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### The Medicare prescription drug program (Part D): Status report



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### **Chapter summary**

In 2022, Part D paid for outpatient prescription drug coverage on behalf of nearly 50 million Medicare beneficiaries. For Part D plan enrollees, Medicare subsidizes about three-quarters of the cost of basic benefits. Part D also includes a low-income subsidy (LIS) that provides assistance with premiums and cost sharing for more than 13 million individuals with low income and assets.

In 2021, Part D program expenditures totaled \$110.8 billion, accounting for about 13 percent of Medicare spending. Of that amount, enrollees paid \$14.9 billion in premiums for basic benefits. Medicare spending for the LIS totaled \$35.1 billion: \$31.3 billion for cost sharing and \$3.8 billion for premiums. Beyond program spending, Part D plan enrollees paid \$17.9 billion in cost sharing and \$7.5 billion in premiums for enhanced benefits.

Since its inception in 2006, Part D has changed in important ways. Part D enrollees have greatly expanded their use of generics, while a relatively small share of prescriptions for high-cost biological products (referred to as biologics hereafter) and specialty medications account for a mounting share of spending. A growing share of Medicare's payments has taken the form of cost-based reimbursements to plans through Medicare's reinsurance. As a result, the financial risk that plans bear, as well as their

### In this chapter

- Enrollment and plan choices have continued to grow
- Part D's market dynamics have evolved
- Although moderated by generic use, brand prices have continued to grow
- Reinsurance has accounted for a growing share of program costs
- While most Part D enrollees were satisfied, room for improvement remains

incentives to control costs, has declined markedly. In 2020, the Commission recommended major changes to the Part D benefit design and Medicare's subsidies in order to restore the role of risk-based, capitated payments that was present at the start of the program. In 2022, the Congress passed the Inflation Reduction Act (IRA), which included numerous policies related to prescription drugs; one such provision is a redesign of the Part D benefit with many similarities to the Commission's recommended changes. The changes adopted in the IRA will be implemented over the next several years and are likely to alter the drug-pricing landscape.

About 300 organizations operate Part D plans, but most beneficiaries are enrolled in plans sponsored by a handful of large health insurers. Most of the largest sponsors have their own pharmacy benefit managers (PBMs) that operate mail-order and specialty pharmacies. Formularies (a plan's list of covered drugs) remain plan sponsors' most important tool for managing drug benefits. In Part D, plans and their PBMs reduce benefit costs with postsale rebates and discounts. Generally, pharmaceutical manufacturers pay larger rebates when a sponsor positions a drug on its formulary in a way that increases the likelihood of winning market share over competing drugs. Plan sponsors also use provisions in network contracts with pharmacies that require postsale recoupments or payments for meeting performance metrics. These rebates and pharmacy fees have grown as a share of Part D spending. Going forward, changes in CMS's program rules and changes resulting from the IRA may affect the magnitude of rebates and pharmacy fees.

**Enrollment in 2022 and benefit offerings for 2023**—In 2022, 77 percent of Medicare beneficiaries were enrolled in Part D plans. An additional 2 percent obtained drug coverage through employer-sponsored plans that received Medicare's retiree drug subsidy. We estimate that among the remaining beneficiaries, just under 10 percent had comparable drug coverage from other sources and less than 12 percent had no coverage or coverage less generous than Part D.

Enrollment in stand-alone prescription drug plans (PDPs) peaked in 2019 at 25.5 million (56 percent of total plan enrollment) but fell to 23.3 million in 2022 (47 percent). Enrollment in Medicare Advantage–Prescription Drug plans (MA–PDs) surpassed enrollment in PDPs for the first time in 2021 and reached 26.5 million in 2022. Relative to the start of Part D, the number of enrollees who received the LIS has grown more slowly than the broader Part D population,

but their share has stabilized. In 2022, LIS enrollees made up 27 percent of total enrollment compared with 28 percent in 2018.

For 2023, beneficiaries continue to have a broad choice of plans. Plan sponsors offered 3,539 general MA–PDs and 1,254 MA–PDs tailored to specific populations (special needs plans)—5 percent and 11 percent more, respectively, than in 2022. That rapid growth is consistent with MA's expansion described in Chapter 11. In 2023, plan sponsors are offering 804 PDPs, nearly 5 percent more than the previous year.

For 2023, the base beneficiary premium declined by 2 percent from 2022 to \$32.74, reflecting a small decrease in the total average estimated cost for basic benefits after taking postsale rebates and discounts into account. However, individual plans' premiums vary substantially, with PDPs typically having higher premiums than MA–PDs. In 2023, 191 PDPs, roughly one-quarter of all PDPs, are available premium free to enrollees who receive the LIS, and all regions have at least three premium-free PDPs for LIS enrollees. Most Part D plans use a five-tier formulary with differential cost sharing between preferred and nonpreferred drugs, as well as a specialty tier for high-cost drugs. For 2023, nearly half of all plans had planned to participate in the Senior Savings Model that covers certain insulins at no more than \$35 for each prescription of a month's supply. Subsequently, the IRA–passed after plan bids for 2023 had already been submitted–required all Part D plans to provide such a benefit for covered insulin products in 2023.

**Part D program costs**—In 2021, Medicare program spending on Part D (excluding the \$14.9 billion in premiums paid by enrollees) totaled \$95.9 billion, up from \$93.0 billion in 2020 (an increase of 3 percent). Those enrollees whose spending reaches the benefit's catastrophic phase increasingly drive program spending. Medicare's reinsurance (which covers 80 percent of spending in the catastrophic phase of the benefit after rebates) continued to be the largest and fastest-growing component of program spending, totaling \$52.4 billion, or about 55 percent of the total. The value of the average basic benefit paid to plans through the capitated direct subsidy has plummeted in recent years. In 2023, direct subsidy payments average less than \$2 per member per month, compared with payments of nearly \$94 per member per month for reinsurance. In 2021, growth in drug prices accelerated, approaching rates observed before the pandemic. Prices of generic drugs declined, which helped moderate overall price growth. However, generics' share of prescriptions has plateaued at about

90 percent since 2017, and further opportunities for generic substitution may be limited, given the shift in the drug development pipeline toward biologics with longer periods of market exclusivity. Inflation in prices for brand-name drugs and biologics will likely continue to drive spending upward unless the program can achieve meaningful savings from the successful launch and adoption of biosimilars by prescribers and beneficiaries. In 2021, about 464,000 enrollees (11 percent of high-cost enrollees) filled a prescription that, by itself, was sufficiently expensive to meet the out-of-pocket threshold, up from just 33,000 enrollees in 2010.

**Beneficiary access and quality in Part D**–According to the 2020 Medicare Current Beneficiary Survey, which is the latest available, 79 percent of Part D enrollees reported overall satisfaction with the program. While satisfaction was quite high regarding the amount paid for drugs, coverage, and participating pharmacies, beneficiaries were less satisfied with the ability to understand the program and the information they received, and 27 percent were not confident their coverage met their needs. Overall, 25 percent of enrollees reported problems with affordability, including 14 percent who did not take their medicine as prescribed because of cost. Although it has long been believed that premiums are paramount among the factors beneficiaries consider when choosing their plan, in 2020 more beneficiaries (30 percent) reported considering their out-of-pocket costs than premiums (26 percent).

The quality of prescription drug care requires a balance between beneficiary access and medication management. For many conditions, effective treatment may hinge primarily on access and adherence to prescription drugs. For this reason, Medicare evaluates Part D plan formularies and network pharmacies. However, one concern is that among beneficiaries without the LIS, high cost sharing for expensive therapies can be a barrier to access. At the same time, Medicare beneficiaries take an average of nearly five prescription drugs and are at higher risk for adverse drug events associated with polypharmacy. Thus, it is also critically important that Part D plans help to manage medication therapies.

By law, Part D plans are required to carry out medication therapy management (MTM) programs and programs to manage opioid use. Between 2017 and 2021, CMS tested an Enhanced MTM model to see if new payment incentives and regulatory flexibilities would spur PDPs to improve their MTM interventions and reduce Medicare spending. Although an evaluation of the entire five-year demonstration is not yet complete, over the first four years, CMS found no

significant reductions in Medicare spending for Part A and Part B services, a net increase in Medicare spending after accounting for model payments, and mixed effects on quality measures.

### Background

In 2022, the Part D program paid for outpatient prescription drug coverage on behalf of nearly 50 million Medicare beneficiaries. Private Part D plans are available broadly: Dozens of standalone prescription drug plans (PDPs) and Medicare Advantage–Prescription Drug plans (MA–PDs) are offered in every region of the country.

For Part D plan enrollees, Medicare subsidizes about three-quarters of the cost of basic benefits, defined as Part D's standard benefit or benefits with the same average value. Separately, Part D includes a low-income subsidy (LIS) that pays for much of the cost sharing and premiums on behalf of 13.3 million individuals with low income and assets. In 2021, Part D expenditures totaled \$110.8 billion on an incurred basis, accounting for about 13 percent of Medicare spending (Boards of Trustees 2022). Of that amount, Part D enrollees paid \$14.9 billion in premiums for basic benefits. Medicare spending for the LIS totaled \$35.1 billion: \$31.3 billion for cost sharing and \$3.8 billion for premiums. Above and beyond program spending, enrollees paid \$17.9 billion in cost sharing and \$7.5 billion in premiums for enhanced benefits.

### Part D's approach

Medicare's payment system for Part D is different from payment systems under Part A and Part B. In Part D, Medicare pays competing private plans to deliver outpatient drug benefits to beneficiaries, whether they enroll in a PDP or MA-PD. Instead of setting prices administratively, Medicare bases payments on bids submitted by plan sponsors. Plan sponsors establish networks of pharmacies and apply formularies-lists of drugs the plan will cover that use differential costsharing tiers-to manage enrollees' use of and spending for prescription drugs. For drug classes that have competing therapies, plan sponsors negotiate with biopharmaceutical manufacturers to place brandname drugs on the plan's formulary, potentially on a preferred (lower) cost-sharing tier, in return for postsale rebates.

### Benefit design

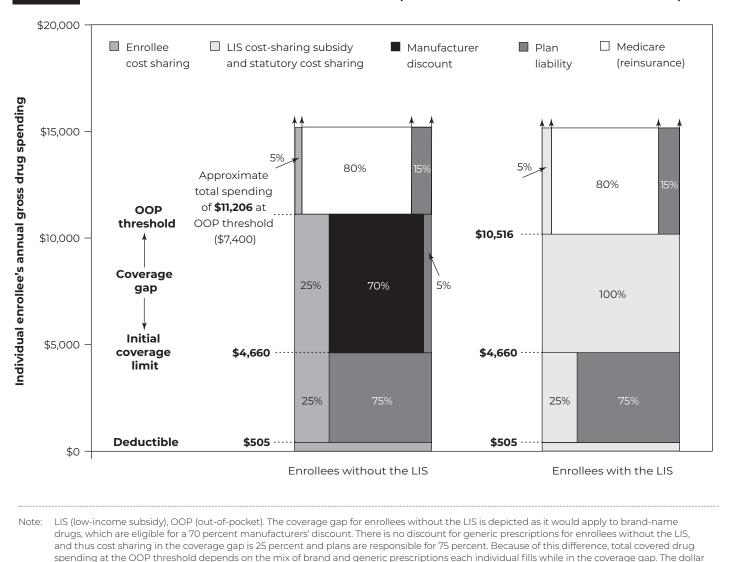
Medicare law defines a standard Part D basic benefit, but in practice, plan sponsors offer alternative benefit designs with equivalent or more generous coverage. Past changes in law have altered the design of the standard benefit for most Part D enrollees (those without the LIS), but those changes did not apply to those who receive the LIS. As a result, there are currently two distinct standard Part D benefit designs. Recent changes in law will again alter Part D's design (as described in a text box, pp. 392–393).

