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IRA key takeaways for U.S. pharmaceutical and healthcare stakeholders

The Inflation Reduction Act (IRA) is a complex law that contains healthcare reforms, tax changes, and environmental policy provisions that impact several layers of the U.S. healthcare ecosystem. These are a few key takeaways for U.S. pharmaceutical and healthcare stakeholders to be aware of.

Information is based on available resources from the Centers for Medicare & Medicaid Services (CMS). This document is not intended to be, and should not be construed as, legal advice.

> Scan or click the QR codes below for additional information

To explore resources from the Centers for Medicare and Medicaid Services (CMS)



To view the Inflation **Reduction Act in full**





What you should know

Medicare Drug Pricing Negotiation Program (MDPNP)

Through the Medicare Drug Pricing Negotiation Program (MDPNP), Medicare can negotiate maximum fair prices (MFP) of certain high expenditure, single source drugs without generic or biosimilar competition in Medicare Part B and Part D.

The first round of Part D drugs were selected for negotiation in 2023 with MFP starting in 2026. The first round of Part B drugs will be selected for negotiation in 2026 with MFP starting in 2028.

Medicare Prescription Payment Plan (MPPP)

Beginning in 2025, the MPPP, also known as copay smoothing, will allow Part D beneficiaries to:

- Opt-in to an alternative payment structure that spreads out-of-pocket drug costs for covered Part D medications over the course of a year
- Cap out-of-pocket drug costs at \$2,000 per year

Medicare Part B biosimilars temporary payment increase

Since October 1, 2022, existing qualifying biosimilars will be paid an average sales price (ASP) plus 8% of the reference biological product's ASP. This temporary payment increase remains in effect for five years.

Inflation rebates

For drugs not selected for negotiation through the MDPNP, new inflation rebate payments from prescription drug manufacturers are required to the Medicare program when their prices rise faster than inflation, as measured by the average manufacturer price (AMP).

Additional changes

- Increased financial liability for Part D plans in the catastrophic phase and for enrollees eligible for the low-income subsidy throughout the benefit. The IRA limits premium rate increases for Part D for the years 2024–2029 at 6 percent year-to-year.
- Beneficiaries with Medicare Part B or Part D coverage pay no more than \$35 for a single month's supply of insulins
- Recommended adult vaccines available at no cost for beneficiaries with Medicare prescription drug coverage
- Expanded eligibility for the low-income subsidy program • ("Extra Help")