KPMG

Center Insight Brief

Center for Healthcare Regulatory Insight

March 2023

Inflation Reduction Act Part D Benefit Reforms: Impacts on Pharmaceutical Manufacturers, Plans, and Patients

On August 16, 2022, President Joe Biden signed into law the *Inflation Reduction Act of 2022* (IRA),[i] which was passed through the budget reconciliation process by the United States Senate on August 7 and House of Representatives on August 12. In addition to the drug negotiation and inflation rebate provisions in the IRA, the law includes several important amendments to the standard Medicare Part D benefit, several of which align closely with recommendations issued by the Medicare Payment Advisory Commission (MedPAC) in its June 2019[ii] and June 2020[iii] reports to Congress. This *Insight Brief* summarizes the Part D benefit-related provisions of the IRA and provides insights on how those changes could affect financial incentives and behaviors of Part D plans and pharmaceutical manufacturers.

Summary of Part D Reforms in the IRA

Beginning in Calendar Year (CY) 2023, the following changes are in effect:

- Cap on Insulin Costs: Part D plans must not apply a deductible to any Part D covered insulin product and must charge no more than $35 per month's supply of a covered insulin product in the initial coverage phase and the coverage gap phase. The monthly cap will be $35 for plan years 2023, 2024 and 2025. Beginning in plan year 2026, the cap would be the lesser of $35, 25% of the maximum fair price (in cases where the insulin product has been selected for negotiation), or 25% of the negotiated price in Part D plans. Covered insulin products are defined as any insulin products (inclusive of rapid-acting, short-acting, intermediate-acting, long-acting, ultra-long-acting and premixed forms of insulin) that are covered under standalone Medicare Part D Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDs) and have received FDA licensure and marketing approval.

- Eliminating Cost-sharing for Vaccines: Part D plans must not apply the deductible to a Part D-covered adult vaccine recommended by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) and must charge no cost-sharing at any point in the benefit for such vaccines. This policy makes coverage of vaccines under Medicare Part D consistent with coverage of vaccines under Medicare Part B, such as the flu and COVID-19 vaccines.

Beginning in CY 2024, the following changes will take effect:

- Eliminating Beneficiary Cost-sharing in the Catastrophic Phase: Cost-sharing for Part D drugs will be eliminated for beneficiaries in the catastrophic phase of coverage (currently 5%).

- Expanding the Low-Income Subsidy (LIS) program: The LIS program under Part D will be expanded so that beneficiaries who earn between 135% and 150% of the federal poverty level and meet statutory resource limit

requirements will receive the full LIS subsidies that were previously only available to beneficiaries earning less than 135% of the federal poverty level. These beneficiaries currently receive partial LIS benefits, which typically subsidize some portion of the Part D premium and standard deductible, limit cost sharing to 15% coinsurance, and require modest co-payments for drugs above the catastrophic threshold; whereas those with full LIS benefits pay no premium or deductible and only modest co-payments for drugs until they reach the catastrophic threshold when cost sharing ends.

- Capping Base Beneficiary Premiums: Growth in the annual base beneficiary premium offered to beneficiaries is limited to no more than a 6% increase per year through 2030.

Beginning in CY 2025, the following changes will take effect:

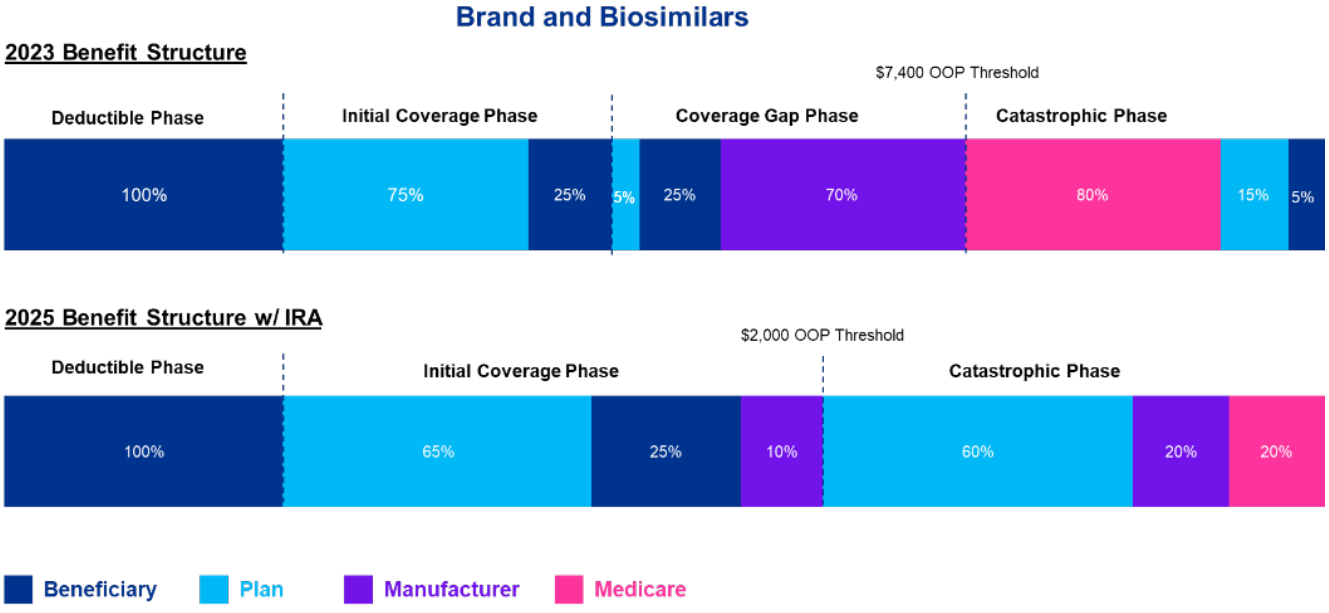
- Cap on Out-of-Pocket Spending: The beneficiary out-of-pocket threshold is capped at $2,000 per plan year for covered Part D drugs, increased annually for inflation.

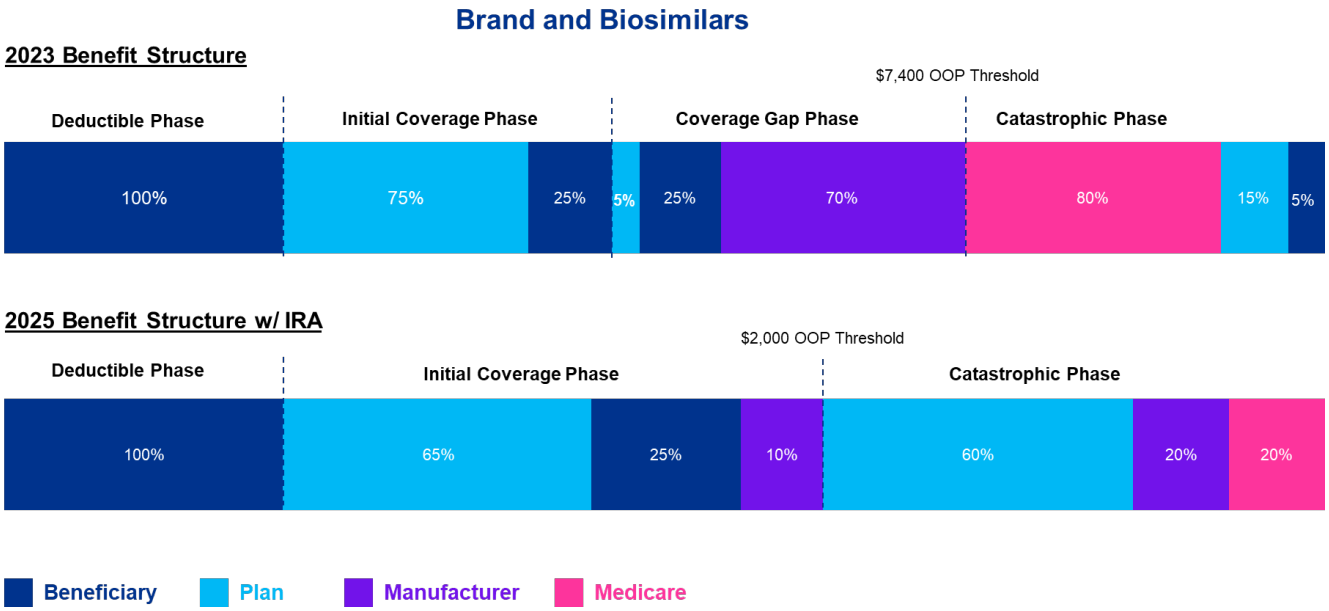
- Permitting Smoothing of Out-of-Pocket Costs: Under certain circumstances, a beneficiary would be able to opt to pay high annual out-of-pocket costs on a monthly basis subject to a cap, defined as the beneficiary's outstanding out-of-pocket costs for a plan year divided by the remaining months in the plan year.