Part D's defined standard benefit For Part D enrollees without the LIS (73 percent in 2022), Part D's defined standard benefit covers 75 percent of drug spending above a deductible and all but 5 percent coinsurance once an enrollee reaches an out-of-pocket (OOP) threshold (Figure 12-1, p. 390). Each year, the standard benefit's parameters change at the same rate as the annual change in beneficiaries' average drug expenses. For 2023, the deductible in Part D's standard benefit is \$505, and enrollees pay 25 percent coinsurance until reaching an OOP threshold of \$7,400 (Centers for Medicare & Medicaid Services 2022b). That threshold is based on "true OOP" costs. This amount excludes beneficiary cost sharing paid by most sources of supplemental coverage, such as employer-sponsored policies and more generous (enhanced) benefits from the beneficiary's Part D plan, but it includes the discount that manufacturers of brand-name drugs must pay in the phase of the benefit called the coverage gap, described in Figure 12-1.

In the past, enrollees without the LIS whose spending exceeded an initial coverage limit were responsible for paying each subsequent prescription's full price at the pharmacy (i.e., 100 percent cost sharing) until they reached an OOP threshold. This range of spending is known as the coverage gap or donut hole.<sup>1</sup> Due to subsequent changes in law, enrollees no longer face higher cost sharing in the coverage gap; however, plans continue to identify whether a prescription is filled in that benefit phase because enrollees without the LIS are eligible for a 70 percent discount from manufacturers on brand-name prescriptions in the coverage gap. No discount is applied to prescriptions for generic drugs or for brand-name prescriptions filled by LIS enrollees. In 2023, brand discounts begin when an enrollee without the LIS has reached \$4,660 in cumulative drug spending, and the discounts continue until the individual reaches \$7,400 in combined OOP spending plus brand discounts. Above this OOP

FIGURE 12-1

Part D has two distinct benefit structures, for enrollees with and without the LIS, 2023



amount shown (\$11,206) was estimated by CMS for an individual with an average mix of drugs who does not receive Part D's LIS and has no other

supplemental coverage. The bar depicting LIS enrollees reflects full rather than partial LIS coverage.

Source: MedPAC depiction of Part D benefit structure for 2023.

threshold, enrollees pay the greater of 5 percent coinsurance or \$4.15 to \$10.35 per prescription.

**Benefit for LIS enrollees** For low-income beneficiaries, Medicare's LIS pays for the difference between cost-sharing amounts set by each plan and nominal copayments set by law (Figure 12-1). In 2023, most individuals receiving the full LIS pay between \$0 and \$4.15 per prescription for generics and between \$0 and \$10.35 per prescription for brand-name drugs. A small share of LIS enrollees (less than 2 percent) with slightly higher levels of income or assets receives a partial subsidy.<sup>2</sup> If, for example, a plan normally charges a \$40 copayment to fill a brand prescription, a full LIS enrollee would pay up to \$10.35 and Medicare's LIS would pay \$29.65; after meeting a \$104 deductible, enrollees receiving the partial LIS would pay 15 percent, or \$6, and Medicare's LIS would pay \$34. Because 100 percent of the costs in the coverage gap count toward the OOP threshold, LIS beneficiaries reach the catastrophic phase at a lower level of spending than other enrollees do. Above the OOP threshold, full LIS enrollees pay no cost sharing, and partial LIS enrollees pay \$4.15 for generics and \$10.35 for brand-name drugs. Medicare's LIS pays 5 percent coinsurance minus the LIS enrollee's copayment (if any).

#### Plan sponsors typically use alternative benefit designs

In practice, the defined standard benefit is used primarily to set the average value of basic benefits that plan sponsors must offer under alternative benefit designs. Most sponsors structure basic benefits in ways that differ from the defined standard benefit, such as setting the deductible lower than \$505 or using tiered copayments rather than coinsurance. Some plans encourage use of lower-cost medicines by not applying a deductible when a prescription is filled with certain preferred generics. However, alternative designs must demonstrate that they have the same average value as the defined standard benefit for an enrollee of average health. CMS also sets maximum cost-sharing amounts for drug tiers to ensure that a sponsor's plan design is not discriminatory (Centers for Medicare & Medicaid Services 2022d).<sup>3</sup> Once a sponsor offers a PDP with basic benefits in a region, it can also offer up to two "enhanced" PDPs that combine basic with supplemental coverage.

### Concerns about Part D and recommended changes

Over time, changes to Part D's benefit design combined with trends in prescription drug pricing and spending led to concerns about whether plan sponsors have incentives for cost control that are as strong as they were at the start of the program (Medicare Payment Advisory Commission 2022c).

Policymakers sought to eliminate the coverage-gap phase of Part D's benefit and financed much of that expansion of benefits by requiring manufacturers of brand-name drugs and biologics to discount prices in the coverage gap. Those discounts made brandname drugs appear less expensive relative to generics and encouraged their use. In addition, because the discounts were counted as the enrollee's own OOP spending, beneficiaries using brand-name drugs reached Part D's catastrophic phase—where Medicare pays most of the costs—more quickly. Those weaker incentives for cost control, as well as the introduction and greater use of higher-priced products, expanded catastrophic spending in Part D and Medicare's spending for cost-based reinsurance subsidies. As a result, between 2007 and 2021, plan sponsors' financial risk for the basic benefit spending of their enrollees has declined markedly, from 75 percent to 34 percent.

Other concerns about Part D relate to enrollee cost sharing. Because beneficiaries pay an unlimited amount of cost sharing in the catastrophic phase, a small but significant share of enrollees have high OOP spending that can pose a financial burden and hinder adherence to treatment. In contrast, limits on cost sharing for LIS enrollees blunt their incentives to use lower-cost drugs and make it more difficult for plan sponsors to manage program spending.

### Changes in law may alter incentives for Part D stakeholders

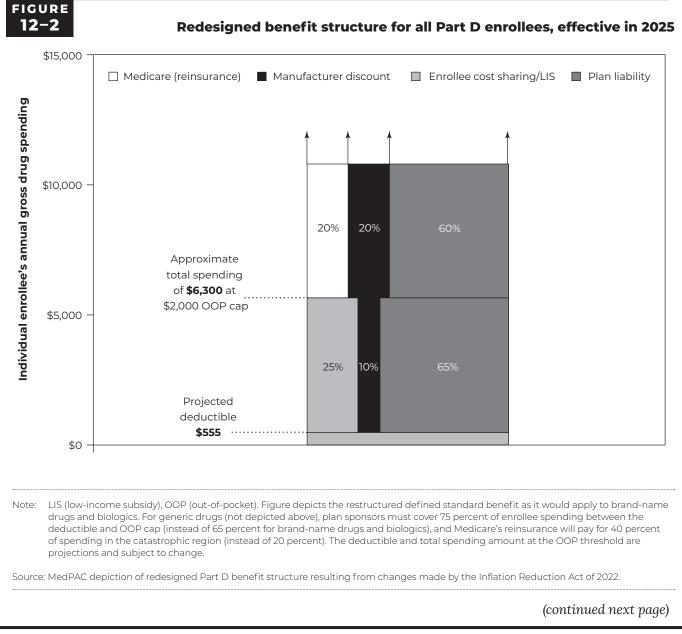
In 2020, the Commission recommended major changes to the Part D program that would restructure its defined standard benefit and restore stronger incentives (Medicare Payment Advisory Commission 2020a). Last year, the Congress passed the Inflation Reduction Act of 2022 (IRA), which included numerous policies related to prescription drugs; one such provision is a redesign of the Part D benefit that reflects many of the Commission's recommendations (see text box on upcoming changes, pp. 392-393). The IRA also imposes financial penalties on manufacturers of drugs sold to Medicare beneficiaries if the price of their drug rises faster than inflation. Penalties for this inflation rebate provision have been applicable for price increases since October 2022. Part D plans are now required to cover all Part D-covered vaccines that are recommended for adults at no cost and insulin at no more than \$35 for each prescription of a month's supply. In 2024, eligibility for the LIS will expand such that those with income between 135 percent and 150 percent of the federal poverty level will be eligible for full subsidies rather than a partial subsidy. Finally, the IRA will require the Secretary of Health and Human Services to negotiate prices for a select number of drugs with the highest total Medicare spending each year; the first 10 drugs subject to negotiation in Part D

### Upcoming changes to Part D's benefit design

he Inflation Reduction Act of 2022 (IRA) restructured Part D's benefit design in significant ways, some of which are consistent with the Commission's 2020 recommendations for the program (Medicare Payment Advisory Commission 2020a).

Instead of the two benefit designs now in use, beginning in 2025, a single benefit design will

apply to all enrollees, whether or not they receive the low-income subsidy (LIS).<sup>4</sup> In that year, enrollees will pay a projected deductible of about \$555 followed by a benefit phase with 25 percent coinsurance until reaching \$2,000 in out-ofpocket (OOP) spending (Figure 12-2).<sup>5</sup> Notably, the redesigned benefit caps enrollee OOP spending thereafter, eliminating what is now open-ended cost sharing, and plan sponsors will be required



### Upcoming changes to Part D's benefit design (cont.)

to offer their enrollees the option to smooth cost-sharing payments over the benefit year. Plan sponsors will continue to be able to offer alternatives to this redesigned standard benefit so long as they demonstrate that the alternative plan has the same average benefit value.

In 2025, the current coverage-gap discount will be eliminated and replaced with a new program under which manufacturers of brand-name drugs and biologics must discount their prices by 10 percent below the OOP cap and by 20 percent above it.<sup>6</sup>

Under the redesigned benefit structure, Medicare's reinsurance will cover 20 percent of prescription spending for brand-name drugs above the OOP cap-a substantial decrease from the current 80 percent. At the same time, Medicare's overall 74.5 percent subsidy of basic benefits will remain unchanged, with much more of it taking the form of capitated rather than cost-based payments. Over time, a larger share of Part D spending has come from drugs on specialty tiers, which typically have very high prices. As a result of Medicare's generous reinsurance subsidies, plan sponsors have been responsible for a declining share of financial risk for their enrollees' prescription spending. The upcoming Part D changes should create incentives for plan sponsors to manage prescription benefits in ways that are more consistent with the incentives that were present at the start of the program. However, many specialtytier drugs are in Part D's protected classes (e.g., antipsychotics and antineoplastics), in which sponsors' inability to exclude products from a plan's formulary keeps them from harnessing competition among alternative therapies to negotiate manufacturer rebates.

The Commission has consistently held that when plan sponsors must bear more insurance risk, they should also be given tools to manage enrollee spending. For example, we recommended that plan sponsors be provided with greater formulary flexibility for drugs in the protected classes (Medicare Payment Advisory Commission 2020a, Medicare Payment Advisory Commission 2019a, Medicare Payment Advisory Commission 2016).<sup>7</sup> The Commission recommended that the Congress establish a higher copayment under the LIS for nonpreferred and nonformulary drugs. Current LIS copayments provide much weaker financial incentives to choose lower-cost medications than incentives faced by other enrollees (Medicare Payment Advisory Commission 2020a). Such tools will be even more important given the increase in their liability that will result from the IRA's restructuring of the benefit.

Carrying out Part D's benefit redesign and other changes mandated by the IRA will involve complex decisions that will affect plan formularies, payments, incentives regarding drug development, and beneficiary access and costs. For example, plan sponsors may modify their formularies (within the constraints of CMS's guidance and formulary review) in response to bearing more risk for enrollee drug spending. The reforms to restructure the benefit design will result in higher capitated payments from Medicare to plans, with a larger impact, in dollar terms, for LIS beneficiaries. CMS will need to recalibrate the Part D risk-adjustment model to ensure that, on average, capitation rates are adequate for both LIS enrollees and other Part D beneficiaries. Setting the OOP cap at \$2,000 will increase the generosity of the Part D benefit and may affect the types of drugs manufacturers choose to develop. Changes to enrollees' access to drugs may differ depending on how CMS carries out the policy of notifying enrollees that they have the option to smooth their cost sharing over the year. The Commission will monitor the many changes to the Part D program that will take place over the next several years, keeping in mind both the need for beneficiary access to drug treatments and for program efficiency.

