MEDICINES IN MEDICARE: PART D

Medicare is the government program that insures many of the nation's retirees and Americans with disabilities. Coverage for prescription medicines filled at a pharmacy first became available in 2006 under the Medicare Part D program. Private health plans administer the program and compete for beneficiary enrollment. These plans also negotiate with manufacturers, without government interference, to secure to secure savings on medicines. This market-based approach has been successful since the program's beginning, but some in Washington now are considering fundamental change. The information that follows is based on the Part D benefit design and program rules in place at the end of 2021.

This chart pack contains information on prescription drug coverage under Part D in four subsections: 101, Choice and Competition, Improved Adherence and Outcomes, and A Prescription for the Future.

As Is Common With Commercial Insurance, Medicare Covers Medicines Under 2 Benefits

Medicare's retail pharmacy benefit is called Part D, and Medicare's medical benefit is called Part B.

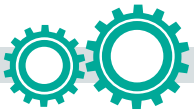
MEDICARE		COMMERCIAL INSURERS
Part D		Retail Pharmacy Benefit
Includes most drugs, which are either picked up by patients at a retail pharmacy or delivered via mail order/specialty pharmacy.		
Part B		Medical Benefit
Includes a minority of drugs, which generally must be administered by a physician or other health care professional		

Source: McDonald R[1]

How Medicare Part D Works

PART D operates with plans competitively bidding against one another. Plans aggressively negotiate with manufacturers to secure discounted prices from manufacturers. In some cases, these negotiated savings are over and above mandatory discounts from manufacturers.

PLANS compete to deliver comprehensive, affordable coverage for beneficiaries and value for taxpayers.



MANUFACTURERS provide significant negotiated rebates and mandatory coverage gap payments that help fund the program.

BENEFICIARIES choose the plan with the coverage and costs that best meet their needs.

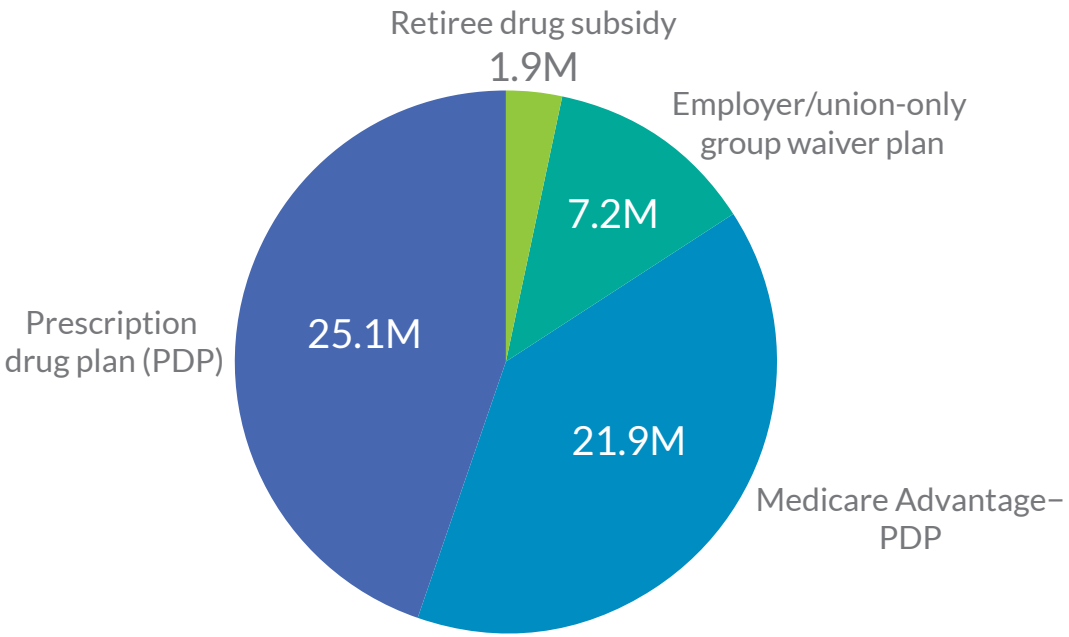
EXTRA HELP is available for enrollees of limited means through the Low-Income Subsidy program.

GOVERNMENT sets standards/oversees competition.

Sources of Prescription Drug Coverage for Seniors and People With Disabilities

Medicare Part D plans covered more than 47 million beneficiaries out of more than 60 million total Medicare enrollees in 2020, either through Medicare Advantage or stand-alone prescription drug plans.

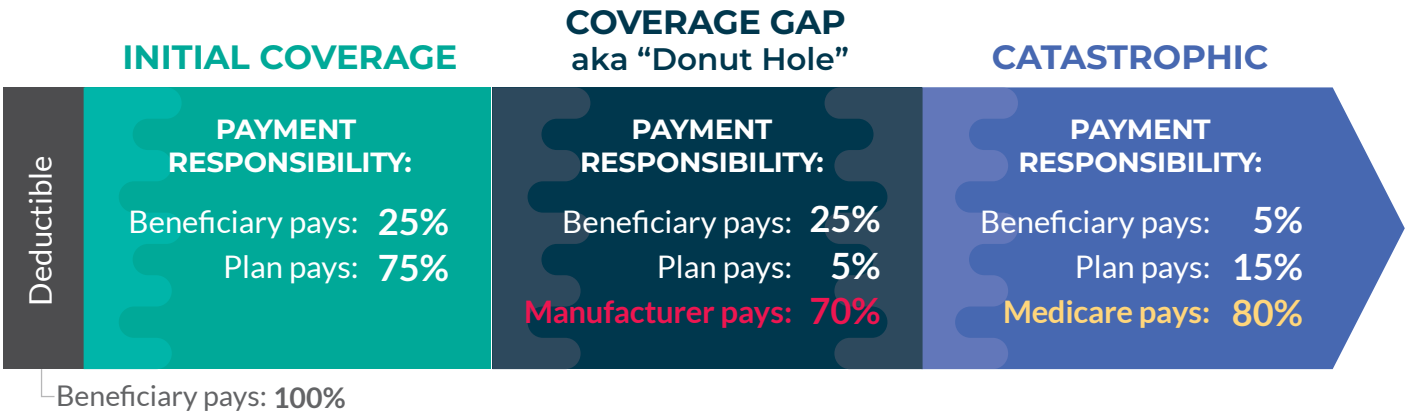
Prescription Drug Coverage Among Part D Medicare Beneficiaries, 2020*



*Excludes federal government and military retirees covered by either the Federal Employees Health Benefit Program or the TRICARE for Life program. Such programs qualify for the retiree drug subsidy, but the subsidy is paid since it would amount to the federal government subsidizing itself. Excludes those who had no drug coverage or had coverage less generous than Part D.

Source: MedPAC[2]

Part D Defined Standard Benefit

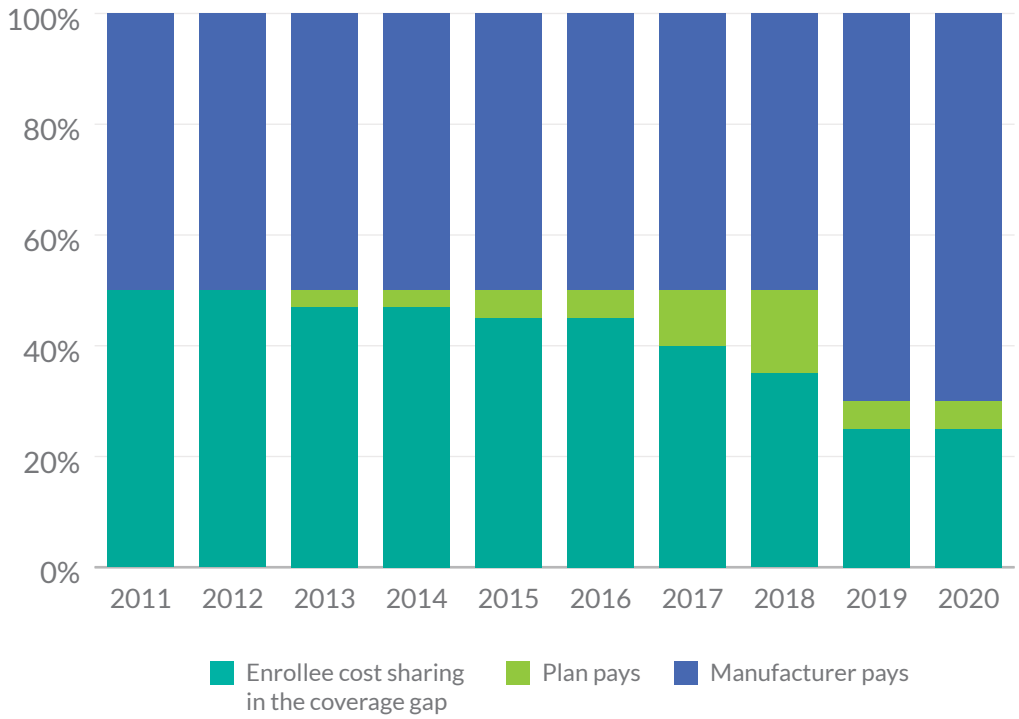


Each year, the standard benefit's parameters change at the same rate as the annual change in beneficiaries' average drug expenses. For 2021, discounts paid by brand manufacturers begin when a beneficiary without the Low-Income Subsidy has reached $4,130 in cumulative drug spending and continue until the individual reaches $6,550 in combined out-of-pocket spending and brand discounts.

