

## MEDICARE PART D

Medicare Part D covers retail prescription drugs for Medicare beneficiaries through unique, stand-alone drug insurance plans.

In its first decade, Medicare Part D has been popular with beneficiaries, providing important benefits to more than forty million people at lower costs than projected. However, recent trends suggesting that spending growth is exceeding that of Medicare overall have revived calls to apply the buying power of Medicare more directly to controlling prescription drug prices.

### Background

The Medicare program was enacted in 1965 to provide subsidized health coverage for the elderly and disabled. The program initially covered hospital stays (Part A) and physician office visits (Part B), and Medicare paid for the prescription drugs used in those settings. The program did not, however, cover retail prescription drugs that consumers purchase from pharmacies—by far the largest volume of prescription drug use then and now.

In 2003 the Medicare Modernization Act created a drug benefit for seniors called Part D. The benefit went into effect on January 1, 2006. A decade later nearly forty-two million people are enrolled in Part D, and the program pays for almost two billion prescriptions annually, representing nearly \$90 billion in spending. Part D is the largest federal program that pays for prescription drugs.

Part D is popular with Medicare beneficiaries, and its costs have been below initial projections. Recently, however, Part D spending has grown faster than the rest of Medicare, and the Medicare Trustees predict that trend to continue for the next decade. In addition, the unique benefit structure of Part D can expose beneficiaries to high costs

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### Part D: What You Need To Know

The Medicare Part D prescription drug benefit includes several features that distinguish it from other public and private models of prescription drug coverage.

#### STAND-ALONE DRUG INSURANCE

The Part D program operates using an insurance model—but one that is designed exclusively to cover prescription drug costs. That differs from most

health insurance plans in the private sector and from the Medicare Advantage (MA) program, which typically cover the full range of medical spending, including hospitals, physician visits, and prescription drugs. The Part D program operates both as a stand-alone benefit and as an add-on to the MA program; so-called Medicare Advantage–Prescription Drug (MA-PD) plans operate like commercial insurance policies in covering the full range of medical spending.

## “The leverage of any individual plan is limited by the size of its enrollee base.”

In contrast, stand-alone Part D plans cover only drugs and so have some unique features. Beneficiaries’ costs for stand-alone Part D plans are directly related to the expected prescription drug spending in the population, so annual premiums and cost sharing generally increase in line with drug spending trends. In addition, stand-alone Part D plans do not have any exposure to increased health care costs outside of the retail drug sector—nor do they benefit from any potential offsetting savings if higher use of drugs reduces other costs, such as hospitalization.

### BENEFIT DESIGN/THE “DONUT HOLE”

While Part D’s drugs-only focus is unique, the basic operation of a Part D plan relies on tools used widely by private insurers. Enrollees pay a monthly premium. There is usually a deductible, and then enrollees pay a share of the cost of their prescriptions, with the plan paying the rest. Plans use formularies, almost always with tiers that assign lower patient cost-sharing amounts to preferred drugs.

Initially, beneficiary spending is supposed to represent 25 percent of drug costs, with the plan covering the other 75 percent. As in many insurance products, there are “catastrophic coverage” protections for beneficiaries with high out-of-pocket expenses (above \$4,950 in 2017). During the catastrophic phase of the benefit, enrollees pay 5 percent of the cost of prescriptions.

Originally, the program included a gap between the initial insurance coverage and the trigger point for catastrophic coverage, universally known as the “donut hole.” The Affordable Care Act of 2010 “filled in” the donut hole: Manufacturers of brand-name drugs were required to provide a 50 percent discount on drugs purchased during that phase of the benefit, with the federal government covering an additional portion of the cost. The federal cost sharing is phasing in, and as of 2020 the basic formula of a 25 percent/75 percent split in costs will apply all the way up to the catastrophic cap.

### PRICE NEGOTIATION AND NONINTERFERENCE

The Part D program design assumes that private insurers offering drug coverage have an incentive to negotiate the lowest possible price for drugs to provide a competitively priced plan to attract enrollees and maximize profits. However, the leverage of any individual plan is limited by the size of its enrollee base. While some large insurers have a national Part D presence, no single entity represents more than 21 percent of Part D lives.

By law, the Medicare program itself is prohibited from “interfering” in price negotiations between plans and manufacturers. That limits the ability to pool the entire Medicare population to improve negotiating leverage.

### LOW-INCOME SUBSIDIES

Federal subsidies for low-income people are built into Medicare Part D, which immediately replaced Medicaid as the source of drug coverage for “dual eligibles”—people who qualify for both Medicaid and Medicare. Low-income Medicare beneficiaries receive sliding-scale, income-based subsidies that limit Part D cost-sharing requirements. Subsidies also greatly limit these beneficiaries’ price-sensitivity when choosing prescriptions.

The transfer of dual eligibles from Medicaid to Medicare Part D eliminated manufacturers’ obligation to pay [Medicaid rebates](#) on those patients’ prescriptions. For certain medicines at the time (for example, antipsychotics), the dual eligibles were a large portion of sales, and relief from Medicaid rebates meant higher profits on those products.

