CHAPTER 11

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

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Chapter summary

In 2023, Part D paid for outpatient prescription drug coverage on behalf of more than 51 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 nearly 14 million beneficiaries with low income and assets.

In 2022, Part D expenditures totaled $117.3 billion. Of that amount, Medicare paid $101.3 billion in subsidies for basic benefit costs and extra help for LIS enrollees and $0.6 billion in retiree drug subsidies, and enrollees paid $15.4 billion in premiums for basic benefits. Medicare spending for the LIS totaled $39.7 billion: $35.2 billion for cost sharing and $4.5 billion for premiums. In addition, Part D plan enrollees paid $18.5 billion in cost sharing and $9.9 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 have taken the form of cost-based reimbursements to plans through

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Medicare's reinsurance and LIS. As a result, the financial risk that plans bear, as well as their 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 Budget Reconciliation Act of 2022, 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 reforms to Part D's benefit structure have begun to be implemented, with more changes coming over the next several years.

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 gaining market share over competing drugs. Historically, most plan sponsors also used provisions in network contracts with pharmacies that required postsale recoupments or payments for meeting performance metrics. Beginning this year, however, sponsors may no longer recoup payments from pharmacies after the point of sale. Rebates and pharmacy fees have grown as a share of Part D spending, but these legislative and regulatory changes may affect their magnitude.

Enrollment in 2023 and benefit offerings for 2024—In 2023, 78 percent of Medicare beneficiaries were enrolled in Part D plans. An additional 1 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 about 11 percent had no coverage or coverage less generous than Part D.

Enrollment in stand-alone prescription drug plans (PDPs) peaked in absolute terms in 2019 at 25.5 million (56 percent of total plan enrollment) but declined to 22.5 million by 2023 (44 percent). Enrollment in Medicare Advantage–Prescription Drug plans (MA–PDs) surpassed enrollment in PDPs for the first time in 2021 and reached 29.1 million in 2023. Since 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. Since 2020, LIS enrollees have comprised 27 percent of total enrollment, and in 2022 they accounted for 46 percent of gross program spending.

For 2024, beneficiaries continue to have a broad choice of plans. Plan sponsors offered 3,507 general MA–PDs and 1,306 MA–PDs tailored to specific populations (special needs plans, or SNPs)—a slight decline in general MA–PDs and 4 percent more SNPs than in 2023. In 2024, plan sponsors are offering 709 PDPs, the fewest since the program began.

The base beneficiary premium (BBP) increased to $34.70 in 2024. A recent legislative change capped the annual increase in the BBP at 6 percent, so the increase this year was less than the 20 percent increase that would have otherwise been incurred. While this cap is intended to protect beneficiaries from bearing the full cost of plan sponsors' increased liability under the new benefit design, cost increases beyond 6 percent will be borne by the Medicare program. Further, although the increase in the BBP was capped, individual plans' premiums still vary substantially, with PDPs typically having higher premiums than MA–PDs. In 2024, 126 PDPs, roughly one-sixth of all PDPs, are available premium free to enrollees who receive the LIS, compared with one-fourth of all PDPs last year. This drop in benchmark plans has left 8 regions out of 34 with just 2 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.

Part D program spending—In 2022, Medicare program spending on Part D (excluding the $15.4 billion in premiums paid by enrollees) totaled $101.9 billion, up from about $95 billion in 2021. That amount includes the monthly capitated payment Medicare pays Part D plans for each Part D enrollee (the "direct subsidy"); the reinsurance amount that Medicare pays plans, which covers 80 percent of costs for those enrollees who reach the benefit's catastrophic phase; the LIS; and the retiree drug subsidy. Reinsurance continued to be the largest and fastest-growing component of program spending, totaling $56.8 billion, or about 56 percent of the total. Medicare's monthly direct subsidy payments have fallen in recent years, as reinsurance payments soared, shifting the financial risk from Part D plans to the Medicare program. In 2023, direct subsidy payments averaged $2 per member per month, while cost-based reinsurance payments averaged about $94 per member per month. However, in 2024, as a result of legislative and regulatory changes, we see a reversal in the

trend toward higher reinsurance payments: Direct subsidy payments increased to an average of nearly $30 per member per month, while average reinsurance payments are expected to decline to about $90 per member per month.

In 2022, drug list prices continued to rise, approaching rates observed before the pandemic. Decreasing prices of generic drugs continued to 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 prices upward. Going forward, meaningful savings for biologics will depend largely on the successful launch and adoption of biosimilars by prescribers and beneficiaries. In 2022, about 482,000 enrollees filled a prescription that, by itself, was sufficiently expensive to reach the catastrophic phase of the benefit, up from just 33,000 enrollees in 2010.

Beneficiary access and quality in Part D—Surveys suggest high overall satisfaction with Medicare Part D. At the same time, focus groups show that both prescribers and beneficiaries are acutely aware of high drug costs. Among beneficiaries without the LIS, high cost sharing for expensive therapies can be a barrier to access. However, the redesigned benefit now places an annual limit on beneficiaries' cost sharing. As a result, going forward, beneficiaries are less likely to face cost-related access issues.

Medicare beneficiaries take an average of nearly five prescription drugs per month and are at higher risk for adverse drug events associated with polypharmacy. By law, Part D plans are required to carry out medication therapy management (MTM) programs and programs to manage opioid use. For years, the Commission has had concerns about the effectiveness of MTM programs, particularly among stand-alone PDPs, which do not bear financial risk for medical spending. A recent evaluation of a CMS demonstration testing an enhanced MTM model found that new payment incentives and regulatory flexibilities surrounding MTM failed to promote better health outcomes for beneficiaries. In addition, the demonstration yielded no significant reductions in Medicare spending for Part A and Part B services, with a net increase in Medicare spending after accounting for model payments. ■

Background

In 2023, 51.5 million Medicare beneficiaries enrolled in the Part D program for outpatient prescription drug coverage. Private Part D plans are available broadly: Dozens of stand-alone 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 13.8 million individuals with low income and assets. In 2022, Part D expenditures totaled $117.3 billion on an incurred basis (Boards of Trustees 2023). Of that amount, Medicare paid $101.3 billion in subsidies for basic benefit costs and extra help for LIS enrollees. Part D enrollees paid $15.4 billion in premiums for basic benefits. Medicare spending for the LIS totaled $39.7 billion: $35.2 billion for cost sharing and $4.5 billion for premiums. In addition, enrollees paid $18.5 billion in cost sharing and $9.9 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, rather than paying directly for prescription drugs. 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, typically on differential cost-sharing 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 brand-name drugs on the plan's formulary, potentially on a preferred (lower) cost-sharing tier, in return for postsale rebates.

The costs of providing Part D benefits are shared by Medicare (taxpayers) and its enrollees. Medicare pays 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.
- ***Reinsurance***—Reimbursement to plans for 80 percent of drug spending (net of all rebates and discounts) above an enrollee's annual out-of-pocket (OOP) threshold (the catastrophic phase of the benefit).

Combined, the direct subsidy and expected reinsurance payments aim to cover 74.5 percent of the expected cost of basic benefits. 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, nominal cost-sharing amounts set in law. Medicare pays all remaining cost sharing and premiums to the plans on behalf of enrollees who are eligible for the LIS.

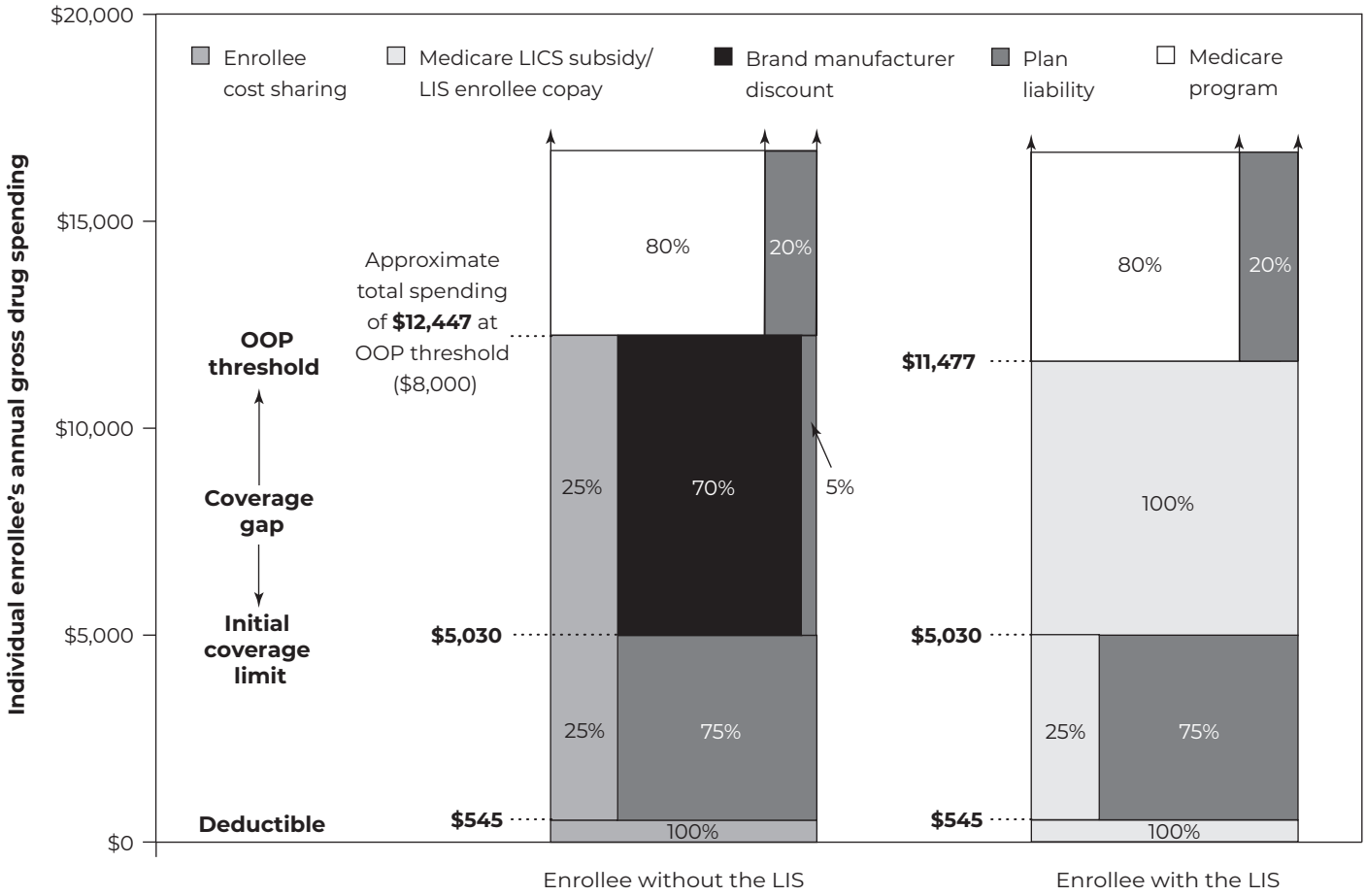
Benefit design

Medicare law defines a standard Part D basic benefit, but in practice, plan sponsors offer alternative benefit designs with equivalent or more generous coverage. Historical changes in law have altered the design of the standard benefit for most Part D enrollees, but those changes did not apply to beneficiaries 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. 324–326).