Source: MedPAC[3]

Bipartisan Budget Act of 2018 Closed the Coverage Gap in 2019 and Beyond

Since 2010, nearly 12 million Medicare beneficiaries have saved over $26 billion on prescription drugs as a result of manufacturer coverage gap discounts—an average savings of about $2,272 per beneficiary.[4]



STARTING IN 2019[5]:

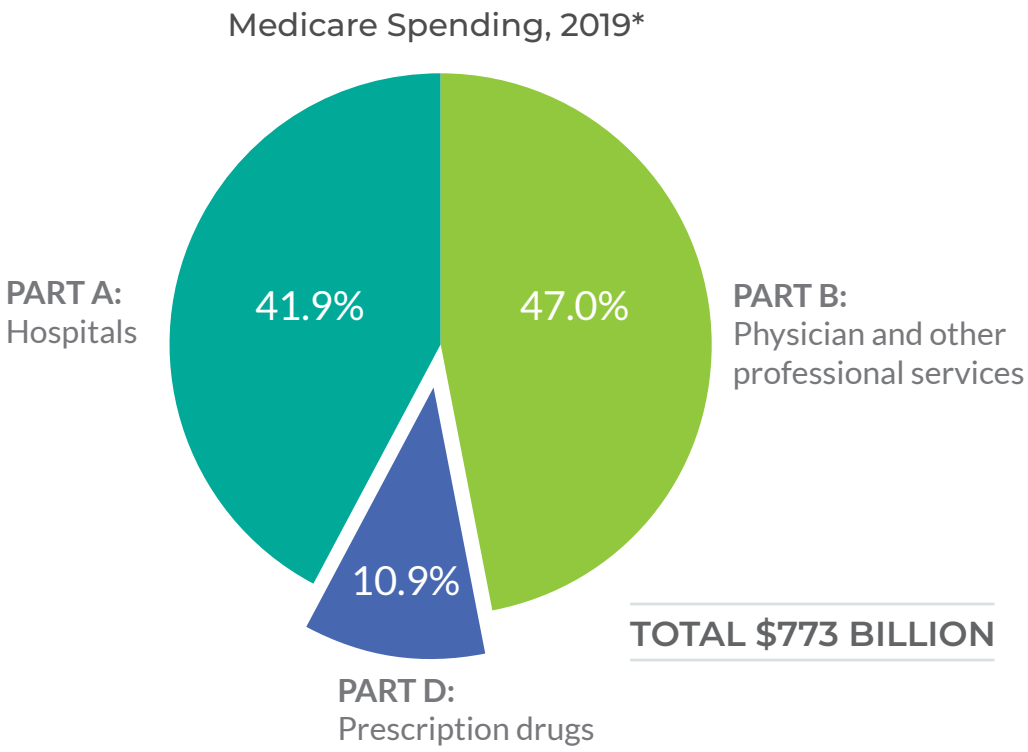
Manufacturers' brand discount increased to 70%, plans' liability decreased to 5%.

Beneficiaries pay 25% cost sharing in the coverage gap, similar to the pre-coverage gap cost sharing in a standard plan.

Sources: CMS[4]; KFF[5]

Part D Share of Medicare Expenditures

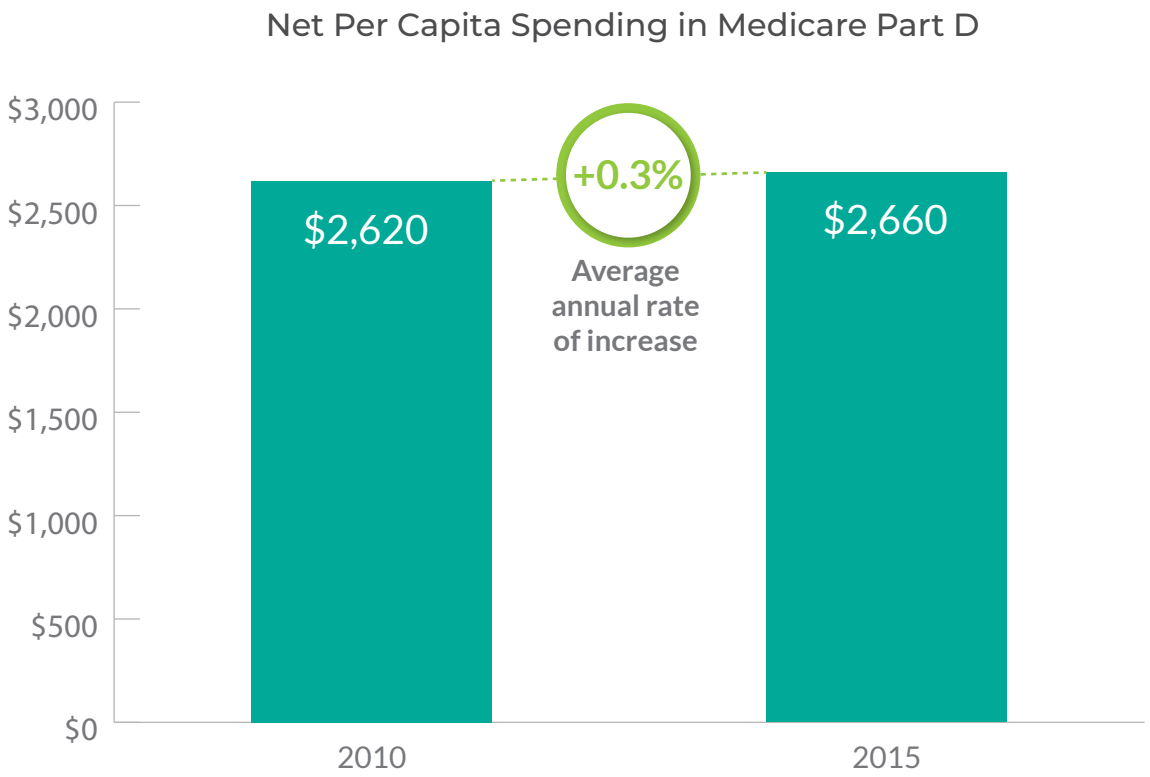
Medicare Part D drug spending, including brand and generic drugs, made up 11% of Medicare spending in 2019.



*Not including outlays for mandatory administration. Medicare Advantage (Part C) expenditures are apportioned among Parts A, B, and D according to type of service. Does not sum to 100% due to rounding.

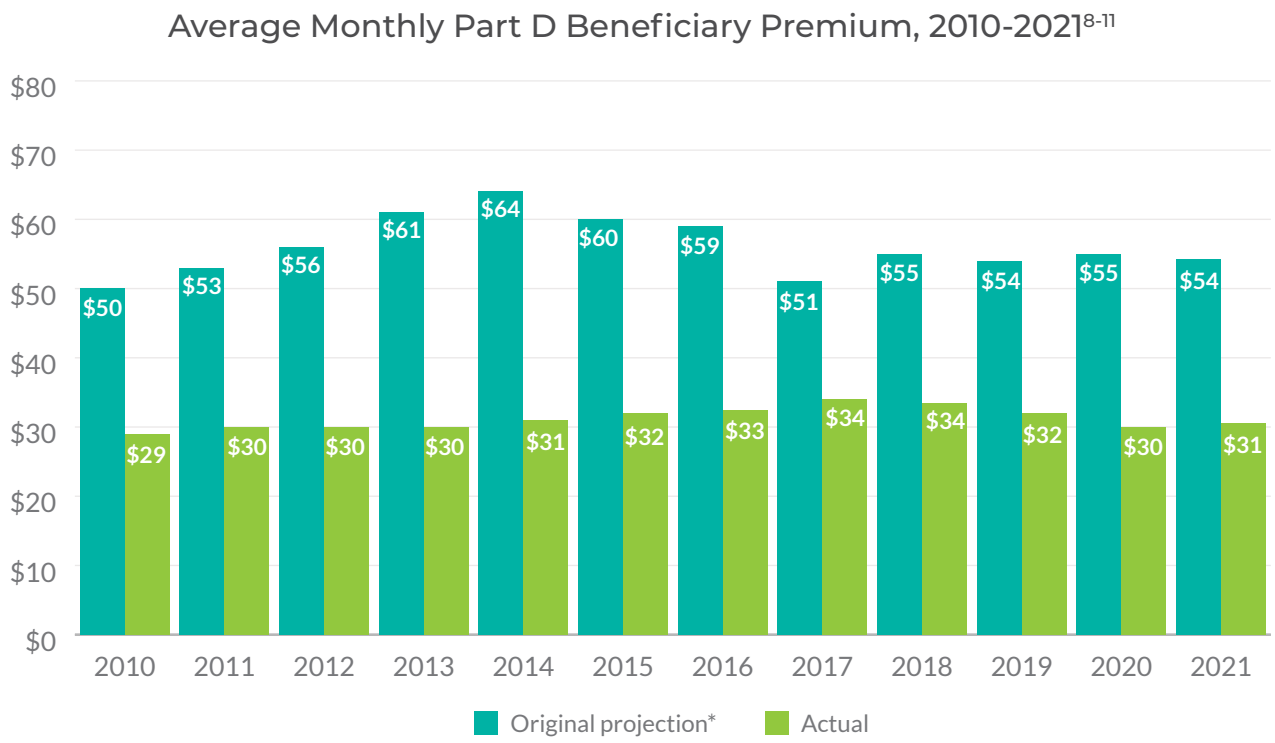
Source: PhRMA calculation of Congressional Budget Office (CBO) data[6]

Medicare Part D Spending Growth per Enrollee Has Been Stable Over Time



Source: CBO[7]

Average Beneficiary Premiums Are Far Below Government's Original Estimates

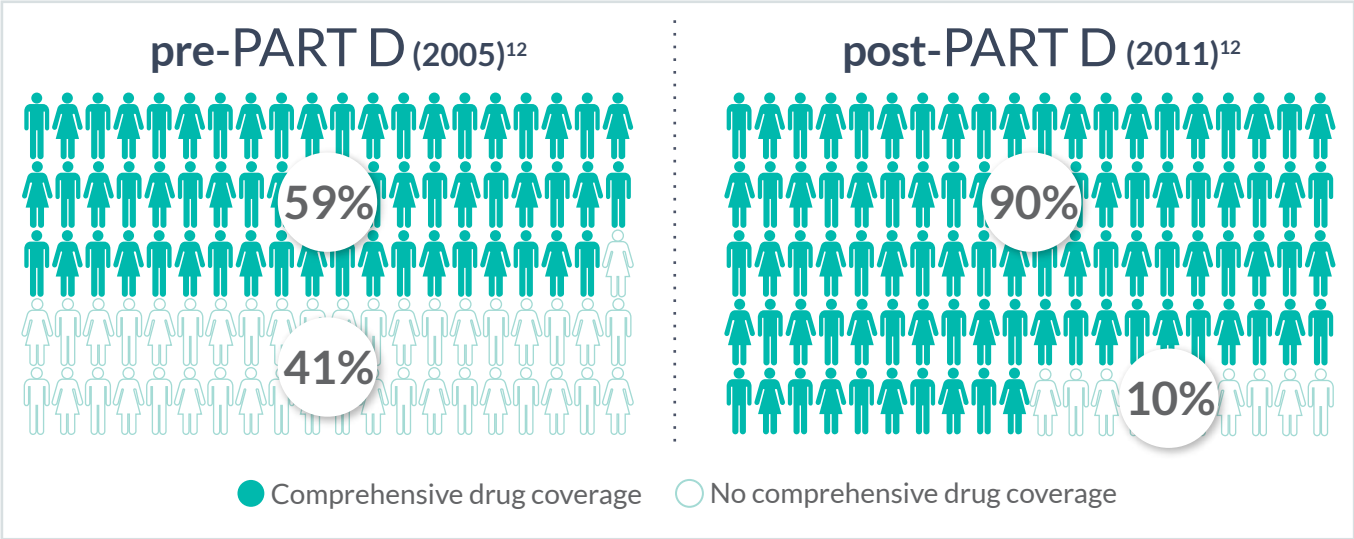


*All prior projection estimates are rounded to the nearest dollar.