#### The share of beneficiaries with Part D coverage has grown slowly in recent years while enrollment has shifted rapidly to MA–PDs from PDPs

	2018	2019	2020	2021	2022	Average annual growth rate 2018–2022
Total Medicare enrollment (in millions)	60.0	61.5	62.9	63.8	65.0	2%
Total enrollment in Part D plans (in millions)	43.9	45.4	47.0	48.3	49.8	3
As a share of total Medicare enrollment	73%	74%	75%	76%	77%	N/A
Part D plan enrollment by plan type (in millions)						
PDP	25.4	25.5	25.1	24.0	23.3	-2
MA-PD	18.5	20.0	21.9	24.3	26.5	9
Full LIS enrollment (in millions)						
PDP	7.6	7.3	6.7	6.0	5.5	-8
MA-PD	4.9	5.4	6.1	6.8	7.7	12

Note: MA-PD (Medicare Advantage-Prescription Drug [plan]), PDP (prescription drug plan) LIS (low-income subsidy), N/A (not applicable). Part D enrollment figures do not include beneficiaries in employer-sponsored plans that receive the retiree drug subsidy or in employer group waiver plans. In addition to beneficiaries who receive full LIS assistance, a small number receive partial assistance (0.3 million in 2022). Totals may not sum due to rounding.

Source: MedPAC analysis based on the 2022 Medicare Trustees' report and CMS Part D enrollment data as of April 1, 2022.

will be selected in 2023, and negotiated prices will be effective in 2026.

The changes adopted in the IRA are likely to alter the drug-pricing landscape. While the reforms to the benefit structure should address many of the concerns highlighted above, it will be difficult to assess those effects separately from those of the IRA's numerous other drug-pricing provisions.

## Enrollment and plan choices have continued to grow

A growing proportion of Medicare beneficiaries have enrolled in MA–PDs while the number and share in stand–alone PDPs has declined. Over the program's first decade, a portion of enrollment shifted from retiree drug plans outside of Medicare to Part D plans set up for employer groups, but growth in those plans has slowed.

#### In 2022, over three-quarters of Medicare beneficiaries were in Part D plans or employer plans that received the retiree drug subsidy

In 2022, 49.8 million individuals—about 77 percent of Medicare's total enrollment—were enrolled in Part D plans (Table 12-1). Another 2 percent of beneficiaries obtained drug coverage through non-Medicare employer-sponsored plans that received Medicare's retiree drug subsidy (RDS) for serving as the primary provider (data not shown). (The RDS is paid from the Part D program.) We estimate that among the remaining beneficiaries, just under 10 percent had creditable drug coverage from other sources and under 12 percent had no coverage or coverage less generous than Part D (data not shown).

The distribution of Part D enrollment has moved gradually toward MA–PDs open to all enrollees and MA–PD special needs plans (SNPs), which are limited to enrollees who have a chronic condition, are dually eligible for Medicare and Medicaid, or are living in an institution. The number of enrollees in PDPs began to decline in 2020, and by 2021, Part D enrollees were split evenly between PDPs and MA–PDs. This move toward MA–PDs is consistent generally with more rapid growth in MA enrollment compared with traditional fee-for-service (FFS) Medicare. Between 2018 and 2022, enrollment in MA–PDs grew an average of 9 percent annually compared with a 2 percent decline in PDPs.

Membership in employer group waiver plans (EGWPs)– Part D plans established for Medicare-eligible retirees of certain employers—totaled 7.4 million in 2022.<sup>8</sup> EGWPs can take the form of PDPs or MA–PDs. Enrollment in EGWPs grew quickly over the Part D program's first decade but slowed subsequently. Similar to overall program trends, enrollment in MA–PD EGWPs has been growing, reaching 3.1 million in 2022, while enrollment in PDP EGWPs has declined modestly over the past two years. Still, at 4.4 million, enrollment in PDP EGWPs was higher than that of MA–PDs in 2022.

In 2022, 13.3 million beneficiaries (27 percent of Part D enrollees) received the full LIS. Of these individuals, 8.7 million were eligible for both Medicare and full Medicaid benefits (Boards of Trustees 2022). The remainder qualified either because they received benefits through the Medicare Savings Programs or Supplemental Security Income program or because they were eligible after they applied directly to the Social Security Administration. Compared with other enrollees, LIS enrollees are more likely to be female; more than twice as likely to be African American, Hispanic, or Asian or Pacific Islander; and over seven times more likely to be under age 65 (Medicare Payment Advisory Commission 2022a).

Between 2018 and 2022, LIS enrollment grew at a comparatively slow average of 2 percent per year, and the share of Part D enrollees who received the LIS fell slightly to 27 percent. In 2022, 58 percent of LIS enrollees were in MA–PDs; the rest were in PDPs. In past years, most individuals receiving the LIS were enrolled in traditional FFS Medicare rather than MA. However, LIS enrollment in MA–PDs has grown rapidly—especially LIS enrollment in SNPs—while LIS enrollment in PDPs has declined.

### Beneficiaries' enrollment decisions in 2022

Most enrollees are in plans that are actuarially equivalent to Part D's defined standard benefit or are

enhanced in some way rather than in plans that follow the defined standard benefit.

### MA-PD enrollees were more likely to be in enhanced plans than PDP enrollees in 2022

Enrollees in MA–PDs tend to have more generous benefits than enrollees in PDPs. The key reason is that MA–PD plan sponsors are permitted to use a portion of their MA payments to supplement their Part D benefits (e.g., by lowering deductibles) or to lower Part D premiums.<sup>9</sup>

In 2022, just under half of PDP enrollees had basic coverage, most with tiered copayments, while a slight majority had enhanced coverage (Table 12-2, p. 396). Enrollees in MA–PDs, excluding SNPs, were overwhelmingly in enhanced plans. Typically, enhanced plans reduce or eliminate the deductible used in the defined standard benefit. Among general MA–PDs, 64 percent of enrollees had no deductible in their plan's benefit design. By comparison, only 14 percent of PDP enrollees and 5 percent of SNP enrollees were in plans with no deductible. However, more than half of PDPs do not apply their deductible to some drugs (usually certain generics), and most SNP enrollees are dualeligible beneficiaries who automatically receive the LIS, which covers the deductible.

### Stable average enrollee premiums in 2022

Average premiums for Part D benefits peaked in 2017 at \$32 per month and declined slightly since then. Many factors explain this trend, including growth in manufacturer rebates and postsale pharmacy fees, a higher coverage-gap discount for brand-name drugs, and the entry into Part D of relatively large cohorts of younger enrollees who typically have lower prescription drug costs. Additionally, growth in enrollment in MA-PDs has contributed to the downward trend in premiums. MA-PD plan sponsors have used larger dollar amounts of Part C payments to offset Part D premiums and supplemental drug benefits that enrollees would otherwise pay themselves through premiums. Finally, in most years, actual reinsurance costs have exceeded the amount plan sponsors estimated in their bids. Because enrollee premiums are based on plans' expected amounts, that discrepancy lowers enrollee premiums. As a result, the growth in Medicare's reinsurance subsidy has also contributed to the slower growth in enrollee premiums.

### Regular MA–PDs were much more likely than PDPs and SNPs to offer enhanced coverage and eliminate or reduce the Part D deductible, 2022

	PDF		General MA-PD		SNP		
	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent	
Total	19.0	100%	18.1	100%	4.3	100%	
Type of benefit							
Basic	8.7	46	0.2	1	2.5	57	
Enhanced	10.3	54	17.9	99	1.8	43	
Type of deductible							
Zero	2.7	14	11.3	64	0.2	5	
Reduced	1.2	6	6.2	34	0.4	9	
Defined standard (\$480)	15.1	79	0.6	3	3.7	86	

Note: MA-PD (Medicare Advantage–Prescription Drug [plan]), PDP (prescription drug plan), SNP (special needs plan). Regular MA-PD enrollment excludes employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B–only plans. Totals may not sum due to rounding.

Source: MedPAC analysis of CMS landscape, plan report, and enrollment data.

In 2022, monthly beneficiary premiums averaged about \$26 across all types of plans (basic and enhanced, stand-alone PDP and MA-PD)—effectively no change from the prior year. However, premiums for individual plans vary widely around that average, from \$0 for many MA-PDs to \$207 for the most expensive enhanced PDP. The \$26 average reflects plan sponsors' extensive use of Part C rebate dollars to offset premium costs that MA-PD enrollees would otherwise pay themselves. In 2022, MA-PD enrollees paid an average of less than \$15 per month but received over \$47 of basic and supplemental drug benefits through Part C rebates (Medicare Payment Advisory Commission 2022a). PDP enrollees paid an average of \$40 per month.

Two other factors, not accounted for in the averages described above, can affect the premium amounts enrollees pay. First, higher-income individuals have a lower federal subsidy of their Part D benefits.<sup>10</sup> In 2022, about 7 percent of enrollees were subject to the income-related premium, compared with less than 3 percent in 2011 (Liu 2022). Second, individuals enrolling

outside their initial enrollment period must have proof that they had drug coverage as generous as the standard benefit to avoid the late enrollment penalty (LEP) that would be added to their premiums for the duration of their Part D enrollment.<sup>11</sup> In 2022, about 5 percent paid the LEP, up from about 1 percent in 2007 (Liu 2022).

### Large cost-sharing differences between preferred generics and other drugs

Most Part D enrollees choose plans that have a five-tier structure: two generic tiers ("preferred" and "other" generics), one preferred brand-name tier, and one nonpreferred drug tier (which may include both brandname and generic drugs), plus a specialty tier (Medicare Payment Advisory Commission 2022a). The costsharing amounts for those tiers differ, but generally plans have kept generic copayments comparatively low. Among PDP enrollees, in 2022, median copayments were \$0 for preferred generics and \$5 for other generic drugs. Median cost sharing was \$42 for preferred brand-name drugs and 40 percent coinsurance for nonpreferred drugs. Among MA–PD enrollees, median copayments for the two generic tiers were \$0 and \$10, respectively, \$47 for preferred brand-name drugs, and \$100 for nonpreferred drugs. PDPs and MA–PDs typically charged a coinsurance of between 25 percent and 33 percent for specialty-tier drugs.

### **Benefit offerings for 2023**

For 2023, plan sponsors are offering 3,539 general MA–PDs and 1,254 SNPs–5 percent and 11 percent more plans, respectively, than in 2022. That rapid growth reflects plan sponsors' interest in gaining a share of MA's expanding enrollment. In 2023, plan sponsors are offering 804 PDPs, nearly 5 percent more than the previous year.

In each of the nation's 34 PDP regions, beneficiaries continue to have broad choice. The number of PDPs ranges from 19 in New York to 28 in Arizona, along with dozens of MA–PDs in most areas. The number of MA plans available to a beneficiary varies by the county of residence, with an average of 26 plans in each county. Because more beneficiaries live in areas with greater numbers of plans, the average beneficiary has 41 MA plans available.<sup>12</sup>

### Changes in premiums

For 2023, CMS calculated that Part D's base beneficiary premium—enrollees' share of the monthly national average expected cost for basic benefits—is \$32.74, a 2 percent decrease from 2022 (Centers for Medicare & Medicaid Services 2022c). However, premiums for individual Part D plans can vary substantially from the base beneficiary premium because they reflect any difference between the sponsor's bid and the national average bid, as well as any enhanced (supplemental) benefits the plan offers. In addition, in 2023, MA–PD sponsors are applying \$54 per month of Part C rebate dollars on average to lower their Part D premiums compared with over \$47 per month the prior year (a nearly 14 percent increase).

In 2022, over 90 percent of all beneficiaries in PDPs (excluding employer-sponsored plans) were enrolled in plans marketed nationally or near nationally by eight large plan sponsors. If enrollees remained in those plans for 2023, most (but not all) saw an increase in their premiums averaging \$4 per month, or 10 percent. However, average monthly premiums for some nationally marketed PDPs (such as WellCare Value Script and SilverScript SmartSaver) fell by a dollar or two, while others (such as Elixir RxPlus, Elixir RxSecure, and AARP MedicareRx Preferred) rose by more than \$10 (and some by considerably more).