For Part D enrollees without the LIS (73 percent in 2023), Part D's defined standard benefit includes a deductible where beneficiaries pay 100 percent of costs until it is met. Next, in the initial coverage phase, beneficiaries are responsible for 25 percent of drug spending until reaching the initial coverage limit. Finally, in the so-called coverage gap, beneficiaries continue to pay 25 percent cost sharing until reaching an OOP threshold (Figure 11-1, p. 322). Each year, the standard benefit's parameters change at the same rate as the annual change in beneficiaries' average drug expenses. For 2024, the deductible in Part D's standard benefit is $545, the initial coverage limit is $5,030, and the OOP threshold is $8,000 (Centers for Medicare & Medicaid Services 2023a). That threshold is based

FIGURE 11–1

Final year with two distinct benefit structures (without and with the LIS), 2024



Note: LIS (low-income subsidy), LICS (low-income cost sharing), OOP (out-of-pocket). This infographic depicts the defined standard benefit design, though most plans use an alternative benefit design that is actuarially equivalent to the defined standard benefit, such as using fixed-dollar copays instead of the 25 percent coinsurance. The coverage gap for enrollees without the LIS is depicted as it would apply to brand-name drugs, which are eligible for a 70 percent manufacturer discount in the coverage gap. There is no manufacturer discount for generic prescriptions, and thus cost sharing in the coverage gap is 25 percent and plans are responsible for 75 percent. Because of this difference, total covered drug spending at the OOP threshold depends on the mix of brand and generic prescriptions each individual fills while in the coverage gap. The dollar amount shown ($12,447) 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.

Source: MedPAC depiction of Part D benefit structure for 2024.

on "true OOP" costs. True OOP spending 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 70 percent discount that manufacturers of brand-name drugs must pay in the phase of the benefit called the coverage gap, described in Figure 11-1.[1]

The coverage gap, or donut hole, has effectively been closed and plans now provide some coverage after the initial coverage limit is reached. Plans continue to identify whether a prescription is filled in that phase because enrollees without the LIS are eligible for a 70 percent discount from manufacturers on brand-name prescriptions filled in the coverage gap.[2] No discount is

applied to prescriptions for generic drugs or for brand-name prescriptions filled by LIS enrollees. In 2024, brand discounts begin when an enrollee without the LIS has reached $5,030 in cumulative drug spending, and the discounts continue until the individual reaches $8,000 in combined OOP spending plus brand discounts (equivalent to $12,447 in total gross drug spending, on average). Above this OOP threshold, enrollees no longer pay any cost sharing for the first time since the Part D program was created; as a result of changes made by the Budget Reconciliation Act of 2022 (BRA), plans are now responsible for the additional 5 percent of costs previously paid by enrollees.

For low-income beneficiaries, Medicare's LIS pays the difference between cost-sharing amounts set by each plan and nominal copayments set by law (Figure 11-1). In 2024, individuals receiving the LIS pay between $0 and $4.50 per prescription for generics and between $0 and $11.20 per prescription for brand-name drugs. (Previously, a small share of LIS enrollees with slightly higher levels of income or assets received a partial subsidy; beginning in 2024, all beneficiaries who previously would have been eligible for a full or partial LIS will receive full subsidy benefits.) If, for example, a plan normally charges a $40 copayment to fill a brand prescription, an LIS enrollee would pay up to $11.20 and Medicare's LIS would pay $28.80. Because 100 percent of the costs in the coverage gap count toward the OOP threshold for LIS beneficiaries, they reach the catastrophic phase at a lower level of spending than other enrollees. (The coverage gap will be eliminated for LIS beneficiaries beginning in 2025, when a single benefit structure will apply to all enrollees. For more detail, see the text box, pp. 324–326, that gives an update on the implementation of recent Part D–related changes.) Above the OOP threshold, LIS enrollees have never paid cost sharing; Medicare's low-income cost-sharing (LICS) subsidy paid the 5 percent coinsurance they would owe if they did not receive the LIS. Beginning in 2024, no beneficiaries pay cost sharing above the OOP threshold. Since these costs had been covered for LIS enrollees by the low-income cost-sharing subsidy, this change has reduced Medicare's expense and increased plans' liability.

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 $545 or using tiered copayments rather than coinsurance.[3] Some plans encourage use of lower-cost medicines by not applying a deductible when a prescription is filled with certain preferred generics. However, sponsors must demonstrate that alternative designs 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 2023e).[4] 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.

Some plan sponsors have taken the opportunity to offer enhanced plans to employ a strategy of segmenting the market such that they offer one basic plan geared toward LIS enrollees and two "enhanced" plans for non-LIS enrollees (Medicare Payment Advisory Commission 2022b). One of these enhanced plans may have a premium that is lower than the basic plan, intended to attract enrollees who expect to have limited drug costs. A second, higher-premium enhanced plan targets beneficiaries who expect to have higher drug costs.

Segmenting the market may make PDPs more profitable than would otherwise be the case. Sponsors want to maximize the revenues they receive for each LIS enrollee, which is easier to do when enrollees with and without the LIS are segmented into separate plans. For beneficiaries, the implications of a segmented market are mixed. Enrollees who do not receive the LIS may benefit from having access to low-premium plans. At the same time, segmentation may make it difficult for beneficiaries to understand the different plan options. For the Medicare program, segmentation likely increases Part D spending because it allows sponsors to charge higher premiums for plans that serve LIS beneficiaries (Medicare Payment Advisory Commission 2022b).

The Commission's Part D recommendations and the Budget Reconciliation Act of 2022

The Commission has long been concerned that changes to Part D's benefit design combined with trends in prescription drug pricing and spending have weakened

Update on implementation of the Part D–related provisions in the Budget Reconciliation Act of 2022

Numerous Part D–related provisions of the Budget Reconciliation Act of 2022 (BRA) are already taking effect. Since October 2022, manufacturers of drugs sold to Medicare beneficiaries face financial penalties if the price of their drug rises faster than inflation. Part D plans are now required to provide 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 of all insulin products included on a plan's formulary.[5] Beneficiaries with income between 135 percent and 150 percent of the federal poverty level are now eligible for full low-income subsidies rather than a partial subsidy. For the first time this year, beneficiaries will have no out-of-pocket (OOP) obligations once they reach the

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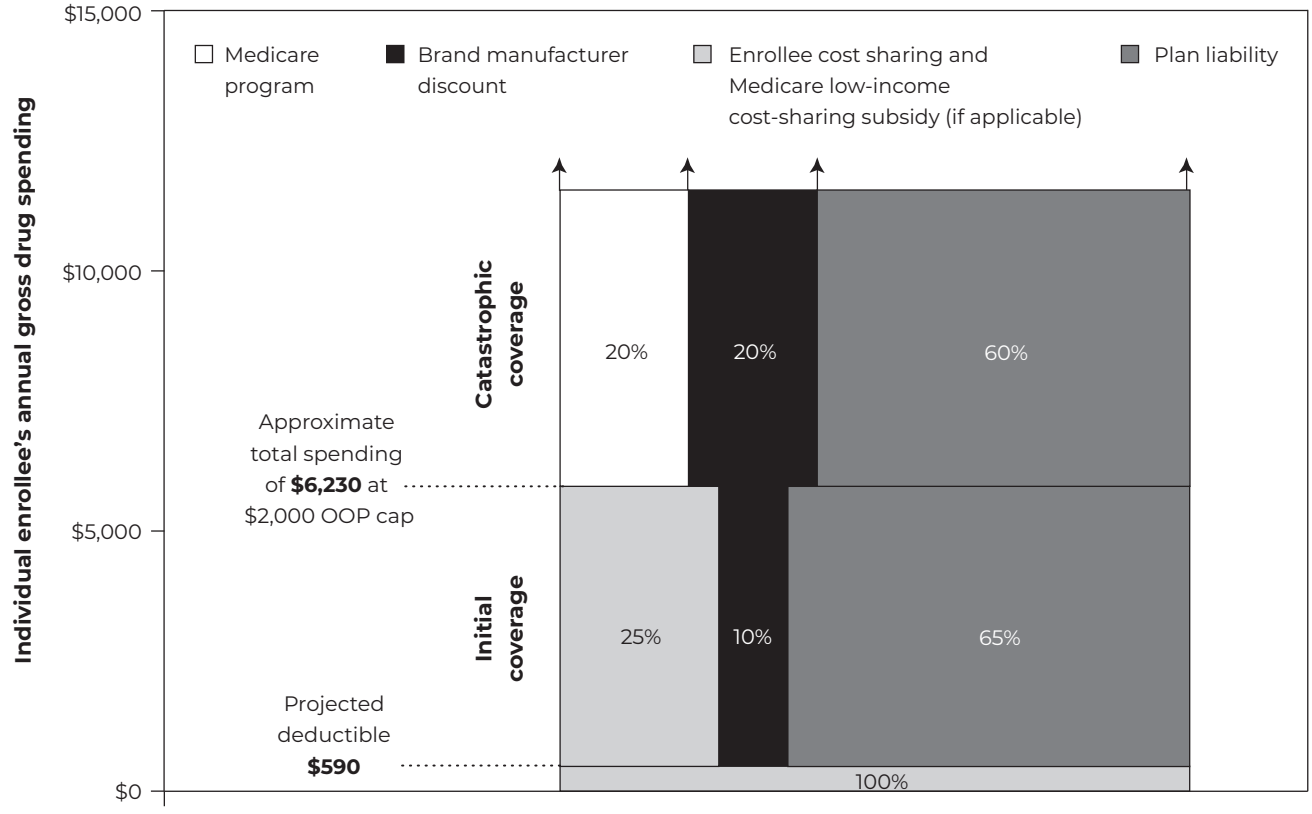
FIGURE 11–2

Redesigned benefit structure for all Part D enrollees, effective in 2025



Note: OOP (out-of-pocket). Figure depicts the restructured defined standard benefit as it would apply to brand-name drugs and biologics. For generic drugs, plan sponsors must cover 75 percent of enrollee spending between the deductible and OOP cap, and Medicare's reinsurance will pay for 40 percent of spending in the catastrophic region.

Source: MedPAC depiction of redesigned Part D benefit structure resulting from changes made by the Budget Reconciliation Act of 2022.