Sources: CMS[8]; Medicare Trustees[9-11]

Part D Expanded Coverage, Improved Access to Medicines, and Reduced Out-of-Pocket Costs

As a result of Part D, nearly 90% of Medicare beneficiaries have comprehensive drug coverage. Peer-reviewed research confirms Medicare Part D substantially reduced out-of-pocket costs and increased access to medicines.



Across several studies[13-17]:

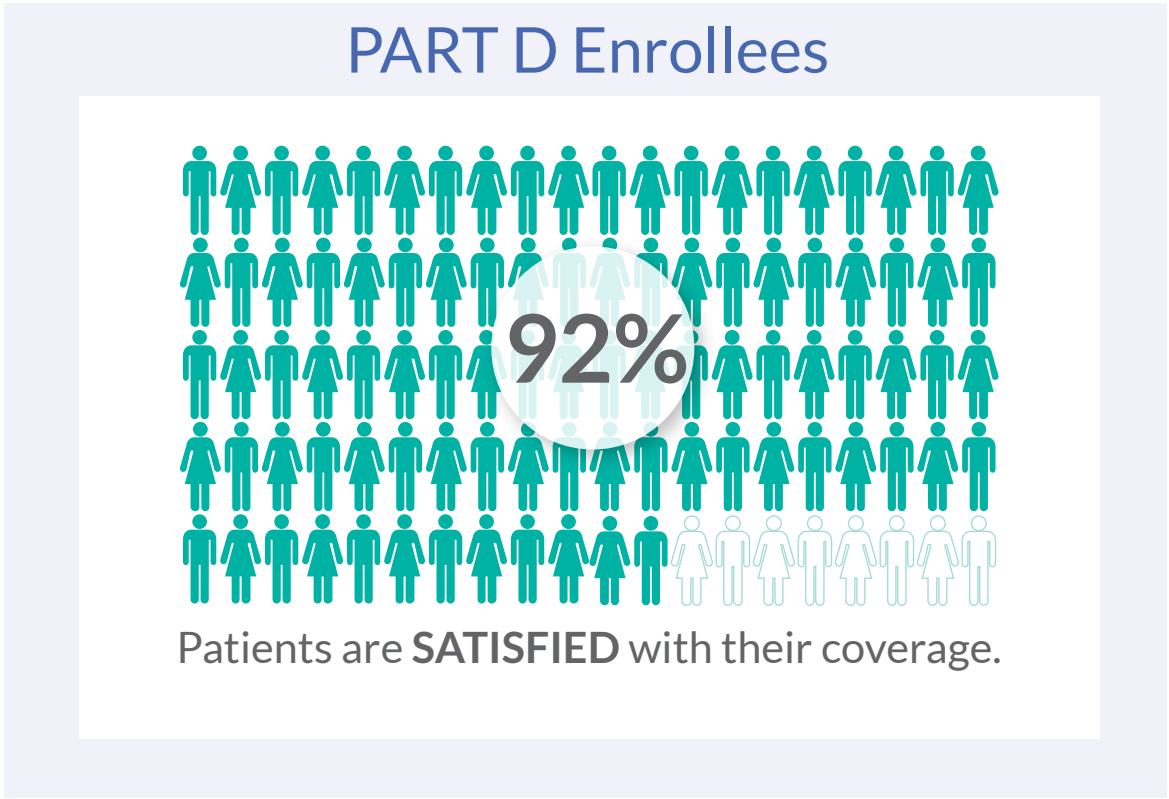
13.1%-24% decrease in out-of-pocket costs

4.7%-12.8% increase in use of prescription medicines

Sources: PhRMA analysis of data from The Lewin Group and CMS[12]; Joyce GF et al[13]; Duggan MG et al[14]; Lichtenberg F et al[15]; Yin W et al[16]; Ketcham JD et al[17]

Beneficiary Satisfaction With Part D

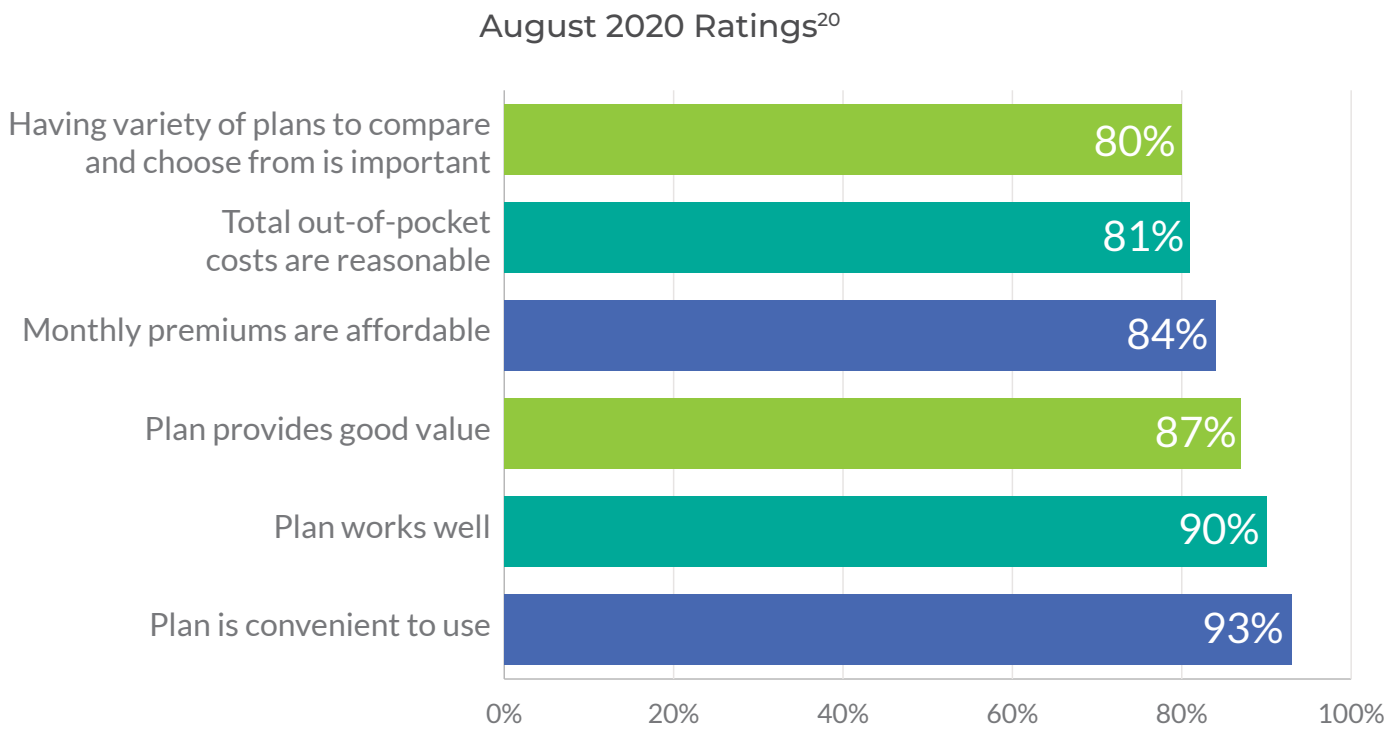
Several surveys show that more than 9 in 10 Part D enrollees are satisfied with their coverage and indicate that their coverage works well.[18,19]



Source: MedPAC[18,19]

Part D Enrollees' Satisfaction Is High Across Several Dimensions

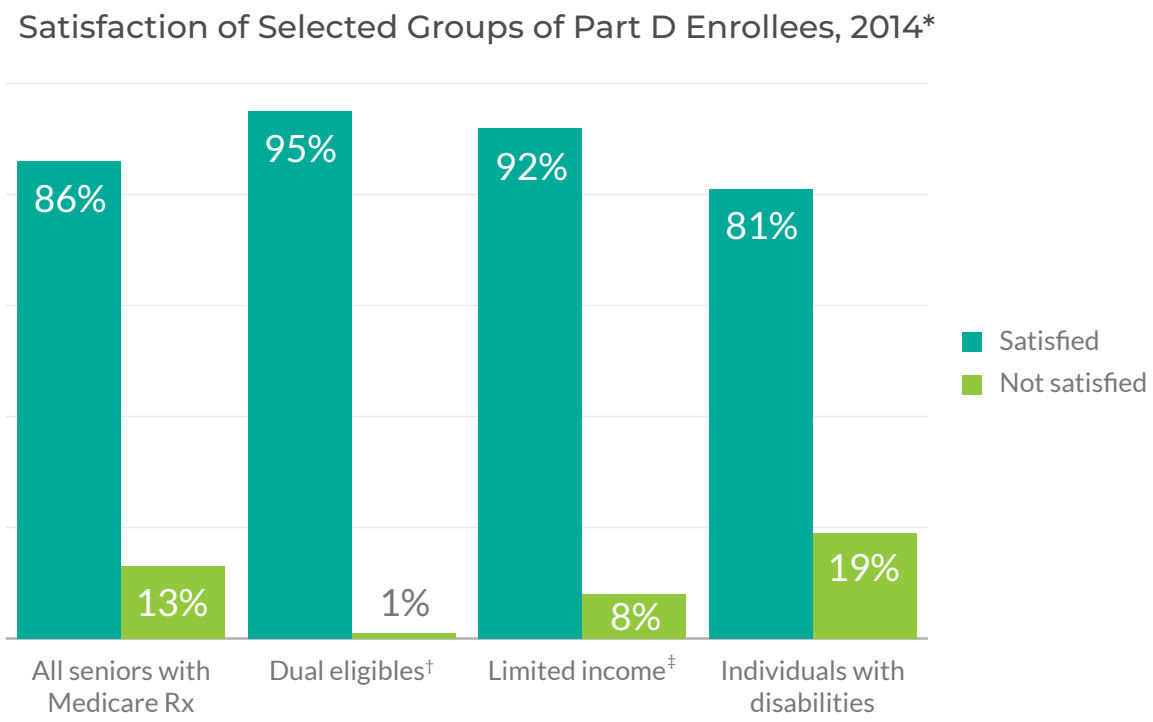
Beneficiaries report that their plans are affordable and work well.



Source: Medicare Today[20]

Satisfaction With Part D Is High Among the Most Vulnerable Beneficiaries

Dual eligibles and beneficiaries with limited incomes exhibit the highest satisfaction rate with their drug coverage.



