-weighted average annualized AMP.

Pilots to Augment IRA

Recall that CMMI was directed to explore drug pricing models per Biden's prescription drug Executive Order (EO) in October 2022 here. HHS reported to the White House on which models complement the IRA in lowering drug costs for patients, as well as CMMI's plan and timeline to test such models.

- **Top Part B therapies, by spend**. CMMI may target Part B reform as those specialty medications and biologics will not be subject to negotiation until 2028, while Part D restructuring starts in 2025 and Medicare Part D negotiation in 2026.

- **The top 10 Part B drugs by Medicare spend (2020)** are Keytruda (oncology – MRK), Eylea (macular degeneration – Regeneron), Prolia (osteoporosis – AMGN), Opdivo (oncology – BMY), Rituxan (autoimmune - Roche), Lucentis (macular degeneration – Roche), Orencia (autoimmune – BMY), Neulasta (oncology – AMGN), Darzalex (oncology - JNJ), Avastin (oncology – Roche). *Source. CMS/Office of Enterprise Data & Analytics (OEDA), Medicare Part B Drugs, 2022.*

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