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Selected Health Provisions of the Inflation Reduction Act

Overview

On August 16, 2022, President Biden signed into law P.L. 117-169, a budget reconciliation measure known as the Inflation Reduction Act (the Act). The Act makes wide-reaching changes to Medicare prescription drug coverage and more targeted changes to Medicaid, the State Children's Health Insurance Coverage Program (CHIP), and private health insurance.

The Act requires the Secretary of Health and Human Services (Secretary) to negotiate prices for certain drugs covered under Medicare Part B (physician-administered drugs) and Part D (retail prescription drugs), starting with 10 high-spending, single-source drugs for 2026 and increasing to 20 by 2029. Effective in 2023, manufacturers that sell drugs through Parts B and D must pay rebates to Medicare if they increase drug prices faster than consumer inflation. Also in 2023, the Act eliminates enrollee cost sharing for certain vaccines in Part D and sets a $35 cap on enrollee cost sharing for insulin in Parts D and B.

Effective in 2025, the Part D benefit is reconfigured to include an annual $2,000 out-of-pocket (OOP) spending cap, expanded subsidies for low-income enrollees, and limits on annual premium increases, among other changes. The Act extends through 2025 more generous premium subsidies for health plans sold on exchanges, which were originally approved in the American Rescue Plan Act (ARPA; P.L. 117-2). Following are the main provisions.

Medicare Prescription Drug Price Negotiation

The Act establishes a Drug Price Negotiation Program (the Program) for certain single-source chemical drugs and biological products covered under Medicare Part B and Part D. The Secretary is required to negotiate Maximum Fair Prices (MFPs) with drug manufacturers for 10 qualifying drugs for 2026, 15 drugs for each of 2027 and 2028, and 20 drugs for 2029 and each following year. (In 2026 and 2027, the Program applies only to Part D.)

The initial negotiations begin in 2023 when the Secretary publishes a list of selected drugs and culminate in 2026 when the first round of MFPs takes effect. (Each following year, the negotiation process begins about two years prior to the date new MFPs take effect.) Each year, the Secretary selects drugs for negotiation from a list of 50 qualifying single-source drugs with the highest total spending in Part B and 50 such drugs from Part D, excluding already selected drugs. To be eligible for negotiation, a chemical drug must have been Food and Drug Administration (FDA)-approved for at least 7 years and a biological product must have been licensed for at least 11 years. To be eligible for negotiation, a qualifying drug cannot have a generic or biosimilar substitute. The Program focuses on single-source drugs with limited market competition.

During negotiations with manufacturers, the Secretary must consider factors including the drug's cost of production; research and development expenditures, including federal support; and alternative treatments. The Act imposes an MFP ceiling for a drug based on the lesser of (1) the price of the drug or biological paid under Part B or D or (2) a percentage of the nonfederal average manufacturer price, which is used to help calculate a maximum price for drugs bought by the "big four" federal purchasers: the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard. The ceiling varies based on the type of drug or biological and the amount of time the product has been marketed. There is a temporary price floor for drugs of small biotechnology firms.

A negotiated MFP would generally be in effect until the first year beginning at least nine months after the date the Secretary determines there is a marketed generic or biological substitute for a drug. The Secretary may delay negotiating an MFP for certain biological products for up to two years if a pending biosimilar that uses the biological as a reference product may come to market in that period.

Drug manufacturers that do not comply with the Program could be subject to a civil monetary penalty or an excise tax. The excise tax amount on the sale of a selected drug would be set as a percentage of the sum of the drug's sales price plus the excise tax imposed by the Act. This percentage could range from 65% to a maximum of 95%, if a manufacturer were out of compliance more than 270 days.

Medicare Parts B and D Drug Inflation Rebates

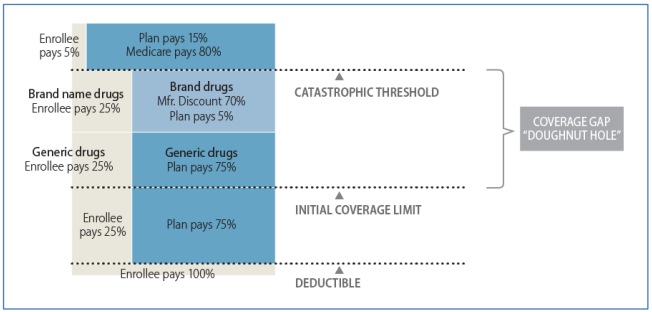
The Act requires drug manufacturers to pay annual rebates to Medicare if they increase prices of certain Part D-covered drugs above an allowable inflation rate from a 2021 base period (based on the Consumer Price Index, all urban consumers [CPI-U]). The program applies in the12-month period starting on October 1, 2022, and each subsequent 12-month period. Likewise, beginning in 2023, manufacturers pay a quarterly rebate to Medicare if the prices of most single-source Part B drugs and biological products exceed a quarterly inflation-adjusted price, also based on CPI-U from a 2021 base.