Update on implementation of the Part D–related provisions in the Budget Reconciliation Act of 2022 (cont.)

catastrophic phase of the benefit. Last, the Secretary of Health and Human Services has begun to exercise its new authority to negotiate prices for select drugs under the Medicare Drug Negotiation Program.[6] The 10 drugs that will first be subject to price negotiation were announced on September 1, 2023, though the resulting prices for these products will not be effective until 2026. If a manufacturer declines to participate in the Negotiation Program, it must either pay an excise tax of up to 1,900 percent on certain sales of the drug or withdraw entirely from the Medicare and Medicaid programs (Congressional Research Service 2023).[7]

The Budget Reconciliation Act of 2022 also changed Part D's benefit structure to fundamentally alter the incentives for plan sponsors. The redesigned structure has many similarities to the Commission's 2020 recommendations for the program (Medicare Payment Advisory Commission 2020a). Starting next year, a single benefit design will apply to all enrollees, whether or not they receive the low-income subsidy (LIS). The benefit will also be simplified with fewer benefit phases: After reaching their deductible, enrollees will pay 25 percent coinsurance until reaching $2,000 in OOP spending (Figure 11-2). The redesigned benefit caps enrollee OOP spending thereafter. Additionally, plan sponsors will be required to offer their enrollees the option to smooth cost-sharing payments over the benefit year (Centers for Medicare & Medicaid Services 2023g).

The current coverage-gap discount will be 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 (for spending above the deductible) and by 20 percent above it.[8] The manufacturer discount will no longer count toward the OOP threshold, which will slow beneficiaries' progression to the catastrophic phase. Medicare's reinsurance will be reduced from 80 percent to 20 percent of prescription spending for brand-name drugs above the OOP cap. At the same time, Medicare's overall 74.5 percent subsidy of basic benefits will remain unchanged (unless required to increase to accommodate the 6 percent cap on annual premium increases), with much more of it taking the form of capitated rather than cost-based payments. In 2024, because this cap is binding, Medicare's subsidy is expected to exceed the statutorily set amount (see text box on p. 339 for more detail).

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.

The changes adopted in the BRA are likely to alter the program's incentives, as well as revenues of the pharmaceutical manufacturers directly or indirectly affected by those provisions. While some provisions (such as the $2,000 cap on OOP spending) could increase revenues for some manufacturers by improving Part D enrollees' access to medications, much of the focus has been on the potential negative effects of the BRA changes on biopharmaceutical research and development (R&D). To the extent that the Negotiation Program results in manufacturer revenues that are lower than they otherwise would have been, there may be negative effects on biopharmaceutical innovation. However, estimates of possible effects have varied widely. For example, the Congressional Budget Office estimated that, as a result of the BRA, one less drug would be introduced to the U.S. market from 2023 to 2032 (Congressional Budget Office 2022). Other studies estimated significantly greater impact, with one estimating more than 100 fewer drugs coming to market in the next 10 years (Avalere 2022, Gassull et al. 2023, Philipson et al. 2023). As we discussed in our previous reports to the Congress, the price that Medicare and other entities pay for drugs is just one of many factors that influence investment in biopharmaceutical R&D (Medicare Payment Advisory

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Update on implementation of the Part D–related provisions in the Budget Reconciliation Act of 2022 (cont.)

Commission 2023b, Medicare Payment Advisory Commission 2022b).[9] There are also uncertainties related to the implementation of the BRA, including certain aspects of the Negotiation Program.[10] As a result, it may be challenging to measure with any certainty the effects on R&D specifically attributable to the Negotiation Program. In the near term, recent commentary suggests that the Negotiation Program's impact on biopharmaceutical R&D so far has been more moderate than anticipated by some stakeholders. For instance, after the selection of the first 10 drugs, one analysis noted that "the overall financial impact of the price negotiations . . . will be modest for the pharmaceutical industry" (Moody's Investors Service 2023). A report monitoring earnings calls of pharmaceutical companies in the first half of 2023 stated that "few actions by large biopharma companies can be directly linked to the [BRA]" (ATI Advisory 2023).

The Commission has often stressed the importance of promoting price competition and balancing a drug's net clinical benefit with an appropriate reward for innovation and affordability for beneficiaries and taxpayers (Medicare Payment Advisory Commission 2023b, Medicare Payment Advisory Commission 2022b, Medicare Payment Advisory Commission 2017b). The Commission will continue to monitor the many changes, keeping in mind both the need for beneficiary access to drug treatments and for program efficiency. ■

plan sponsors' incentives for cost control (Medicare Payment Advisory Commission 2022c, Medicare Payment Advisory Commission 2021, Medicare Payment Advisory Commission 2020a, Medicare Payment Advisory Commission 2016). Between 2007 and 2022, plan sponsors' overall financial risk for the basic benefit spending of their enrollees declined markedly, from 75 percent to 30 percent.

The Commission has also voiced concerns about enrollee cost sharing under Part D. Because beneficiaries historically have paid an unlimited amount of cost sharing in the catastrophic phase, a small but significant share of enrollees had high OOP spending that could pose a financial burden and hinder adherence to treatment. At the same time, limits on cost sharing for LIS enrollees have blunted their incentives to use lower-cost drugs and make it more difficult for plan sponsors to manage program spending.

In 2020, the Commission recommended major changes to the Part D program that would restructure its defined standard benefit and restore stronger financial incentives for plan sponsors and beneficiaries to use lower-cost medicines (Medicare Payment Advisory Commission 2020a). The Commission has consistently held that when plan sponsors must bear more insurance risk, they should also be given tools to manage enrollee spending.[11] Subsequently, the BRA included a redesign of the Part D benefit that reflects many of the Commission's recommendations (see text box for more details on this and other Part D–related provisions in the Budget Reconciliation Act, pp. 324–326).[12]

The upcoming changes to the Part D benefit design should provide stronger incentives for plan sponsors to manage prescription drug benefits in ways that are more consistent with the incentives present at the start of the program. The restructured benefit design will result in higher capitated payments from Medicare to plans, with payments for LIS beneficiaries being most affected. 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.

Carrying out Part D's benefit redesign and other changes mandated by the BRA 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. Setting an OOP cap will increase the generosity of the Part D benefit, which may affect patients' decisions regarding which drugs to take: Patients may be more likely to fill their prescriptions, and they may be less incentivized to take generic or biosimilar medicines. Changes in patient and prescribing behavior, along with other recent legislative changes, may alter the types of drugs that manufacturers choose to develop. Changes to enrollees' access to drugs may also differ depending on how CMS carries out the policy of notifying enrollees that they have the option to smooth their cost-sharing expenses over the year.

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.

Share of Medicare beneficiaries enrolling in Part D continues to grow

In 2023, 51.5 million individuals—about 78 percent of Medicare's total enrollment—were enrolled in Part D plans (Table 11-1, p. 328). Another 1 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. About 11 percent had no coverage or coverage less generous than Part D (data not shown).[13]

The distribution of Part D enrollment has moved gradually toward MA–PDs, both those that are 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 2023, about 22.5 million Part D enrollees (less than 44 percent) were in stand-alone PDPs (Table 11-1, p. 328). This shift toward MA–PDs is consistent generally with more rapid growth in MA enrollment compared with traditional fee-for-service (FFS) Medicare. Between 2019 and 2023, enrollment in MA–PDs grew an average of 10 percent annually compared with a 3 percent decline in PDPs.

Membership in employer group waiver plans (EGWPs)—Part D plans established for Medicare-eligible retirees of certain employers—totaled 7.6 million in 2023 (data not shown).[14] 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 3.6 million in 2023, while enrollment in PDP EGWPs has declined modestly over the past two years. Still, at 4.0 million, enrollment in PDP EGWPs was higher than that of MA–PDs in 2023.

In 2023, 13.8 million beneficiaries (27 percent of Part D enrollees) received the full LIS. Of these individuals, 9.1 million were eligible for both Medicare and full Medicaid benefits (Boards of Trustees 2023).[15] Compared with other enrollees, LIS enrollees are more likely to be female; nearly three times as likely to be either African American or Hispanic; and six times more likely to be under age 65 (Medicare Payment Advisory Commission 2023a).

Between 2019 and 2023, LIS enrollment grew at an average of just over 2 percent per year, slightly below the enrollment growth for other enrollees, but the share of Part D enrollees who received the LIS remained at 27 percent. In 2023, 63 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, climbing 12 percent per year, on average, between 2019 and 2023, while LIS enrollment in PDPs has declined. LIS enrollment in SNPs has grown particularly rapidly (data not shown).

TABLE 11–1

Enrollment shift toward MA–PDs maintained momentum, particularly among LIS beneficiaries

	2019	2020	2021	2022	2023	Average annual change 2019–2023
Total Medicare enrollment (in millions)	**61.5**	**62.9**	**63.8**	**65.0**	**66.3**	**1.9%**
Total enrollment in Part D plans (in millions)	**45.4**	**47.0**	**48.3**	**49.8**	**51.5**	**3.2**
As a share of total Medicare enrollment	*74%*	*75%*	*76%*	*77%*	*78%*	*N/A*
Part D plan enrollment by plan type (in millions)						
PDP	25.5	25.1	24.0	23.3	22.5	–3.1
MA–PD	20.0	21.9	24.3	26.5	29.1	9.9
Full LIS enrollment (in millions)						
PDP	7.3	6.7	6.0	5.5	5.2	–8.3
MA–PD	5.4	6.1	6.8	7.7	8.6	12.4
Overall	12.7	12.8	12.8	13.3	13.8	2.1

Note: MA–PD (Medicare Advantage–Prescription Drug [plan]), LIS (low-income subsidy), PDP (prescription drug plan). Part D enrollment figures do not include beneficiaries in employer-sponsored plans that receive the retiree drug subsidy but do include enrollees in employer group waiver plans. In addition to beneficiaries who receive full LIS assistance, a small number receive partial assistance (0.2 million in 2023). Totals may not sum due to rounding.

Source: MedPAC analysis based on the 2023 Medicare Trustees' report and CMS Part D enrollment data as of April 1, 2023.

Majority of enrollees choose enhanced plans

Most enrollees are in plans that are actuarially equivalent to Part D's standard benefit or are enhanced in some way rather than in plans that follow the defined standard benefit. For example, an enhanced plan may wrap around a beneficiary's Part D plan benefit by lowering or eliminating the deductible or providing more generous coverage in the coverage gap.

Because 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, enrollees in MA–PDs tend to have more generous benefits than enrollees in PDPs.[16] Indeed, 99 percent of enrollees in regular (non-SNP) MA–PDs were in enhanced plans in 2023 (Table 11-2). By contrast, 58 percent of PDP enrollees chose enhanced plans in 2023, up from 54 percent in 2022 (2022 data not shown). Typically, enhanced plans reduce or eliminate the deductible used in the defined standard benefit. Among general MA–PDs, 76 percent of enrollees had no deductible in their plan's benefit design. By comparison, only 14 percent of PDP enrollees and 6 percent of SNP enrollees were in plans with no deductible. However, half of PDP enrollees were not required to meet a deductible for select drugs (usually certain generics), and most SNP enrollees are dual-eligible beneficiaries who automatically receive the LIS, which covers the deductible (data not shown).

