ABARCA

THE INFLATION REDUCTION ACT OF 2022:

The Impact on Healthcare

BACKGROUND

On August 16th, President Biden signed into law the Inflation Reduction Act of 2022 *(the "Act")*. This legislation, previously referred to as the "Build Back Better Act," implements far-reaching changes to multiple industries.

The Act's healthcare provisions will be implemented over the next several years, and fall into two major categories:

1. Redesigning the Medicare Part D prescription drug benefit.
2. Pricing and negotiation changes for select Medicare Part D and Part B drugs.

In this report, we will summarize the changes brought by this legislation, as well as the impact on relevant stakeholders.

THE CURRENT STATE OF MEDICARE PART D

The existing standard Medicare Part D benefit is structured around four phases. During the benefit year, members will move through the phases based on their out-of-pocket spending on prescriptions:

1. Deductible: The beneficiary is responsible for 100% of the deductible.

2. Initial Coverage: The beneficiary is responsible for 25% of the drug cost and the plan sponsor for 75%.

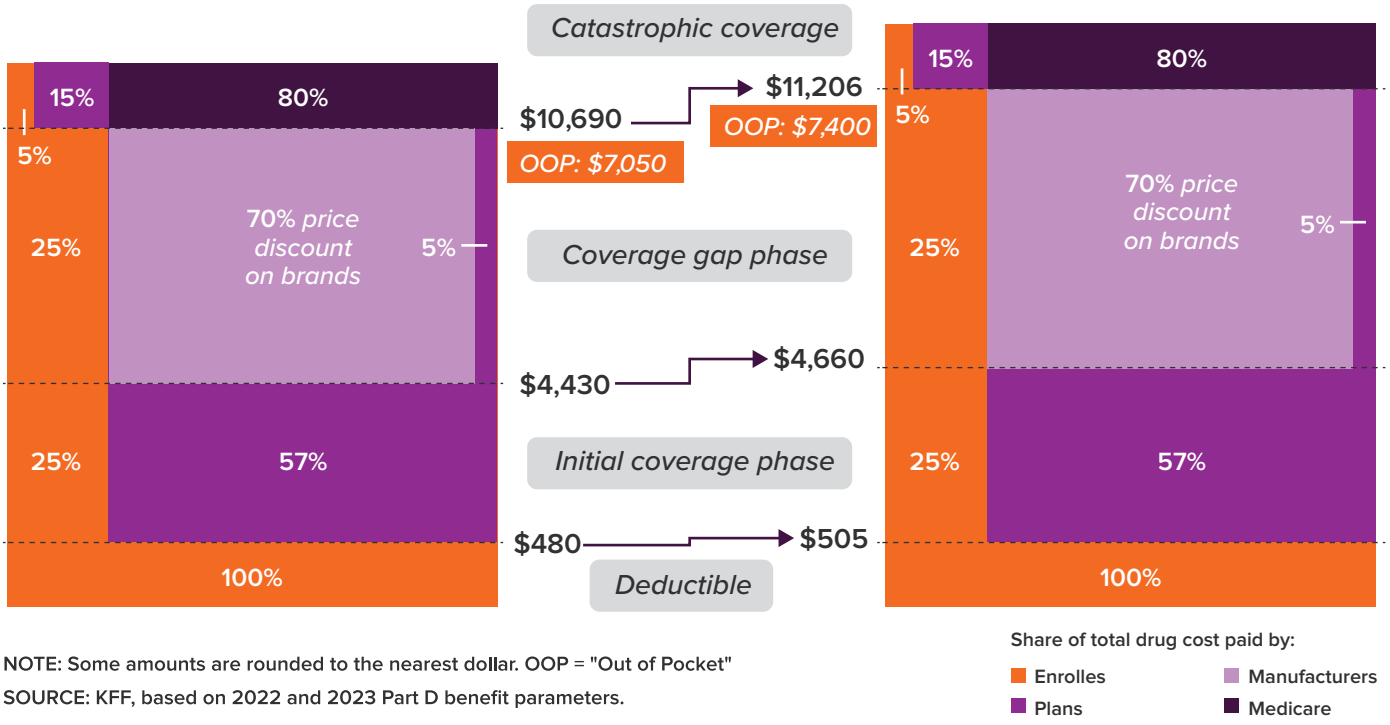
3. Coverage Gap or "Donut Hole": Coverage is dependent on the type of medication.

- **a. Brand name drugs:** The beneficiary is responsible for 25% of the cost, the plan for 5%, and the drug manufacturer for the remaining 70%.
- **b. Generic drugs:** The beneficiary is responsible for 25% of the cost and the plan covers the remaining 75%.

4. Catastrophic Coverage: The beneficiary is responsible for 5% of the cost, the plan for 15%, and Medicare covers the remaining 80%.

Medicare Part D Standard Benefit Parameters Will Increase in 2023

Today, the Department of Health and Human Services (DHHS) Secretary, may not interfere with the negotiations between manufacturers, pharmacies, and plan sponsors, nor may the Federal government require a particular formulary or price reimbursement methodology for Part D drugs.



