CRA Insights: Life Sciences

CRA Charles River Associates

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Inflation Reduction Act: Increasing healthcare coverage, reducing healthcare prices. How will it impact manufacturers?

Part 3: Reforms to patient cost-sharing

The Inflation Reduction Act (IRA) of 2022, signed into law on August 16, contains some of the most significant changes in healthcare regulation since the introduction of the Medicare Modernization Act of 2003. There are many healthcare-related policy changes contained in the IRA, which can be categorized into three major sections:

1. Expansion of patient access to affordable insurance
2. Adjustments to medication pricing and reimbursement
3. Reforms to patient cost-sharing

In the third installment of CRA's review of the Inflation Reduction Act (IRA) of 2022 we cover several reforms to patient cost-sharing for Medicare Part D Plans (PDP) and Medicare Advantage Prescription Drug (MA-PD) Plans. Our first installment covered the expansion of access for consumers and can be viewed **here**. Our second installment discussed the implementation of medication pricing and reimbursement rules, which can be viewed **here**.

We welcome any feedback or questions you might have about our analysis and look forward to discussing how your products and organization may be impacted.

- **Medicare Part D out-of-pocket cap**

  Patient cost sharing for Medicare Part D drugs has gone through a variety of revisions since the introduction of the Medicare Modernization Act in 2003. Many changes have focused on reducing or eliminating the donut hole where consumers were initially responsible for the full payment of medications. However, patients have always been responsible for 5% co-insurance once they reached the catastrophic phase of their benefit. The IRA will remove patient responsibility for the catastrophic phase starting in 2024.[1] Further, in 2025 the IRA will establish an annual out-of-pocket cap of $2,000 for all Part D beneficiaries and will finally eliminate the "donut hole" such that there is only an initial coverage phase from a patient perspective.

[1] IRA, p. 162, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

To assist in paying for these changes to patient out-of-pocket costs the IRA will sunset the existing Medicare Coverage Gap Discount Program and create a new discount program which will require manufacturers to pay a 10% rebate in the initial coverage phase and a 20% rebate in the catastrophic phase. Similar to the previous program, these rebates will apply to branded drugs, biologics, and biosimilars on the Part D benefit. It also appears that these rebates will apply to drugs that have negotiated a maximum fair price, further eroding net price.

- **Monthly Part D out-of-pocket caps to smooth cost sharing**

  At the start of each year, PDP and MA-PD beneficiaries who are taking high-cost medications typically see a significant out-of-pocket burden as they pay their deductible during initial coverage and in the coverage gap. As part of the IRA, starting in 2025, consumers can smooth their out-of-pocket expenses over the course of the year. This would be implemented at any point in the year by dividing the amount of money the beneficiary owes the plan sponsor by the remaining months in the year. Pharmacies would still be paid in full by the plan sponsor at the time of sale. If a beneficiary fails to pay their smoothed out-of-pocket costs in any month, their participation in the cost smoothing program would be terminated, they would owe the full out-of-pocket cost amount, and they would not be allowed to participate in the cost-smoothing program in the next year. This smoothing of cost-sharing is expected to ease payment for many patients, especially those living on fixed incomes.

- **Insulin out-of-pocket caps**

  The rising cost of insulin to consumers has been a target of criticism in recent years; the IRA seeks to limit insulin out-of-pocket costs for Medicare beneficiaries. For the plan years of 2023 and 2024, the standard Part D deductible will not apply to insulin and insulin out-of-pocket cost will be limited to $35 per month. [2]Starting in 2025, the deductible will apply, but cost sharing will remain limited to $35 per month. Finally, in 2026 and beyond, cost sharing will be limited to the lesser of:

  - $35 per month,
  - 25% of the maximum fair price (see installment 2 here if you'd like to understand more about this new negotiated price), or
  - 25% of the negotiated price of the product under the beneficiary's plan.

- **Eliminating cost-sharing for vaccines**

  Most vaccines are covered under Medicare Part D with the major exceptions of influenza, pneumonia, hepatitis B, COVID-19, and post-exposure prophylaxis vaccines (e.g., tetanus and rabies) all of which are covered under Medicare Part B. There are already provisions which ensure that vaccines provided under Medicare Part B have no patient cost-sharing, but that has typically been untrue for vaccines covered under Medicare Part D. The IRA eliminated cost-sharing for Part D covered vaccines that have been recommended by the Advisory Committee on Immunization Practices (ACIP). It further provides a temporary (2023-2025) subsidy to plans to assist in paying for the expected increased uptake of vaccinations for Medicare beneficiaries.

In summary, the IRA provides several mechanisms to help reduce the out-of-pocket burden on Medicare Part D and Medicare Advantage Prescription Drug Plan beneficiaries.

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[2] IRA, p. 229, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

Implications for life sciences companies

- Certain high-cost Part D products faced patient affordability challenges due to the uncapped 5% catastrophic co-insurance. **Removal of catastrophic co-insurance combined with the removal of the coverage gap and the institution of out-of-pocket cost caps may help more patients afford their medications**, which could increase prescription and compliance rates for high-cost therapies.
- All else equal, **lower out-of-pocket costs for patients could cause upward pressure on drug prices**, as manufacturers face less price-sensitivity, especially for products with high Medicare exposure.
- **Upward price pressure is likely limited to the inflation rate** as any additional price increase would need to be paid back to CMS in the form of inflation rebates (as covered in Part 2 (link) of this series of articles).
- Due to reduced need, there will likely be **reduced contributions to non-profit copay foundations** dedicated to assisting Medicare patients paying for high-cost medications.
- Part D sponsors will need to adjust their bid prices, premiums, benefit designs, and/or utilization management strategies to pay for the reduced contributions from patients. Another possibility would be that we see **fewer plans offered in the Medicare space** with fewer options for consumers to choose from. In either case, **manufacturers will need to consider the implications of benefit design changes on their target patients as they consider their own Part D contracting strategies.**

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