Medicare Part D Program Changes

Part D is a voluntary prescription drug benefit for Medicare beneficiaries, with plans offered by private insurers. Under the Part D "standard" benefit specified in current law (see **Figure 1**), enrollees pay 100% of drug costs in the deductible, average 25% coinsurance from the deductible to the catastrophic threshold, and a maximum 5% coinsurance above the catastrophic threshold. Medicare covers a greater share of costs for low-income enrollees through the Low Income Subsidy (LIS), including capping OOP spending at

the catastrophic threshold for LIS enrollees with the lowest income and assets.

Figure 1. Current Medicare Part D Standard Benefit



Source: Based on Centers for Medicare & Medicaid Services data.

Notes: Insurers submit annual bids to offer Part D plans, which contain their projected cost for providing the standard benefit. Medicare provides subsidies to insurers equal to about 74.5% of the standard benefit cost, including a risk-adjusted per enrollee payment, LIS payments, and reinsurance for 80% of drug spending above the catastrophic threshold. Insurers charge enrollees monthly premiums, which are pegged to an annual base premium equal to 25.5% of the average of the insurers' plan bids.

Manufacturers that sell brand-name and biologic drugs through Part D must pay a 70% discount on sales in the doughnut hole (the period in the standard benefit from the initial coverage limit to the catastrophic threshold). The discount applies to non-LIS enrollees, who count the discount as OOP spending.

The Act restructures the Part D standard benefit by (1) modifying enrollee cost sharing and the formula for setting premiums; (2) reducing the Medicare reinsurance subsidy; and (3) establishing a new manufacturer discount program. For all enrollees, the Act caps Part D OOP spending at the catastrophic threshold, beginning in 2024, and reduces OOP spending required to reach the catastrophic threshold (set at $7,050 in 2022) to $2,000 in 2025. (The threshold is indexed to Part D drug inflation in following years). Starting in 2024, the Act enhances LIS subsidies for certain low-income enrollees and allows all enrollees to spread out cost sharing in capped, monthly amounts. Starting in 2025, enrollees may count certain third-party payments as their own OOP spending, including reimbursement by health insurance, a group health plan, or other third party.

For insurers, the Act reduces the reinsurance subsidy from 80% to 20% for brand-name biologic and biosimilar drugs and to 40% for generic drugs, beginning in 2025. The Act sets a 6% cap on annual increases in the Part D base premium from 2024 to 2029 and, in 2030, resets the base premium formula, subject to a floor of 20% of plan bids.

The current Part D manufacturer coverage gap discount program ends in 2024 and is replaced with a new manufacturer discount program in 2025. Under the new program, manufacturers provide a 10% discount for brand-name drugs, biologics, and biosimilars dispensed to any enrollee who has exceeded the deductible but has not reached the catastrophic threshold and a 20% discount on such drugs dispensed to enrollees who reach the catastrophic threshold. The discount is to be phased in gradually for certain manufacturers that account for a small share of Part D spending. The new manufacturer discount does not count as enrollee OOP spending.

Medicare Part D, Medicaid, and CHIP Vaccines

Medicare Part D generally covers commercially available vaccines, except those covered under Part B. Currently, Part D plans may impose cost sharing for vaccines. By comparison, Part B beneficiaries have no cost sharing for covered vaccines, except those used to treat an injury or exposure to a disease. Under the Act, starting in January 2023, Part D plans may not apply a deductible, coinsurance, or other enrollee cost-sharing requirement for Part D-covered adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), such as the shingles (herpes zoster) vaccine.

Beginning in October, 2023, the Act expands coverage of ACIP-recommended adult vaccines without enrollee cost sharing under Medicaid and CHIP by mandating such coverage for (1) enrollees who receive coverage under traditional Medicaid; (2) all Medicaid Medically Needy enrollees in specified states (i.e., states that offer services in institutions for mental diseases or in an intermediate care facility for the mentally retarded [or both] to any Medically Needy subgroup in the state); and (3) CHIP enrollees 19 years of age or older.

Insulin Under Medicare Parts B and D

Starting January 2023, Medicare Part D enrollees no longer have a deductible for insulin and have a $35 monthly co-payment cap. Beginning in 2026, the cap could be less than $35, if 25% of the Part D negotiated price or 25% of an insulin's MFP is lower than that amount. Starting July 2023, the Part B deductible is waived for insulin furnished to a beneficiary via durable medical equipment. Beneficiary coinsurance for such insulin is not to exceed $35 a month.

Premium Tax Credits

Individuals (and families) who meet income eligibility criteria, are not eligible for subsidized health coverage (e.g., Medicaid), and meet other requirements may receive federal financial assistance in the form of a *premium tax credit* (PTC), which reduces the cost of buying certain health plans offered through exchanges (or marketplaces).

The Act extends the ARPA provision that expands eligibility for, and the amount of, the PTC for three years, to sunset at the end of the tax year 2025 rather than 2023. The Act (1) eliminates the eligibility phaseout for households with annual incomes above 400% of the federal poverty level (FPL) and (2) uses the ARPA percentages (0.0% to 8.5% of annual household income) to calculate the PTC amount. As under ARPA, the provision provides the largest benefit to those with household incomes at or below 150% of FPL; such individuals are to receive full subsidies to cover benchmark plan premiums. Eligible households with annual incomes at or above 400% of FPL must spend up to 8.5% of their income (prorated monthly) before receiving any credit. For some higher-income households, this results in individuals receiving no credit despite being eligible.

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