NOTE: Some amounts are rounded to the nearest dollar. OOP = "Out of Pocket"

SOURCE: KFF, based on 2022 and 2023 Part D benefit parameters.

REDESIGNING THE MEDICARE PART D PRESCRIPTION DRUG BENEFIT

THE CHANGES

Medicare	
Changes beginning calendar year (CY) 2023	• Insulin copays will be capped at $35 per month under Medicare Part D. • Vaccines covered under Medicare Part D will have $0 beneficiary cost share (influenza and pneumonia vaccines are currently covered under Part B with a $0 copay).
Changes beginning CY2024	• The elimination of the 5% coinsurance that beneficiaries are responsible for during the Catastrophic Phase. • Eligibility to receive full Part D low-income subsidies (LIS) will be extended to beneficiaries with incomes up to 150% of the federal poverty level, eliminating a partial LIS benefit for beneficiaries between 150 and 135% of the federal poverty level.

Medicare	
Changes beginning CY2024	• The Medicare Part D monthly premium cannot grow more than 6% per year until at least 2030.
Changes beginning CY2025	• The Coverage Gap Phase will be removed, and the Initial Coverage Phase will start once a beneficiary has met his or her deductible and end when he or she has met the catastrophic threshold. • Plan sponsor responsibility during the new Initial Coverage Phase will be reduced from 75% to 65% on brand name drugs, and manufacturers will be responsible for 10% of the cost. • The amount a beneficiary must spend out-of-pocket to reach the catastrophic threshold will be capped at $2,000. That number is subject to change in the future. • During the new Catastrophic Coverage Phase, the beneficiary will continue to have $0 out-of-pocket expenses. The plan sponsor will now be responsible for 60% of the drug cost and the manufacturers and Medicare will each be responsible for 20%.

Additionally, the Act delayed the implementation of the Trump Administration's final rule—that aimed to eliminate rebates negotiated between manufacturers and PBMs or plan sponsors by removing the current safe harbor protections—until at least CY2032.

Medicaid & CHIP

Starting in CY2023, all ACIP (the Advisory Committee on Immunization Practices recommended adult vaccines will be mandated to be covered without enrollee cost share for all Medicaid and Children's Health Insurance Programs (CHIP) plans.

THE IMPACT

For Beneficiaries	• The $2,000 cap will have a substantial impact for Part D beneficiaries who are currently experiencing high out-of-pocket drug spend. As high-cost medications can reach this threshold with a single fill, this provision provides relief for beneficiaries who do not otherwise qualify for low-income subsidies. • The $35 cap on insulin (including for prescriptions filled in the Coverage Gap and Catastrophic Phases) will increase access to this medication for patients who do not receive low-income subsidies. • Older patients requiring Part D-covered vaccines, such as the shingles vaccine will have $0 out-of-pocket spend starting CY2023. This will remove barriers to vaccinations and better align with the $0 copay currently offered through commercial coverage.

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For Medicare & Plan Sponsors	• Due to the shifting responsibilities laid out by the Act, both plan sponsors and Medicare will be footing a higher portion of the bill for drugs. • With little ability to impact premiums in CY2023 and the 6% cap of premium increase starting in CY2024, plans will need to explore greater cost control measures. (For example, additional or stricter utilization management measures and increasing generic drug utilization)

PRICING & NEGOTIATION CHANGES FOR SELECT MEDICARE PART D & PART B DRUGS

THE CHANGES

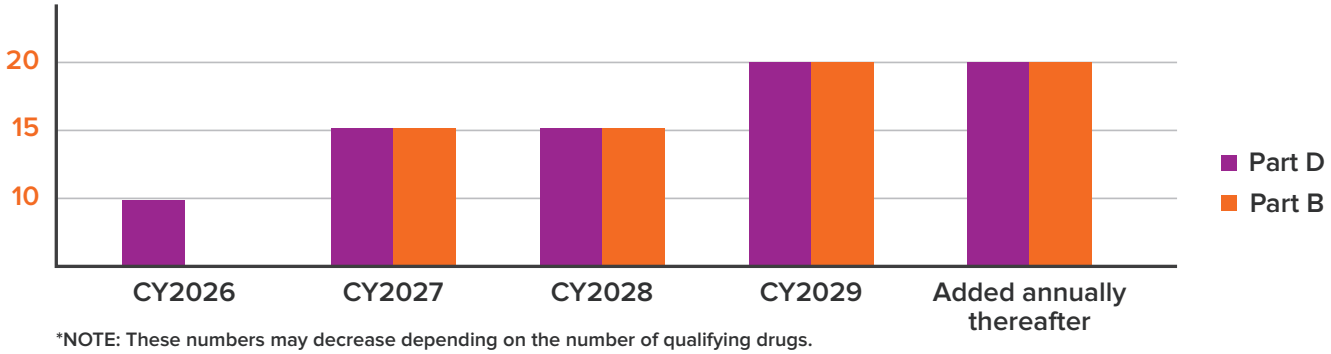
Drug Price Negotiation Program

The Act has created the Drug Price Negotiation Program (the "Program") that allows for the DHHS Secretary to negotiate a fair price for certain drugs covered under Medicare Part B and Part D. Each year, with initial negotiations starting in 2023, the Secretary will choose from a list of 50 qualifying single-source drugs with the highest total spending in Part B and in Part D to establish the Maximum Fair Price (or MFPs) for the selected drugs (refer to the table below for the full list of criteria for qualifying drugs).