- Eliminating the Coverage Gap: Beneficiaries who have met their deductible (if applicable) will proceed through an initial coverage phase followed by a catastrophic phase. The current "coverage gap" drug manufacturer discount program will be replaced with a new drug manufacturer discount program providing discounts in both the initial and catastrophic phase.

- Modifying Cost Liability for Medicare, Part D Plans, and Drug Manufacturers: Medicare Program liability for spending above the beneficiary spending cap ("reinsurance") will decrease from 80% to 20% for brand name drugs and to 40% for generic drugs. Part D plan liability will increase from 15% to 60% for both brand and generic drugs above the beneficiary spending cap. Meanwhile, drug manufacturers will be required to provide a 20% price discount on brand name drugs above the beneficiary spending cap and provide a 10% discount on brand name drugs during the initial coverage phase, thereby reducing the plan liability from 75% to 65% in the initial coverage phase. *See Figure 1*

Figure 1. Changes to Medicare Part D Benefit Structure (2023 vs. 2025)





Next Steps

The Centers for Medicare and Medicaid Services (CMS) has already issued implementing guidance on several IRA provisions through Health Plan Management System (HPMS) memos, most notably those applying to CY 2023 requirements to cap monthly insulin costs and eliminate cost-sharing for vaccines recommended by CDC.[iv] CMS has also detailed changes in the CY 2024 MA and Part D Advance Notice.[v] CMS may implement further requirements for plan years 2024, 2025 and 2026 through program instruction and other guidance instead of through formal rulemaking.

Meantime, changes to the Part D benefit are expected to impact the financial incentives and behaviors of Part D plan sponsors and pharmaceutical manufacturers. Most notably, changes taking effect in 2025, such as the reduced beneficiary out-of-pocket cap and increased plan and manufacturer liability for Part D benefits will increase the financial responsibility for Part D plans and drug manufacturers. These changes are likely to "provide stronger incentives for [Part D] plan sponsors to manage enrollees' spending and potentially restrain manufacturers' incentives to increase drug prices or launch new products at high price."[vi]

The increased liability for benefit spending, the caps on total beneficiary spending and on monthly insulin cost sharing, and the requirement to remove cost-sharing for vaccines will require Part D plan sponsors to fund more benefits from the premiums paid in part by beneficiaries, while also being constrained by new caps on the growth in premiums. These changes will require plans to manage the benefit more efficiently to remain competitive on premiums. All other things being equal, plan sponsors would be disincentivized from promoting high-cost, high-rebate drugs over less expensive therapeutic alternatives, such as biosimilars. As noted by MedPAC, the increased plan liability for benefits will require plans to "bear more insurance risk for their enrollees' spending," aligning more closely with the "original intent of Part D [to] provide access to beneficiaries' medications while managing spending so that premiums remain competitive."[vii] CBO scoring released February 17, 2023 estimates that the Part D redesign will result in "increased federal subsidies, premium stabilization, and increased use of drugs [that] will put upward pressure on the deficit. Other aspects of the benefit redesign will put downward pressure on the deficit. On net, the deficit is estimated to rise by $2 billion in 2031 because of the redesign."[viii]