## FORMULARY OVERSIGHT

In overseeing Part D, the Centers for Medicare and Medicaid Services (CMS) seeks to prevent drug insurers from enrolling only healthy beneficiaries or discouraging use of medically necessary drugs to lower costs. For example, CMS requires Part D plans to cover at least two different drugs in each therapeutic class and all drugs in six “protected classes,” including drugs for cancer, HIV, depression, schizophrenia, transplants, and epilepsy.

## ■ Key Questions For Drug Pricing

There are several outstanding questions about how the Part D program could be improved to control drug costs or lower beneficiary spending.

### IMPACT OF HIGH-PRICE DRUGS

Part D includes a government-paid subsidy to protect plans from significant losses resulting from outlier enrollees. The result is that plans are exposed to only 15 percent of the cost of drugs over the catastrophic limit, with the beneficiary paying 5 percent and the federal subsidy (known as reinsurance) paying the remaining 80 percent.

As noted, the catastrophic limit is currently \$4,950 of beneficiary spending, implying about \$7,500 in total drug costs. Because many prescription drugs now cost significantly more than \$7,500 annually, the reinsurance portion of Part D has become the [fastest-growing cost](#) in the program.

In addition, while the share of expenses paid by beneficiaries is only 5 percent during the catastrophic phase of the benefit, there is no cap on total annual out-of-pocket spending, so individual costs can be quite high for enrollees with very high prescription costs. Among other factors, high beneficiary costs have led to proposals to change the catastrophic benefit design to increase plans’ exposure to those expenses, encouraging them to negotiate more aggressively for savings on high-price drugs.

### PLANS’ MANAGEMENT OF FORMULARIES

In 2014 CMS proposed changing the six-protected-class rule to promote price competition in several of

the categories, estimating a savings of \$720 million over five years. However, CMS dropped the proposal in response to negative feedback, particularly from patient organizations, who were more concerned about plans [denying coverage of appropriate medicine](#) than about the impact of higher prices.

### THE RIGHT USE OF REBATES

In Medicare Part D, as in other drug markets, some stakeholders are concerned about the difference between list (or retail) prices and net prices after manufacturer rebates to purchasers. Manufacturers argue that consumers are often charged cost-sharing amounts based on a list price that does not reflect discounts and rebates negotiated with the plan. Those amounts are carefully tracked and accounted for in the insurer’s bid to participate in Part D, but they are often applied to lower the monthly premium, not the amount paid by individual beneficiaries at the point of sale. In its approval of individual bids, CMS could encourage different approaches to applying rebate dollars. The question is whether rebates should be used to lower the price paid by individuals who need a particular drug or to lower the premiums paid by all beneficiaries who buy the insurance product.

### MEDICAID-LEVEL REBATES

The transfer of the dual-eligible population to Medicare Part D was a significant benefit to manufacturers in 2006. The Health and Human Services Inspector General [estimated](#) in 2012 that the average Part D rebate among the 200 top-selling drugs was 15 percent, compared to 47 percent in Medicaid. The main reason for the difference is that Medicaid rebates are adjusted for inflation, while Part D plans (like other private purchasers) negotiate rebates off of current list prices. Those findings led to proposals to impose Medicaid-level rebates on Part D for beneficiaries receiving low-income subsidies, including dual eligibles. According to the [Congressional Budget Office \(CBO\)](#), that proposal would save \$145 billion in federal spending over ten years.

### SHOULD MEDICARE NEGOTIATE PRICES?

The call for Medicare drug price negotiation is almost as old as the Part D program itself and tied to the “noninterference” clause. However, the CBO [found](#)

that government negotiation would offer no inherent savings to the program. That is largely because there are no structures in place to allow Medicare to exclude drugs from the entire Part D program if a manufacturer refuses to negotiate a price. Moreover, the CBO concluded that private plans are already reasonably successful in driving price concessions, given that they can exclude drugs from their own formularies when there are multiple entrants in a given class. The CBO's analysis also acknowledges that the noninterference clause doesn't eliminate the federal government's ability to jawbone manufacturers into reducing prices case by case.

Recent work by policy development groups has fleshed out proposed price negotiation systems, including calls for a binding arbitration process that would involve third-party cost-effectiveness reviews to define a "fair" price. It is not clear whether those proposals would, in fact, deliver savings.

## Key Terms

- **"Noninterference" clause:** A provision in the Medicare Modernization Act states that the Department of Health and Human Services "may not interfere with the negotiations between drug manufacturers and pharmacies and Prescription Drug Plan sponsors; and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."
- **Dual eligible:** People who qualify for both Medicare (because of age or disability status) and Medicaid (based on income). Prior to Part D, dual-eligible beneficiaries had drug coverage through the Medicaid program. They are now enrolled in Part D.
- **Protected classes:** Informal shorthand for six therapeutic categories for which CMS determined that Part D plans must cover each different drug approved for that use. (CMS refers to them as the six "classes of clinical concern.")

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