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

Most Part D beneficiaries enroll in 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 brand-name and generic drugs), plus a specialty tier

TABLE 11–2

More enrollees chose conventional MA–PDs, which are much more likely than PDPs and SNPs to offer enhanced coverage, 2023

	PDP		General MA–PD		SNP	
	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent
Total	18.5	100%	18.9	100%	5.6	100%
Type of coverage						
Basic	7.9	42	0.1	<1	3.9	70
Enhanced	10.6	58	18.8	99	1.7	30
Type of deductible						
Zero	2.6	14	14.4	76	0.4	6
Reduced	2.0	11	4.2	22	0.2	4
Defined standard	13.9	75	0.3	2	5.0	90

Note: MA–PD (Medicare Advantage–Prescription Drug [plan]), PDP (prescription drug plan), SNP (special needs plan). Conventional MA–PD enrollment excludes employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B–only plans. "Defined standard" deductible category includes plans that are actuarially equivalent. Totals may not sum due to rounding.

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

(Medicare Payment Advisory Commission 2023a). The cost-sharing amounts for those tiers differ, but generally plans have kept generic copayments comparatively low. Among PDP enrollees, in 2023, median copayments were $1 for preferred generics and $5 for other generic drugs. Median cost sharing was $44 for preferred brand-name drugs and 45 percent coinsurance for nonpreferred drugs. Among MA–PD enrollees, median copayments for the two generic tiers were $0 and $6, 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.

Average premiums remained stable in 2023

In 2023, 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 two years. However, premiums for individual plans vary widely around that average, from $0 for many MA–PDs to $201 for the most expensive enhanced PDP. The $26 average reflects plan sponsors' use of Part C quality bonus payments (or rebates) to offset premium costs that MA–PD enrollees would otherwise pay. In 2023, MA–PD enrollees paid an average of less than $15 per month but received over $54 of basic and supplemental drug benefits through Part C rebates (Medicare Payment Advisory Commission 2022a). PDP enrollees paid nearly $42 per month, on average.

Two other factors, not accounted for in the averages described above, can affect the premium amounts that enrollees pay. First, higher-income individuals have a lower federal subsidy of their Part D benefits.[17] In 2023, over 8 percent of enrollees were subject to the income-related premium, compared with less than 3 percent in 2011 (Liu and Centers for Medicare & Medicaid Services 2023). 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.[18] In 2023, about 5 percent paid the LEP, up from about 1 percent in 2007 (Liu and Centers for Medicare & Medicaid Services 2023). Some of the increase in enrollees subject to the LEP may be due to the lack of a notification process to ensure that individuals are aware of their eligibility for and need to enroll in Medicare, including Part D, as they turn 65 (Medicare Payment Advisory Commission 2019b).

Benefit offerings and premium changes for 2024

For 2024, plan sponsors are offering 3,507 general MA–PDs and 1,306 SNPs—a 1 percent drop in general MA–PD plans, but 4 percent more SNPs relative to 2023. Plan sponsors are offering 709 PDPs, nearly 12 percent fewer than the previous year.

Still, in each of the nation's 34 PDP regions, beneficiaries continue to have broad choice. The number of PDPs ranges from 15 in New York to 24 in Alabama and Tennessee, 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 28 plans in each county. Because more beneficiaries live in areas with greater numbers of plans, the average beneficiary has 43 MA plans available.[19]

For 2024, CMS calculated that Part D's base beneficiary premium (BBP)—an enrollee's share of the monthly national average expected cost for basic benefits—is $34.70, a 6 percent increase from 2023 (Centers for Medicare & Medicaid Services 2023f). Importantly, the cap on annual increases in the BBP from 2024 to 2029 at 6 percent per year prevented a 20 percent increase in the BBP (see text box on Part D premium stabilization on p. 339).

While the BBP has been limited to a 6 percent annual increase, individual plan premiums may increase by more (or less) than 6 percent. Premiums for individual Part D plans can vary substantially 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 2024, MA–PD sponsors are applying $47 per month of Part C rebate dollars on average to lower their Part D premiums compared with over $54 per month the prior year (a decrease of nearly 13 percent) as plans, on average, allocated more rebate dollars toward Part C supplemental benefits instead.

In 2023, 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 2024, most (but not all) saw an increase in their premiums averaging more than $8 per month, or 22 percent. However, average monthly premiums for some nationally marketed PDPs fell by up to $9, while others rose by roughly $30. Most beneficiaries will have access to a plan with a premium of less than $1 per month.

In 2024, the benchmarks that reflect the maximum amount Medicare will pay for monthly premiums on behalf of LIS beneficiaries range from $28 in Texas to $49 in New York. Compared with 2023, the number of zero-premium PDPs available to LIS enrollees in 2024 dropped by 34 percent to 126 plans, or about one-sixth of all PDPs. This drop significantly affects plan choice for LIS beneficiaries: Eight regions in 2024 have just two zero-premium PDPs available. Wisconsin has a high of seven premium-free PDPs. As a result, CMS expects to reassign roughly 1.4 million LIS enrollees in 2024, up from less than 0.5 million in 2023, so that they may continue to have coverage with no premium cost (Liu and Centers for Medicare & Medicaid Services 2023).

Plan sponsors, PBMs, and market concentration

About 300 organizations operate Part D plans. Most plan sponsors offer MA–PDs, but only about 50 operate stand-alone PDPs.[20] 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.

Many of the largest plan sponsors have their own pharmacy benefit managers (PBMs) that negotiate

rebates with pharmaceutical manufacturers and achieve economies of scale in 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.[21] As a result, PBMs' market concentration is higher than that of plan sponsors. We estimate that in 2022, 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. Rebates can help reduce premiums for all enrollees, but the trade-off is that Medicare faces higher costs for its cost-based reinsurance and LICS subsidy, and patients who must pay a percentage coinsurance on a rebated drug pay disproportionately higher cost sharing.

The roles of plan sponsors and PBMs

In addition to their role as insurers, plan sponsors conduct marketing, enrollment, and customer support services. They also use PBMs (either a subsidiary firm or an unaffiliated firm under contract) to perform other administrative and clinical services such as developing formularies, processing claims, establishing networks of pharmacies, and negotiating with drug manufacturers and pharmacies for postsale rebates, discounts, and fees.

PBMs combine purchasing leverage across plans and plan sponsors to create stronger competition among therapies and counter drug manufacturers' pricing power. Our analysis has found that the differential between rebates obtained by large and smaller plan sponsors can be substantial (Medicare Payment Advisory Commission 2023b).

Formulary management and manufacturer rebates

Formularies remain plan sponsors' most important tool for managing drug spending. Sponsors and PBMs decide which drugs to include or exclude, which cost-sharing 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 addition, rebates may vary based on the degree of therapeutic competition and Medicare's formulary coverage policies (Medicare Payment Advisory Commission 2023a, Medicare Payment Advisory Commission 2023b). Between 2010 and 2022, the magnitude of aggregate rebates grew from $8.6 billion (11 percent of gross Part D spending) to $57.3 billion (24 percent).[22]

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 2024, if enrollees remained in the same plan as in the previous year, over 90 percent of PDP enrollees, 38 percent of general MA–PD enrollees, and less than 5 percent of SNP enrollees would be in plans that use preferred cost-sharing pharmacies.[23] 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

Recent regulatory change to the definition of "negotiated price"

In May 2022, CMS finalized a rule redefining the "negotiated price" of Part D–covered drugs to include all possible pharmacy price concessions, such that the price reflects the lowest possible reimbursement a network pharmacy may receive for a particular drug, effective January 1, 2024. (This policy does not apply to manufacturer rebates.) The negotiated price is the price paid at the point of sale (POS) to a network pharmacy or dispensing provider. When plans require a percentage coinsurance, beneficiary cost sharing is calculated based on this price.

Historically, negotiated prices have not included performance-based pharmacy price concessions because they cannot "reasonably be determined" at the POS and thus were excluded from the negotiated price. These price concessions were typically paid in lump sum at a later date (e.g., at the end of each quarter) and reported to CMS as direct and indirect remuneration (DIR).

Pharmacy DIR has grown from less than $500 million in 2014 to $17.1 billion in 2022.[24] CMS became concerned about the impact of these fees and their retroactive application because the more the price concessions grow, the more disconnected beneficiaries' cost sharing is from the actual price of the drug. Additionally, the large and growing magnitude of pharmacy DIR raises other concerns: In recent years, the amount of DIR that sponsors receive has consistently exceeded the amount projected in plan bids, which has primarily contributed to plan profits rather than lower premiums. Further, CMS noted that when sponsors "opt for higher negotiated prices in exchange for higher DIR . . . [it] shifts costs from the part D plan sponsor to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies" (Centers for Medicare & Medicaid Services 2018). The lack of transparency and unpredictability of these price concessions has also caused cash-flow challenges for some pharmacies.

Requiring all possible pharmacy price concessions to be applied at the point of sale will affect all Part D stakeholders. (The cost estimates provided by CMS were calculated prior to passage of the Budget Reconciliation Act of 2022; the benefit redesign set

(continued next page)

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 since LIS enrollees do not face any financial incentives to choose preferred pharmacies.[25]

Over time, some major plan sponsors began requiring pharmacies in their networks to make postsale payments depending on their performance.[26] Because these payments rely on evaluations of performance metrics, 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 2022, they totaled $17.1 billion (7 percent of gross Part D spending), a 36 percent increase from $12.6 billion in 2021.[27]

For some medications, such as those placed on nonpreferred or specialty tiers, enrollee cost sharing is typically calculated based on the price negotiated between plan sponsors (or PBMs on their behalf) and pharmacies. But until this year, the "negotiated price" did not include performance-based pharmacy payments, similar to the exclusion applied to postsale

Recent regulatory change to the definition of "negotiated price" (cont.)

to go in effect in 2025, as well as other drug pricing–related provisions in the law, are likely to alter the expected impacts on costs.)

All beneficiaries would, on average, likely face higher premiums (relative to the prior status quo), but the out-of-pocket cost savings expected for a subset of beneficiaries are projected to more than offset the total increase in premiums, ultimately reducing total beneficiary spending, on net (Carver et al. 2022). CMS estimated beneficiary savings of $26.5 billion from 2024 to 2032.

Federal spending is expected to increase as a result of higher premiums and thus higher costs for the direct subsidy, without sufficient reductions in low-income cost-sharing subsidies and Medicare's reinsurance to fully offset those higher costs. CMS estimates the net cost to the federal government will be $46.8 billion, or a 3 percent increase, from 2024 to 2032.

Manufacturers' obligations through the coverage-gap discount program are expected to decrease (since their discounts are calculated as a percentage of the negotiated price and because fewer beneficiaries would reach the coverage gap) by approximately $16.8 billion.

Plans will likely face higher liability (reflected in higher premiums, as mentioned above) and some transactional costs estimated at $0.1 million (Avalere 2023).