The MFP will be set based on the lesser of the following:

1. The price of the drug or biologic paid under Part B or Part D net of all price concessions.
2. The percentage (which is scaled based on number of years since its FDA-approval) of the drug's non-federal average manufacturer price (non-FAMP).

The Secretary will negotiate the MFPs for the "selected drugs" which will be implemented per the following schedule:



*NOTE: These numbers may decrease depending on the number of qualifying drugs.

Providers will then be reimbursed based on the MFP for the selected drugs. For those selected under Part B, the providers will be reimbursed based on 106% of the MFP, rather than currently 106% of the average sales prices (ASP). For those drugs selected under Part D, the providers will be reimbursed no more than the MFP.

And, starting October 1, 2022 through December 31, 2027, Medicare will reimburse providers for biosimilars furnished under Part B at 108% ASP.

In addition, penalties have been created for manufacturers that do not comply with the Drug Price Negotiation Program requirements, including:

- If a manufacturer of a selected drug does not participate in the negotiation process, it is subject to an excise tax up to 95% of the selected drug's sales. Those that do not want to pay the penalty may choose to withdraw all their drugs Medicare and Medicaid coverage.
- If a manufacturer of a selected drug sets prices above the MFP, it is subject to a civil monetary penalty of up to 10 times the difference between the prices.

ELIGIBILITY CRITERIA FOR THE DRUG PRICE NEGOTIATION PROGRAM

The following is the criteria for a drug to be selected as eligible for the Drug Price Negotiation Program as defined in the Act. The Secretary will select from these eligible drugs those to be negotiated directly with the pharmaceutical manufacturers.

Single-source drugs that do not currently have an available generic or biosimilar, or will not have one within the next two years.

Biological drugs that are less than 11 years from their FDA-approval date.

Small-molecule drugs that are less than seven years from their FDA-approval date.

Drugs that are not derived from human whole blood or plasma, nor drugs that are approved for a single rare condition (i.e., orphan drugs).

Drugs from small biotech manufacturers where the drug itself accounts for <1% of the Medicare expenditure (either Part D or separately Part B) but >80% of the company's revenue from Medicare (either Part D or separately Part B).

Drugs that cost at least $200,000,000 between 6/1/2022 and 5/31/2023.

REBATES FOR PRICE INCREASES ABOVE INFLATION

Starting **CY2023**, the Act will require manufacturers to cap annual price increases of their drugs sold under Medicare below the rate of inflation. If a Part D drug receives an AMP increase between **CY2022** and **CY2023** that exceeds the rate of inflation, then the manufacturers will be required to pay the difference back to Medicare as a rebate. Similarly, starting **CY2024**, if a Part B drug receives an ASP increase between **CY2023** and **CY2024** that exceeds the rate of inflation, the manufacturer will be required to pay a rebate back to Medicare.

THE IMPACT

For Medicare & Plan Sponsors

The Drug Price Negotiation Program is expected to generate savings for Medicare and plan sponsors, which will help lessen the impact of the Part D redesign and offset some of the expected increases to premiums and out-of-pocket costs for beneficiaries. However, the amount of savings is dependent on which drugs are selected and the final price reductions.

For Drug Manufacturers

Drug manufacturers may need to make adjustments to their US strategy, including:

- Pursue further research in products chosen as the selected drugs to initiate renegotiations with the DHHS Secretary.
- Consider patent litigation and settlement allowances that facilitate faster introduction of generics/biosimilars.
- Evaluate participation in copay and patient assistance programs.

FOR PHARMACIES & PART B PROVIDERS

- Overall volume of dispensed prescriptions should increase as beneficiary out-of-pocket costs decline, benefiting retail pharmacies.
- Higher dispensing of biosimilars driven by the increased reimbursement margin and availability under Part B.
- Further impacts will become clear as operational processes are defined between plan sponsors and PBMs. For example, if overpayment is identified retrospectively, then future reimbursement may be reduced to offset this, impacting the pharmacy's financials.
- Reporting systems may also need enhancements.

FOR PART B PROVIDERS

- A more rigorous evaluation of the optimal channels for dispensing will likely occur by Part B providers. For example, whether to pursue buy and bill for biosimilars or gain access through white/brown bagging.
- The Act may also result in more vertical integration between physician groups and hospital systems to maximize margins. In particular, if a hospital system operates as a covered entity under 340B, integrations would allow a physician group to access 340B prices for patients, and drive revenue.

IN CONCLUSION

The Act helps address some longstanding challenges in healthcare, namely barriers to medication access and inconsistent pricing practices. For beneficiaries, this often results in opportunities to reduce out-of-pocket spend and improve their health. For plan sponsors, the shift in drug spend responsibility will likely necessitate new ways to control costs—creating opportunities for innovation in healthcare.

And, while the upcoming changes are primarily targeted at Medicare beneficiaries, they may play an important role in facilitating a new way forward in other lines of business.