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Negotiation of Drug Prices in Medicare Part D

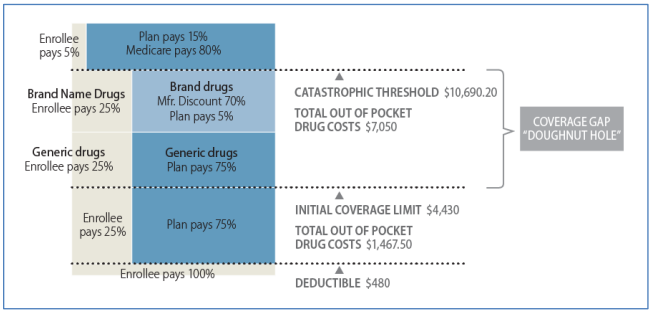
The 117th Congress is considering a number of approaches to address prescription drug prices and spending, including proposals to allow the Secretary of Health and Human Services (HHS) to negotiate prices in the Medicare Part D program. This In Focus provides an overview of how drug prices are established under Part D and describes various proposals for HHS secretarial negotiation.

Overview of Medicare Part D

Congress created the voluntary Medicare outpatient prescription drug benefit, Part D, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173). The program began operation in 2006, and about 50 million Medicare beneficiaries are now enrolled. In 2022, Part D spending is estimated to be approximately $120 billion. (See CRS Report R40425, *Medicare Primer*, and CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.)

Part D coverage is provided by private health payers (*plan sponsors*) that offer drug-only plans (PDPs) or Medicare Part C (Medicare Advantage) plans with a Part D benefit (MA-PDs). Congress designed Part D as a market-oriented program where sponsors compete for enrollees based on benefit scope and price, such as premiums and cost sharing.

Figure 1. 2022 Medicare Part D Standard Benefit



Source: CRS analysis of the Centers for Medicare and Medicaid Studies (CMS), 2022 Part D Payment Policies.

Note: Enrollees also pay monthly premiums. In the standard benefit, an enrollee pays 100% of costs in a deductible, then has average 25% cost sharing until accumulating enough out-of-pocket spending to reach the catastrophic threshold, where cost sharing is capped at 5%. Medicare/plan subsidies vary in different benefit stages, as seen in the right portion of the graphic. Manufacturers provide a 70% discount on brand drugs in the "doughnut hole." In 2022, enrollees enter the doughnut hole with $4,430 in total drug spending.

Sponsors submit annual bids to HHS to offer drug plans. At a minimum, Part D plans must offer a "standard" benefit defined in law or alternative coverage that is at least actuarially equivalent to a standard benefit. (See **Figure 1.**) Medicare pays plan sponsors a monthly per person amount for standard coverage, as well as monthly payments for low-income enrollees and cost-based "reinsurance" payments for enrollees with the highest drug spending.

Determination of Drug Prices in Medicare Part D

To bolster market competition and limit the federal role, the MMA includes a *noninterference provision* (Social Security Act [SSA] §1860D-11(i)), which states that in carrying out the Part D program, "the Secretary: (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."

Although there is no Part D central *formulary* (i.e., list of covered drugs), plans must cover at least two drugs in each category or class used to treat the same medical condition and substantially all drugs in six protected classes: immune-suppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic (cancer). HHS has existing authority to modify these general formulary requirements, including the six protected classes. Most Part D sponsors offer alternative plans that include tiered formularies, which impose different levels of co-payments (flat dollar amount) or coinsurance (percentage of drug price) for generic, brand-name, and specialty drugs. Part D specialty drugs are defined as those with a price of at least $830 per month in 2022. Specialty drugs (which can be defined in different ways depending on the payer), a relatively small share of total prescriptions in Part D and private plans, accounted for more than 50% of U.S. retail drug spending in 2020, up from 27% in 2010, according to industry estimates.

Part D sponsors, working with pharmacy benefit managers (PBMs), negotiate prices with drug manufacturers and contract with pharmacies to dispense drugs to plan enrollees. Negotiated price concessions mainly take the form of rebates (after-sale reductions) from a manufacturer's list price for brand-name drugs. Plan sponsors and PBMs can secure rebates by including a drug on a plan formulary and, further, by putting the drug on a low cost-sharing tier. Sponsors and PBMs have the most leverage to negotiate rebates when there are competing drugs on the market; they have less ability to secure rebates for sole-source drugs or those in the protected classes. A rebate's value may be tied to the drug's sales volume or market share and may be aggregated and paid to a plan over time, such as quarterly. Part D plan sponsors may pass on rebates and other price concessions to enrollees in the form of lower drug prices at the pharmacy, but the vast majority do not, according to CMS. Instead, sponsors use rebate revenue to buy down, or reduce, premiums, thus spreading price concessions across all enrollees.

