Inflation Reduction Act – Implications of the Drug Pricing Regulations

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This deck focuses on the implications for specific sectors of the new drug pricing regulations enacted by the Inflation Reduction Act (IRA). Please see our decks “Inflation Reduction Act – Drug Price Negotiation & Maximum Fair Price Provisions” and “Inflation Reduction Act – Medicare Part B and Part D Provisions” for additional overviews.

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Overview: Changes Implements by IRA

The IRA includes a sweeping overhaul of prescription drug pricing regulation.

The IRA makes arguably the most significant changes to U.S. prescription drug pricing regulation Congress has ever enacted.

- **Price Negotiation:** Allows the government to regulate the price of certain drugs under Medicare for the first time under the Drug Price Negotiation Program, through which the government must establish a "maximum fair price (MFP)" for certain drugs.
- **Inflation Penalties:** Requires pharmaceutical manufacturers to pay rebates on drugs covered under Medicare Part B and Part D if they increase prices faster than the rate of inflation.
- **Medicare Part D:** Overhauls the Medicare Part D benefit by creating an annual $2,000 out-of-pocket (OOP) cap on beneficiary Part D prescription drug spending and alters the financial responsibility among beneficiaries, plan sponsors, the government, and pharmaceutical companies.
  - The law also caps insulin costs for Medicare beneficiaries at $35 per month.

Overview: Drug Selection Timeline

Number of Drugs Selected by Year

Price Applicability Year 2026

Drugs Selected

10 qualifying Part D drugs with highest Medicare spending in reference period

Medicare Spending Reference Period: Jun 1, 2022 – May 31, 2023

Selected Drug Publication Date: Sep 2023

Price Applicability Year 2027

Drugs Selected

15 additional qualifying Part D drugs with highest Medicare spending in reference period

Medicare Spending Reference Period: Nov 1, 2023 – Oct 31, 2024

Selected Drug Publication Date: Feb 2025

Price Applicability Year 2028

Drugs Selected

15 additional qualifying Part B or D drugs with highest Medicare spending in reference period

Medicare Spending Reference Period: Nov 1, 2024 – Oct 31, 2025

Selected Drug Publication Date: Feb 2026

Number of Drugs Selected by Year

Price Applicability Year 2029

Drugs Selected

20 additional qualifying Part B or D drugs with highest Medicare spending in reference period

Medicare Spending Reference Period: Nov 1, 2025 – Oct 31, 2026

Selected Drug Publication Date: Feb 2027

Price Applicability Year 2030 and Beyond

Drugs Selected

20 additional qualifying Part B or D drugs with highest Medicare spending in reference period

Medicare Spending Reference Period (period in year prior to selected drug publication date): Nov 1 – Oct 31

Selected Drug Publication Date: Feb, two years prior to applicability

Note: For each year, the number of selected drugs may be less than the number specified if there is not a sufficient number of qualifying drugs.

