

CHAPTER

# 13

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

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

## Chapter summary

In 2020, the Part D program paid for outpatient prescription drug coverage on behalf of more than 47 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 to nearly 13 million individuals with low income and assets. The 2020 benefit year was extraordinary due to the coronavirus pandemic and its toll on Medicare beneficiaries and health care providers. However, Medicare beneficiaries experienced comparatively less disruption of access to medicines than to other types of health care services; only 7 percent had to forgo medications compared with 36 percent for medical services.

In 2019, Part D program expenditures totaled \$102.3 billion, accounting for about 12 percent of Medicare spending. Enrollees paid \$13.9 billion of the \$102.3 billion in plan premiums for basic benefits and separately were responsible for paying an additional \$16.7 billion in cost sharing plus additional amounts in premiums for enhanced benefits. Part D has been a success in many respects. It has improved beneficiaries' access to prescription drugs. Generic drugs account for nearly 90 percent of the prescriptions filled. More than 9 in 10 Part D enrollees report they are satisfied with the program.

## In this chapter

- Part D's approach
- Enrollment, plan choices in 2020, and benefit offerings for 2021
- Plan sponsors and their tools for managing benefits and spending
- Drug pricing
- Program costs
- Beneficiaries' access to prescription drugs
- Quality in Part D

However, changes to Part D's benefit design combined with trends in drug spending have eroded plans' incentives for cost control. Over time, a growing share of Medicare's payments to plans have taken the form of cost-based subsidies rather than capitated payments, and the financial risk that plans bear has declined markedly. Last year, the Commission recommended major changes to the Part D benefit design and Medicare's subsidies to restore the role of risk-based, capitated payments that was present at the start of the program and provide drag on drug price increases. Separately, we are concerned that the LIS has features that limit premium competition among plans that serve low-income beneficiaries.

Nearly 300 organizations sponsor Part D plans, but most beneficiaries are enrolled in plans sponsored by a handful of large health insurers. Most large plan sponsors are vertically integrated with their own pharmacy benefit manager (PBM) and many also operate mail-order and specialty pharmacies. Formularies remain plan sponsors' most important tool for managing drug benefits. Generally, pharmaceutical manufacturers pay larger rebates when a sponsor positions a drug on its formulary in a way that increases the likelihood of winning market share over competing drugs. Plan sponsors and PBMs have negotiated rebates that have grown as a share of Part D spending. However, the wide gap between spending before and after rebates raises concerns about the accuracy of Part D's risk adjustment system.

***Enrollment in 2020 and benefit offerings for 2021***—In 2020, 74.6 percent of Medicare beneficiaries were enrolled in Part D plans. An additional 1.9 percent obtained drug coverage through employer-sponsored plans that received Medicare's retiree drug subsidy. The remaining 23.5 percent were divided roughly equally between those who had creditable drug coverage from other sources and those with no coverage or coverage less generous than Part D.

Between 2019 and 2020, enrollment in stand-alone prescription drug plans (PDPs) declined from 25.5 million to 25.1 million, while enrollment in Medicare Advantage–Prescription Drug plans (MA–PDs) expanded. As a result, in 2020, 47 percent of enrollees were in MA–PDs compared with 30 percent in 2007. The number of enrollees who received the LIS has grown more slowly than the broader Part D population. In 2020, LIS enrollees made up 27 percent of total enrollment.

For 2021, beneficiaries have a broad choice of plans. Compared with plan offerings in 2020, sponsors are offering 5 percent more PDPs, 12 percent more MA–PDs open to all beneficiaries, and 14 percent more MA–PDs tailored to specific populations (special needs plans). In 2021, over 1,600 plans are participating in the Center for Medicare and Medicaid Innovation's new Part D senior savings model that covers certain insulins at cost sharing of no more than \$35 per one-month

supply. Most plans use a 5-tier formulary that uses differential cost sharing between preferred and nonpreferred drugs, as well as a specialty tier for high-cost drugs. For 2021, the \$33.06 base beneficiary premium increased by 1 percent, reflecting the increase in the total average estimated cost for basic benefits. However, individual plans' premiums can vary substantially. In 2021, 259 premium-free PDPs are available to enrollees who receive the LIS, a 6 percent increase from 2020. All regions have at least five premium-free PDPs for LIS enrollees.