Pharmacies should have more predictable revenues in the long term but may experience cash-flow challenges in the first quarter of 2024: Some pharmacies will simultaneously need to pay any price concession obligations from 2023 while also having their current reimbursements reduced to account for all possible pharmacy price concessions.

In responding to the proposed rule, some commenters suggested that this policy would reduce competition among pharmacies for preferred network placement. However, because no evidence was provided to support this claim, CMS rejected the argument and suggested that post-point-of-sale bonus payments can be just as effective as post-point-of-sale recoupments. Further, CMS expects that standardizing the application of price concessions will increase transparency and information symmetry between plan sponsors and enrollees choosing their Part D plan and deciding which pharmacy to use. Greater transparency, in turn, could improve competition among pharmacies and empower beneficiaries to make better plan comparisons. ■

manufacturer rebates. This arrangement has meant that enrollees who use highly rebated drugs may pay disproportionately high cost sharing relative to the net benefit cost of their medicines, and Medicare, in turn, spends relatively more on reinsurance subsidies and low-income cost-sharing subsidies.

Beginning in 2024, the definition of "negotiated price" must reflect all pharmacy price concessions, including performance-based ones that were previously assessed after the point of sale (see text box on recent regulatory change to the definition of "negotiated price"). Plan sponsors' negotiated price is 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.

Concerns about vertical integration and high market concentration

Large PBMs have significant market power to negotiate rebates with pharmaceutical manufacturers and

achieve economies of scale in mail dispensing. As noted above, while rebates can benefit all enrollees in the form of lower premiums, PBMs' focus on rebates and the lack of price transparency can increase costs for payers and patients who need expensive medications (Loftus and Hopkins 2023). At the same time, a PBM may face conflicting interests as a PBM providing services to the payer and as an owner of a pharmacy facing financial incentives to dispense a greater volume of prescription drugs, particularly those with higher pharmacy spreads (Herman 2022).

A concern is that vertical integration combined with a highly concentrated market 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 that PBM (Greaney 2019).

The prices established between upstream and downstream entities of vertically integrated organizations are less transparent to CMS and commercial payers.[28] As a result, profits accruing to wholly owned downstream entities may be reflected as higher costs for Part D plans (Herman 2022). Similarly, when pharmacies are owned by insurers and/or PBMs, the use of these vertically integrated pharmacies may not necessarily result in lower costs (Medicare Payment Advisory Commission 2023b). In turn, the lack of information about prices established among vertically integrated plan sponsors, PBMs, and pharmacies makes it difficult to assess the profitability of Part D plans and their affiliated organizations (Office of Inspector General 2021).

Although moderated by generic use, overall Part D prices have continued to rise

Much attention has been focused on growth in prices at the pharmacy counter—referred to here as gross or point-of-sale (POS) prices. 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 are 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' focus on developing drugs and biologics for smaller patient populations means that many products 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).

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.[29]

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. The indexes reported in this section reflect POS prices before postsale rebates and discounts.

In 2022, growth in overall Part D prices remained above prepandemic growth rates

Between 2006 and 2022, prices for all drugs and biologics, measured by individual national drug codes (NDCs), more than doubled on average (an index value of 2.17) (Table 11-3).[30] Overall, growth in drug prices slowed in 2022 to 3.8 percent, down from 4.1 percent in 2021; however, it still exceeded price growth observed prior to 2021 (price growth averaged 3.0 percent per year between 2018 and 2020).

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 2022 (data not shown). However, the rate of decrease in generic prices has slowed in recent years, and as a result, our overall price index

TABLE 11–3 **Part D prices, after accounting for generic substitution, continued to rise in 2022**

	2018	2019	2020	2021	2022
	Price index as of 4th quarter (1st quarter 2006 = 1.00)				
All drugs and biologics					
Before accounting for generic substitution	1.90	1.95	2.00	2.09	2.17
After accounting for generic substitution	1.14	1.11	1.13	1.17	1.20
Biologics (excluding insulin)	3.16	3.32	3.51	3.79	4.06
	Annual percentage change*				
All drugs and biologics					
Before accounting for generic substitution	3.6%	2.9%	2.6%	4.1%	3.8%
After accounting for generic substitution	1.7	–2.1	1.3	3.4	2.6
Biologics (excluding insulin)	7.3	5.2	5.7	7.9	7.1
Share of gross Part D spending accounted for by biologics**	9	10	12	13	15

Note: Indexes are calculated using chain-weighted Fisher price indexes and are measured at the median of the distribution relative to prices as of the first quarter of 2006. Prices reflect total amounts paid to pharmacies before rebates or discounts from manufacturers and pharmacies. Indexes shown are rounded. Price indexes reflect changes in the prices of existing products. These indexes do not reflect the effect of launch prices of new products.
*Annual percentage changes reflect growth in the price index since the fourth quarter of the previous year, calculated using unrounded data.
**Gross spending for biologics excludes insulin. Biologics including insulin accounted for 18 percent of total gross Part D spending in 2018 and rose to 21 percent by 2022.

Source: Acumen LLC analysis for MedPAC.

that takes generic substitution into account rose in both 2021 and 2022 (by 3.4 percent and 2.6 percent, respectively), up from an average growth rate of less than 1 percent observed before 2020.[31]

Successful adoption of biosimilars will be key to lowering prices of biologics

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. Medicare now 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. In 2022, biologics (not including insulin products) accounted for 15 percent of gross Part D spending, up from 9 percent in 2018 (Table 11-3). (Including insulin products, biologics accounted for 18 percent of gross Part D spending in 2018 and 21 percent by 2022.) Many biologics command high prices, often meeting the price threshold to be placed on a specialty tier ($950 for a 30-day supply in 2024) (Assistant Secretary for Planning and Evaluation 2023). Prices of

Formulary coverage of Humira and its biosimilars

Humira (adalimumab) is a biological product manufactured by AbbVie and belongs to a class of medications known as tumor necrosis factor-alpha inhibitors. Humira is used to treat a wide range of autoimmune conditions, such as rheumatoid arthritis and ulcerative colitis. It is available in different doses and strengths, as well as in several injection devices, including autoinjector pens, prefilled syringes, and vials (Goodrich 2023).

Today, most of the Humira products sold in the U.S. are for the high-concentration (HC) formulation that requires less volume to be injected, which may be associated with less injection site–related pain (Goodroot 2023, Nash et al. 2016). Launched in July 2018, the HC products rapidly gained market share (Hagen 2021, Medicare Payment Advisory Commission 2022c). In 2022, over 80 percent of gross Part D spending for Humira products was for the HC formulation, up from less than 5 percent in 2018.

In 2023, nearly all Part D plans included all Humira products on their formularies. Annual therapy costs for Humira at list price can exceed $80,000, and in 2022, gross Part D spending for Humira totaled $5.4 billion (before postsale rebates and discounts), making it one of the products with the highest Part D spending.

Multiple Humira biosimilar products were launched in 2023

In 2023, nine adalimumab biosimilar products carrying mostly the same indications as Humira entered the market (Goodrich 2023). Differences between Humira biosimilar products and the reference product are likely to have implications for formulary coverage as well as prescriber and patient willingness to switch to a biosimilar product. For example, many of the biosimilar products are available in the 40 mg dose but not in the 80 mg dose or in convenient package sizes for patients newly starting on adalimumab (Goodrich 2023). Other differences that could affect the uptake of Humira biosimilars include:

- ***Formulation***—To date, only three biosimilar products (Hadlima, Hyrimoz, and Yuflyma) are available in the HC formulation. All other biosimilar products were approved in the original (low-concentration) formulation.
- ***Interchangeability***—Currently, two products (Cyltezo and Abrilada) have the interchangeable designation, which allows pharmacists to substitute the biosimilar products for the reference product without obtaining a new prescription from the prescriber.[32]
- ***Pricing***—Some biosimilar manufacturers have launched their products with list prices that are 5 percent below Humira's list price, while others have priced their products at a steep discount (ranging from 55 percent to 86 percent relative to Humira's list price) (Fein 2023). Three manufacturers have launched products with both high and low list prices.

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biologics have grown by between 5.2 percent and 7.9 percent per year for the past five years, following years of double-digit growth (latter data not shown). Going forward, meaningful savings for biologics in Part D will largely depend on successful launch and adoption of biosimilars by prescribers and beneficiaries.

Several top-selling products for autoimmune conditions are now facing or are expected to face biosimilar competition in the next few years. In 2023, Humira, one of the top-selling products for the treatment of autoimmune conditions, began facing biosimilar competition (see text box on Humira

Formulary coverage of Humira and its biosimilars (cont.)

In 2024, most plans continue to cover Humira products

Humira biosimilars' success in gaining acceptance among patients and their prescribers crucially depends on their inclusion on plan formularies. To get a sense of how Part D plans are treating Humira biosimilars, we examined the formularies that Part D plans submitted for the 2024 benefit year.[33]

While nearly all Part D plans will continue to provide broad coverage of Humira products, in 2024, nearly 60 percent of all Part D enrollees are in plans that include at least one Humira biosimilar product on their formularies.[34] About half of these enrollees are in plans that cover just one biosimilar product, while the other half are in plans that cover two or more. Roughly two-thirds of enrollees in plans that covered at least one biosimilar product are in Medicare Advantage–Prescription Drug plans (including special needs plans).

When a biosimilar product is on a plan's formulary, most plans place the biosimilar product on the same cost-sharing tier as Humira. (Note that when both Humira and its biosimilars are placed on the same tier (typically on a specialty tier with 25 percent or 33 percent coinsurance), the extent to which beneficiaries will use the biosimilar product depends, to some extent, on the size of the differences in list prices.) One exception is Kaiser Permanente plans: Amjevita is placed on a preferred brand tier (with a fixed-amount copayment), while Humira products are placed on a specialty tier with 33 percent coinsurance.

Among the biosimilar products, Cyltezo, an interchangeable biosimilar available only in a low-concentration formulation, is most likely to be included on plan formularies. In 2024, Cyltezo is covered by about 50 percent of plans (accounting for just under 60 percent of Part D enrollees). While the vast majority of plans are covering both Cyltezo and Humira products (at parity), one sponsor is covering only Cyltezo in its nationwide prescription drug plan.

Hyrimoz, one of the two biosimilar products available in HC formulation, is covered by about a quarter of the plans (just under 30 percent of all enrollees). Because Hyrimoz is available in multiple dosage forms and package sizes, this product may offer more opportunities for patients and their prescribers to switch from Humira to a biosimilar product.

All other Humira biosimilar products are covered by less than 5 percent of plans. Having a low list price did not appear to give the biosimilar product an advantage in formulary placement over biosimilar products with higher list prices. Manufacturer rebates play an important role in plans' formulary coverage decisions. As a result, plans may opt to cover a biosimilar product (or a reference product) with a higher list price when the rebate makes such a decision more financially advantageous. ■

biosimilars). The experience of Humira and its biosimilar products could provide insights into the extent to which entries of biosimilar products help restrain Part D's prices of and spending for biologics. Part D plans' coverage of the biosimilar products will be critical to the success of biosimilar manufacturers that, in turn, will provide patients and Medicare with opportunities to benefit from the competitive pressure that lowers the prices of biologics.