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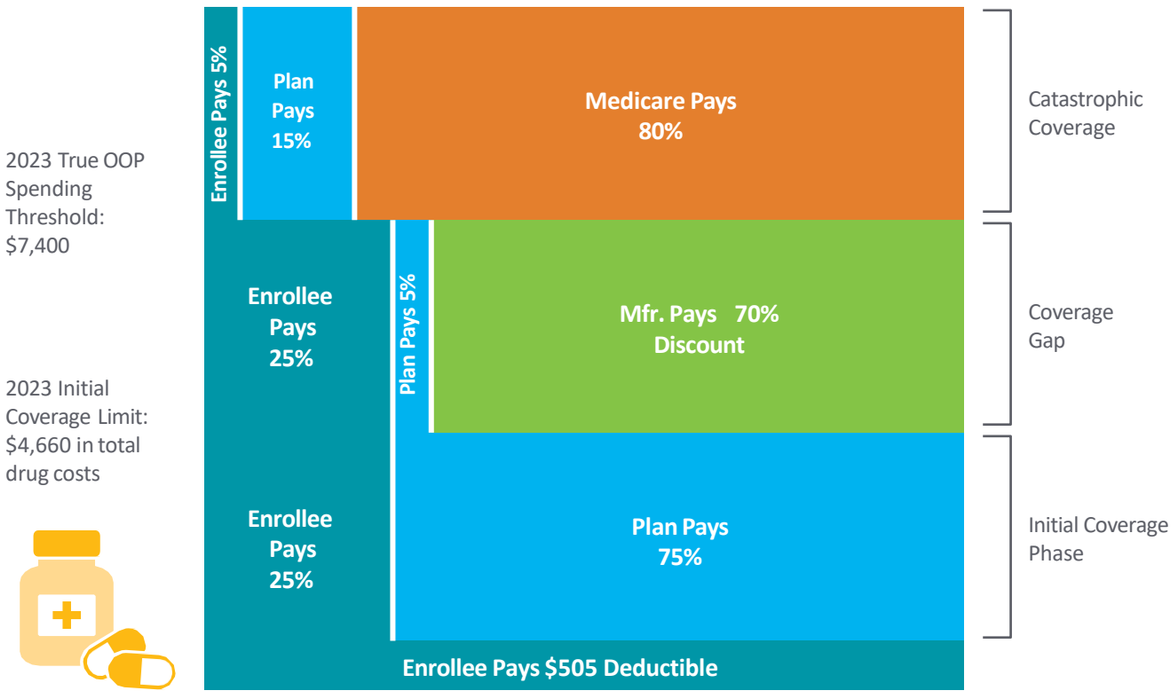
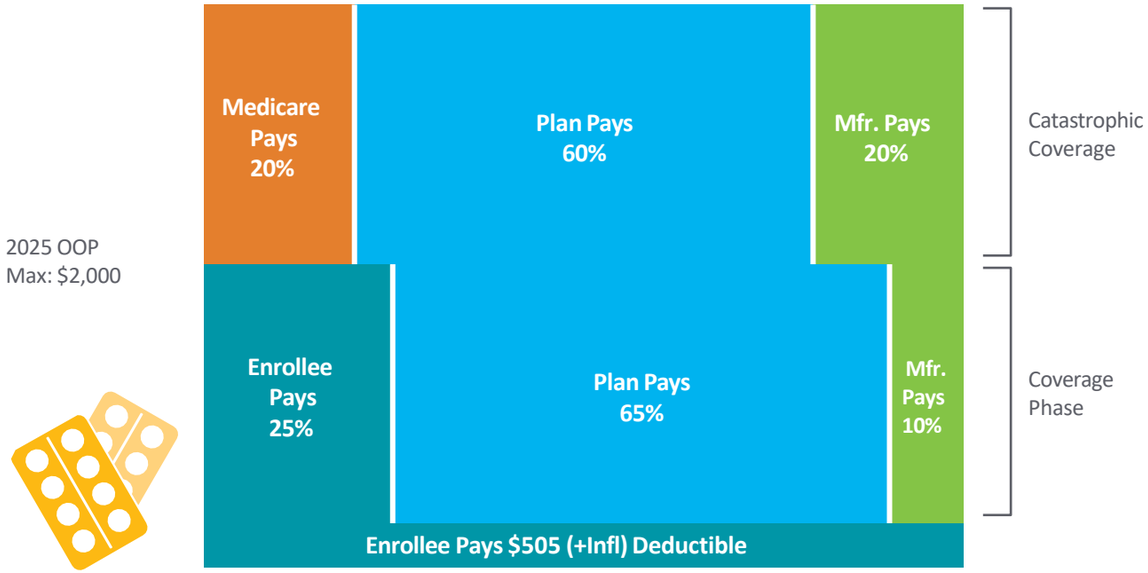
Overview: Changes in Part D Benefit for Brand Drugs

Old Standard Medicare Part D Benefit



New Standard Medicare Part D Benefit



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Sector-Specific Implications: Manufacturers

Brand Drug Manufacturers

- The Drug Negotiation Program will reduce manufacturers' Medicare revenue from existing brand drugs.
- Manufacturers of drugs that are not subject to negotiation may also see lower revenue as they compete against complementary products that have a negotiated price.
- Inflation caps will limit price increases and expected revenue from brand drugs.

PROS

- ✓ Part D redesign will lower patient OOP costs.
  - ✓ Biggest impact on specialty, insulin and vaccines.
  - ✓ May also lower spending on charitable donations, free drug programs.
- ✓ No regulation of launch prices.
- ✓ No Part D manufacturer discounts for selected drugs.