**Part D program costs**—Between 2007 and 2019, Part D program spending increased from \$46.2 billion to \$88.4 billion (average annual growth of 5.6 percent). Medicare's reinsurance (which covers 80 percent of spending in the catastrophic phase of the benefit) continues to be both the largest and fastest growing component of program spending, at an annual average rate of about 16 percent since 2007. As a result, between 2007 and 2019, the portion of the average basic benefit paid to plans through the capitated direct subsidy fell from 54.7 percent to 15.3 percent. In 2019, Part D saw the largest increase ever in beneficiaries without the LIS reaching the benefit's catastrophic phase (high-cost enrollees). This growth was due, in large part, to changes in law that increased the coverage-gap discount paid by brand manufacturers from 50 percent to 70 percent. In 2019, high-cost enrollees accounted for 64 percent of Part D spending, up from about 40 percent before 2011. Overall, our index of Part D prices declined in 2019, owing to increased generic competition. However, the price decline was not uniform across therapeutic classes. In classes dominated by brand-name drugs or biologics, prices continued to rise. Despite deceleration in overall price growth, inflation in prices of drugs taken by high-cost enrollees will likely continue to drive their spending upward. In 2019, over 483,000 enrollees (11 percent of high-cost enrollees) filled a prescription for which a single claim was sufficient to meet the out-of-pocket threshold, up from just 33,000 in 2010. The increase in the number of beneficiaries with such claims has accelerated in recent years, rising by more than 100,000 since 2017.

**Beneficiary access and quality in Part D**—Data from CMS audits and Part D appeals processes suggest that beneficiaries may be less likely to encounter access issues for most drugs than in previous years. However, among beneficiaries without the LIS, high cost sharing for expensive therapies may be a barrier to access. Part D enrollees have experienced comparatively less disruption of access to medicines due to the pandemic than access to other types of health care services. In 2021, the average star rating among Part D plans increased somewhat for PDPs and decreased for MA-PDs. While average star ratings for MA-PDs continue to exceed those of PDPs, the trend among MA-PD sponsors of consolidating contracts leads us to question the validity of MA-PD ratings. It is not clear that current quality

metrics help beneficiaries make informed choices among their plan options. In the past, the Commission has expressed concerns about the effectiveness of plans' medication therapy management (MTM) programs to improve the quality of pharmaceutical care due to the lack of financial incentives for sponsors of stand-alone PDPs. In 2017, CMS implemented the Enhanced MTM program that rewards PDPs for reducing medical spending. However, the evaluation of the first two years of the five-year demonstration program has found no significant reductions in Medicare spending for Part A and Part B services among enrollees in Enhanced MTM plans. ■

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## Background

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Each year, the Commission provides a status report on Part D that examines several performance indicators: enrollment, plan benefit offerings, market structure, drug pricing, program costs, beneficiaries' access to medications, and quality. In 2020, the Part D program paid for outpatient prescription drug coverage on behalf of more than 47 million Medicare beneficiaries. 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 nearly 13 million individuals with low income and assets. In 2019, Part D program expenditures totaled \$102.3 billion on an incurred basis, accounting for about 12 percent of Medicare spending (Boards of Trustees 2020). Of that amount, Medicare spending for the LIS totaled \$29.8 billion: \$26.0 billion for cost sharing and \$3.8 billion for premiums. Of the \$102.3 billion program spending total, Part D enrollees paid \$13.9 billion in plan premiums for basic benefits. Above and beyond program spending, enrollees paid \$16.7 billion in cost sharing plus additional amounts in premiums for enhanced benefits.