*Excludes nonrespondents
†Dual eligibles are those enrolled in both Medicare and Medicaid. Dual eligibles not choosing a Part D plan are autoenrolled in a plan.
‡Limited income is defined as less than $15,000.

Source: KRC Research[21]

Competition in Part D Promotes Access and Helps Control Costs

Mechanisms to PROMOTE ACCESS

- Plans compete for enrollees based on benefits, quality, and price.
- Beneficiaries have a choice among plans to best meet their needs.
- Enrollees can switch plans each year during open enrollment.
- Premium and cost-sharing subsidies assist low-income beneficiaries.
- There are no limits on the number of prescriptions.
- Defined standard benefit and formulary rules set minimum plan requirements.

Mechanisms to CONTROL COSTS

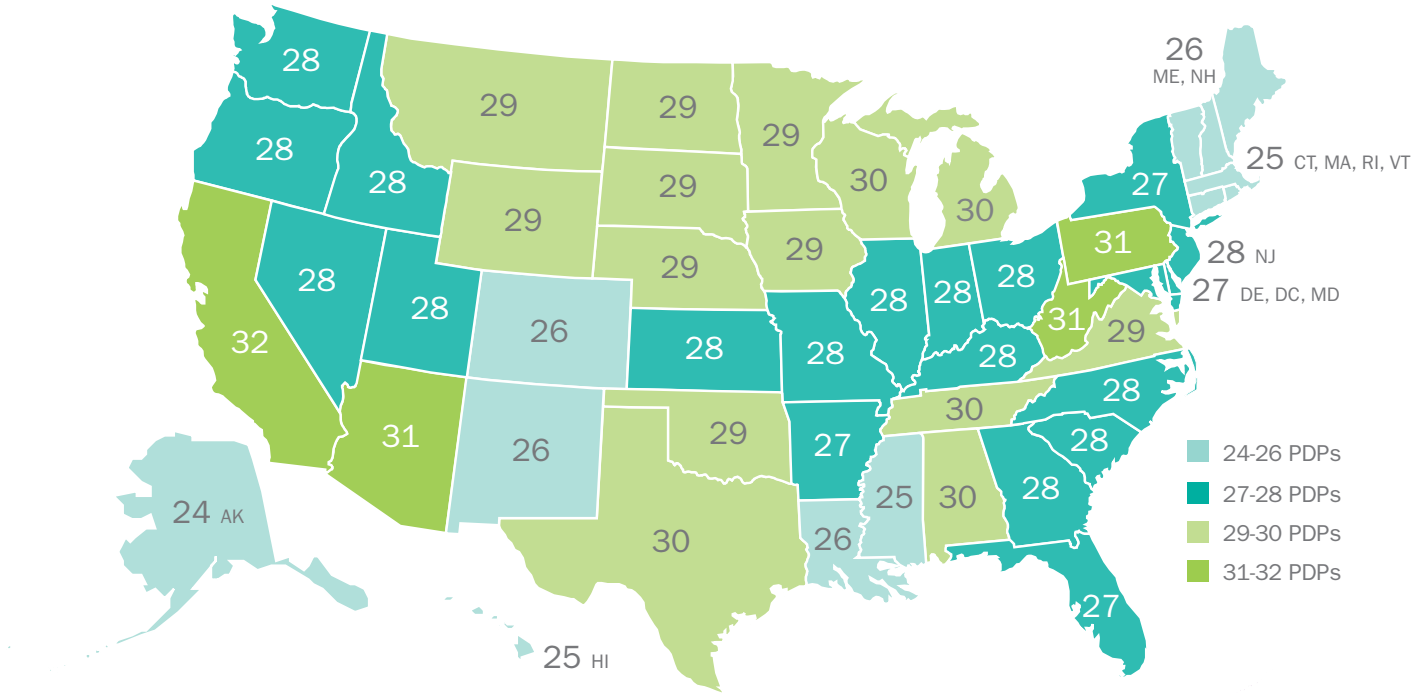
- Plans are paid based on competitive bids submitted each year.
- Plans and manufacturers negotiate discounts for covered medicines.
- Plans attract enrollment through lower premiums and quality of coverage.
- Plans use tiered formularies, tiered copays, and other utilization management tools.

Source: PhRMA analysis of data from MedPAC[22]

Beneficiaries Have Broad Choice of Plans

Part D beneficiaries have 24 to 32 stand-alone prescription drug plan options in each state. More than 80% of beneficiaries indicate that having a variety of plans to choose from is important to them.[23]

Number of Stand-Alone PDPs per State (2020)[24]



Sources: Medicare Today[23]; Avalere Health[24]

Six Protected Classes Policy Ensures Access to Appropriate Medicines for Vulnerable Enrollees

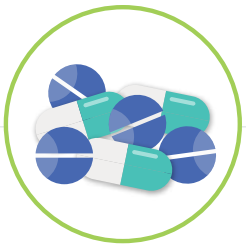
Part D plans are required to cover "all or substantially all" medications within 6 classes and categories: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.

THE SIX PROTECTED CLASSES POLICY PROTECTS PATIENTS

- Ensures enrollees with serious and debilitating conditions, including HIV, epilepsy, organ transplants, cancer, and mental health conditions, have access to appropriate treatments, as many medicines are not interchangeable[25]
- Ensures that Medicare enrollees reliant on these medicines would not be substantially discouraged from enrolling in Part D plans[26]

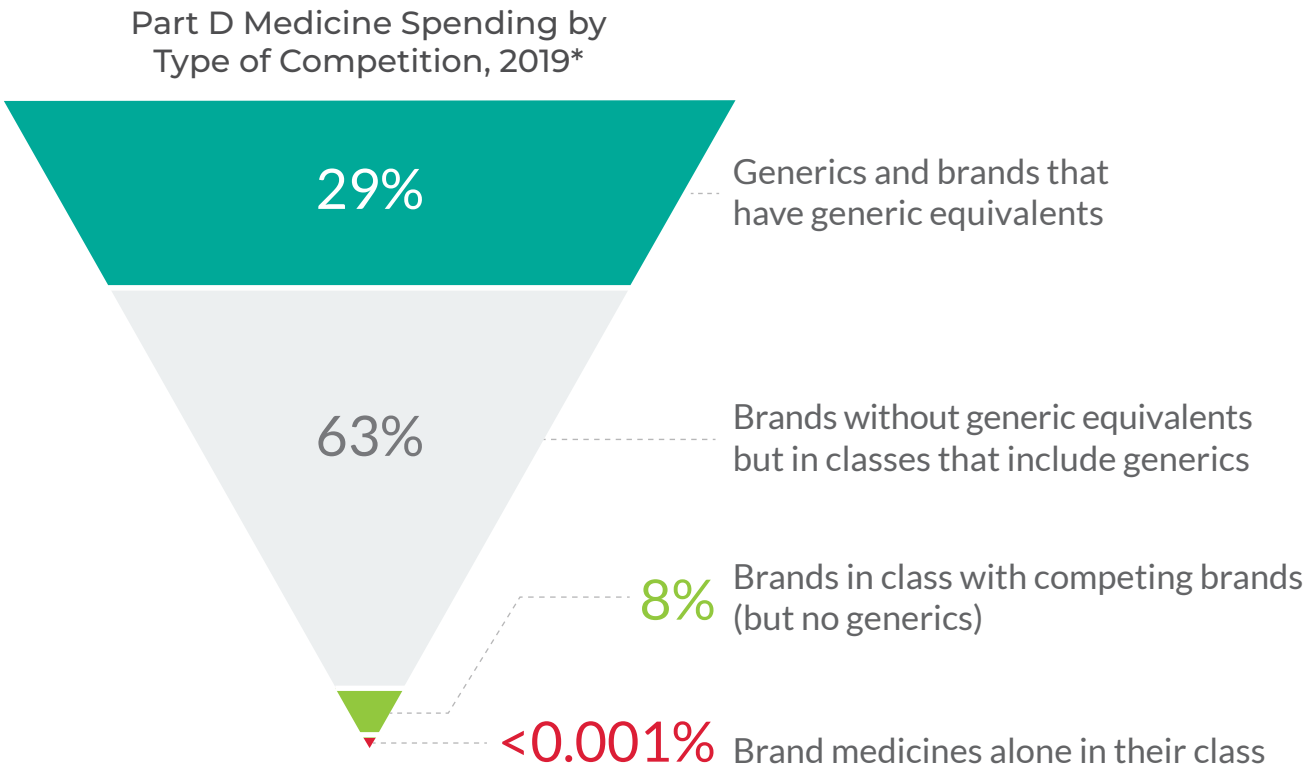
TOOLS ARE IN PLACE TO CONTROL UTILIZATION IN THE SIX PROTECTED CLASSES

- Plans use formulary tiers and cost sharing to spur competitive utilization of generics.
  > The generic utilization rate in the six protected classes is as high as **84%**.[27]
- There is widespread evidence that plans have ample flexibility to manage utilization among Part D beneficiaries.
  > Plans apply **prior authorization** or **step therapy policies** for a majority of branded drugs (54%) in the protected classes.[28]



Sources: CMS[25]; SSA[26]; The PEW Chartiable Trusts[27]; Partnership for Part D Access[28]

Virtually All Brand Medicines Covered in Part D Have at Least 1 Competitor



*Class analysis is based on United States Pharmacopeia (USP) classification system. Part D plans are generally required to cover 2 medicines per USP class, and Centers for Medicare & Medicaid Services (CMS) uses USP to review Part D plan formularies to ensure plans meet formulary standards.