In 2023, the benchmarks that reflect the maximum amount Medicare will pay for monthly premiums on behalf of LIS beneficiaries range from \$25 in Texas to \$43 in Wisconsin. Compared with 2022, the number of zero-premium PDPs available to LIS enrollees in 2023 dropped by 4 percent to 191 plans. That total equals about one-quarter of all PDPs. All regions have at least three zero-premium PDPs available, while Arizona has a high of eight such PDPs.

### **Market segmentation**

In 2023, five large sponsors of nationally marketed PDPs followed an approach of dividing, or segmenting, their enrollees.<sup>13</sup> To do so, sponsors use one plan geared toward LIS beneficiaries and two plans aimed at other beneficiaries—one for those with low drug costs and one for those with high drug costs. Sponsors differentiate their plans through a mix of program rules and changes in premiums, cost sharing, formularies, and pharmacy networks. In this strategy, the sponsor aims to (1) keep the premium for the plan geared toward LIS beneficiaries just below the LIS benchmark subsidy amount and (2) offer one PDP with enhanced coverage that has a lower premium than plans with basic coverage (Medicare Payment Advisory Commission 2022b).

Segmenting the market may make PDPs more profitable than would be the case if plan sponsors did not do so. Sponsors want to maximize the revenues they receive for each LIS enrollee, which is easier to do when LIS enrollees are segmented into separate plans. For other beneficiaries, sponsors want to capitalize on the fact that beneficiaries are sensitive to premiums when they first select a PDP but rarely switch plans after that. Sponsors' strategy in this case is to pair a newer, low-premium plan that attracts new Part D enrollees with an older, more established plan with premiums they can increase more easily.

For beneficiaries, the implications of a segmented market are mixed. Enrollees who do not receive the LIS may benefit from greater access to low-premium plans. At the same time, segmentation may make it harder for beneficiaries to understand their plan options. As the common-sense distinction between basic and enhanced plans has been lost, it can be difficult to determine what extra benefits are provided by enhanced PDPs with low premiums, and beneficiaries in enhanced PDPs with high premiums likely pay more for their coverage than they otherwise would. For the Medicare program, segmentation likely increases Part D spending because it allows sponsors to charge higher premiums for plans that serve LIS beneficiaries and for older plans that serve beneficiaries who do not receive the LIS.

### Part D's market dynamics have evolved

About 300 organizations operate Part D plans. In addition to their role as insurers, plan sponsors carry out marketing, enrollment, customer support, claims processing, coverage determinations, and exceptions and appeals processes. Other key functions are performed by plans' pharmacy benefit managers (PBMs).

### The roles of plan sponsors and PBMs

Most plan sponsors offer MA–PDs, but only about 50 operate stand-alone PDPs.<sup>14</sup> As plan sponsors merged throughout the earlier years of the program, Part D enrollment grew more concentrated (Medicare Payment Advisory Commission 2019c). However, over the past several years, enrollment concentration has stabilized. In 2022, the top five PDP sponsors ranked by enrollment accounted for 88 percent of covered lives, while the top five sponsors of MA–PDs accounted for 68 percent of enrollment.

Drug plan sponsors use PBMs to develop formularies, establish networks of pharmacies, and negotiate with drug manufacturers and pharmacies for postsale rebates and discounts. Many of the largest plan sponsors are vertically integrated with their own PBMs, and they operate mail-order and specialty pharmacies. Other sponsors perform some PBM functions in house but contract with outside PBMs (that may be owned by a competitor) for services such as rebate negotiations.<sup>15</sup> As a result, PBMs' market concentration is higher than that of plan sponsors. We estimate that in 2021, the top five PBMs (ranked either by Part D-covered lives or number of prescriptions) negotiated rebates on behalf of more than 90 percent of all Part D enrollees and prescriptions.

### Formulary management and manufacturer rebates

Formularies remain plan sponsors' most important tool for managing drug benefits. Sponsors and PBMs decide which drugs to include or exclude, which costsharing tier is appropriate for each drug, and whether a drug will be subject to utilization management quantity limits, step therapy, and prior authorization. Those decisions require that plan sponsors strike a balance between providing access to medications and encouraging enrollees to use preferred therapies.

CMS reviews each plan's formulary as part of the process of deciding whether to approve a plan sponsor's bid. For most drug classes, plans must cover at least two distinct drugs that are not therapeutically equivalent or bioequivalent, as well as "all or substantially all drugs" in six protected classes anticonvulsants, antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

In drug classes that have competing therapies, PBMs negotiate with brand manufacturers for rebates that the manufacturers pay after each prescription has been filled. Generally, manufacturers pay larger rebates when a sponsor positions a drug on its formulary in a way that increases the likelihood of winning market share over competing drugs. In 2020, rebates and discounts in Part D averaged 12 percent for brand-name specialty drugs and 47 percent for brand-name nonspecialty drugs, which often have larger numbers of competing therapies (Congressional Budget Office 2021). Between 2010 and 2021, the magnitude of aggregate rebates grew from \$8.6 billion (11 percent of gross Part D spending) to \$49.3 billion (23 percent).<sup>16</sup>

### Pharmacy networks and postsale fees

Under Part D, plan sponsors must permit within their networks any pharmacy that is willing to accept the sponsors' terms and conditions; that is, plan sponsors cannot use exclusive pharmacy contracts. Sponsors must also demonstrate that their network meets pharmacy access standards.

However, sponsors can designate a subset of network pharmacies that offer preferred (lower) cost sharing. For 2023, if enrollees remained in the same plan as in the previous year, 99 percent of PDP enrollees, 41 percent of general MA–PD enrollees, and 11 percent of SNP enrollees would be in plans that use preferred cost-sharing pharmacies.<sup>17</sup> The strategy of designating certain pharmacies as preferred has the potential to lower costs for Medicare and enrollees if it encourages enrollees to fill prescriptions at pharmacies that, for example, are more effective at encouraging generic drug use. Researchers found that over the period from 2011 to 2014, Part D enrollees without the LIS were highly sensitive to preferred cost sharing, and the approach reduced overall drug spending by about 2 percent (Starc and Swanson 2021a, Starc and Swanson 2021b). However, tiered pharmacy networks have been controversial because of concerns that some members have less access to preferred pharmacies or that tiering pharmacy networks could lead to higher low-income cost-sharing subsidies.

Over time, some major plan sponsors began requiring pharmacies to make postsale payments depending on their performance.<sup>18</sup> Because these payments rely on periodic evaluations, they can flow from a plan sponsor and its PBM to a pharmacy or vice versa. On the whole, however, pharmacies have paid increasing amounts to plan sponsors; in 2021, they totaled \$12.6 billion, or 6 percent of gross Part D spending.<sup>19</sup>

Beginning in 2024, CMS will adopt a new definition of "negotiated price" to include all pharmacy price concessions, including performance-based ones assessed after the point of sale.<sup>20</sup> Plan sponsors' negotiated price must reflect the lowest possible reimbursement a network pharmacy could receive, and that amount will be the basis for assessing enrollee cost sharing when it takes the form of deductibles or coinsurance.

### Vertical integration and plan profitability

Many large plan sponsors have acquired PBMs along with mail-order, specialty, and sometimes retail pharmacies. This strategy offers the combined companies a number of advantages. When PBMs operate under contract to a health plan (as opposed to being part of a vertically integrated company), they may have an incentive to design formularies that reduce or minimize drug spending, even when prescriptions could prevent or forestall other health care spending. Health plans may find it beneficial to purchase a PBM and internalize trade-offs between drug and medical expenses (Garthwaite 2019). Vertical mergers with PBMs also give health plans access to large amounts of prescription claims that can be used to monitor patient adherence, predict enrollees' use of services, encourage service use at lower-cost sites of care, and potentially coordinate care among prescribers.

Through vertical mergers, health plans can also gain access to information about net prices for drugs both for generics (because PBM-owned mail-order pharmacies obtain steep discounts) and brandname drugs (through PBM data about manufacturer rebates). Because of the complexity of drug pricing, the highly proprietary nature of rebates, and imperfect competition among PBMs, information about net prices for drugs has been difficult to obtain through contracts (Lieberman et al. 2017, Scott Morton and Boller 2017). A health plan may overcome the information asymmetry by purchasing the PBM (Garthwaite 2019).

However, a few plan sponsors have stepped back from vertical integration. For example, one large plan sponsor (Centene) has decided to sell off its PBM and specialty pharmacy (Waddill 2022). Other health plans have chosen to use PBM aggregators (also called PBM group purchasing organizations) to negotiate rebates on behalf of their commercial clients (Pifer 2020).

A concern is that vertical integration could be associated with anticompetitive behavior. For example, a health plan that also owns pharmacies and a PBM could attempt to restrict pharmacy network participation or raise the prices of PBM services for competing health plans that contract with them (Greaney 2019). Inflated transfer prices between a PBM and its mail-order and specialty pharmacies could be a mechanism for raising rivals' costs. In addition, when insurers and PBMs are integrated with pharmacies, the use of preferred networks may not necessarily result in lower costs.

The prices established between upstream and downstream entities of vertically integrated organizations are less transparent to CMS and commercial payers.<sup>21</sup> For example, the Department of Health and Human Services Office of Inspector General (OIG) described one Part D plan sponsor that did not negotiate reimbursement contracts with its wholly owned pharmacies. OIG cautioned that profits included in the sponsor's payments to its pharmacies for ingredient costs accrued to the sponsor but could not be identified and separated from pharmacy costs. In turn, the lack of clarity prevents CMS from being able to evaluate whether the margins included in the sponsor's Part D bids are reasonable (Office of Inspector General 2021).

For similar reasons, vertical integration among plan sponsors, PBMs, and pharmacies makes it difficult to assess the profitability of Part D plans. Under Part D's risk corridors, Medicare shares in some of the profits and losses of plan sponsors. The Medicare program made aggregate risk-corridor payments to plan sponsors in the years 2019 through 2021 and is projected to do so for 2022 (Boards of Trustees 2022). Aggregate risk-corridor payments from Medicare to plans indicate that, overall, sponsors experienced losses-costs for pharmacy benefits that were higher than their bids.<sup>22</sup> However, plans include some profit within their administrative costs, which are not reflected in risk-corridor calculations and thus could offset some of the higher-than-expected benefit spending. Moreover, profits accruing to wholly owned downstream entities could more than offset Part D plan sponsors' losses (Herman 2022).

### Although moderated by generic use, brand prices have continued to grow

Growth in prices at the pharmacy counter—referred to here as gross or point-of-sale (POS) prices—has been the focus of much attention. Most Part D enrollees primarily use generic drugs, and many (but not all) generic prices remain low. However, enrollees without the LIS who use brand-name drugs often feel the effects of rising POS prices when they pay a deductible or coinsurance. These effects especially involve the relatively small share of enrollees who use high-priced specialty drugs. At the same time, drug prices net of postsale rebates and discounts affect the premiums paid by all Part D enrollees and subsidized by the Medicare program.

All levels of the drug supply chain include incentives that drive POS prices higher, particularly when payments are based on a percentage of prices (Fein 2018, Feldman 2018, Garthwaite and Morton 2017, Sood et al. 2021). Meanwhile, manufacturers now focus on developing drugs and biologics for smaller patient populations, products that are launched at high prices and may not have direct therapeutic competitors. Over time, these factors, combined with the consolidation of supply-chain participants, have pushed POS prices higher (Sood et al. 2020).

Prices paid at the pharmacy are an important indicator of Part D's costs because POS prices affect beneficiary cost sharing and the rate at which enrollees reach Part D's catastrophic phase. To examine growth in prices, the Commission contracted with Acumen LLC to construct a series of volume-weighted price indexes that reflect total amounts paid to pharmacies for Part D prescriptions, including ingredient costs and dispensing fees. The indexes reflect prices measured at the median of the distribution.

# In 2021, the growth in average prices accelerated, exceeding prepandemic growth rates

Between 2006 and 2021, prices for all drugs and biologics, measured by individual national drug codes (NDCs), more than doubled on average (an index value of 2.04) (Table 12-3).<sup>23</sup> Overall, drug prices grew by 4.2 percent in 2021, exceeding price growth observed before 2020 (averaging 3.5 percent annually).