In several ways, Part D has been a success. Since 2006 when it began, the program has improved Medicare beneficiaries' access to prescription drugs; from 2006 to 2018, the share with Part D or drug coverage at least as generous as Part D increased from 75 percent to 88 percent. Stand-alone prescription drug plans (PDPs) and Medicare Advantage–Prescription Drug plans (MA–PDs) are available in every region of the country. Nearly 90 percent of Part D prescriptions filled are for generic drugs, which tend to have lower prices and cost sharing than brand-name drugs. More than 9 in 10 Part D enrollees report they are satisfied with the program and with their plan (Medicare Today 2020).

Initially, most of Medicare's subsidies to Part D plans took the form of fixed-dollar payments per enrollee, giving plan sponsors strong incentives to manage benefit spending. However, changes in Part D's benefit design and trends in drug spending have resulted in a growing share of Part D subsidies taking the form of cost-based reimbursements to plans, and the financial risk that plans bear has declined markedly (Medicare Payment Advisory Commission 2020c). Last year, the Commission recommended major changes to the Part D benefit design

and Medicare's subsidies to restore the role of risk-based, capitated payments and provide some drag on drug price increases. These changes would shift more responsibility for Part D spending from Medicare (that is, the taxpayers) to Part D plans sponsors and drug manufacturers.

The 2020 benefit year was extraordinary due to the coronavirus pandemic and its toll on Medicare beneficiaries and health care providers. However, the pandemic's effects on the use of outpatient prescription drugs under Part D have been less pronounced than the effects on other health care services (see text box on the effects of COVID-19, p. 412).

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## Part D's approach

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Medicare's payment system for Part D is different from payment systems under Part A and Part B. In Part D, Medicare pays competing private plans to deliver outpatient drug benefits to beneficiaries whether they enroll in a PDP or MA–PD. Instead of setting prices administratively, Medicare bases payments on bids submitted by plan sponsors. Plan sponsors establish networks of pharmacies and apply formularies—lists of drugs the plan will cover that use differential 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.

## 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. Most LIS enrollees pay nominal copayments throughout the benefit; Part D's LIS pays for the remainder of plans' cost-sharing requirements on their behalf. Changes in law altered the design of the standard benefit for most Part D enrollees (those without the LIS, about 72 percent in 2019); the law did not do so for those who receive the LIS. As a result, there are two distinct standard Part D benefit designs.

## Part D's defined standard benefit

For the majority of Part D enrollees (those without the LIS), Part D's defined standard benefit covers 75 percent of drug spending above a deductible and all but 5 percent

## Effects of COVID-19 within Part D

**A**lthough the coronavirus pandemic has affected Medicare beneficiaries' lives in many ways, Part D enrollees have experienced comparatively less disruption of access to medicines than to other types of health care services. Results of a nationally representative survey of community-dwelling Medicare beneficiaries conducted in the fall of 2020 found that while 36 percent had missed a regular check-up or treatment for an ongoing condition due to the pandemic, only 7 percent had forgone prescription drugs or medications (Centers for Medicare & Medicaid Services 2020f).

In March 2020, as state and local governments placed restrictions on the operation of many businesses, most grocery stores and retail pharmacies were permitted to stay open, which helped to maintain access to medicines. Consumers stockpiled prescriptions, many with 90-day supplies. CMS encouraged Part D plan sponsors to allow extended fills of prescriptions without requiring face-to-face contact through relaxation of “refill-too-soon” restrictions and home delivery. Although we do not yet have 2020 claims for Part D, dispensing data that include claims from many payers show that in late March, pharmacies experienced about a 20 percent increase in prescription volume adjusted for days' supply (National Council for Prescription Drug Programs 2020). Throughout April and May, data for all payers show that individuals drew down those stockpiles and pharmacy dispensing volumes experienced single-digit declines. By August, however, the volume of adjusted prescriptions had rebounded somewhat closer to the volume for August 2019. Mail-order volume expanded, but patterns of patients visiting community pharmacies reverted closer to previous years' trends.