Source: Avalere Health[29]

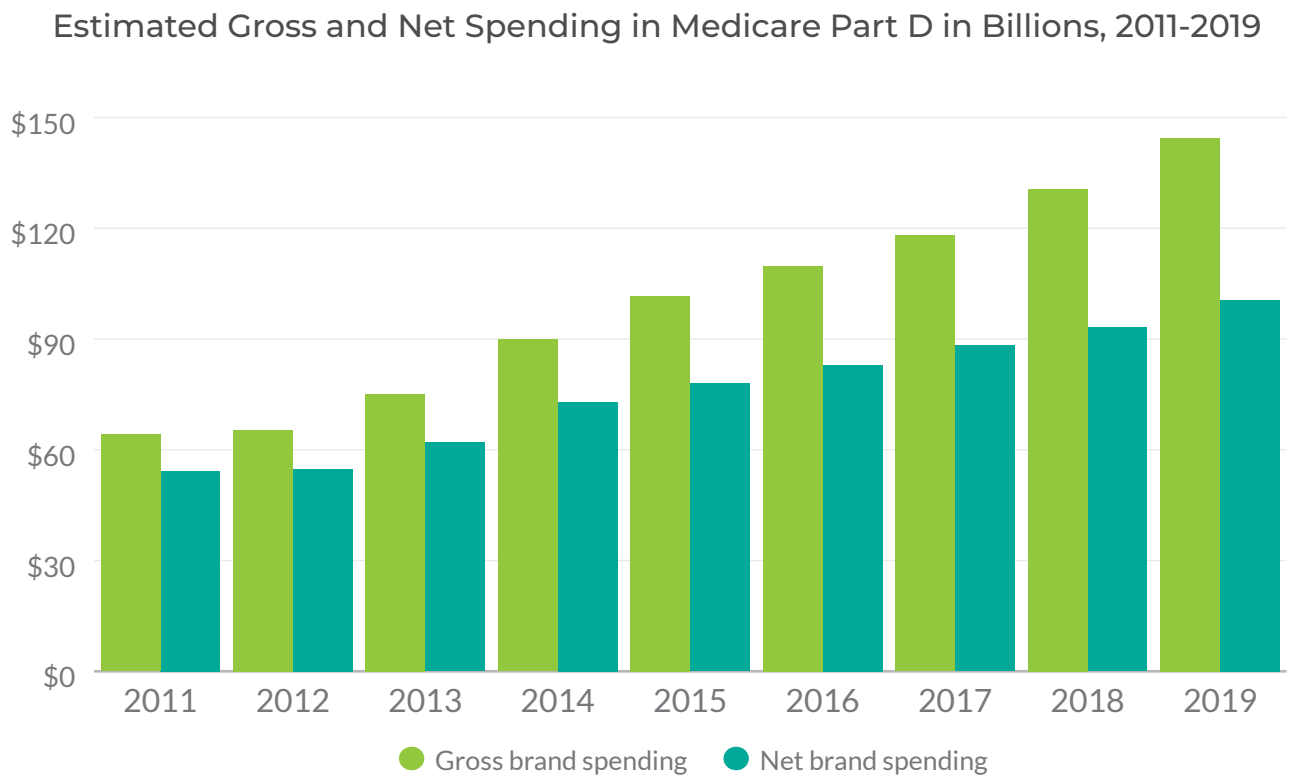
Enrollees Typically Do Not Benefit From Rebates and Discounts at the Pharmacy

Large, powerful Part D purchasers negotiate sizable discounts and rebates with drug manufacturers on behalf of Medicare beneficiaries. For the top-200 brand medicines ranked by total Part D spending, rebates and discounts nearly doubled from 2014 to 2016.[30] According to the Medicare Trustees, Part D rebates have increased each year of the program.[31]

These savings are often used to help reduce **premiums**, not enrollees' **cost sharing**.

Sources: GAO[30]; Medicare Trustees[31]

The Gap Between List and Net Price Growth for Medicines Is Driven by Rebates and Discounts



Source: Avalere Health[32]

Medicare Plan Finder Is a Tool for Beneficiaries to Help Make Part D Plan Selections Each Year

The Medicare Plan Finder, available on Medicare.gov, allows beneficiaries to enter their individual drug lists and find out which plans cover their medicines and their expected out-of-pocket costs for the year. Beneficiary choice of plans is a key feature of Part D's competitive structure.*

OPEN ENROLLMENT

The annual open enrollment period is from October 15 to December 7 each year.

STAR RATINGS

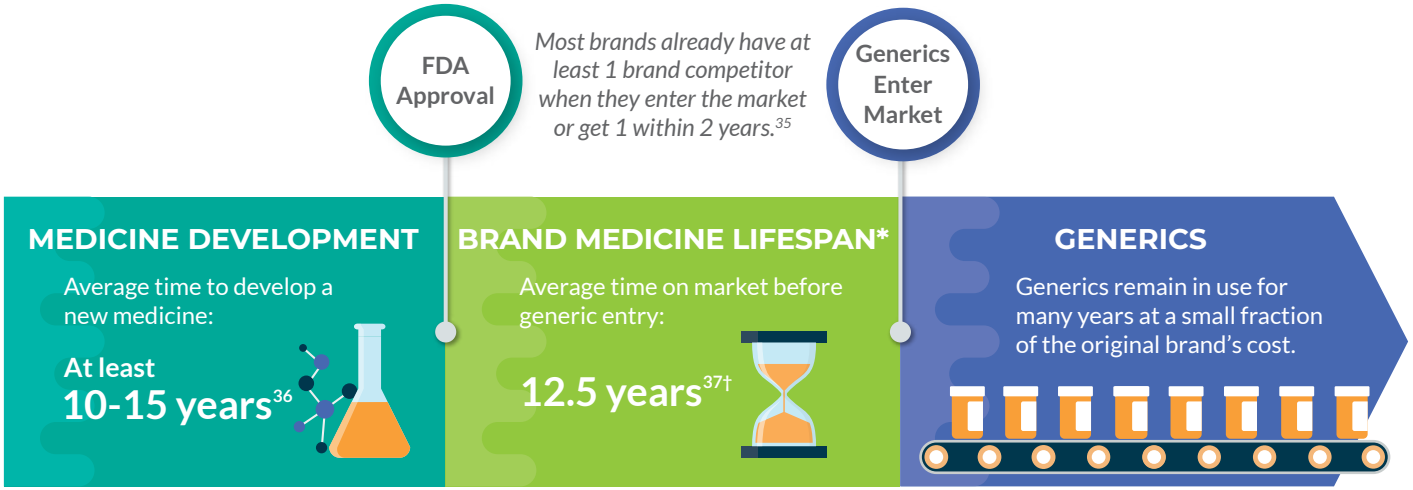
Plans are rated overall using a 5-star rating system, and Plan Finder provides information on how plans are performing on specific dimensions, such as customer service and patient safety.

*It is important to know what is and is not reflected in Plan Finder drug prices to ensure the information is not interpreted in a misleading way. For example, Plan Finder drug prices typically do not reflect the rebates and discounts negotiated between Part D plans and biopharmaceutical manufacturers.

Source: Medicare.gov[33]

Illustrative Pharmaceutical Lifecycle

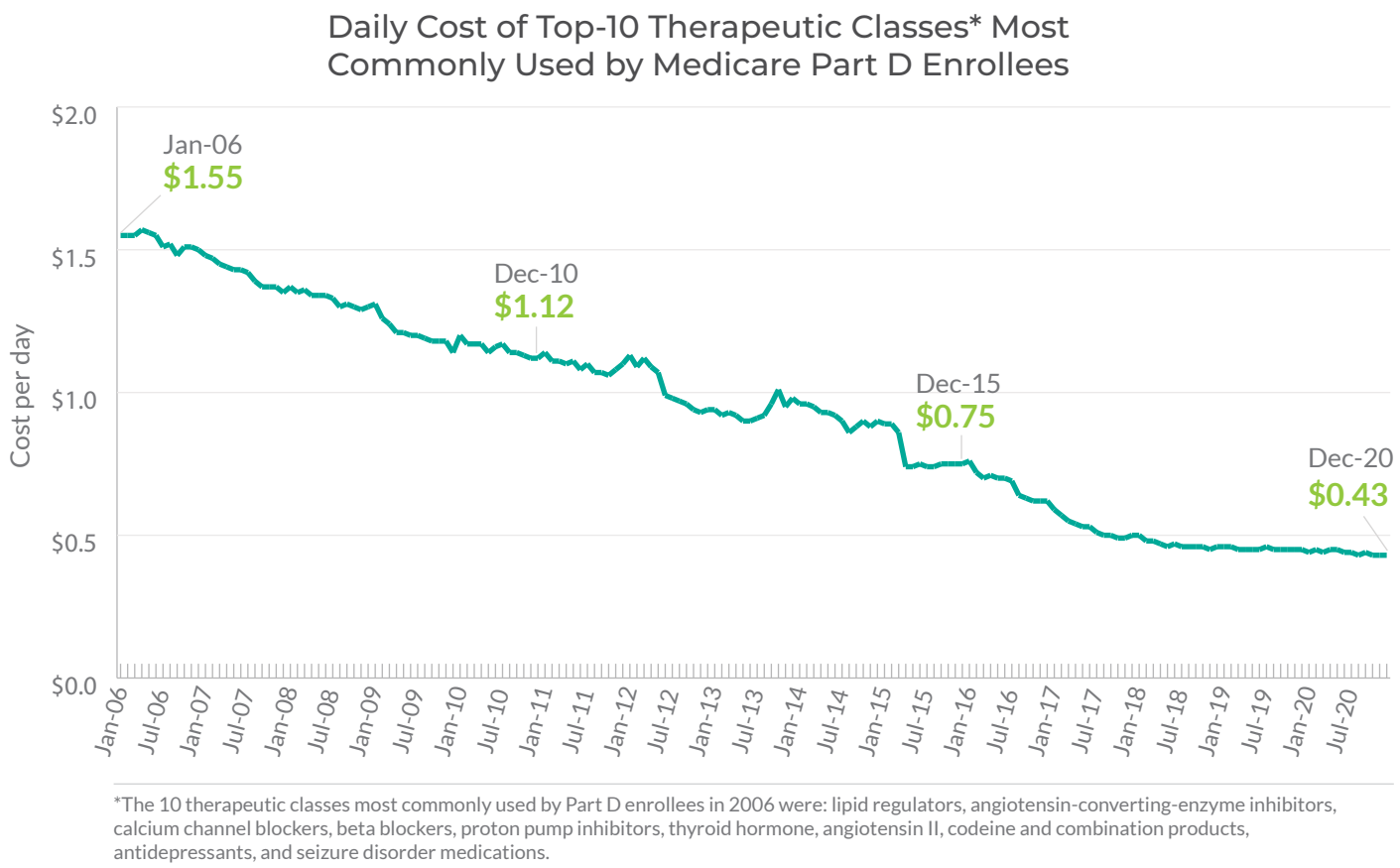
New prescription medicines typically face competition after a relatively short time on the market, first from brand competitors and eventually from generics.