Single-source drugs and biologics command increasingly high prices, averaging nearly 40 times that of average generic prices in 2021, up from less than six times in the early years of the program (data not shown). Their prices have grown at a mid- to highsingle-digit percentage for most of the past five years, following years of double-digit growth (latter data not shown) (Table 12-3).

Because generic drugs account for 90 percent of all prescriptions, decreases in generic prices help moderate overall price growth. Our price index for generic drugs has declined consistently in the past and continued to do so in 2021. However, the rate of decrease in generic prices has slowed in recent years, from annual decreases in the low- to mid-double digits before 2017, to an annual decrease of about 9 percent between 2017 and 2020 and a decrease of 7.5 percent in 2021 (Table 12-3). As a result, in 2021, our overall price index that takes generic substitution into account rose by 3.5 percent, up from an average growth rate of less than 1 percent observed before 2020.<sup>24</sup>

#### TABLE 12-3

### Measured at the point of sale, overall growth in Part D prices accelerated in 2021

	2017	2018	2019	2020	2021
	Price inc	lex as of D	ecember (	January 200	06 = 1.00)
All drugs and biologics, before accounting for generic substitution	1.80	1.86	1.91	1.96	2.04
Single-source drugs and biologics		3.35	3.54	3.72	3.97
Generic drugs	0.18	0.17	0.15	0.13	0.12
All drugs and biologics, after accounting for generic substitution	1.12	1.14	1.11	1.13	1.17

	Annual percentage change*					
All drugs and biologics, before accounting for generic substitution	4.4%	3.5%	2.6%	2.5%	4.2%	
Single-source drugs and biologics	8.0	6.9	5.7	5.2	6.7	
Generic drugs	-9.3	-9.0	-10.7	-9.2	-7.5	
All drugs and biologics, after accounting for generic substitution	1.8	1.6	-2.1	1.3	3.5	

Note: Indexes are calculated using chain-weighted Fisher price indexes and are measured at the median of the distribution relative to prices as of January 2006. Prices reflect total amounts paid to pharmacies before rebates or discounts from manufacturers and pharmacies. Indexes shown are rounded.

\*Annual percentage changes reflect growth in the price index since December of the previous year calculated using unrounded data.

Source: Acumen LLC analysis for MedPAC.

# Limited opportunity for further generic substitution means future savings will depend on adoption of biosimilars

Prices for generics are often a fraction of the prices for their brand-name counterparts (Association for Accessible Medicines 2021, Government Accountability Office 2016, Schondelmeyer and Purvis 2019). Part D enrollees have embraced their use, with generic dispensing growing in the decade between 2007 and 2017 from just over 60 percent of all prescriptions to nearly 90 percent (Medicare Payment Advisory Commission 2022c). Broad acceptance of generic medicines among prescribers and patients has provided significant savings to beneficiaries and the Medicare program.

However, generics' share of prescriptions has plateaued since 2017, driven primarily by the shift in the drug development pipeline. Now, Medicare spends significant amounts on products for which generic versions are not available because they are biologics, which are given longer periods of market exclusivity when they are licensed. Another factor contributing to the stagnation in the share of generic prescriptions in Part D may be the increased use of pharmacy discount cards that bypass insurance to obtain lower prices (see text box on pharmacy discount cards, p. 402). A recent report by IQVIA estimated that, among Medicare beneficiaries, claims processed using pharmacy discount cards accounted for about 2 percent of total Medicare pharmacy claims (Adolph et al. 2022).

Going forward, further opportunities for generic substitution will likely be limited, and any meaningful savings will have to come from the successful launch and adoption of biosimilars by prescribers and beneficiaries (see text box on top-selling biologics, p. 404).

# Reinsurance spending has accounted for a growing share of program costs

The costs of providing Part D benefits are shared by Medicare (taxpayers) and its enrollees. Medicare pays

### Pharmacy discount cards improve access but have drawbacks

s more patients face high out-of-pocket (OOP) costs for medicines, pharmacy L discount cards have gained prominence among patients and clinicians (Adolph et al. 2022, NORC at the University of Chicago 2022). Unlike manufacturer coupons, which are offered directly to patients for specific brand-name drugs, pharmacy discount cards provide access to lower (negotiated) prices for both brand-name and generic drugs. Between 2017 and 2021, the share of prescriptions dispensed with a discount card (across all payers, including commercial) nearly doubled from 3.3 percent to 5.4 percent (Adolph et al. 2022). Most of that growth was attributable to one company, GoodRx, which had 46 percent of the discount card market in 2021 (Adolph et al. 2022).

Pharmacy discount cards allow patients to search online for the lowest prices for their medicines across pharmacies. The digital platform allows discount card companies to take advantage of differences in discounts negotiated by pharmacy benefit managers (PBMs) to offer patients access to the lowest price. (Some discount cards, such as the Walmart Rx program, may work more like a cash discount card with discounted prices available only at certain pharmacies.) The discount may vary by drug and by vendor but can be as much as 80 percent below retail (cash-pay) prices (Feke 2022). Both the PBM and the marketer of the discount card earn fees from participating pharmacies, who, in turn, may see an increase in prescription volume, "potentially boosting overall revenue from items other than prescription medications despite the potential reduction in revenues" from discounts and pharmacy-transaction and marketing fees (Fein 2022, Hilas 2021).

Most pharmacy discount cards are available at no cost, and patients can access the discounted prices simply by presenting the card at participating pharmacies. Uninsured or underinsured individuals who face full retail prices at the pharmacy are most likely to benefit from using them. However, individuals with health insurance may also benefit from discount cards, for example, if they have a high deductible or if the medicines they need are not covered by their insurance. In 2021, just under 20 percent of Medicare beneficiaries used a discount card for at least one of their medicines compared with 12 percent for patients with commercial insurance (Adolph et al. 2022). Among the commercially insured, patients who faced a deductible were twice as likely to use a discount card compared with patients who did not face a deductible (Adolph et al. 2022).

By lowering OOP expenses, pharmacy discount cards can increase access to medicines. However, because discount cards operate outside of patients' insurance, there are drawbacks to their use. For example, discount cards "may result in a disservice to the patient in the long run because bypassing their insurance . . . will mean that the patient's OOP expense will not contribute to their plan deductible" (Balick 2020). For Part D enrollees, it also means that their OOP spending will not count toward the annual OOP limit. Use of discount cards may also make it difficult for a patient's prescriber and insurance plan to ensure the patient adheres to their medication regimens (Balick 2020). For Part D plans, lacking knowledge of patients' medication purchases could also affect their star ratings, for which adherence is used as a measure of a plan's quality.

plan sponsors two subsidies on behalf of each enrollee in their plans:

- **Direct subsidy**—A monthly prospective amount set as a share of the national average bid for Part D basic benefits, adjusted for the risk of the individual enrollee.
- **Reinsurance**—Reimbursement to plans for 80 percent of drug spending above an enrollee's annual OOP threshold (the catastrophic phase of the benefit). Plans receive prospective payments for reinsurance that are reconciled with actual spending (net of postsale rebates and discounts) for each enrollee who reached the OOP threshold after the end of the benefit year.

#### Medicare's reimbursement amounts for Part D

	Annual spending, in billions					Average annual growth rate
	2017	2018	2019	2020	2021	2017-2021
Capitated payments (direct subsidy)	\$14.6	\$13.5	\$11.8	\$10.9	\$7.8	-14.5%
Cost-based reinsurance payments	37.6	40.6	46.1	48.5	52.4	8.7
Subtotal, basic benefits	52.2	54.1	57.9	59.4	60.2	3.6
Low-income cost-sharing and premium subsidy	27.3	28.5	29.7	33.0	35.1	6.5
Retiree drug subsidy*	<u>0.8</u>	<u>0.7</u>	0.7	0.6	0.6	<u>-6.9</u>
Total Part D	80.3	83.3	88.3	93.0	95.9	4.1
Enrollee premiums for basic benefits**	14.0	14.2	13.8	13.6	14.9	1.6

Note: Figures for capitated payments account for risk-sharing payments that plans make or receive under Part D's risk corridors. Figures for amounts that are paid prospectively (cost-based reinsurance and low-income subsidy) have been reconciled to actual spending amounts. Components may not sum to stated totals due to rounding.

\*Subsidy for employers providing comparable or more generous coverage than the basic Part D benefit.

\*\*Excludes low-income premium subsidies. In addition, in 2021, enrollees paid \$7.5 billion in premiums for enhanced benefits.

Source: MedPAC analysis based on Table IV.B10 of the 2022 annual report of the Boards of Trustees of the Medicare trust funds.

Combined, the direct subsidy and expected reinsurance payments aim to cover 74.5 percent of the expected cost of basic benefits. Today, nearly all of Medicare's payments take the form of reinsurance (cost-based reimbursement) rather than the direct subsidy (capitated payments). In 2023, direct subsidy payments to plans average less than \$2 per member per month, compared with payments of nearly \$94 per member per month for reinsurance.<sup>25</sup> In addition to reinsurance, Medicare shares financial risk with plan sponsors by risk adjusting direct subsidy payments to reflect the expected costliness of a plan's enrollees and by limiting each plan's overall losses or profits through risk corridors if actual benefit spending, excluding reinsurance, is much higher or lower than the plan sponsor anticipated in its bid.

Beneficiary premiums are designed to cover the remaining 25.5 percent of the expected cost of basic benefits. In addition to monthly premiums, Part D enrollees also pay any cost sharing required by plan sponsors or, in the case of LIS enrollees, cost-sharing amounts set in law.

#### Trends in program subsidies and costs

Between 2017 and 2021, program spending rose from \$80.3 billion to \$95.9 billion (Table 12-4), or an average of 4.1 percent per year. In 2021, Medicare paid \$7.8 billion for direct subsidies, \$52.4 billion for reinsurance, \$35.1 billion for the LIS, and \$0.6 billion for the RDS. Medicare payments for reinsurance have grown faster than other components of Part D spending. Between 2017 and 2021, reinsurance payments rose by 8.7 percent annually, compared with a decline of 14.5 percent for the capitated direct subsidy payments. Multiple other factors have contributed to the decline in direct subsidy payments, including the increased use of generic drugs by Part D enrollees and the rapid growth in direct and indirect remuneration (DIR) that disproportionately offsets basic benefit costs paid by plans.

### Top-selling biologics are now facing or will soon face biosimilar competition

The biosimilar market has only recently expanded to retail prescription drugs in the U.S. market and is therefore just beginning to have an impact on Part D spending, though that impact so far has been quite limited. With the recent and expected introduction of biosimilars for some top-selling Part D drugs, however, the trend is expected to change over the coming years.

In 2020, less than \$1 billion was spent on biosimilar products in Part D, all of which was for insulin products, and most of those were authorized generics as opposed to true biosimilar competitors (Medicare Payment Advisory Commission 2022a).<sup>26</sup> However, Lantus-which had \$3.7 billion in gross sales in Part D in 2020-now faces competition from two interchangeable biosimilars: Semglee, which received interchangeable status in 2021, and Rezvoglar, which received interchangeable status in November 2022. Interchangeable status permits pharmacists, in some states, to automatically substitute a biosimilar for a brandname prescription.<sup>27</sup> Still, the use of Semglee remained limited as of March 2022, particularly in the Part D market, which was probably largely influenced by plans' limited coverage of Semglee or their preference for Lantus and not necessarily a reflection of patient choice (Fein 2023, IQVIA 2022). Several other top-selling products for autoimmune conditions are now facing or are expected to face biosimilar competition.

- Humira—with gross Part D spending of \$4.2 billion in 2020—began facing biosimilar competition in January 2023, and another seven biosimilars are expected by the end of 2023, including one that has interchangeable status.
- Multiple biosimilars for Enbrel—with gross Part D sales of \$2.1 billion in 2020—have already been approved and are expected to enter the U.S. market in 2028, following patent expirations.
- Stelara—which had \$1.1 billion in gross Part D sales in 2020—has at least nine potential biosimilar candidates currently in the development pipeline.