Initiation of new drug therapies has been affected by the pandemic more than prescription refills have. Between March and May 2020, as fewer patients visited providers in person, new starts of prescriptions fell by one third and, by August, remained more than 7 percent below 2019 levels (IQVIA Institute 2020,

National Council for Prescription Drug Programs 2020). Even though patients substituted telehealth for some in-person visits, providers were more likely to have telehealth visits with existing patients than with new patients and were less willing to initiate drug therapy remotely (National Council for Prescription Drug Programs 2020). Subsequently, providers developed protocols for safe in-person visits and the volume of new prescriptions gained ground but did not recover fully.

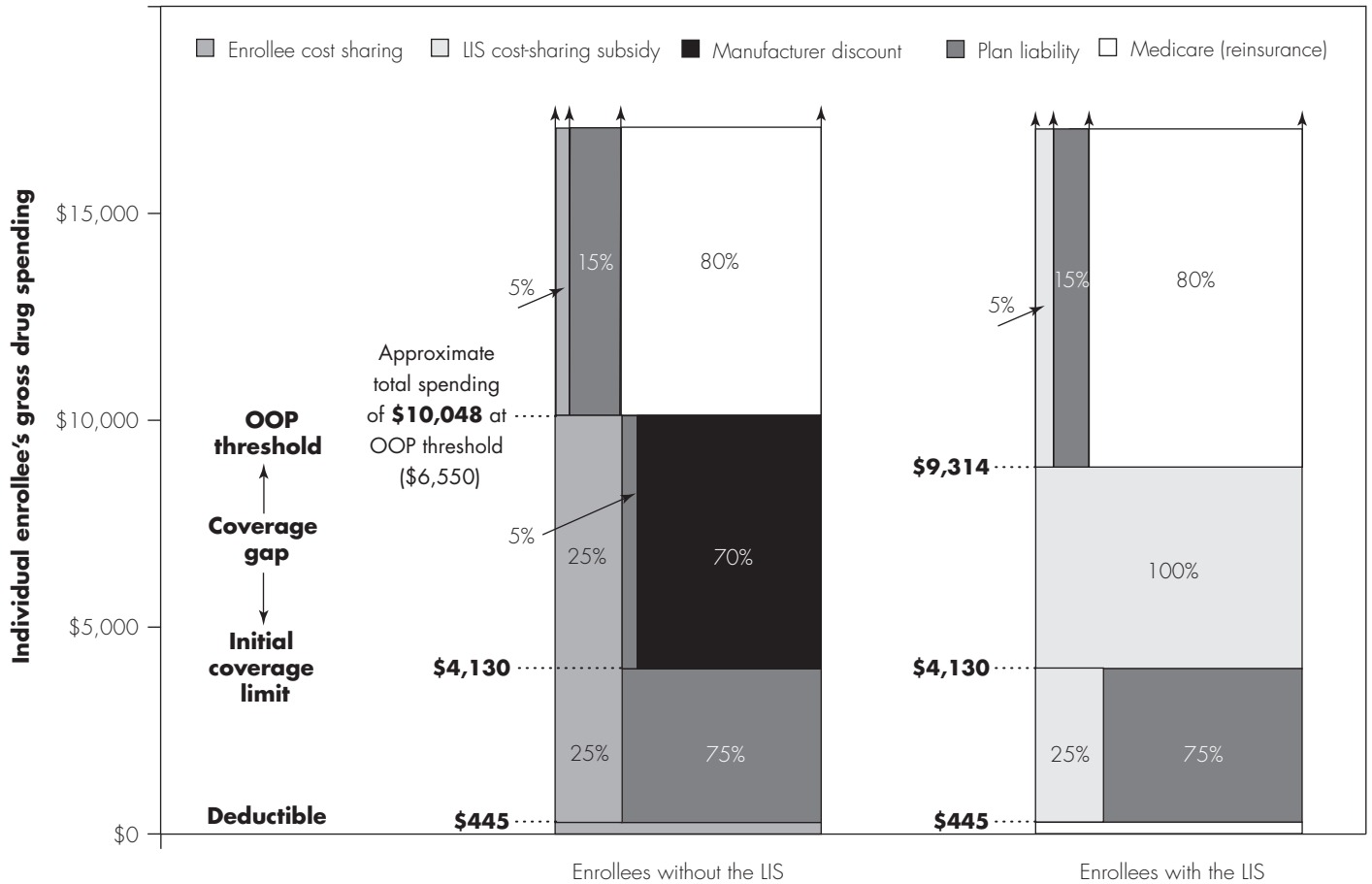
The overall effects of the coronavirus pandemic on prescription use and spending remain uncertain but are much less likely to have adversely affected Part D plans than Medicare fee-for-service providers. Much of plans' revenues do not depend on how frequently enrollees seek health care services because Medicare pays Part D plans monthly capitated amounts. Those payments are based on plan sponsors' bids for the cost of providing prescription drugs rather than updates to administered prices. Because plans submitted their bids for 2020 benefits in June 2019, well before the pandemic began, and because prescription volume had been modestly lower, bids were more likely to have been too high than too low. Bids that were, on average, higher than actual plan costs would result in plan profits. However, Part D applies symmetric risk corridors around plan bids. If actual benefit spending is significantly lower than what plans bid, Medicare recoups some of the profit associated with payments that are too high.