The requirement for drug manufacturers to provide new discounts in the initial coverage and catastrophic phases could temper high drug launch prices and deter drug manufacturers from aggressively increasing prices since high-priced drugs and biologics will be subject to a greater financial liability.[ix] Increased financial liability in both the initial coverage and catastrophic phase will make manufacturers more responsible for higher drug costs as the beneficiary moves

through the benefit, as compared to the current benefit with drug manufacturer liability in just the coverage gap phase. Additionally, drug manufacturers will be more sensitive to increased drug costs due to other IRA provisions requiring payment of rebates for drugs that have price increases faster than inflation. Finally, because of new plan incentives to better control costs, MedPAC concluded in 2020 that it would be "difficult for manufacturers of high-priced products to offer rebates large enough to make their products financially advantageous for plan sponsors when lower cost products are available." As a result, plan sponsors would likely prefer lower priced products to "high-priced, high-rebate products."[x]

Although the restructured benefit, particularly the cap on beneficiary out-of-pocket spending and increased plan liability, could theoretically lead to higher enrollee premiums and federal subsidies, the actual impact on premiums is unclear. In fact, the drug manufacturer discount could help to offset most if not all increased costs associated with the benefit redesign, thereby helping to control premium growth.[xi]

Changes to the program's risk corridors, as recommended by MedPAC in 2020, could also be used in future years to help reduce plans' aggregate risk as they assume a greater share of spending in the catastrophic phase. In addition, when MedPAC originally recommended similar Part D restructuring in 2019, they noted that including more costs in the bid would likely change certain counterproductive bidding behaviors before it would raise premiums. Currently plan bids can underestimate catastrophic spending and overestimate the rest of the benefits in their bids. The underbidding on catastrophic allows plans to charge lower-than-warranted premiums, and the overbidding on the rest of benefit spending allows plan sponsors to keep most of the difference as profits due to the risk corridors. If plan sponsors are incentivized to change these behaviors before raising premiums, it is possible that premium competition will drive lower than predicted premium increases.

The overall impacts of the Part D restructuring are hard to predict, although they are likely to alter the current financial incentives of plan sponsors and drug manufacturers. Part D plan sponsors will need to find ways to manage benefit costs more efficiently, while continuing to compete on premiums. Drug manufacturers will need to make important decisions about pricing of their products, recognizing that their financial liability will increase and pricing decisions could more significantly impact formulary placement. Beneficiaries will generally have lower out-of-pocket costs; but they must also watch for possible changes to their benefits, including whether their drugs are still included on plan formularies.

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[i] Public Law 117-369. Inflation Reduction Act of 2022. 117th Congress

[ii] Medicare Payment Advisory Commission. Restructuring Medicare Part D for the era of specialty drugs. June 2019 Report to the Congress: Medicare and the Health Care Delivery System.

[iii] Medicare Payment Advisory Commission. Realigning incentives in Medicare Part D. June 2020 Report to the Congress: Medicare and the Health Care Delivery System.

[iv] See: Centers for Medicare and Medicaid Services. HPMS Memo Archive. Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin, September 26, 2022; PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023, September 26, 2022; and Additional CY 2023 PDSS Model Guidance Related to Inflation Reduction Act (IRA) Changes to Part D Coverage of Insulin.

[v] Centers of Medicare and Medicaid Services. Calendar Year (CY) 2024 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Advance Notice).

[vi] Medicare Payment Advisory Commission. Restructuring Medicare Part D for the Era of Specialty Drugs. June 2019 Report to the Congress: Medicare and the Health Care Delivery System, pg. xv.

[vii] Id. at 41

[viii] Congressional Budget Office. How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. February 2023.

[ix] Medicare Payment Advisory Commission. Realigning incentives in Medicare Part D. June 2020 Report to the Congress: Medicare and the Health Care Delivery System.

[x] Id. at 130, 151

[xi] Id.

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