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The Inflation Reduction Act of 2022: Key Health Care Provisions

On Aug. 7, 2022, the U.S. Senate passed the Inflation Reduction Act of 2022 (IRA), which the House of Representatives passed five days later, on Aug. 12. President Biden is expected to sign the sweeping piece of legislation into law Aug. 16. The IRA includes provisions aimed at addressing a range of issues – including energy and climate, tax, and health care.

The health care provisions include significant reforms that will directly impact consumers and health care stakeholders. This GT Alert summarizes the IRA's key health care provisions.

Prescription Drug Pricing Reform

Lowering Prices Through Drug Price Negotiation

One of the most widely publicized provisions of the bill authorizes the Centers for Medicare & Medicaid Services (CMS), to negotiate drug prices for the Medicare program. The "Drug Price Negotiation Program" will require CMS to negotiate maximum prices for brand name drugs that do not have generic equivalents and that account for the greatest Medicare spending. The program will begin in 2026 and include 10 negotiation-eligible drugs, then will increase to 15 negotiation-eligible drugs in 2027 and 2028, then 20 drugs in 2029 and each year following.

The secretary of the Department of Health and Human Services (HHS) will be tasked with entering into agreements with the drug manufacturers to determine the maximum fair price to individuals, pharmacies, hospitals, physicians, and other providers of services who administer or dispense the drugs. The legislation includes a specific negotiation process and timeline, and also outlines factors to be considered in setting fair market value, including research and development costs.

Prescription Drug Inflation Rebates

In addition to authorizing CMS to directly negotiate prices for applicable drugs, the bill also requires drug manufacturers to issue rebates to CMS for brand-name drugs without generic equivalents under Medicare that cost $100 or more per year per individual with prices increasing faster than inflation. Drugs will be evaluated every calendar year on or after Jan. 1, 2023, through a reporting requirement for Medicare drugs. CMS will determine the inflation-adjusted payment amount with a reduction or waiver for shortages and severe supply chain disruption. Manufacturers that fail to comply will be subject to civil monetary penalties.

Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries

The bill includes a benefit structure redesign beginning in 2026 that modifies the reinsurance payment amount to 20% of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred for applicable drugs; for non-applicable drugs, the amount is 40% of such allowable reinsurance costs attributable.

The bill also establishes a manufacturer discount program where the secretary of HHS is authorized to enter into agreements with manufactures participating in Medicare Part D. Under such agreements, manufacturers will provide discounted prices for applicable drugs dispensed to applicable beneficiaries on or after Jan. 1, 2025. Agreements must be for a minimum of 12 months and include data and compliance requirements.

A manufacturer that fails to provide discounted prices for applicable drugs under a covered agreement will be subject to a civil monetary penalty for each failure.

Continued Delay of Implementation of Prescription Drug Rebate Rule

The IRA extend the moratorium on implementation of the final rule that relates to eliminating the anti-kickback statute Safe Harbor Protection for Prescription Drug Rebates, issued by the Office of the Inspector General on Nov. 30, 2020. The moratorium is extended until Jan. 1, 2032.

Additional Items

The IRA includes required coverage for adult vaccines recommended by the Advisory Committee on Immunization Practices under Medicare Part D. It also includes expanding eligibility for low-income subsidies under Part D and improving access to adult vaccines under Medicaid and the Children's Health Insurance Program.

While there was significant debate related to capping out-of-pocket insulin costs for all consumers, the final law imposes a $35 monthly cap on out-of-pocket spending on insulin for Medicare beneficiaries only. The cap does not apply to private payers.

There is also a limitation on monthly coinsurance and adjustments to supplier payments under Medicare Part B for insulin furnished through durable medical equipment. Additionally, there is a safe harbor for high-deductible health plans that do not impose a deductible for insulin-related products. Under the safe harbor, such a plan may still be treated as a high-deductible health plan.

Affordable Care Act Subsidies

Finally, the bill extends the value of Affordable Care Act subsidies to certain consumers who receive subsidies for health care insurance through the marketplace through 2025.

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