Inflation Reduction Act: What Does It Mean for Drug Pricing?

What Is It?

The Inflation Reduction Act (IRA) of 2022 is a law aimed at reducing inflation through investment in key sectors, including clean energy and healthcare. The IRA's healthcare provisions focus largely on reducing the costs of prescription drugs over time. Crucially, the law provides the Centers for Medicare & Medicaid Services (CMS) the authority to negotiate the cost of certain Part D and Part B drugs for the first time. It also imposes a rebate requirement on manufacturers that raise the cost of their drugs over the inflation rate.

What Does It Do?

The IRA provisions impact both beneficiary costs and systemic drug pricing in several ways. Below, we provide a summary of these key provisions.

1. Patient Cost Provisions:

    - *Out-of-Pocket Caps in Part D*: For 2024, the IRA eliminates the 5% beneficiary coinsurance requirement above the catastrophic coverage threshold, effectively capping out-of-pocket costs at approximately $3,250 that year. Beginning in 2025, the legislation adds a hard cap on out-of-pocket spending of $2,000, indexed in future years to the rate of increase in per capita Part D costs.

    - *Insulin Price Cap*: The IRA limits monthly cost sharing for insulin products to no more than $35 for Medicare beneficiaries, including insulin covered under both Part D and Part B, and no deductible will apply. All Medicare Part D plans, both stand-alone drug plans and Medicare Advantage drug plans, will be required to charge no more than $35 for whichever insulin products they cover, although plans will not be required to cover all insulin products. For 2026 and beyond, the law limits monthly Part D copayments for insulin to 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.

    - *Elimination of Cost-Sharing for Part D Vaccines*: The IRA requires that adult vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP), such as for shingles, be covered at no cost. This 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. The law also requires state Medicaid and CHIP programs to cover all approved adult vaccines recommended by ACIP and vaccine administration, without cost sharing.

- *Expansion of Medicare Low-Income Subsidy (LIS) Program Eligibility*: The IRA makes individuals with incomes up to 150% of poverty and resources at or below the limits for partial LIS benefits eligible for full benefits under the Part D Low-Income Subsidy Program. The law eliminates the partial LIS benefit currently in place for individuals with incomes between 135% and 150% of poverty.

2. Drug Pricing Provisions

- *Price Negotiation*: The IRA requires the HHS Secretary to negotiate prices with drug companies for a small number of single-source brand-name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026 with 10 drugs) and Part B (starting in 2028 with 15 drugs). These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. CMS has just released its list of the first 10 Part D drugs targeted for negotiation, with the negotiated prices to take effect in 2026.

    - Eliquis (apixaban)
    - Jardiance (empaglifozin)
    - Xarelto (rivaroxaban)
    - Januvia (sitagliptin)
    - Farxiga (dapagliflozin)
    - Entresto (sacubitril/valsartan)
    - Enbrel (etanercept)
    - Imbruvica (ibrutinib)
    - Stelara (ustekinumab)
    - Fiasp/Novolog (insulin aspart)

  In selecting these drugs, CMS looked for medications that had been on the market for at least 9 years for small-molecule drugs and 13 years for biologics to allow manufacturers to recoup the costs of development. Additionally, CMS excluded orphan drugs approved for only one indication (orphan drugs with more than one indication are not exempt from the IRA's negotiation provisions).

- *Price Rebates*: The IRA requires drug manufacturers to pay a rebate to the federal government if prices for single-source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation. Price changes will be measured based on the average sales price for Part B drugs and the average manufacturer price for Part D drugs. If price increases are higher than inflation, manufacturers will be required to pay the difference in the form of a rebate to Medicare. The rebate amount is equal to the total number of units sold in Medicare multiplied by the amount, if any, by which a drug's price in a given year exceeds the inflation-adjusted price. For Part B drugs with price increases greater than inflation, beneficiary coinsurance will be based on 20% of the drug's

lower inflation-adjusted price. The base year for measuring cumulative price changes relative to inflation is 2021. The Part D inflation rebate provision takes effect in 2022, the starting point for measuring drug price increases, with rebate payments required beginning in 2023. The Part B inflation rebate provision takes effect in 2023.

Implementation of IRA Provisions

As noted above, the provisions are being rolled out at different times. The insulin cap, vaccine cost-sharing, and LIS provisions have already taken effect, while the out-of-pocket cap provision will take effect in 2024.

The systemic provisions, including negotiated drug pricing and drug rebates are still working their way through the administrative rulemaking process. As noted above, CMS has just released its list of Part D medications for 2026, but we do not yet know what the negotiated prices will be (they are slated to be released on September 1, 2024), and implementation may still prove bumpy. Manufacturers can opt out of negotiated pricing by paying a very high excise tax (65-95%) or by pulling their medications from Medicare coverage. Additionally, there are a number of lawsuits winding through various courts challenging the legality of the IRA provisions on both statutory and regulatory grounds. ASHP will be monitoring those cases and updating members as more information becomes available.