*Brand medicines limited to small molecule drugs. Brand medicine market share typically declines rapidly after generic entry.
†For brand medicines with more than $250 million in annual sales in 2008 dollars, which account for 92% of sales of the brand medicines analyzed

Sources: PhRMA[34]; DiMasi JA et al[35,36]; Grabowski H et al[37]

The US Prescription Drug Lifecycle Promotes Innovation and Affordability



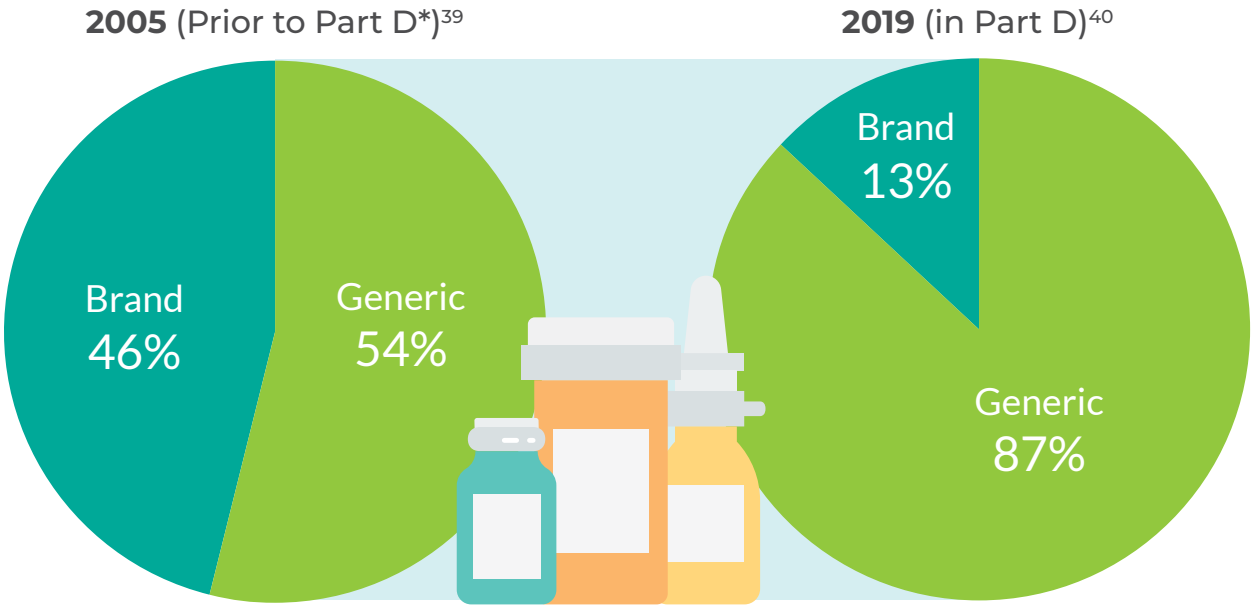
*The 10 therapeutic classes most commonly used by Part D enrollees in 2006 were: lipid regulators, angiotensin-converting-enzyme inhibitors, calcium channel blockers, beta blockers, proton pump inhibitors, thyroid hormone, angiotensin II, codeine and combination products, antidepressants, and seizure disorder medications.

Source: The IQVIA Institute[38]

Nearly Nine out of Ten Part D Prescriptions Are Generic

Before Part D, seniors used generic drugs at low rates, with about 54% generic utilization in 2005. Since Part D's inception, generic utilization has steadily increased to 88% in 2018.

Share of Brand and Generic Prescriptions



*Part D went into effect on January 1, 2006.

Sources: PhRMA analysis of data from IMS Health Vector One[39]; Medicare Trustees[40]

Better Use of Medicines Yields Significant Health Gains by Avoiding the Need for Other Medical Services

Due to a growing body of evidence, in 2012 the Congressional Budget Office (CBO) began recognizing reductions in other medical expenditures associated with an increased use of medicines in Medicare.

> Pharmaceuticals have the effect of improving or maintaining an individual's health . . . adhering to a drug regimen for a chronic condition such as diabetes or high blood pressure may prevent complications . . . taking the medication may also avert hospital admissions and thus **reduce the use of medical services** [emphasis added]."
>
> **CBO**[41]

Since the CBO announcement, the evidence has continued to develop, broadening the potential for cost offsets in the health care system.

CHRONIC DISEASES

Medicare savings due to better use of medicines may be **3 to 6 times greater** than estimated by the CBO for seniors with common chronic conditions, including heart failure, diabetes, and hypertension.[42]

MEDICAID

Increased use of medicines is associated with **reductions in Medicaid expenditures** from avoided use of inpatient and outpatient services.[43,44]

Sources: CBO[41]; Roebuck MC[42]; Roebuck MC et al[43,44]

Seniors Experienced Beneficial Health Outcomes Following Part D Implementation

RESULTS OF GAINING PART D PRESCRIPTION DRUG COVERAGE

8.0% decrease
in hospital admissions[45]

18.3% decrease
in non-emergency Emergency Department visits[47]

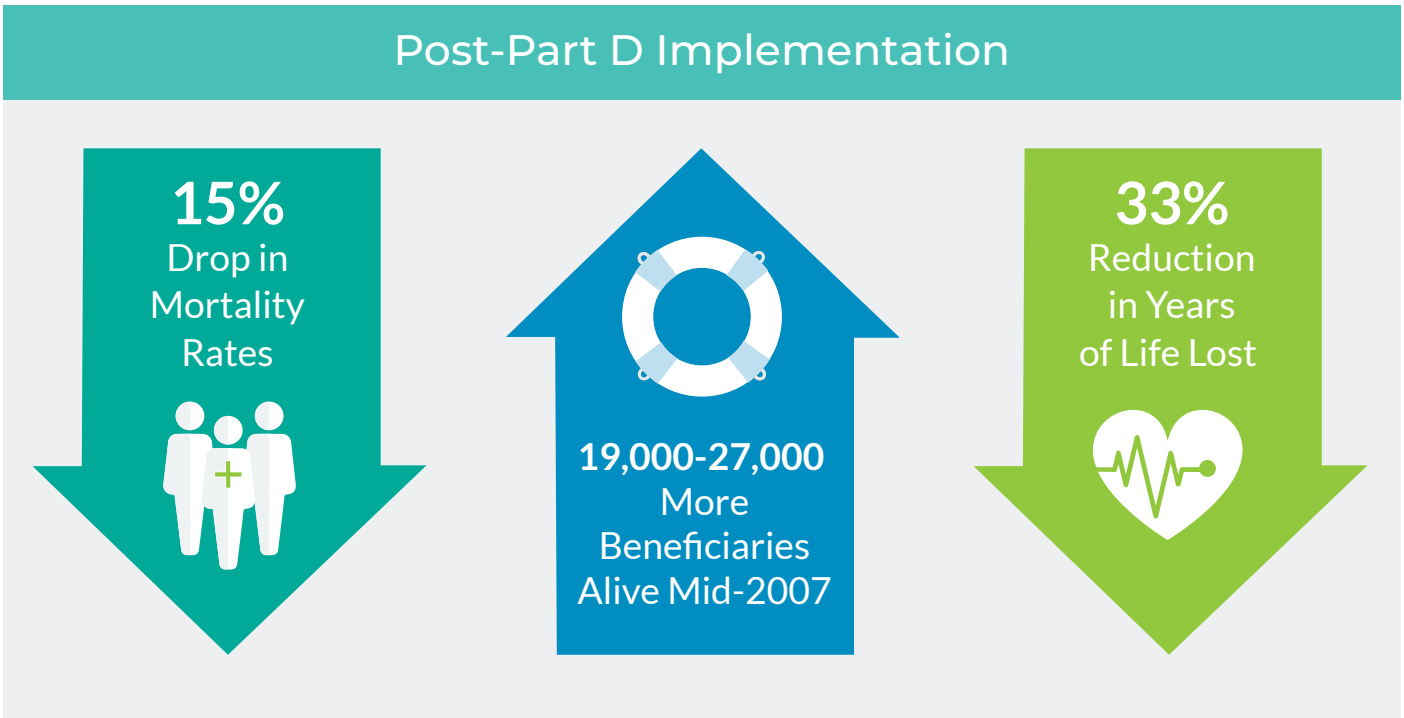
2.2% reduced
risk of mortality[46]

1.6% increase
in cognitive functioning, resulting in a 1.1-year delay in cognitive aging[48]

Sources: Kaestner R et al[45]; Huh J et al[46]; Ayyagari P et al[47]; Pak T et al[48]

Cardiovascular-Related Mortality Dropped Significantly Following Part D Implementation

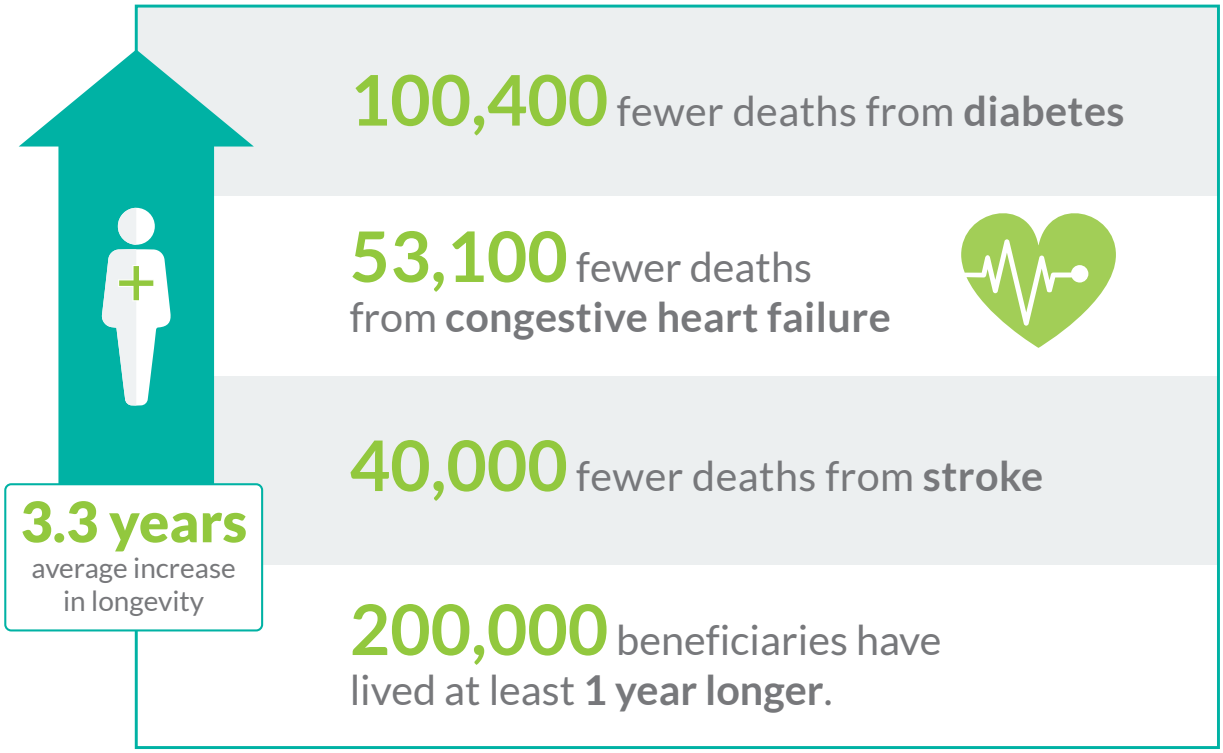
Mortality rates dropped, and years of life lost due to cardiovascular disease declined significantly following the implementation of Part D. The estimates suggest that as many as 27,000 more beneficiaries were alive mid-2007 as a result of Part D implementation.