The approval of biosimilars for each of these products presents an opportunity for patients and the Medicare program to save significantly. While OptumRx and Cigna have announced they would cover biosimilars of Humira in their commercial plans, it was not clear as of December 2022 whether these products will similarly be covered in Part D. ■

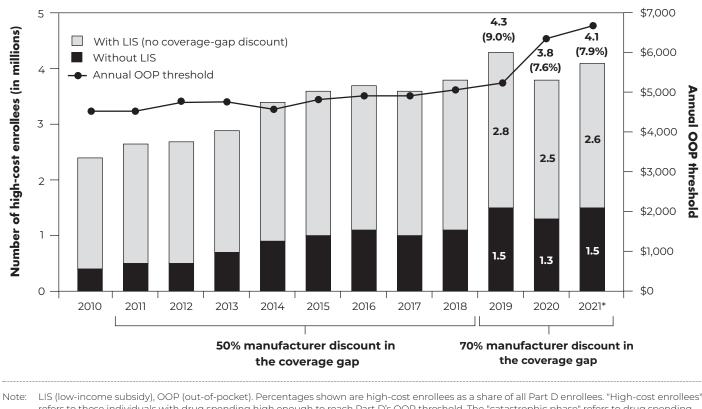
In 2021, Part D enrollees paid \$14.9 billion in premiums for basic benefits (not including the premiums paid by Medicare on behalf of LIS enrollees), up nearly 10 percent from 2020. In addition, enrollees paid \$7.5 billion in premiums for enhanced benefits.

#### In 2021, the number of beneficiaries reaching the catastrophic phase rebounded after a drop in 2020

In 2021, the number of Part D high-cost enrollees—those with spending high enough to reach the

catastrophic phase of the benefit—rose by more than 6 percent to 4.1 million (Figure 12-3) after dropping by 11 percent in 2020. (Much of the decline in 2020 was likely driven by an unusually large, statutory 25 percent jump in the OOP threshold from its 2019 level.<sup>28</sup>) In 2021, the number of high-cost enrollees without the LIS continued to grow more rapidly than the number of high-cost enrollees with the LIS. As a result, in 2021, enrollees without the LIS accounted for 36 percent of all high-cost enrollees, up from less than 20 percent before 2012. FIGURE 12-3

Part D enrollees reaching the benefit's catastrophic phase, 2010–2021



Note: LIS (low-income subsidy), OOP (out-of-pocket). Percentages shown are high-cost enrollees as a share of all Part D enrollees. "High-cost enrollees" refers to those individuals with drug spending high enough to reach Part D's OOP threshold. The "catastrophic phase" refers to drug spending above that threshold. Under Part D, manufacturers of brand-name drugs must provide a discount in the coverage gap to enrollees who do not receive the LIS. Components may not sum to stated totals due to rounding.
\*Amounts are based on preliminary Part D prescription drug event data.

Source: Enrollee counts for 2010 to 2021 are based on MedPAC analysis of Part D prescription drug event data.

CMS adjusts the annual OOP threshold each year based on a formula set in law. Between 2020 and 2021, the annual OOP threshold increased from \$6,350 to \$6.550. Because LIS enrollees continued to make up most of those with high costs and the LIS pays for nearly all costs in the coverage gap (above any nominal copayments required by law), the effects of the increase in the OOP threshold fell almost entirely on Medicare (see Figure 12-1, p. 390). In contrast, for enrollees without the LIS, the financial impact of a higher OOP threshold differed depending on whether the prescription was for a generic or a brand-name drug. For brand-name drugs, the manufacturer's coverage-gap discount is treated as though it were the enrollee's own OOP spending (see Figure 12-1). In 2021, coverage-gap discounts among high-cost enrollees without the LIS averaged just under \$4,500, accounting for 69 percent of the OOP threshold amount (\$6,550).

In 2021, the number of enrollees who used drugs with very high prices—where a single prescription was sufficiently expensive to meet the OOP threshold rose by just under 5 percent to 11 percent of highcost enrollees (over 464,000 enrollees). That figure is lower than the corresponding figure for 2019 (483,000 enrollees) but still substantially higher than the 2010 figure (33,000 enrollees). High-cost enrollees without the LIS were more likely to have such claims compared with high-cost enrollees with the LIS (18 percent compared with just under 8 percent, respectively).

### Part D plans bear less than one-third of the risk for Part D spending

Insurance risk provides an incentive for plan sponsors to offer attractive benefits while managing their enrollees' spending through formularies and other

#### Plans bore less than one-third of the risk for Part D spending in 2021

	All	By plan type*				
	Part D plans	PDPs	MA-PDs**	SNPs		
As a share of spending net of all DIR and coverage-gap discounts:						
Plans at risk	26%	15%	33%	12%		
Medicare at risk	61	69	50	86		
Reinsurance	38	43	33	44		
Low-income cost-sharing subsidy	23	26	17	42		
Beneficiary cost sharing	13	16	16	٦		

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), SNP (special needs plan), DIR (direct and indirect remuneration). Plans are at risk for a portion of basic benefit costs and any supplemental benefits not subsidized by Medicare. Components may not sum to totals due to rounding. \*Excludes employer group waiver plans.

\*Excludes employer grou

\*\*Excludes SNPs.

Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

tools. The Commission has been concerned that the shift of risk from plan sponsors to Medicare has eroded plans' incentives to manage spending (Medicare Payment Advisory Commission 2022c). In 2021, plans were at risk for 26 percent of Part D spending net of all DIR and coverage-gap discounts (Table 12-5). Medicare, on the other hand, was at risk for over 60 percent of net Part D spending, consisting of 38 percent for reinsurance and 23 percent for the low-income costsharing subsidy.

The extent to which plans bear insurance risk varied by plan types. For example, MA–PDs' share of insurance risk was more than double that of PDPs. The difference may reflect the fact that nearly all MA–PD enrollees are in enhanced plans that offer supplemental benefits for which plans are fully at risk. In comparison, about half of PDP enrollees were in plans that offered basic coverage and did not include supplemental benefits. SNPs, which consist mostly of dual-eligible special needs plans that serve beneficiaries who receive both Medicare and Medicaid benefits, had a comparatively lower risk (12 percent) than other Part D plans. That difference may, in part, be due to the lack of plan liability in the coverage gap for beneficiaries with the LIS (see Figure 12-1, p. 390).

# While most Part D enrollees were satisfied, room for improvement remains

Measuring the quality of the pharmacy benefit and enrollees' medication use is critical for assessing Part D's value, but it is a task that requires nuance. On the one hand, effective treatment for many conditions may hinge primarily on access and adherence to prescription drugs. For this reason, Medicare evaluates how well Part D plans make medicines available through their formularies and network pharmacies. On the other hand, Medicare beneficiaries are likely to have multiple chronic conditions, they take an average of nearly five prescription drugs, and they are at higher risk for adverse drug events associated with polypharmacy. Thus, the degree to which Part D plans help to manage enrollees' medication therapies is critically important as well. CMS collects quality and performance data to monitor plan sponsors' operations and evaluate access to medicines, enrollee experience, and patient safety. A subset of these data is used in the 5-star rating system made available through Medicare's Plan Finder at Medicare.gov to help beneficiaries evaluate their plan options. The agency also uses star ratings that are based in part on prescription drug benefits to determine MA quality bonus payments. (Although both MA-PDs and stand-alone PDPs are evaluated with star ratings, only MA-PDs are eligible for quality bonus payments through the Part C payment system.) The agency displays other Part D quality measures on the CMS website, including some metrics that are either being removed from or evaluated for addition to the star rating system. In addition, by law, Part D plans are required to carry out medication therapy management (MTM) programs and programs to manage opioid use.

For 2023, average star ratings fell relative to 2022 levels, but the 2022 ratings were affected by changes CMS made to address the coronavirus pandemic in how it calculated the ratings. The average ratings for 2023 were more comparable with those for 2021. Star ratings could provide useful information when enrollees are choosing among plan options or when rewarding plan sponsors for effective management of drug use and spending. However, none of the beneficiaries who participated in Commission-sponsored focus groups in the summer of 2022 mentioned using the Medicare star ratings as a source of information for choosing a health plan (NORC at the University of Chicago 2022). The Commission supports the use of quality measurements that are patient oriented, encourage coordination across providers, and promote positive change in the delivery system. Because the provision of prescription drugs is different from the provision of medical services, the quality measures currently used for Part D may not help beneficiaries make informed choices among plan options or allow CMS to reward plan sponsors that provide better value to beneficiaries and taxpayers.

Formulary management is the most important tool used by plan sponsors to manage beneficiaries' medication use and is a key determinant affecting beneficiary access to medications. Greater flexibility to use formulary tools could help plan sponsors manage spending while ensuring that prescribed medicines are safe and appropriate for the patient, potentially reducing overuse and misuse. However, for some enrollees, those same tools could limit access to needed medications. To ensure access, CMS reviews each plan's formulary to check that it includes medicines in a wide range of therapeutic classes used by the Medicare population and applies utilization management tools in appropriate ways. Further, Part D law requires sponsors to have a transition process to ensure that new enrollees, as well as current members whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.<sup>29</sup>

Medicare also requires plan sponsors to establish a process for coverage determination and appeals. Part D requires quicker adjudication times than the time frames used for most medical benefits covered by MA plans.<sup>30</sup> If an enrollee is dissatisfied with a plan's final coverage decision, the enrollee may appeal the decision to an independent review entity and then to higher levels of appeal.

### For some beneficiaries, high OOP costs may be a barrier to access

More than 80 percent of elderly Part D enrollees report that their Part D plans provide good value and that their OOP costs are reasonable (Medicare Today 2021). At the same time, in focus groups convened for the Commission, physicians and beneficiaries were acutely aware of high drug costs and reported having frequent discussions about ways to lower costs (NORC at the University of Chicago 2022). These seemingly conflicting results reflect the dichotomy between the majority of beneficiaries who take generic drugs for common conditions and the relatively small number of beneficiaries who use many brand-name drugs or high-cost specialty drugs.

For an enrollee without the LIS (and even those qualifying for only the partial LIS), the cost-sharing burden for brand-name drugs and biologics can be substantial (see text box on reducing cost sharing for insulins, pp. 408–410). For high-cost specialty drugs, cost sharing can total thousands of dollars in the catastrophic phase of the benefit alone (Cubanski et al. 2019). (Most enrollees who receive Part D's LIS do not face a large financial hurdle because their cost sharing is limited to nominal copayments.)

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For many reasons, beneficiaries have not always

to prefer the brand version that has lower costs

benefited from lower-priced alternatives (Dusetzina et

al. 2020). For example, the difference in the list prices

for a specialty generic and its brand counterpart may

be relatively small. As a result, sponsors may continue

### Insulin and the Inflation Reduction Act of 2022

The Inflation Reduction Act of 2022 (IRA) includes a \$35 per month limitation on copayments for an insulin product covered under Part D and exempts those products from any plan deductibles. These changes are effective in 2023. An estimated 3.3 million Medicare beneficiaries took insulin in 2020 (Centers for Medicare & Medicaid Services 2022e). In 2021, more than 10 percent of insulin users ages 65 and older reported rationing insulin, raising concerns about its affordability among Medicare beneficiaries (Gaffney et al. 2022).

In 2021, the Center for Medicare & Medicaid Innovation began a voluntary demonstration-the Senior Savings Model (SSM)-that allows Part D plans that offer enhanced coverage and insulin manufacturers to provide insulin for \$35 per prescription for a month's supply, regardless of the enrollee's benefit phase at the time, just as the IRA now requires. An analysis of prescription drug event claims data found the average monthly out-ofpocket (OOP) cost across insulin products in 2020 was \$54 per prescription for those beneficiaries not receiving the low-income subsidy, indicating that the \$35 per month price limit could save, on average, \$19 in lower cost sharing per fill (Cubanski and Damico 2022). Findings from the two years of experience with this model provide insights as to what impacts we can expect from the IRA provision.