CONS

- X Lower overall revenue.
- X Implementation uncertainty: Unanswered questions about selection & negotiation.
- X Risk that MFP prices will spillover to commercial market (via diversion or negotiations).
- X Reduced incentives to research new indications for existing drugs, especially orphan drugs.
- X Research shift to products with commercial market exposure.
- X M&A activity may shrink to preserve small manufacturer exemptions.
- X New compliance costs to ensure drugs are priced and sold correctly.
- X Part D manufacturer rebates may be more costly for some than current Coverage Gap Discount Program (CGDP).

Sector-Specific Implications: Manufacturers

Generic/Biosimilar Manufacturers

- The IRA's focus on brand drugs limits direct impact on generic manufacturers.
- However, market shifts caused by IRA may complicate market for generics.

PROS

- ✓ Creates incentives for potential "friendly" market access agreement with brands to eliminate brand exposure to negotiation.
- ✓ Biosimilar manufacturers can delay negotiation of reference biologic.
- ✓ Introduces Medicare five-year enhanced payment for biosimilars.
- ✓ Part D redesign increases affordability for generics, with no manufacturer discounts on generics (yes on biosimilars).

CONS

- X Inflation rebates on biosimilars.
- X Reduces incentive to develop generics based on brand products that will be subject to the MFP, including by reducing or eliminating the benefits of first-to-market, six-month exclusivity.
- X Generates uncertainty about future market for biosimilars, which could reduce incentives for continued development investments.

Sector-Specific Implications: Payers

Medicare Part D Plan Sponsors

- $2,000 annual beneficiary cost-sharing cap effective 2025, catastrophic beneficiary cost-sharing eliminated for 2023 and 2024
- Plan liability above the cost-sharing cap is 60% (up from 15% today).
- *Beneficiary* premiums capped for 2024 through 2029.

PROS

✓ At least initially, overall premiums will increase due to cost-sharing limits, while beneficiary premium increases will be limited.

✓ Existence of MFP drugs may allow Part D plans to leverage higher rebates from competitors.

✓ "Rebate rule" delayed.

CONS

X Plans will be at substantially more risk for high-cost drugs, which may result in more aggressive utilization management.

X Plans may lose rebate revenue from formerly high-priced drugs.

X Plans will need to operationalize cost-sharing smoothing.

Once MFP and redesign are in place and premium hike cap expires, unclear what the overall impact of MFP and higher plan liability will be on premiums.

Sector-Specific Implications: Payers

Medicare Advantage Plans

- Medicare Advantage organizations will be impacted by price negotiation and inflation rebates of Part B drugs.

PROS

✓ Negotiated drug prices and inflationary rebates may reduce Medicare Advantage plans' costs for Part B drugs.

CONS

X Overall federal payment to Medicare Advantage plans may decline (or not rise as fast) as Part B drug spending moderates, which impacts the fee-for-service benchmark.

CMS will need to clarify whether Part B inflationary rebates will apply to Medicare Advantage utilization.

Sector-Specific Implications: Payers

Employers

- While prescription drug provisions mostly do not regulate employment-based coverage directly, there are hopes (and concerns) that the Medicare provisions will spill over.

PROS

- ✓ Sponsors of employer/union group Medicare plans may see lower costs overall from lower negotiated prices for selected drugs and reductions in drug price inflation.
- ✓ Supplemental benefits in group Medicare plans will count toward the new $2,000 patient Part D OOP maximum, making it more attractive for employers to supplement benefits.
- ✓ New safe harbor for pre-deductible insulin benefit in high-deductible health plans.

CONS

- X Some employers fear that drug costs will shift from Medicare to employers.
  - X On the other hand, the high visibility of the lower Medicare prices could create additional leverage for commercial payers to negotiate lower net prices.

Not a drug pricing provision, but the IRA extension of enhanced individual market premium tax credits could erode employer-sponsored coverage.

Sector-Specific Implications: Providers

Physicians and Other Prescribers

- Physicians and other prescribers will see both positive and negative impacts of the drug pricing legislation, but the impact will vary significantly depending on the individual circumstances of a specific prescriber.

PROS

- ✓ Annual cap on Part D OOP costs may result in better medication adherence among Medicare beneficiaries.
- ✓ Cap on insulin costs may result in better patient outcomes for diabetic patients.
- ✓ Better patient outcomes/lower costs could impact provider risk-sharing arrangements.