Cost-based payments account for a growing share of program spending

The costs of providing Part D benefits are shared by Medicare (taxpayers) and its enrollees. Medicare pays plan sponsors two subsidies on behalf of each enrollee in their plans:

- ***Direct subsidy***—A monthly (capitated) prospective amount set as a share of the national average bid

TABLE 11–4

Medicare spending and enrollee premiums for Part D

	Annual spending, in billions					Average annual change
	2018	2019	2020	2021	2022	2018–2022
Total Part D spending	$83.3	$88.3	$93.0	$94.8	$101.9	5.2%
Capitated payments (direct subsidy)	13.5	11.8	10.9	7.1	4.8	–22.8
Cost-based reinsurance payments	40.6	46.1	48.5	52.1	56.8	8.8
Subtotal, basic benefits	54.1	57.9	59.4	59.2	61.6	3.3
Low-income cost-sharing and premium subsidy	28.5	29.7	33.0	35.0	39.7	8.6
Retiree drug subsidy*	0.7	0.7	0.6	0.6	0.6	–3.8
Enrollee premiums for basic benefits**	14.2	13.8	13.6	15.0	15.4	2.0

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 coverage that is comparable with or more generous than the basic Part D benefit.
**Excludes low-income premium subsidies. In addition, in 2022, enrollees paid $9.9 billion in premiums for enhanced benefits.

Source: MedPAC analysis based on Table IV.B10 of the 2023 annual report of the Boards of Trustees of the Medicare trust funds.

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) after the end of the benefit year for each enrollee who reached the OOP threshold.

Combined, the direct subsidy and expected reinsurance payments aim to cover 74.5 percent of the expected cost of basic benefits. 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. For enrollees who qualify for Part D's LIS, Medicare pays plans most or all of their cost sharing and premium liabilities on their behalf.

Medicare provides additional protection for the portion of the benefit for which plans are at risk (i.e., basic benefit costs, excluding cost-based reinsurance) by establishing symmetric "risk corridors" separately for each plan to limit its overall losses or profits. Under the risk corridors, Medicare finances a portion of the costs that are higher than expected or recoups a portion of profits that are higher than expected.

Between 2018 and 2022, program spending rose from $83.3 billion to $101.9 billion (Table 11-4), or an average of 5.2 percent per year. (Total Part D enrollment grew by about 3 percent per year on average during this period.) In 2022, Medicare paid $4.8 billion for the monthly capitated direct subsidy, $56.8 billion for reinsurance, $39.7 billion for the LIS, and $0.6 billion for the RDS. Part D enrollees paid $15.4 billion in premiums for basic benefits in 2022 (not including the premiums paid by Medicare on behalf of LIS enrollees). In addition, enrollees paid $9.9 billion in premiums for enhanced benefits.

Medicare's payments for the monthly capitated direct subsidy have declined sharply in recent years, falling

Effects of Part D premium stabilization provision on Medicare's overall subsidy rate

Each Part D plan submits a bid annually to CMS prior to the start of a benefit year. The bids reflect the plans' expected benefit costs (for a Part D enrollee of average health) plus administrative costs after deducting expected federal reinsurance subsidies. CMS calculates the national average bid for expected basic benefit costs (i.e., not including costs related to any supplemental benefits the plan may choose to include). The base beneficiary premium (BBP) is a share of the nationwide average bid.

Medicare provides plans with a subsidy that aims to average 74.5 percent of basic benefit costs. That subsidy takes the form of a direct subsidy—a capitated payment to plans calculated as a share of the national average of plan bids—and individual reinsurance, which currently covers 80 percent of spending above the out-of-pocket threshold. The remainder, 25.5 percent, is the base beneficiary premium.[35]

Between 2023 and 2024, average basic benefit costs are expected to increase by about 20 percent. Under prior law, the BBP, calculated as a share of that total, would have also increased by about 20 percent. However, beginning in 2024, a provision included in the Budget Reconciliation Act of 2022 limits the annual increase in the BBP to no more than 6 percent. Because of this 6 percent cap, the base beneficiary premium is $34.70 per month in 2024. (Without the 6 percent cap, the base beneficiary premium amount would have been $39.35 per month in 2024 (Centers for Medicare & Medicaid Services 2023c).) When the 6 percent cap is binding, Medicare's overall subsidy rate automatically increases to cover a larger share of basic benefit costs than the 74.5 percent originally set in law.[36] For 2030 and subsequent years, the BBP would be based on the lower of the 2029 BBP increased by 6 percent or the BBP calculated based on 2030 plan bids. However, the BBP in any given year may not be set at less than 20 percent of the average basic benefit costs (including expected average reinsurance) for that year (i.e., Medicare's subsidy rate can be no greater than 80 percent). ■

22.8 percent, on average, from 2018 to 2022. Multiple factors have contributed to this decline, including the increased use of generic drugs by Part D enrollees and the rapid growth in manufacturer rebates and pharmacy fees that disproportionately offsets basic benefit costs paid by plans. Meanwhile, Medicare's cost-based reinsurance payments continued to climb, rising 8.8 percent per year, on average, over the period, as the number of enrollees reaching the catastrophic phase of the benefit increased, as discussed below. As a result, by 2022 over 90 percent all of Medicare's basic benefit payments took the form of reinsurance (cost-based reimbursement) rather than monthly capitated direct subsidy payments. However, in 2024, average direct subsidy payments to plans will increase to nearly $30 per member per month, up from an average of less than $2 per member per month in 2023. At the same time, average reinsurance payments will decrease to about $90 per member per month, down from nearly $94 per member per month in 2023.[37]

A combination of legislative and regulatory changes likely contributed to the reversal of this trend toward higher reinsurance payments. In 2024, overall average basic benefit costs are expected to rise by 20 percent. That increase is due primarily to the increased generosity of Part D's basic benefits for specific products such as insulins and vaccines and to the elimination of cost sharing in the catastrophic phase of the benefit (see text box on implementation of the Part D–related provisions in the Budget Reconciliation Act of 2022, pp. 324–326).[38] An additional factor that is likely to increase benefit costs is the change in the

definition of negotiated prices. As discussed above, beginning in 2024, CMS now requires that enrollee cost sharing paid at the point of sale reflect all pharmacy price concessions; this regulatory change will, on average, reduce prices at the pharmacy and beneficiary cost sharing and thereby further increase benefit costs (Boards of Trustees 2023) (see text box on recent regulatory change to the definition of "negotiated price," pp. 332–333). Lower beneficiary OOP costs, in turn, will slow the progression toward the OOP threshold. As a result, reinsurance costs are expected to decrease as some beneficiaries may no longer reach the catastrophic phase of the benefit. Finally, the annual increase in the base beneficiary premium is limited to no more than 6 percent. Consequently, most of the 20 percent increase in the average basic benefit costs (including expected average reinsurance) will be paid in the form of a higher direct subsidy (see text box on the effects of Part D premium stabilization provision, p. 339). Still, reinsurance continues to be a much larger share of the cost of the basic benefits.

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.

In 2022, the number of beneficiaries reaching the catastrophic phase continued to rise after a drop in 2020

In 2022, the number of Part D high-cost enrollees—those with spending high enough to reach the catastrophic phase of the benefit—rose by about 5 percent to 4.3 million, following an increase of a similar magnitude in 2021 after a drop of 11 percent in 2020 (Figure 11-3). (Much of the decline in 2020 was likely driven by an unusually large, statutorily required 25 percent jump in the OOP threshold from its 2019 level.[39]) In 2022, enrollees with the LIS continued to account for the majority (just over 64 percent) of all high-cost enrollees.[40] Beneficiaries with the LIS tend to use more medications and incur higher average spending compared with beneficiaries without the LIS (Medicare Payment Advisory Commission 2023a). While LIS enrollees accounted for less than 30 percent of all Part D enrollees, in 2022, they accounted for about 46 percent of gross Part D spending.

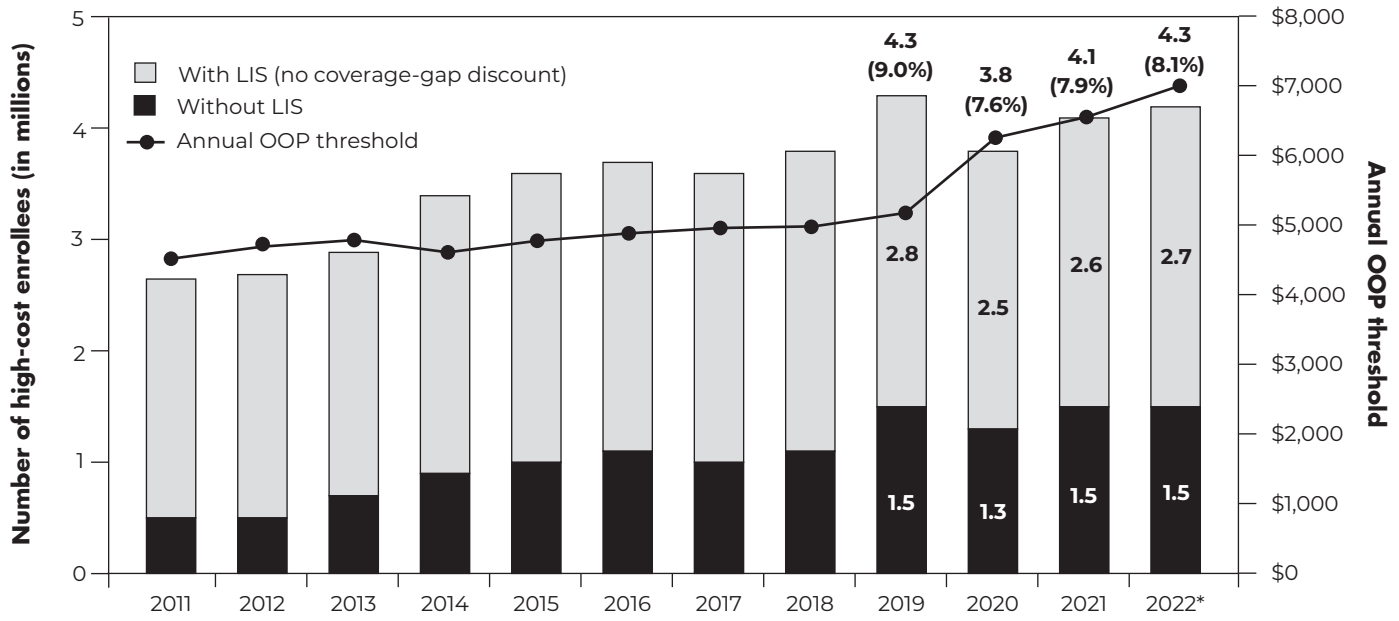
Unlike in the previous years, the number of high-cost enrollees with the LIS grew more rapidly than the number of high-cost enrollees without the LIS. This faster growth in high-cost enrollees with the LIS may, in part, be due to more individuals retaining Medicaid eligibility (and therefore their LIS eligibility) during the COVID-19 public health emergency (Tolbert and Ammula 2023).