Source: Dunn A et al[49]

Part D Implementation Increased Longevity and Reduced Mortality

FROM 2006 TO 2014, PART D IMPLEMENTATION RESULTED IN:



Source: Semilla AP et al[50]

Medicare Could Achieve Billions in Savings From Improved Use of Medicines

Between 20% and 40% of Medicare beneficiaries with common chronic diseases are not adherent to their medicines. Improved medication adherence can result in billions of dollars in cost savings from avoidable hospital stays.

Improved Outcomes With Better Adherence

	Cost Savings From Avoided Hospital Stays	Avoidable Hospital Inpatient Days	Annual Medicare Savings per Person
 DIABETES	$4.5B	2.9M	$5,170
 HYPERLIPIDEMIA	$5.1B	5.2M	$1,847
 HEART FAILURE	$5.6B	4.2M	$7,893
 HYPERTENSION	$13.7B	7.3M	$5,824

Source: Lloyd JT et al[51]

Medicare Part D Could Be Strengthened and Improved to Modernize the Benefit for Beneficiaries

Medicare Part D beneficiaries who are not eligible for Low-Income Subsidies (LIS) face multiple affordability challenges today due, in part, to the way the benefit is structured and how cost sharing is calculated.

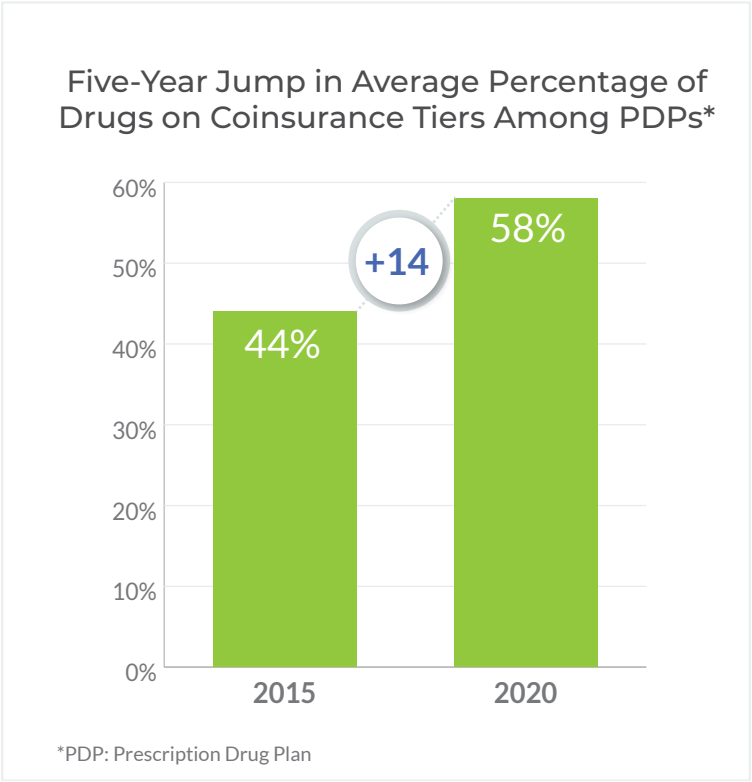
The Part D benefit can be strengthened and improved for patients if changes address these affordability challenges:

High coinsurance based on list prices

Lack of an **out-of-pocket cap**

Uneven distribution of out-of-pocket costs over the course of the year

Part D Plans Have Shifted Costs to Seniors Through Increased Use of Coinsurance



IN 2020:

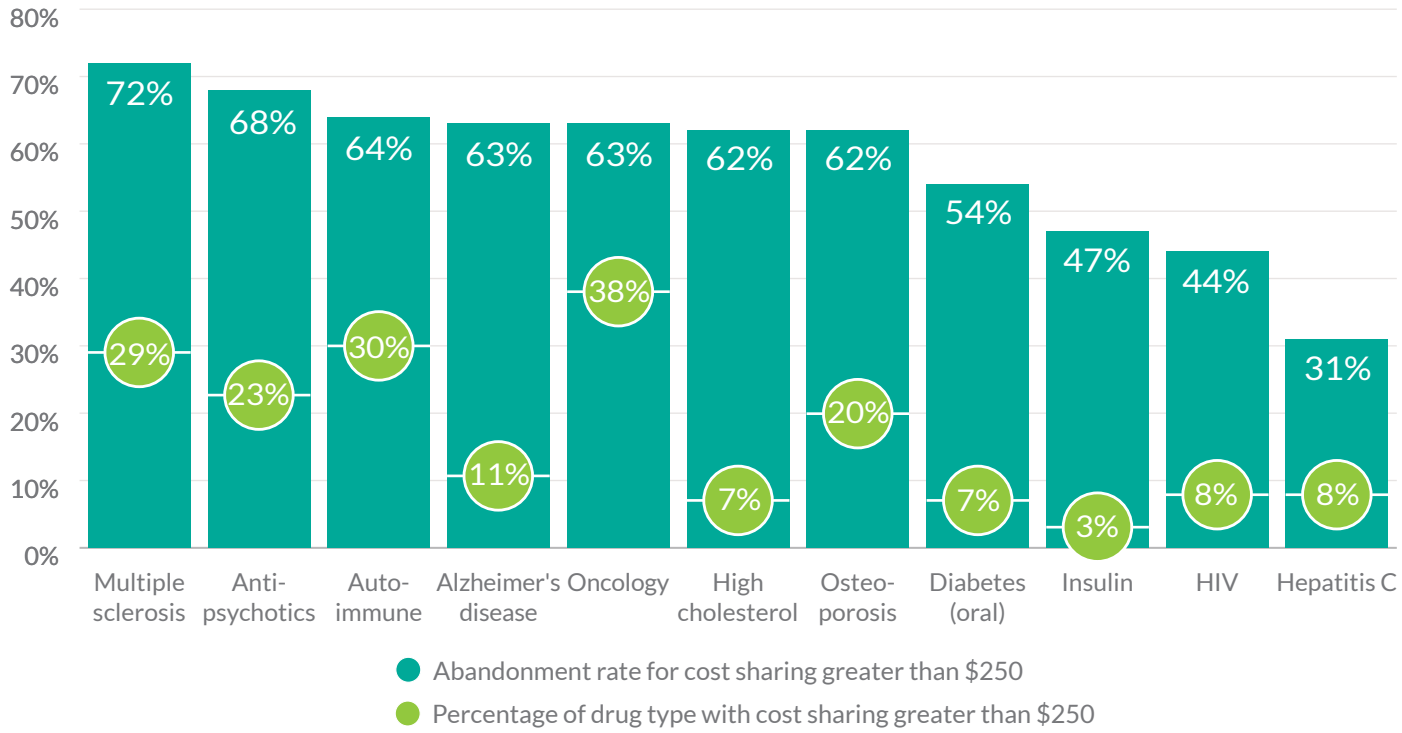
Coinsurance is replacing copays.
>99% of PDPs have either 2 or 3 coinsurance tiers.

Increased use of complex, multi-tiered formularies:
Most PDPs (93%) use 5-tier formularies.

Among PDPs with 5-tier formularies,
enrollment-weighted average coinsurance ranges from 23% on the preferred brand tier to 39% on the non-preferred brand tier.

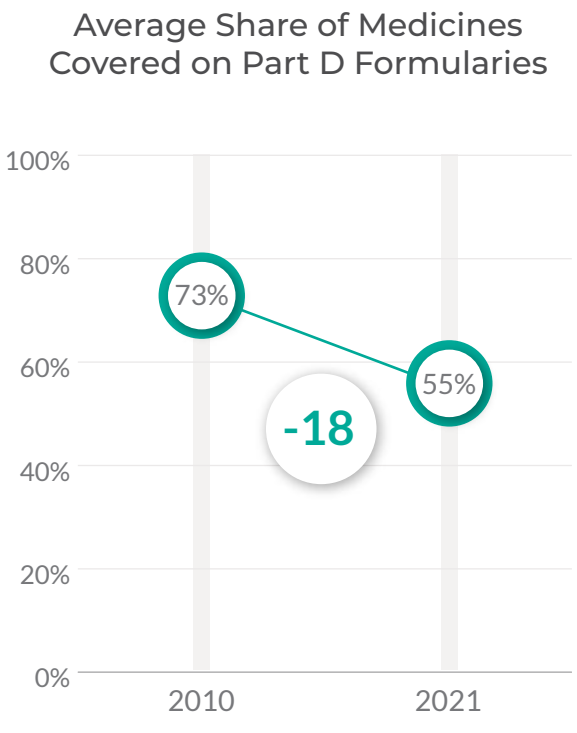
Source: Avalere Health[52]

Abandonment Is Very High for Prescriptions With Cost Sharing Greater Than $250 No Matter How Critical the Medicine



Source: Amundsen Consulting[53]

Part D Plans Are Covering Fewer Medicines and Increasingly Restricting Access

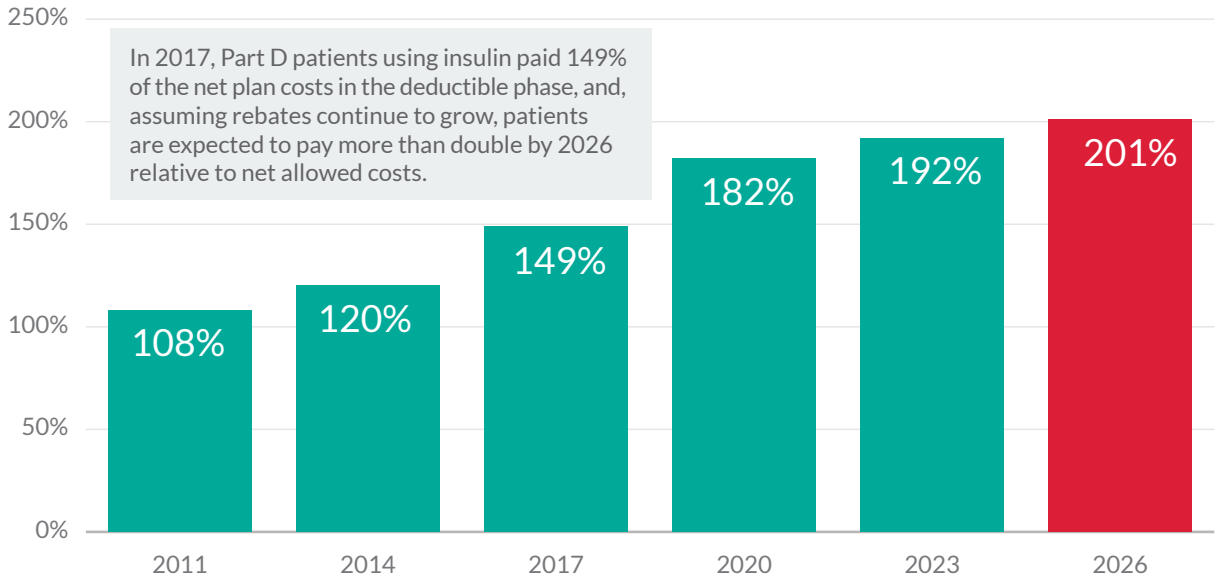


Source: Marsh T et al[54]

Beneficiaries Often Pay Cost Sharing Based on a Medicine's Full Price, Even When Their Part D Plan Receives a Discount

Most plan sponsors don't share rebates with patients at the pharmacy counter. Instead, patients pay cost sharing based on the medicine's full list price, sometimes exceeding the Part D plan net price.

