



September 23, 2019

Negotiation of Drug Prices in Medicare Part D

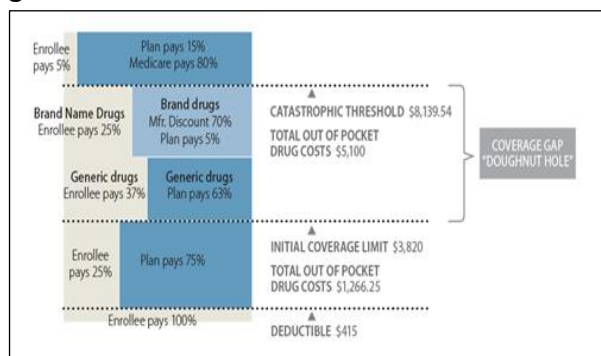
The 116th Congress is considering a number of approaches to address prescription drug prices and spending, including proposals to allow the Secretary of Health and Human Services (the Secretary) to negotiate prices in the Medicare Part D program. This In Focus provides an overview of how drug prices are established under Part D and describes elements of various proposals for Secretarial negotiation.

Overview of Medicare Part D

Congress created a 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 started in 2006, and about 46 million Medicare beneficiaries are currently enrolled. In 2019, Part D spending is estimated to reach approximately \$98 billion. Part D is also the primary source of drug coverage for individuals enrolled in both Medicare and the state-federal Medicaid program (dual eligibles). (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 (PDP), or by Medicare Part C (Medicare Advantage) plans with a Part D benefit (MA-PD). Congress designed Part D as a market-oriented program in which sponsors compete for enrollees based on the scope and price of benefits, such as premiums and cost-sharing.

Figure 1. 2019 Medicare Part D Standard Benefit



Source: CRS analysis of CMS, 2019 Part D Payment Policies.

Note: Enrollees also pay monthly premiums for Part D coverage.

Sponsors submit annual bids to offer drug plans. At a minimum, Part D plans must offer a “standard” benefit defined in law, or alternative coverage at least actuarially equivalent to a standard benefit. (See Figure 1.) Medicare pays plan sponsors a monthly per person amount for standard benefit coverage. Plan sponsors may also receive additional Medicare payments for low-income enrollees and

cost-based “reinsurance” payments for those with high drug spending.

Determination of Drug Prices in Medicare Part D

To bolster market competition and limit the federal role, the MMA included a *non-interference provision* (Social Security Act (SSA) §1860D-11(i)), which states that in carrying out the requirements of 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., a 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, anti-depressant, 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 copayments (flat dollar amount) or co-insurance (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 \$670 per month.

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 manufacturer’s drug on a plan formulary or by putting it on a low cost-sharing tier. Sponsors and PBMs have the most leverage to negotiate rebates when there are competing drugs on the market, and less ability to secure rebates for sole-source drugs, or those in the protected classes. The value of a rebate may be tied to the sales volume or market share of a drug, and may be aggregated and paid to a plan over time, such as quarterly.

Plan sponsors can 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. Instead sponsors generally 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 has been below initial estimates by the Congressional Budget Office (CBO) and the HHS

Actuary, due to lower-than-expected enrollment and high use of cheaper generic drugs, which constitute about 90% of Part D prescriptions. However, the Medicare Trustees indicate that Part D spending is growing rapidly, and project it will double to \$201 billion in CY2028. The projection is based in part on a slowing of the trend toward greater generic drug utilization, and an increase in the use and the prices of specialty drugs. Specialty drugs are about 1% of Part D prescriptions but account for more than 25% of spending, up from 6% in 2007. (See CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*.)

Plan sponsors have significantly increased negotiated rebates for brand-name drugs, with rebates rising from 11.1% of Part D costs in 2008 to 25.3% in 2018. Although manufacturers have provided greater rebates, they have continued to raise or set high initial *list* prices for brand-name drugs. Because Part D sponsors base enrollee prescription cost-sharing on list prices, the higher prices have increased beneficiary out-of-pocket spending, as well as Medicare spending on reinsurance. In addition, studies by the CBO, HHS, and the Government Accountability Office (GAO) have found that Part D pays higher average net prices (prices after rebates and other discounts) for brand-name drugs (including specialty drugs) than Medicaid. Medicaid requires a 23.1% rebate on new innovator drugs, a 13% rebate on generic drugs, and a supplemental rebate if drug prices rises faster than U.S. retail inflation. (CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*.)

Part D Drug Price Negotiation Proposals

Proposals to repeal or modify the noninterference provision to give the Secretary the authority to negotiate drug prices have been introduced since the start of the Part D program. 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 can be obtained by plan sponsors. Opponents note that Part D enrollment is concentrated in a few plans—two sponsors alone have 40% of enrollees—that already have substantial bargaining power, and that changing the noninterference provision could limit formulary coverage. In 2007, the House approved H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007, which would have partially repealed the noninterference provision to allow for Secretarial negotiation. A CBO analysis said the approach would have a “negligible effect” on spending and that the Secretary was not likely to have sufficient negotiating leverage unless given authority to create a central formulary, set prices administratively, and/or take other actions if manufacturers failed to cut prices.

In a May 2019 letter to the Chairman of the Senate Finance Committee, CBO continued to conclude that “(n)egotiation is likely to be effective only if it is accompanied by some source of pressure on drug manufacturers ... providing broad negotiating authority by itself would likely have a negligible effect on federal spending.” CBO indicated that the Secretary might achieve savings by negotiating prices for select drugs, such as those with no close substitutes or

with relatively high prices that are needed to address a public health emergency, however, such negotiations may have only a modest impact on federal spending.

Key Elements of Recent Negotiation Proposals

Several bills have been introduced in the 116th Congress to allow the Secretary to negotiate Part D drug prices. Several of the proposals are designed to increase the Secretary’s leverage by imposing penalties on manufacturers if negotiations are not successful. Below is a general overview of approaches to Secretarial negotiation. Because CBO has not issued scores for recent legislative proposals, the overview does not address possible impacts on drug prices or Part D spending.

Formularies—Legislative proposals regarding HHS formulary development differ widely. 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 that includes many of the current formulary requirements.

Scope of Negotiation—Some legislative proposals include general language that would allow the Secretary to negotiate prices, while others would direct the Secretary to prioritize negotiations on Part D drugs with the highest cost, the largest price increase, or the least market competition. Some proposals list criteria for determining the appropriate negotiated price for a drug, including the drug’s clinical and cost-effectiveness, budgetary impact, patient financial burden, and sales. While some would require annual negotiations, others would set prices for longer periods. Some proposals would also allow plan sponsors to continue to negotiate for lower prices than those set by the Secretary.

Fallback Pricing/Penalties—Some legislative proposals include fallback pricing to be triggered if the Secretary and manufacturers were unable to 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 select industrialized nations; or (3) Medicaid’s best price, which is the lowest price that a manufacturer offers to a U.S. buyer. Under other proposals, manufacturers that refused to negotiate could be subject to financial penalties, such as special tax assessments.

Compulsory Licensing—One proposal would give the Secretary authority to issue compulsory licenses to third parties to manufacture prescription 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 determined that broader market or price distortions necessitated federal involvement. Any entity that manufactured a drug under such a compulsory license would have to provide “reasonable compensation” to the original manufacturer. (See CRS Report R45666, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress*.)

Binding Arbitration—Another suggested approach is to set drug prices through arbitration, a dispute resolution process in which a neutral third party makes a binding decision.

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IF11318

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