CMS adjusts the annual OOP threshold each year based on a formula set in law. Between 2021 and 2022, the annual OOP threshold increased from $6,550 to $7,050. Because LIS enrollees continued to make up most beneficiaries with high costs and Medicare's LIS pays for nearly all costs in the coverage gap (above any nominal copayments required by law; see Figure 11-1, p. 322), the effects of the increase in the OOP threshold fell almost entirely on the program (and taxpayers) rather than beneficiaries themselves. For those enrollees without the LIS who did reach the coverage gap, 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 11-1). For example, an enrollee who filled only brand-name drugs in the coverage gap would be responsible for paying about a quarter of that increase. Meanwhile, beneficiaries who took only generic drugs would be responsible for the full increase. In 2022, coverage-gap discounts among high-cost enrollees without the LIS averaged more than $4,800, accounting for 69 percent of the OOP threshold amount ($7,050).

In 2022, 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 about 4 percent to over 482,000 enrollees—just over 11 percent of high-cost 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 (about 18 percent compared with just under 8 percent, respectively).

FIGURE 11–3

Part D enrollees reaching the benefit's catastrophic phase, 2011–2022



Note: LIS (low-income subsidy), OOP (out-of-pocket). Percentages shown are high-cost enrollees as a share of all Part D enrollees. 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 2011 to 2022 are based on MedPAC analysis of Part D prescription drug event data.

Plans bear less risk for Part D spending than Medicare

Insurance risk provides an incentive for plan sponsors to offer attractive benefits while managing their enrollees' spending through formularies and other 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 2022, plans were at risk for 25 percent of Part D spending net of all DIR and coverage-gap discounts (Table 11-5, p. 342). Medicare, on the other hand, was at risk for 62 percent of net Part D spending, consisting of 38 percent for reinsurance and 24 percent for the low-income cost-sharing 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 in 2022. 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 in 2022 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 (9 percent) than other Part D plans. That difference may be due, in part, to the lack of plan liability in the coverage gap for beneficiaries with the LIS (see Figure 11-1, p. 322).

The distribution of insurance risk among stakeholders, however, is expected to change dramatically in 2025. The BRA restructured Part D benefits to replace much of what is now Medicare's cost-

TABLE 11–5

In 2022, plans' share of the insurance risk for Part D varied from 9 percent for SNPs to 34 percent for MA–PDs

	All Part D plans	By plan type*		
		PDPs	MA–PDs**	SNPs
As a share of spending net of all DIR and coverage-gap discounts:				
Plans at risk	25%	11%	34%	9%
Medicare at risk (reinsurance)	38	45	33	45
Low-income cost-sharing subsidy	24	27	17	44
Total, Medicare	62	72	50	89
Beneficiary cost sharing	12	17	16	1

Note: SNP (special needs plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), PDP (prescription drug 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.
*Excludes employer group waiver plans.
**Excludes SNPs. Components may not sum to totals due to rounding.

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

based payments—reinsurance and the low-income subsidy—with capitated payments (see text box update on implementation of the BRA's Part D–related provisions, pp. 324–326). As a result, plans will be at risk for a larger share of Part D spending. That change, in turn, is expected to restore incentives for plans to manage drug spending—incentives that have eroded over the years.

Most Part D enrollees were satisfied

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. On the other hand, Medicare beneficiaries are likely to have multiple chronic conditions and take an average of nearly five prescription drugs per month, putting them 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 important as well.

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.[41] CMS has also established network adequacy requirements to ensure that beneficiaries have a sufficient number of pharmacies in network within the plan's geographic area. In addition, Medicare requires plan sponsors to establish a process for coverage determination and appeals.[42] 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.

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.

Plans offered in 2024 have lower average overall ratings for the second straight year, though the share of beneficiaries in a plan with 4 or more stars increased among MA–PD enrollees relative to 2023. Among PDPs, just 27 percent of plans being offered in 2024 received 4 or more stars, and these plans enrolled just 2 percent of PDP beneficiaries in 2023. MA–PDs, on the other hand, enrolled 73 percent of MA–PD beneficiaries in the 42 percent of such plans that earned 4 or more stars, reflecting a high concentration in high-performing plans. In total, 31 MA–PDs and 2 PDPs earned 5 stars. Nonprofit plans and plans with a longer history were more likely to score higher than for-profit and newer plans. One explanation for at least some of the decline in high-performing plans is a methodological change that created higher thresholds that were more difficult for plans to meet.[43]

Dissatisfaction tied to costs is likely to be lessened by new OOP cap

Overall beneficiary satisfaction with Medicare Part D exceeds 90 percent, according to multiple surveys. More than 80 percent of Part D enrollees report that their Part D plans provide good value and that their costs are reasonable, though cost has been the most common reason for any dissatisfaction. Among respondents to the Medicare Current Beneficiary Survey (MCBS), 82 percent of Part D enrollees were satisfied with the amount they paid for prescriptions, which averaged $608 annually (Centers for Medicare & Medicaid Services 2021b). 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 2023). More specifically, findings show that the satisfaction rate pertaining to the affordability of cost sharing for brand-name medicines is significantly lower (76 percent) than for generic medicines (89 percent) (*Medicare Today* 2023). Nevertheless, because the majority of prescriptions are for inexpensive generic drugs and a relatively small number of beneficiaries use brand-name or high-cost specialty drugs, overall satisfaction remains high.

For enrollees who do use expensive medications, high cost sharing can result in beneficiaries not initiating therapy or abandoning prescriptions at the pharmacy (Doshi et al. 2018, Dusetzina et al. 2020).[44] One recent study of fee-for-service Medicare beneficiaries who were newly prescribed a specialty drug found that LIS enrollees—who pay limited cost sharing—were twice as likely to fill their prescription within 90 days as enrollees without the LIS (Dusetzina et al. 2022).[45] Nearly one-fourth of enrollees responding to the MCBS reported an affordability issue, including 15 percent who did not take their medicine as prescribed because of cost (Table 11-6, p. 344) (Centers for Medicare & Medicaid Services 2021b).[46] These beneficiaries, on average, incurred higher OOP costs ($703) than those who were satisfied ($608).

Affordability issues were most prevalent among non-White beneficiaries (Centers for Medicare & Medicaid Services 2021b). There were no significant differences in rates of affordability challenges between PDP and MA–PD enrollees or LIS and non-LIS enrollees, although the amounts paid by these subgroups varied substantially (Table 11-6, p. 344).

The presence of chronic conditions may also affect enrollees' satisfaction with their costs and coverage. Only 61 percent of beneficiaries without a chronic condition were satisfied with their coverage compared with 81 percent of those with a chronic condition (data not shown) (Centers for Medicare & Medicaid Services 2021b). This distinction may be explained by the fact that most chronic conditions can be well managed with generic medicines that tend to be broadly covered and inexpensive (Centers for Medicare & Medicaid Services 2023b).

While premiums have long been viewed as the main factor that beneficiaries consider when choosing their plan, the MCBS found that only 28 percent considered plan premiums, while 32 percent considered the cost they would pay for drugs and 33 percent considered

TABLE 11–6 **Beneficiary satisfaction and affordability issues varied by subgroup, 2021**

	Overall satisfaction	Beneficiary experienced a cost-related access issue	Average OOP cost among beneficiaries with a cost-related access issue
Overall	80%	15%	$621
Race/ethnicity			
White	81	14	717
Asian	69	9	184
Black	77	21	369
Hispanic	78	13	370
Multiple races	77	22	272
LIS status			
Not receiving LIS	82	14	858
Receiving LIS	73	16	140
Plan type			
PDP	76	15	704
MA–PD	84	15	543

Note: OOP (out-of-pocket), LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Cost-related access issues include not filling a prescription or skipping or taking smaller doses than prescribed because of affordability challenges.

Source: Acumen analysis of Medicare Current Beneficiary Survey (2021).

the convenience of the pharmacy options available (data not shown) (Centers for Medicare & Medicaid Services 2021b). Average OOP costs among those who considered premiums most important were somewhat lower than for those who considered prescription costs most important. With the new OOP cap, however, premiums may once again become the primary factor to consider when choosing a plan.

Overall, White enrollees were more likely than enrollees of other races to be satisfied with the program (81 percent vs. 69 percent to 78 percent) (Table 11-6) (Centers for Medicare & Medicaid Services 2021b). Enrollees without the LIS were more likely to be satisfied with their Part D plan than LIS enrollees (82 percent vs. 73 percent). MA–PD enrollees were also more likely to be satisfied with the program than PDP enrollees (84 percent vs. 76 percent).

Recent medication therapy management demonstration yielded no significant impacts

Part D plan sponsors must operate MTM programs to improve therapeutic outcomes and reduce adverse drug events for certain high-risk beneficiaries: (1) those who have multiple chronic conditions, take multiple medications, and are likely to have drug spending that exceeds an annual cost threshold ($5,330 for 2024, slightly above the initial coverage limit), and (2) those who are at risk for opioid misuse or abuse. Plan sponsors are required to enroll, with opt-out provisions, all eligible beneficiaries in their MTM programs and report certain measures annually to CMS to evaluate the outcomes of their interventions. These programs must offer interventions 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.[47] MTM programs may also include services such as patient-directed medication counseling, immunization assessments and reminders, and care coordination.

For years, the Commission has had concerns about the effectiveness of MTM programs, particularly in stand-alone PDPs, which do not bear financial risk for medical spending like MA–PDs. In measures used for the 2024 star ratings (based on 2022 data), an average of just 55 percent of enrollees in PDP MTM programs received a comprehensive medication review, compared with an average of 84 percent in MA–PD MTM programs (Centers for Medicare & Medicaid Services 2023d).

Over the period from 2017 to 2021, CMS tested an enhanced MTM model to see if new payment incentives and regulatory flexibilities would spur stand-alone PDPs to improve their MTM programs and reduce Medicare spending. The demonstration's flexibilities allowed participating sponsors to set their own targeting criteria and better tailor their MTM interventions to their enrollees.[48] CMS made prospective payments per beneficiary per month to the sponsors to cover the estimated costs of more extensive interventions. Plans could also earn performance-based payments if they sufficiently reduced expenditures for Part A and Part B services, paid via reductions in beneficiary premium obligations in future years to reward their success through expected higher enrollment.

Six Part D sponsors operated 22 participating PDPs in 5 PDP regions over the 5-year period. In 2021, about 1.1 million enrollees in those plans were eligible for enhanced MTM services, and about 40 percent of those eligible received services, a rate that remained steady for model years two through five (Acumen LLC 2023).