By 2022, a total of 2,058 plans covering 16.9 million beneficiaries participated in the SSM, with 62

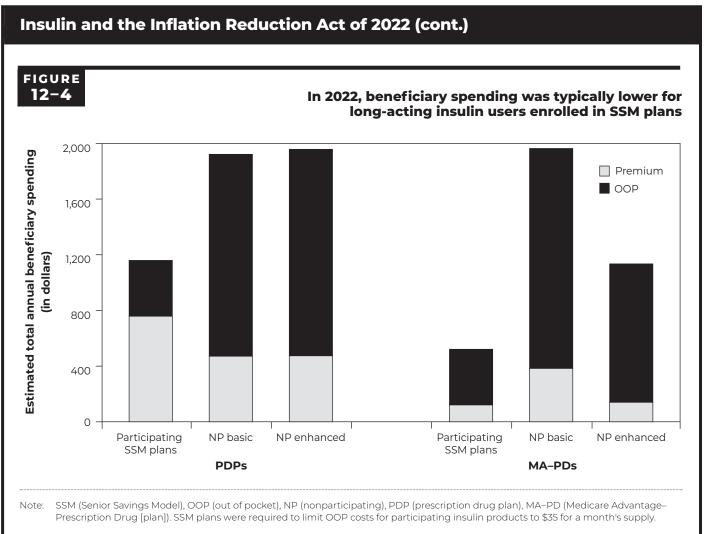
percent of those beneficiaries enrolled in Medicare Advantage–Prescription Drug plans (MA–PDs) (Medicare Payment Advisory Commission 2022a). When plans submitted their Part D bids for 2023, which occurred prior to the passage of the IRA, 2,617 plans had voluntarily chosen to participate. Plan participation has grown 60 percent since 2021, suggesting a continued increase in interest in this model.

An evaluation conducted after the first two years found that monthly enrollment-weighted premiums for MA–PD plans were similar (approximately \$1 to \$2 less per month) for participating plans compared with nonparticipating plans in each year (Taylor et al. 2022). Participating prescription drug plans (PDPs), on the other hand, had significantly higher premiums (ranging from \$28 to \$31 more per month) in the first two years, relative to nonparticipating PDPs. That said, participating MA–PDs and PDPs were both more likely than nonparticipants to offer no or reduced deductibles, and participating PDPs were more likely than nonparticipants to offer additional gap coverage.

After accounting for OOP spending, insulin users were expected to save money if they switched to a model-participating plan, even in PDPs with higher premiums, although average overall savings were significantly greater in MA–PDs (Figure 12-4) (Baig and Dusetzina 2022). This estimate was based on the premium, deductible, and cost–sharing amounts for participating and nonparticipating plans (weighted

(continued next page)

rebates paid by the manufacturer. Even when entries of multiple generic competitors result in substantially lower prices and plan sponsors adjust their formularies to prefer the generic version, beneficiaries can still pay relatively high OOP costs because the coverage-gap discount does not apply to generic drugs and because, unlike their brand counterparts, generic specialty drugs



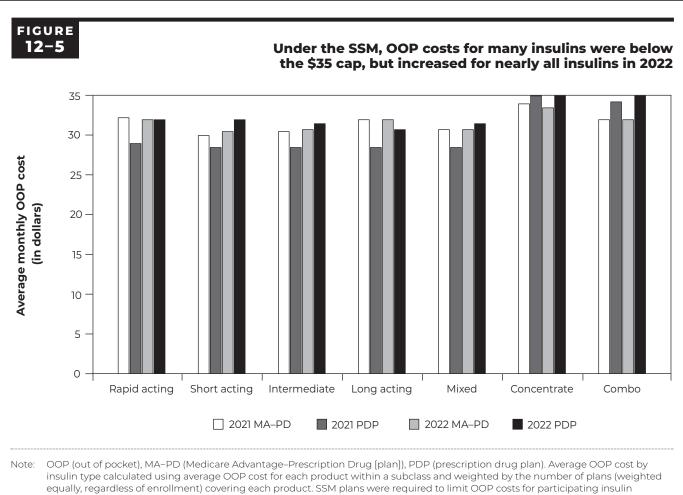
Source: MedPAC based on data from Baig and Dusetzina 2022.

by plan enrollment) and assumed 12 fills of a long-acting insulin pen (Lantus Solostar, Levemir FlexTouch, Basaglar KwikPen, or Tresiba FlexTouch), weighted by use of each product in 2020.

Participating and nonparticipating plans all covered a median of between 12 and 13 insulins (Taylor et al. 2022). Figure 12-5 (p. 410) shows the average OOP cost for model-covered insulin products. Some plans chose to cover additional insulin products, beyond those covered under the model, allowing additional choice for patients—though often at a higher cost. Plans covered more nonmodel products in 2022 than 2021 and charged higher prices for them: Average copayments for these products ranged from \$0 to \$80 in 2021 and \$42 to \$100 in 2022. MA–PDs were more likely to cover additional insulins than PDPs.

Plans were less likely to cover follow-on, biosimilar, and authorized generic insulins—which have lower list prices but may have similar net prices than their branded counterparts. For instance, Basaglar—a follow-on product—was covered by only one-third or fewer of participating plans in either year, while branded long-acting insulins were covered by 67 percent to 90 percent of plans (Taylor et al. 2022). Coverage for authorized generics ranged from 0 percent to 39 percent of participating plans.

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products to \$35 for a month's supply.

Source: MedPAC based on data from Taylor et al. 2022.

Semglee, the first official interchangeable biosimilar insulin, was covered by only 16 MA–PDs in 2022.

While insulin-dependent beneficiaries are likely to save money, a few other possible effects from this coverage change may be of interest to policymakers. First, providing an OOP cap for beneficiaries reduces pressure on manufacturers to keep prices low, at least for Part D enrollees. Second, the role of rebates may change under this model, though their use seems to continue through 2021 (the latest year for which direct and indirect remuneration data are available). Given rebates' typical use to negotiate preferential formulary status, which may not be as beneficial with OOP costs already limited, some analysts may have expected rebates to diminish under this model. The data, however, indicate rebates are still influential: Monthly OOP costs for many model insulins were below \$35, and coverage of brand-name products continues to be significantly higher than that of nonbranded insulins with lower list prices. Manufacturers, therefore, may continue to use rebates to ensure inclusion as a covered product, to help patients pay even lower OOP costs, or to avoid prior authorization requirements. are "less likely to be covered by patient-assistance programs that Medicare beneficiaries might have used" to lower their OOP costs (Dusetzina et al. 2020).

High cost sharing can result in beneficiaries not initiating therapy or abandoning prescriptions at the pharmacy (Doshi et al. 2018, Dusetzina et al. 2020).<sup>31</sup> One recent study of fee-for-service Medicare beneficiaries who were newly prescribed a specialty drug found that LIS enrollees were twice as likely to fill their prescription within 90 days than enrollees without the LIS (Dusetzina et al. 2022). The study found that patients did not fill their initial prescriptions for 30 percent of anticancer medicines, 22 percent of hepatitis C treatments, and 50 percent of diseasemodifying therapies for immune conditions and high cholesterol. For drugs on specialty tiers, beneficiaries have little recourse because they may not request a tiering exception to obtain the specialty-tier drugs at lower (preferred) cost sharing.<sup>32</sup> It is not possible to measure the full extent to which high prices impede access to needed medications. However, growth in the number of therapies that command very high prices is likely to raise the number of beneficiaries who face affordability issues (Dusetzina et al. 2020, Park and Look 2020).

### Beneficiary survey on satisfaction, costs, and plan choice

The Medicare Current Beneficiary Survey (MCBS) asks a nationally representative sample of the Medicare population about their health status, expenditures, and experience with the Medicare program. We examined the findings of the 2020 survey to assess beneficiaries' satisfaction with the Part D program, the costs they pay, and demographic information to better understand certain subpopulations of enrollees. In the 2020 MCBS, 79 percent of enrollees reported being satisfied with the Part D program (Table 12-6, p. 412).

While approximately 80 percent to 90 percent of enrollees reported satisfaction with the amount paid for their prescriptions, the drugs covered, and the pharmacies participating, enrollees were less satisfied with other aspects of the program. Just over half reported the program was easy to understand, two-thirds were satisfied with the information they received, and more than one-fourth reported not being confident their coverage met their needs. Despite some dissatisfaction, only 11 percent of enrollees reported comparing benefits among PDPs, and 6 percent compared the drug benefits of MA–PD plans (data not shown).

White enrollees were more likely than enrollees of other races to be satisfied with the program (81 percent vs. 73 percent to 77 percent) (Table 12-6, p. 412). Enrollees without the LIS were less likely to report having cost issues, and their satisfaction rate is 10 percentage points higher than the rate for LIS enrollees (82 percent vs. 72 percent). MA–PD enrollees were slightly more likely to be satisfied with the program than PDP enrollees (82 percent vs. 76 percent).

Overall, 83 percent of enrollees were satisfied with the amount they paid for prescriptions, which averaged \$617 annually, compared with an average of \$977 paid by those who reported being dissatisfied (data not shown).

As for drug coverage, only 60 percent of beneficiaries without a chronic condition were satisfied with coverage compared with 85 percent of those with a chronic condition. The average beneficiary payment of those satisfied with drug coverage was \$649 annually compared with \$902 for those dissatisfied with coverage.

Overall, 25 percent of enrollees reported an affordability issue, including 14 percent who did not take their medicine as prescribed because of cost.<sup>33</sup> Affordability issues were most prevalent among beneficiaries with incomes between 100 percent and 250 percent of the federal poverty level (FPL), with roughly one-third reporting a cost issue, compared with one-fifth of beneficiaries with higher incomes. Still, nearly a quarter of beneficiaries eligible for full LIS subsidies (with income of less than 100 percent FPL) reported having cost issues, suggesting that these subsidies help but do not fully eliminate affordability challenges. Affordability challenges can also be quite pronounced for those with disabilities. In the 2020 MCBS, 39 percent of respondents under age 65 (most of whom have qualified for Medicare because of a disability) reported an affordability challenge, and 27 percent did not take their medicine on time or as prescribed because of cost issues (Cubanski et al. 2016).<sup>34</sup>

Premiums have long been viewed as the main factor that beneficiaries consider when choosing their plan,

### Beneficiary satisfaction and affordability issues vary by subgroup, 2020

		Beneficiary experienced a	In choosing plan, be	beneficiary considered:		
	Overall satisfaction	cost-related access issue	Premium	Prescription cost		
Overall	79%	14%	26%	30%		
Race/ethnicity						
White	81	13	29	31		
Asian	77	18	24	29		
Black	73	18	21	31		
Hispanic	73	13	15	21		
Native American	75	27	15	26		
Multiple races	76	22	19	24		
LIS status						
Not receiving LIS	82	13	30	33		
Receiving LIS	72	17	13	21		
Plan type						
PDP	76	14*	23	23		
MA-PD	82	15*	31	39		

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). \*All figures here are statistically significant except those marked with an asterisk.

Source: Acumen analysis of Medicare Current Beneficiary Survey, 2020.

but the survey found that only 26 percent considered plan premiums, while 30 percent considered the cost they would pay for drugs (Table 12-6), and 32 percent considered the convenience of the pharmacy options available (latter data not shown). Individuals eligible for at least a partial LIS subsidy (having income at 150 percent of FPL or lower) were less likely to consider financial aspects (premium, deductible, OOP costs, or formulary coverage).

### Medication therapy management programs

Medicare requires each Part D plan sponsor to carry out MTM programs that focus on the quality of pharmaceutical care for high-risk beneficiaries by improving their therapeutic outcomes and reducing adverse drug events. CMS reviews and must approve a sponsor's description of its MTM program as part of the annual Part D bidding process. The programs target two categories of beneficiaries: (1) those who have multiple chronic conditions, take multiple medications, and are likely to have drug spending that exceeds an annual cost threshold (\$4,935 for 2023), and (2) those who are at risk for opioid misuse or abuse.