Part D Drug Spending and Prices

Actual Part D spending was below initial estimates by the Congressional Budget Office (CBO) and the HHS Actuary for 2006-2013. Part D drug spending growth spiked in 2014 and 2015 due to use of new specialty hepatitis C drugs but has since moderated. Still, the Medicare Trustees project that from 2021 to 2030, Part D aggregate benefits will rise about 6% a year on average, faster than other areas of medical spending. The increase is due partly to an expected reduction in growth in the use of generic drugs, which are already about 90% of Part D prescriptions, and higher unit prices for specialty drugs.

Increases in manufacturer rebates and fees from participating pharmacies (direct and indirect remuneration, or DIR) have helped plan sponsors keep premiums low. DIR is estimated to be equal to 31% of Part D costs in 2022, up from 12% in 2008. Although manufacturers have provided larger rebates, they have continued to raise or set high initial *list* prices for brand-name drugs. Because Part D sponsors generally base enrollee prescription cost sharing on list prices, higher prices can increase beneficiary out-of-pocket costs. Studies by CBO and HHS, among others, have found Part D pays higher average net prices (prices after rebates and other discounts) for brand-name drugs (including specialty drugs) than the state-federal Medicaid program. Medicaid requires a 23.1% rebate on new innovator drugs, a 13% rebate on generics, and a supplemental rebate if prices rises faster than U.S. retail inflation. (See CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*.)

Part D Drug Price Negotiation Proposals

Since Part D was enacted, some lawmakers have introduced bills to repeal or modify the noninterference provision so the HHS Secretary could negotiate drug prices. Supporters of secretarial negotiation maintain that by leveraging the combined purchasing power of tens of millions of Part D enrollees, the Secretary could secure larger discounts and rebates than individual plan sponsors can obtain. Others note that nearly 60% of Part D enrollment is now concentrated in three large insurers that already have substantial bargaining power and that changing the noninterference provision could result in formulary limits.

In 2007, the House approved H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007, which would have repealed part of the noninterference provision to allow secretarial negotiation of Part D prices. CBO analyses said the approach would have a "negligible effect" on federal spending and that the Secretary was unlikely to have sufficient negotiating leverage unless also given authority to create a central formulary and/or take other actions if manufacturers failed to cut prices. During the 116th Congress, in a May 2019 letter to the Senate Finance Committee chair, CBO again stated that negotiation likely would be effective only if accompanied by a source of pressure on drug manufacturers. CBO indicated the Secretary might achieve savings by negotiating prices for selected drugs, such as those with no close substitutes or those with relatively high prices needed to address a public health emergency. Such negotiations could have a modest budget impact.

Later in 2019, CBO analyzed H.R. 3, a House-passed bill that, among other changes, would have given the HHS Secretary authority to negotiate prices for selected Part D drugs and make them available to commercial insurers. The bill limited negotiated prices to a maximum of 120% of the average price in a reference group of six industrialized nations. H.R. 3 would have modified the noninterference provision to allow negotiations and would have imposed an excise tax on drug sales if manufacturers declined to negotiate or failed to agree to a price. CBO scored this title of the bill as reducing Part D drug spending, because the excise tax would provide an incentive for successful negotiations. Subsequently, in the117th Congress, CBO scored another House-passed bill, H.R. 5376, as producing Part D savings by allowing the Secretary to negotiate prices of a smaller set of single-source drugs covered under Medicare Parts D and B, after they had been approved or licensed for a specified number of years. Manufacturers would face an excise tax for noncompliance.

Key Elements of Other Negotiation Proposals

Other bills in the 116th and 117th Congresses would give the HHS Secretary authority to negotiate Part D prices. Below is an overview of negotiation approaches.

Formularies. Some bills would retain noninterference language barring a central Part D formulary. Others would repeal the entire noninterference provision without providing guidance on future formularies or would repeal the noninterference provision and instruct the Secretary to set a central formulary based on many current requirements.

Scope of Negotiation. Some proposed bills include general language allowing the HHS Secretary to negotiate prices; others would direct the Secretary to prioritize Part D drugs with the highest cost, the largest price increase, or the least market competition. Some proposals set criteria for determining the appropriate negotiated drug price, such as the drug's clinical and cost effectiveness. A number of bills would allow plan sponsors and manufacturers to negotiate prices below those set via secretarial negotiation.

Fallback Pricing/Penalties. Some bills include fallback pricing and/or penalties to be triggered if the Secretary and manufacturers cannot reach agreement. Examples include basing Part D prices on (1) prices charged to the Veterans Health Administration, which procures drugs for its own facilities; (2) prices in selected industrialized nations; or (3) Medicaid's best price, which is the lowest price that a manufacturer offers to a U.S. buyer.

Compulsory Licensing. Proposed legislation in the 116th Congress would have given the HHS Secretary authority to issue compulsory licenses to third parties to manufacture drugs—including drugs with federal patent and exclusivity protections—in cases where the Secretary and manufacturers could not agree on a price or where the Secretary found broader market or price distortions necessitated federal involvement. An entity manufacturing a drug under a compulsory license would have to provide "reasonable compensation" to the original manufacturer.

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