CONS

- X Reduces profits on certain physician-administered drugs in Medicare, as reimbursement will typically be 106% of MFP instead of 106% of average sales price (ASP).
- X Prescribers could lose revenue on commercial reimbursement calculated based on ASP, which would fall when MFP is implemented.
- X With less manufacturer-funded research on new indications, it may be harder to prescribe off-label.
- X Increases Part D utilization management of high-cost drugs.

Not a drug pricing provision, but the extension of Affordable Care Act premium assistance will help patients maintain insurance coverage and enable them to continue to access care through physicians and other prescribers.

Sector-Specific Implications: Providers

Pharmacies

- The drug pricing provisions of the Inflation Reduction Act do not directly regulate pharmacies but will nonetheless have indirect implications for pharmacies.

PROS

✓ The Medicare Part D redesign could reduce medication abandonment.

✓ The extension of ACA premium assistance and the expansion of eligibility for Part D low-income subsidies may help patients maintain insurance coverage and enable them to access drugs through pharmacies.

CONS

X To the extent that pharmacies are paid a percentage of cost, profits may decrease if drug costs go down.

X Pharmacies will need to update their claims systems to include indicators for drugs that are subject to MFP.

Implications could vary by type of pharmacy (retail, specialty, mail). For example, if research is skewed toward biologic products, more prescription drug volume could go to specialty pharmacies.

Sector-Specific Implications: Providers

340B Covered Entities

- The drug pricing provisions of the IRA are a mixed bag for 340B covered entities.

PROS

- ✓ Negotiated prices may result in lower 340B ceiling prices for selected drugs, meaning 340B covered entities can purchase these drugs at lower prices.
- ✓ If MFP is less than the 340B ceiling price, 340B covered entities will be able to access the MFP.

CONS

- X 340B covered entities may pay more for other drugs as manufacturers try to recoup lost revenue.
- X 340B covered entities will likely see their profits on Part B drugs decline, as their reimbursement will be MFP + 6% rather than ASP + 6%.
- X 340B covered entities will likely see their spread on Part D drugs subject to MFP (i.e., the difference between the amount covered entities are reimbursed for a drug and the amount they pay for a drug) decrease.

Reduced profits on drugs for physician practices may incentivize greater consolidation with 340B covered entities.

Sector-Specific Implications: Medicaid Agencies

State Medicaid Agencies

- Although negotiated prices apply to Medicaid and not just Medicare, there are concerns about potential budget impacts of higher launch prices.

PROS

✓ Mandatory Medicaid rebates paid to states for MFP drugs will increase as the MFP is included in the best price calculation.

CONS

X The Congressional Budget Office estimates that the Medicare inflation rebates will be an overall increase to Medicaid expenditures.
  - x Because price increases may now be limited to inflation, manufacturers may seek to increase launch prices.
  - x Reduced price increases could impact benefit to states from Medicaid inflation rebates.

X In theory, manufacturers could drop out of Medicaid rather than selling drugs at the MFP.

X If launch prices go up or generic availability goes down, overall costs could increase for state Medicaid programs.

Open question as to impact of law on research and development in therapeutic categories for Medicaid enrollees.

Sector-Specific Implications: Patients

Patients

- Medicare beneficiaries with high Part D drug costs are one of the big winners under the law, as it may save them thousands of dollars annually.
- But many patients will see little changes to their drug costs, and some could even face higher premiums.

PROS

- ✓ Medicare beneficiaries with high Part D drug costs may see substantial savings due to the new OOP maximum and will have less of a need to seek other assistance.
- ✓ Part D enrollees using insulin will benefit from $35 monthly cost-sharing limit.
- ✓ Part B inflationary rebates may reduce coinsurance for certain Part B drugs.
- ✓ $0 cost sharing for Medicare and Medicaid beneficiaries for Advisory Committee for Immunization Practices (ACIP)-recommended recommended vaccines.
- ✓ More Medicare beneficiaries will qualify for low-income subsidies.
- ✓ Patients with rare diseases could see even more focus on rare disease drugs that qualify for the orphan drug exclusion to negotiation.

CONS

- X If IRA does have a negative impact on drug development, then some patients may see reduced access to new drugs.
- X Potential for higher premiums under Medicare Part D, particularly when cap on premium increase is lifted in 2031.
- X Higher list prices could lead to higher cost-sharing, particularly for Part B drugs and those receiving commercial insurance coverage.

For many patients, a key question is whether the law will result in lower prices without having a significant impact on access to drugs.

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