

Mintz IRA Update — The First Anniversary of the Inflation Reduction Act: A Year in Review

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August 16, 2023 marked the one-year anniversary of the enactment of the Inflation Reduction Act (“IRA”). The first 365 days since the IRA’s passage brought the implementation of a number of significant changes to the Medicare program, each with the intended goal of improving access to care and lowering prescription drug costs. Over the past year, the Centers for Medicare & Medicaid Services (“CMS”) has adopted changes for 2023 in response to IRA requirements and has been furiously preparing to implement key features of the law that become effective in the next few years. CMS [published](#) numerous guidance documents and created the Medicare Drug Rebate and Negotiations Group (the “**Rebate and Negotiations Group**”), which is responsible for administering the Medicare Prescription Drug Inflation Rebate Program (“**Inflation Rebate Program**”) and the Medicare Drug Price Negotiation Program (“**Negotiation Program**”). Below, we provide an overview of the IRA’s provisions and associated initiatives in effect thus far.

IRA Provisions Currently in Effect:

- **Medicare Part B Biosimilar Reimbursement.** As of October 1, 2022, Medicare temporarily increased Part B reimbursement for certain qualifying biosimilar biological products from average sales price (“ASP”) plus 6% to ASP plus 8%. CMS hopes this increase will “encourage competition, lower costs for prescription drugs, and improve patient access to biosimilars.”
- **Medicare Parts B and D Inflation Rebates.** The IRA included provisions requiring manufacturers to pay rebates to Medicare if the prices of certain of their Medicare Part B and Medicare Part D drugs increase faster than the rate of inflation. These provisions went into effect last year, with (i) October 1, 2022 commencing the first 12-month period for which drug manufacturers would pay inflation rebates to Medicare if their prices for certain Part D drugs increase faster than the rate of inflation, and (ii) January 1, 2023, beginning the first quarter for which drug manufacturers would pay inflation rebates to Medicare if their prices for certain Part B drugs increase faster than the rate of inflation. On March 15, June 9, and September 13, 2023, CMS published its lists of Part B drugs for which prices increased faster than inflation. Further, as of April 1, 2023, traditional [Medicare and Medicare Advantage beneficiaries were projected to see slower increases in their out-of-pocket costs](#) for Part B

drugs that were subject to inflation rebates. Part B beneficiary coinsurance for these drugs is now 20% of the inflation-adjusted payment amount, rather than a manufacturer's ASP, when dispensed by Medicare Providers for original Medicare and dispensed by providers considered to be in-network for Medicare Advantage plans. Because inflation rebates for Part D drugs are calculated on an annual basis, we will not know which Part D drugs are subject to such rebates until late 2023. [Please see here for a more detailed overview of the Inflation Rebate Program.](#)

- ***Insulin Cost-Sharing.*** As of January 1, 2023, Medicare Part D beneficiaries' monthly cost-share for insulin is capped at \$35, and Part D deductibles will not apply to covered insulin products. As of July 1, 2023, Medicare beneficiaries who use an insulin pump covered under Medicare Part B pay no more than \$35 for a month's supply of insulin, and Part B deductibles do not apply to insulin costs.
- ***Adult Vaccines for Medicare Part D, Medicaid, and CHIP Beneficiaries.*** As of January 1, 2023, all adult vaccines recommended by the Advisory Committee on Immunization Practices ("ACIP") are covered by Part D plans with no member cost-share. CMS issued clarifying [guidance](#) indicating that Part D plans must apply the \$0 cost-share requirement with an effective date that aligns with the date the CDC adopts ACIP's recommendation, or the date after the last day of the ACIP meeting at which ACIP's recommendation for a particular vaccine was approved if the CDC does not publish a date adopting ACIP's recommendation. CMS also [clarified](#) that Part D plans must apply the \$0 cost-share regardless of whether the plan adds the vaccine to its formulary midyear or whether the member obtains a formulary exception. Starting October 1, 2023, most adults with Medicaid and CHIP coverage will receive coverage of all adult vaccines recommended by ACIP at no cost to the beneficiary. CMS has issued [guidance](#) to state officials providing instructions for implementation of the requirement.
- ***Low-Income Subsidy.*** [On April 12, 2023, CMS published a final rule](#) implementing an IRA provision that expands eligibility for the full low-income subsidy benefit (also known as "Extra Help") under Part D to Medicare beneficiaries with incomes up to 150% of the federal poverty level who meet certain eligibility criteria. As a result, approximately 300,000 low-income individuals are expected to receive expanded premium and co-pay assistance for out-of-pocket Part D drug costs when the rule goes into effect on January 1, 2024.
- ***The Medicare Negotiation Program Is Underway.*** As discussed in other portions of this IRA update, the Negotiation Program is moving full speed ahead (at the moment) while fending off multiple legal challenges. On August 29, 2023, CMS published the list of the first 10 Medicare Part D drugs selected for negotiation under the Negotiation Program for 2026, and manufacturers of the selected drugs are expected to enter into program agreements by October 1, 2023. We provide an in-depth [review of the mechanics of this program here](#), and also provide an overview of the [legal challenges facing the Negotiation Program here](#).

What to Watch For:

As 2023 comes to a close, we will be monitoring further developments with respect to the Inflation Rebate Program, as CMS is scheduled to issue detailed guidance regarding implementation of the program later this fall, and the IRA generally. We are also closely tracking the numerous lawsuits challenging the legality of the Negotiation Program, as manufacturers are required to sign agreements for participation by October 1, 2023.

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