Plan sponsors are required to enroll, with optout provisions, all eligible enrollees in their MTM programs and report certain measures annually to CMS about all eligible beneficiaries. MTM programs must offer interventions—such as medication reviews, patient-directed education and counseling, and care coordination—for both beneficiaries and prescribers. At a minimum, the programs must provide enrolled beneficiaries with a comprehensive medication review (CMR) at least annually and a targeted medication review (TMR) at least quarterly for ongoing monitoring and follow-up of any medication-related issues.<sup>35</sup> CMS expects plan sponsors to have a process in place to measure and evaluate the outcomes of their interventions. Sponsors must also provide MTM program enrollees with information about the safe disposal of prescription drugs that are controlled substances.

For years, the Commission has had concerns about the effectiveness of MTM programs, particularly in standalone PDPs, which do not bear financial risk for medical spending like MA–PDs. In measures used for the 2023 star ratings (based on 2021 data), an average of just 53 percent of enrollees in PDP MTM programs received a comprehensive medication review, compared with an average of 83 percent in MA–PD MTM programs (Centers for Medicare & Medicaid Services 2022a). A study found that MTM was effective in MA–PDs operated by one plan when the program was targeted to resolve medication-related problems (MRPs); CMR, however, was not effective when the reviews were conducted for other eligible individuals with no MRPs (Ferries et al. 2019).

Over the period from 2017 to 2021, CMS tested an Enhanced MTM model to see if new payment incentives and regulatory flexibilities would spur standalone PDPs to improve their medication management interventions and reduce Medicare spending. Participating sponsors were allowed to set their own targeting criteria and tailor their MTM interventions to their enrollees.<sup>36</sup> CMS made prospective payments per beneficiary per month and performance-based payments to the sponsors to cover the estimated costs of their interventions. Six participating Part D sponsors operated 22 PDPs in 5 regions of the country over the 5-year period. In 2020, about 1.3 million enrollees in those plans were eligible for enhanced MTM services, and about 39 percent of those eligible received services (Acumen LLC 2021). Although an evaluation of the entire five-year demonstration is not yet complete, the evaluations of the first four years found no statistically significant effects on Medicare spending for Part A and Part B services, while plan payments under the model were larger than observable decreases in spending, resulting in net costs to Medicare of \$271 million thus far (Acumen LLC 2022). Measures of use of diabetes medications showed modest improvement, but measures of potentially unsafe medication use in the elderly did not improve.

### Endnotes

- 1 Even today, when the defined standard benefit has 25 percent coinsurance in both the initial coverage phase and coveragegap phase, many Part D plans structure their cost sharing differently across the two phases, charging copayments for generics and preferred drugs initially but charging 25 percent coinsurance in the coverage gap.
- 2 In 2023, individuals with the partial LIS pay a \$104 deductible and 15 percent coinsurance on prescriptions up to the OOP threshold. Above the OOP threshold, those LIS enrollees pay \$4.15 for each generic prescription and \$10.35 for brand prescriptions. (For more on the magnitude of cost sharing for partial LIS enrollees, see Dusetzina et al. 2021.) As a result of the Inflation Reduction Act of 2022, starting in 2024, beneficiaries who now receive the partial LIS subsidy will instead receive the full LIS subsidy.
- 3 For example, in 2023, generic tiers cannot have copayments that exceed \$20 per prescription or charge coinsurance of more than 25 percent in the benefit phase between the deductible and the initial coverage limit. Plans may not use copayments of more than \$100 or coinsurance higher than 50 percent for drugs on nonpreferred tiers.
- 4 In 2024, eligibility requirements for full LIS benefits will expand. As a result, nearly 300,000 beneficiaries who currently receive partial benefits and pay higher cost sharing will become eligible to pay lower cost sharing.
- 5 Under the IRA, Part D will eliminate cost sharing above Part D's OOP threshold in 2024 and then, in 2025, lower that threshold from current-law levels to \$2,000. Each year thereafter, CMS will increase that threshold by the annual change in per capita drug spending.
- 6 Drugs selected for price negotiation will not be subject to the manufacturer discount. For LIS beneficiaries and for certain smaller manufacturers, the new manufacturer discount program will be phased in over time, reaching final levels by 2031.
- 7 The Commission also recommended that plans be allowed to establish preferred and nonpreferred tiers for specialtytier drugs to encourage their enrollees to use lower-priced therapies. CMS began permitting sponsors to use two specialty tiers in 2022, but so far only a handful of plans do so.
- 8 EGWPs are sponsored by employers that contract directly with CMS or EGWPs are sponsored on a group basis with an insurer or pharmacy benefit manager to administer the Part D benefit. They differ from employer plans that receive the

RDS in that Medicare Part D is the primary payer rather than the employer.

- 9 A portion of the difference between an MA plan's payment benchmark and its bid for providing Part A and Part B services is referred to as "MA rebate dollars." Plan sponsors can use MA rebate dollars to supplement benefits or lower Part D or MA premiums. In 2022, MA-PD sponsors applied on average more than \$47 per month (28 percent) of their Part C rebate dollars to Part D benefits. Of that amount, 46 percent was used to lower Part D premiums for basic benefits and the rest was used for supplemental drug benefits.
- 10 As with the income-related premium for Part B, higher Part D premiums apply to individuals with an annual adjusted gross income greater than \$97,000 and to couples with an adjusted gross income greater than \$194,000. A beneficiary whose income exceeds these levels pays a monthly adjustment amount in addition to their Part D plan premium. For 2023, adjustments range from \$12.20 to \$76.40 per month, depending on income.
- 11 The LEP amount depends on the length of time an individual goes without coverage as generous as Part D and is calculated by multiplying 1 percent of the base beneficiary premium by the number of full, uncovered months an individual was eligible but was not enrolled in a Part D plan and went without other creditable coverage.
- 12 Most MA plans are MA–PDs, offering combined medical and outpatient drug benefits. However, a small share of MA plans (including Medicare Savings Account plans) do not offer prescription drug coverage.
- 13 The five sponsors are UnitedHealth, Cigna, Humana, Aetna (owned by CVS Health), and Centene. Other sponsors of nationally or near-nationally marketed PDPs (Elixir and Clear Spring Health) offer one basic and one enhanced plan in a region. Mutual of Omaha operates in 33 of 34 Part D regions and has expanded its offerings in 2023 to include a second enhanced plan in addition to its basic and existing enhanced plan. While it also segments its enrollees, Mutual of Omaha has premiums for its basic plans that are typically higher than either of its enhanced plans, and none of its basic premiums fall below LIS benchmarks.
- 14 Most of the 50 organizations operate both PDPs and MA-PDs.About 20 of those 50 sponsors offer PDPs that are available only to employer groups.

- 15 Some vertically integrated PBMs operate exclusively for the plan sponsor that owns them. Humana Pharmacy Solutions (Humana), IngenioRx (Anthem/Elevance), and Kaiser Pharmacy (Kaiser) are examples. Other PBMs serve the sponsor that owns them as well as other clients, e.g., CVS/ Caremark (CVS Health), OptumRx (UnitedHealth Group), and Express Scripts (Cigna) (Guardado 2022).
- 16 The Commission's calculation is based on Part D prescription drug event and direct and indirect remuneration data from CMS.
- 17 Among plans that have them in 2023, preferred pharmacies make up an average of 37 percent, 46 percent, and 48 percent of all PDP, general MA–PD, and SNP network pharmacies, respectively.
- 18 Examples include incentive bonuses (such as bonuses that encourage generic dispensing), fees that are assessed on other measures such as medication adherence that are set by the sponsor or its PBM, or other contingent amounts that cannot reasonably be determined at the point of sale.
- 19 The Commission's calculation is based on Part D prescription drug event and direct and indirect remuneration data from CMS.
- 20 The policy does not apply to manufacturer rebates.
- 21 CMS requires Part D plan sponsors to report PBM-negotiated rebates so that Medicare can appropriately pay the program's share of net-of-rebate drug spending rather than listprice spending. However, postsale rebates and discounts received by PBM subsidiaries such as mail-order and specialty pharmacies are not reported (Medicare Payment Advisory Commission 2017). In interviews conducted for the Commission, PBM auditors and consultants voiced concerns that there is less visibility into the transfer prices that PBMs pay to their mail-order and specialty pharmacies, which affects what payers are subsequently charged (Hargrave 2017). PBMs noted that they have corporate firewalls to keep transactions between subsidiaries at arm's length. However, information firewalls are difficult to enforce.
- 22 In reconciliation data for 2021, just over 50 percent of Part D plans received risk-corridor payments from Medicare, indicating their bids were lower than actual benefit costs.
- 23 An individual NDC uniquely identifies the drug, its labeler, dosage form, strength, and package size.
- 24 For this index, Acumen groups NDCs that are pharmaceutically identical, aggregating prices across drug trade names, manufacturers, and package sizes. As a result,

brand-name drugs are grouped with their generics if they exist, and this price index more closely reflects the degree to which market share has moved between the two.

- 25 Calculated from information in CMS's announcement of the 2023 Part D national average monthly bid amount and base beneficiary premium (Centers for Medicare & Medicaid Services 2022c).
- 26 Authorized generics are produced by the same manufacturer as the branded version or by another manufacturer with the approval of the maker of the branded version. Some competing insulin products were produced by other manufacturers but are referred to as "follow-on" products rather than biosimilars. While the biosimilar approval pathway was created in 2010 following passage of the Biologics Price Competition and Innovation Act (included in the Affordable Care Act of 2010), biosimilar insulin products were unable to use this pathway until March 2020.
- 27 The Food and Drug Administration can require additional information from a biosimilar manufacturer to provide evidence that switching between an originator product and the biosimilar is safe and effective, in order to be approved as interchangeable.
- 28 The Affordable Care Act of 2010 required Medicare to temporarily apply slower growth rates to the OOP threshold between 2014 and 2019. However, for 2020 and thereafter, the OOP threshold reverted to the levels that would have been in place had the slower growth rates never applied.
- 29 The transition fill is a temporary one-month supply provided within the first 90 days of coverage in a new plan or the new contract year for existing enrollees.
- 30 Plan sponsors must make coverage determination and exception decisions within 72 hours of a request or within 24 hours for expedited requests. If the initial request for an exception does not include the necessary supporting statement, the plan has up to 14 calendar days to obtain the information. See our March 2020 report to the Congress for more details (Medicare Payment Advisory Commission 2020b).
- 31 The relationship between higher cost sharing and adherence, treatment initiation, or the rate of prescription abandonment is likely to vary widely across therapeutic classes. For example, patients may be less sensitive to higher cost sharing for certain cancer treatments compared with therapies for chronic conditions such as rheumatoid arthritis (Medicare Payment Advisory Commission 2019b).

- 32 Part D enrollees can apply to bona fide independent charity patient assistance programs (PAPs) for help with cost sharing. Pharmaceutical manufacturers can provide cash donations to independent charity PAPs without invoking anti-kickback concerns if the charity is structured properly. However, recent enforcement actions regarding manufacturer donations to charities suggest that some PAPs are in violation of the anti-kickback statute (Office of Inspector General 2018, Sagonowsky 2017).
- 33 We assessed the number of people who experienced affordability issues by examining the number who reported doing any of the following because of cost: delaying filling or not getting a prescription, skipping or taking smaller doses, using a credit card in order to pay over time, asking for their doctor's approval to stop taking a medicine, spending less to save for a prescription, or not using coverage because the cost was too high.
- 34 Among enrollees 65 and older, depending on age bracket, between 19 percent and 23 percent reported any affordability challenge and 8 percent to 13 percent did not take a medicine as prescribed because of cost issues.

- 35 CMRs must include a person-to-person or telehealth consultation performed by a pharmacist or other qualified provider and a written summary of the review that includes a medication list and action plan, if any, provided to beneficiaries in CMS's standardized format. A TMR is distinct from a CMR because it is focused on specific medication-related problems, actual or potential. A TMR can be conducted person to person or be system generated, and details of interventions can be delivered by mail or faxed to the beneficiary or the prescriber, as appropriate (Centers for Medicare & Medicaid Services 2021).
- 36 For example, a sponsor might choose to provide more counseling services on medication adherence and devote fewer resources to CMRs.

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