The Part D Enhanced MTM Model, however, did not improve beneficiary health outcomes, as measured by reductions in drug-therapy problems and in downstream medical expenditures (Acumen LLC 2023).[49] A final evaluation of the entire five-year demonstration found no statistically significant effects on Medicare spending for Part A and Part B services, while prospective payments for the enhanced MTM services under the model were larger than decreases in spending, resulting in net costs to Medicare of $288.8 million (Acumen LLC 2023). The evaluation also found no significant improvements in medication adherence or measures of potentially unsafe medication use among beneficiaries receiving enhanced MTM services. For example, relative to nonparticipating enrollees, high statin adherence decreased, drug-drug interactions increased, and high-risk medication use decreased by less than that of comparators.

Plan sponsors expressed support for the program's flexibilities, noting that it allowed for innovative outreach and targeting of beneficiaries, but they reported that meaningfully engaging prescribers to play an active role in promoting the use of enhanced MTM by their patients was challenging (Acumen LLC 2023). Prescribers reported mixed views about plan sponsor involvement in their patients' care, and most reported that sponsors did not understand the goals of their prescribed medication therapy; still, three-fourths reported making changes to their patients' medications based on recommendations resulting from an MTM service.

Sponsors also reported that providing MTM services to LIS beneficiaries was challenging because of inaccurate contact information (Acumen LLC 2023). Thus, while they were more likely than non-LIS beneficiaries to be eligible for services, they were less likely to receive them.

The five-year demonstration did provide some valuable insights into ways in which Part D MTM programs could be improved. First, for an MTM to be effective, it is important to target and provide services at "clinically meaningful" times (Acumen LLC 2023). In particular, beneficiaries were most likely to receive MTM services when they experienced a transition of care (e.g., a hospital discharge) or changes to their medications. Beneficiaries and other stakeholders thought that MTM services that were too frequent or duplicative (such as CMRs offered at regular intervals) have limited value. Second, beneficiaries were more receptive to recommendations from community pharmacists with whom they have a longstanding

relationship but preferred conversations over the phone because of privacy concerns (Acumen LLC 2023). Finally, the report noted operational changes that could improve the efficiency of MTM services.

For example, for identifying beneficiaries with a recent transition of care, health information exchange data provided more timely information compared with Part A and Part B claims data. ■

Endnotes

1 Examples of other sources of payments that qualify as true OOP spending include AIDS Drug Assistance Programs, qualified State Pharmacy Assistance Programs, and certain charities.

2 Even today, when the defined standard benefit has 25 percent coinsurance in both the initial coverage phase and coverage-gap 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.

3 However, while a plan may set fixed-dollar copayments for certain tiers in the initial coverage phase, the way the coverage-gap discount is implemented requires cost sharing in the coverage gap to be calculated as a percentage of costs rather than fixed copayment amounts.

4 For example, in 2024, 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.

5 Insulin cost sharing must be capped at the lesser of 25 percent or $35 for a month's supply.

6 Under the Medicare Drug Negotiation Program, the Secretary must select negotiation-eligible drugs from among the qualifying single-source drugs with the highest gross spending, for which at least 7 years (or 11 years for biologics) have elapsed between approval by the Food and Drug Administration (FDA) and the selected drug publication date (Centers for Medicare & Medicaid Services 2023h). By law, the "ceiling" for the maximum fair price (MFP) is the lower of (1) a weighted average of prices negotiated by Part D plans net of manufacturer rebates and discounts (not including the coverage-gap discount or any manufacturer discounts retained by pharmaceutical supply chain participants, such as specialty pharmacies); or (2) an amount calculated based on the nonfederal average manufacturer price and the number of years on the market since a drug was approved by the FDA. The Secretary may negotiate a lower MFP beyond the discounts required under law by taking into account factors such as the manufacturer's research and development costs, current unit costs of production and distribution, and prior federal financial support for novel therapeutic discovery and development, as well as evidence regarding alternative treatments (Centers for Medicare & Medicaid Services 2023h). The negotiated price could be higher or lower than the price that would have prevailed if the manufacturer's drug had not been selected, depending on the ultimate level of discount negotiated by the Secretary and other rebates and discounts the manufacturer would have paid, including any mandatory discounts (Berger et al. 2023).

7 If a manufacturer agrees to participate in the Negotiation Program but fails to honor the negotiated price, it will face civil monetary penalties.

8 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.

9 Examples of other factors that affect investment in biopharmaceutical research and development include federal regulatory policies related to drug approval and patents and intellectual property; federal tax policy; payment policies of other payers in the U.S. and internationally; the cost of drug development, including capital availability and costs; and collaboration between pharmaceutical manufacturers and academic institutions (Congressional Budget Office 2021). In addition, the federal government contributes to innovation both directly and indirectly through its funding for basic science research and drug development research for some products (Galkina Cleary et al. 2018, Sampat and Lichtenberg 2011).

10 In addition, multiple lawsuits have been filed by pharmaceutical manufacturers and other stakeholders, including the National Infusion Center Association, which may affect the implementation of the Negotiation Program (O'Neill Institute 2023).

11 The Commission has also recommended establishing higher copayment amounts for nonpreferred and nonformulary drugs under the LIS benefit and giving plans greater flexibility regarding coverage of drugs in the protected classes, though these proposals have not yet been adopted (Medicare Payment Advisory Commission 2020a, Medicare Payment Advisory Commission 2019a, Medicare Payment Advisory Commission 2016).

12 The Budget Reconciliation Act of 2022 is often referred to as the Inflation Reduction Act.

13 Examples of creditable drug coverage from sources other than Part D include the Federal Employees Health Benefits Program, TRICARE, and coverage from the Department of Veterans Affairs.

14 EGWPs are sponsored by employers that contract directly with CMS or 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.

15 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.

16 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 2023, MA–PD sponsors applied on average $54 per month (26 percent) of their Part C rebate dollars to Part D benefits. Of that amount, 42 percent was used to lower Part D premiums for basic benefits and the rest was used for supplemental drug benefits.

17 As with the income-related premium for Part B, higher Part D premiums apply to individuals with an annual adjusted gross income greater than $103,000 and to couples with an adjusted gross income greater than $206,000. A beneficiary whose income exceeds these levels pays a monthly adjustment amount in addition to their Part D plan premium. For 2024, adjustments range from $12.90 to $81.00 per month, depending on income.

18 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.

19 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.

20 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.

21 Some PBMs that are vertically integrated with plan sponsors 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).

22 The Commission's calculation is based on Part D prescription drug event and direct and indirect remuneration data from CMS.

23 Among plans that have them in 2024, preferred pharmacies make up an average of 40 percent, 48 percent, and 49 percent of all PDP, general MA–PD, and SNP network pharmacies, respectively.

24 The Commission's calculation is based on Part D prescription drug event and direct and indirect remuneration data from CMS.

25 Anecdotal evidence suggests that there may be situations in which cost-sharing amounts charged at a preferred pharmacy are higher than at other (nonpreferred) pharmacies. Such situations may be possible if, for example, the prices are higher at the preferred pharmacy (compared with other pharmacies) and the beneficiary pays a percentage coinsurance based on that higher price.

26 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. Pharmacies, however, contend that these fees "remain unpredictable, inconsistent, and based on unattainable standards" (National Association of Chain Drug Stores 2022).

27 The Commission's calculation is based on Part D prescription drug event and direct and indirect remuneration data from CMS.

28 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 list-price spending. However, postsale rebates and discounts received by PBM subsidiaries such as mail-order and specialty pharmacies are not reported (Medicare Payment Advisory Commission 2017a). 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.

29 The price index reflects changes in the prices of existing products. It does not reflect the effect of launch prices of new products.

30 An individual NDC uniquely identifies the drug, its labeler, dosage form, strength, and package size.

31 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.

32 Abrilada is an interchangeable biosimilar product launched in the fall of 2023. The formulary files available at the time that the analysis was conducted did not include Abrilada.

33 The analysis was conducted in the fall of 2023 using the formulary files released in November. Consequently, the results do not reflect any formulary changes made after November 2023 files were released.

34 Enrollment for 2024 is estimated using 2023 enrollment, assuming beneficiaries remained in the same plan for 2024.

35 Monthly premiums paid by individual beneficiaries will vary as they pay the base premium plus any difference between their plan's bid and the nationwide average bid. Enrollees in costlier plans face higher-than-average premiums for standard Part D coverage; similarly, enrollees in less expensive plans pay lower-than-average premiums.

36 Based on the national average bid and the base beneficiary premium amounts for 2024, we calculate that, in 2024, Medicare's average subsidy rate (before reconciliation) will be about 77.5 percent.

37 Amounts are calculated from information in CMS's announcement of the 2024 Part D national average monthly bid amount and base beneficiary premium (Centers for Medicare & Medicaid Services 2022).

38 Although the legislative change to cap insulin cost sharing at $35 for each prescription of a month's supply became effective January 1, 2023, because the change was made after plan bids for 2023 had already been submitted, bids for basic benefits in 2023 did not fully reflect the expected costs of the more generous insulin coverage. Note that, for 2023, about half of all plans had planned to participate in the Senior Savings Model that covered certain insulins at no more than $35 for each prescription of a month's supply under their enhanced benefits.

39 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.

40 However, going forward, the elimination of cost sharing in the catastrophic phase of the benefit beginning this year and the lowering of the OOP threshold in 2025 is expected to lessen cost-related access issues, particularly among enrollees without the LIS. As a result, in both 2024 and 2025, we may see an uptick in the number of high-cost enrollees without the LIS.

41 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.

42 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).

43 The Tukey outlier deletion methodology was employed for the first time this year to remove outliers from the data before determining threshold cut points for each of the measures. Because the outliers tended to be on the lower end of the spectrum, the cut points were higher than they would have been if those outliers were not deleted, and thus fewer plans were able to meet the higher thresholds.

44 The relationship between higher cost sharing and adherence, treatment initiation, and the rate of prescription abandonment is likely to vary widely across therapeutic classes. For example, patients may be less likely to abandon or not adhere to treatment plans for certain cancer regimens compared with therapies for chronic conditions such as rheumatoid arthritis (Medicare Payment Advisory Commission 2019b). This difference may reflect the varying availability of patient assistance programs for different disease types.

45 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.

46 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.

47 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 2021a).

48 For example, a sponsor might choose to provide more counseling services on medication adherence and devote fewer resources to CMRs.

49 Assessments of whether beneficiary outcomes improved or expenditures declined were determined by comparing outcomes and expenditures of beneficiaries enrolled in plans participating in the demonstration with beneficiaries in plans not participating in the demonstration using a propensity score matching approach, and results are expressed relative to nonparticipants. Expenditure assessments included both Medicare Part A and Part B spending, as well as prospective and performance-based payments made as part of the demonstration, but not Part D (outpatient prescription drug) spending.

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