Cost Sharing for Non-LIS Insulin Users Over Time in the Deductible Phase



Across all phases of the benefit, out-of-pocket costs for patients using insulin have been increasing as a share of net plan costs, despite the increased generosity of the Part D benefit through filling in the coverage gap.

Source: Milliman[55]

How Could Medicare Part D Work Better for Enrollees?

SHARE NEGOTIATED REBATES AT THE POINT OF SALE

- Share rebate savings directly with patients at the pharmacy counter

MODIFY THE BENEFIT DESIGN

- Reduce cost sharing and add an annual out-of-pocket limit

IMPROVE AFFORDABILITY

- Smoothing uneven distribution of out-of-pocket costs

Lowering Cost Sharing for Seniors at the Pharmacy Counter Can Generate Medicare Savings

Sharing a portion of negotiated manufacturer rebates directly with patients could improve medicine adherence and result in savings for seniors and Medicare Part D.

BENEFITS OF SHARING NEGOTIATED REBATES:

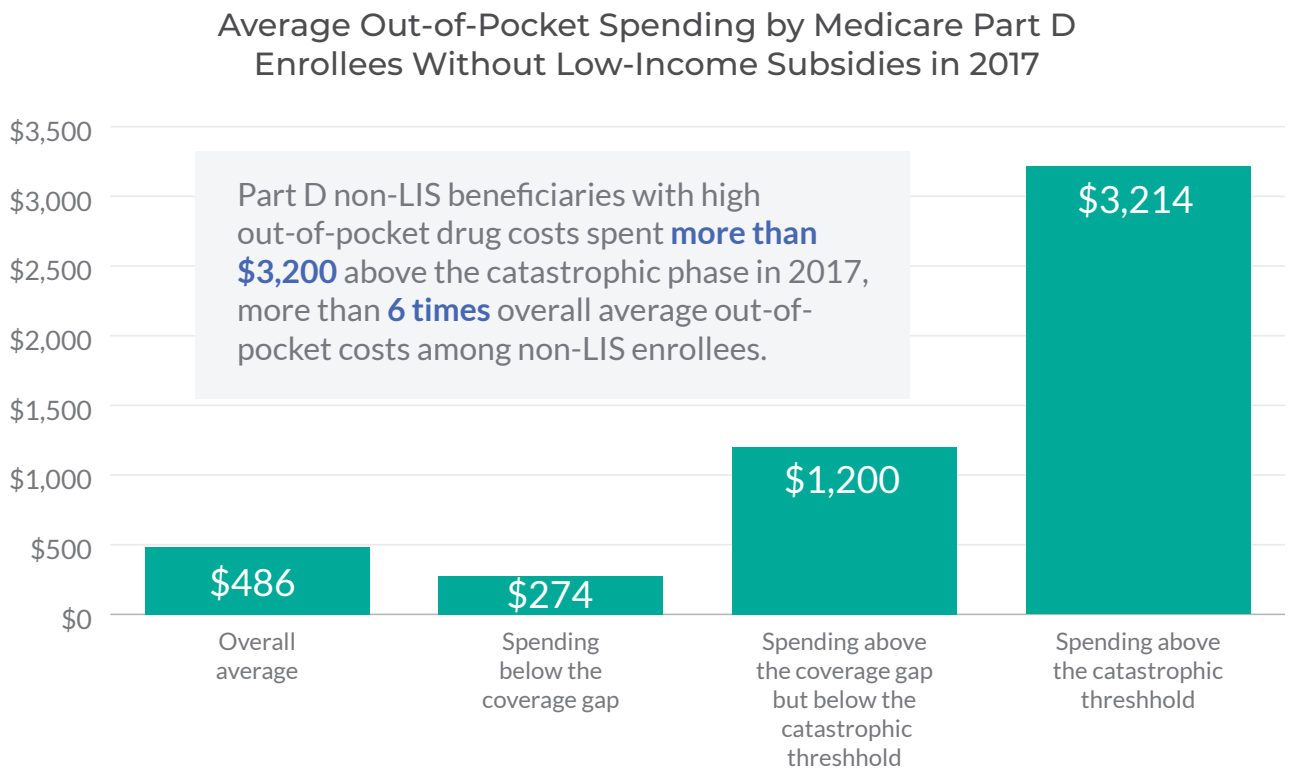
Lower beneficiary out-of-pocket spending by an average of **$350 per year**

Save Medicare nearly **$1,000 per year** for every senior taking diabetes medicine

Reduce total health care spending by approximately **$20B over 10 years**

Source: IHS Markit[56]

An Out-of-Pocket Limit Would Provide True Catastrophic Coverage for Enrollees With High Out-of-Pocket Spending and Align Medicare Part D With Other Markets



Source: KFF[57]

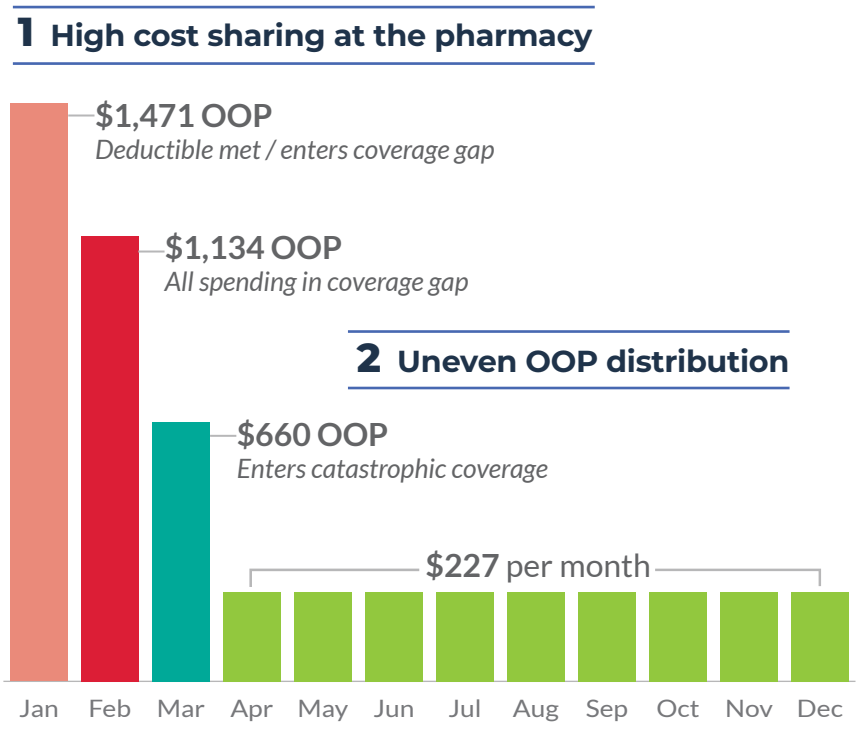
A Smoothing Policy Would Help Part D Beneficiaries Who Have High Out-of-Pocket Costs Early in the Year

A smoothing policy would allow beneficiaries to spread their out-of-pocket costs over a longer period (eg, over multiple months), rather than pay these costs up front.

Hypothetical Patient Facing High Out-of-Pocket (OOP) Costs at the Beginning of the Year

- 71 years old
- Lives in Memphis, TN
- Part D enrollee
- Takes 2 medicines:
  1. Brand TNF inhibitor for rheumatoid arthritis
  2. Generic beta blocker

Total annual OOP burden: $5,306

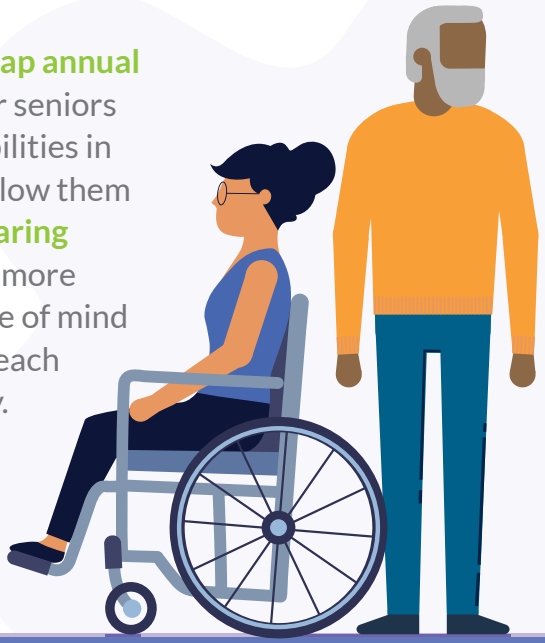


A smoothing policy would particularly benefit beneficiaries who incur high OOP in a short period.

Measured Improvements Could Strengthen the Medicare Part D Program for the Future

The Medicare Part D program works well for seniors and those with disabilities, but there are ways to make it work even better for those who are facing increasingly higher out-of-pocket costs at the pharmacy.

Policymakers need to **cap annual out-of-pocket costs** for seniors and patients with disabilities in Medicare Part D and allow them to **spread their cost sharing across the year** to give more predictability and peace of mind about what they'll pay each month at the pharmacy.



High and unpredictable cost sharing is a problem for seniors and patients with disabilities, who shoulder a much higher share of the cost burden and who need targeted reforms that will improve affordability.

Plans should also **share the savings from negotiated rebates** directly with Part D beneficiaries at the pharmacy counter.

These reforms could lower out-of-pocket costs for millions of people, generate savings for the federal government, and strengthen the successful Part D program.

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