Similarly, for the 2021 benefit year, plan sponsors submitted bids to CMS in June 2020—amid the public health emergency. It is unclear what specific assumptions about use and spending plans incorporated into their bids. However, nationwide, plans' average bid for basic benefits in 2021 was fairly similar to that for 2020—about 1 percent higher. Because Part D's risk corridors are symmetric, they provide protection for plans that underbid relative to actual costs and allow the program to recoup profits if actual drug spending is lower than expected. ■



**FIGURE 13-1**

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



Note: LIS (low-income subsidy), OOP (out of pocket). For beneficiaries without the LIS (left bar), the coverage gap is depicted as it would apply to brand-name drugs, which are eligible for a 70 percent manufacturers' discount in the coverage gap. There is no 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 (\$10,048) was estimated by CMS for an individual with an average mix of drugs who does not receive Part D's LIS and has no other supplemental coverage. The bar depicting LIS enrollees (right) reflects full rather than partial LIS coverage. LIS enrollees do not receive brand discounts from manufacturers. For most LIS enrollees, Medicare's LIS pays for all cost sharing except nominal copayments, thereby including most spending in the coverage gap.

Source: MedPAC depiction of Part D benefit structure for 2021 as set by law.

coinsurance once an enrollee reaches an out-of-pocket (OOP) threshold (Figure 13-1). Each year, the standard benefit's parameters change at the same rate as the annual change in beneficiaries' average drug expenses. For 2021, the deductible in Part D's standard benefit is \$445 and enrollees pay 25 percent coinsurance until reaching an OOP threshold of \$6,550. That threshold is based on "true OOP" costs because it excludes beneficiary cost

sharing paid by most sources of supplemental coverage, such as employer-sponsored policies and more generous (enhanced) benefits from their Part D plan.

In the past, enrollees without the LIS whose spending exceeded an initial coverage limit were responsible for paying each subsequent prescription's full price at the pharmacy (i.e., 100 percent cost sharing) until they

reached an OOP threshold. This range of spending is known as the coverage gap or donut hole.<sup>1</sup> Enrollees no longer face higher cost sharing in the coverage gap; however, plans continue to identify whether a prescription is filled in that benefit phase because, under changes in law, enrollees without the LIS are eligible for a 70 percent discount from manufacturers on brand-name prescriptions in the coverage gap. No discount is applied to prescriptions for any generic drugs or for brand-name prescriptions filled by LIS enrollees. In 2021, brand discounts begin when an enrollee without the LIS has reached \$4,130 in cumulative drug spending and continue until the individual reaches \$6,550 in combined OOP spending plus brand discounts. Above this OOP threshold, enrollees pay the greater of 5 percent coinsurance or \$3.70 to \$9.20 per prescription.

### **Benefit for LIS enrollees**

For low-income beneficiaries, Medicare's LIS pays for the difference between cost-sharing amounts set by each plan and nominal copayments set by law (Figure 13-1, p. 413). In 2021, most individuals receiving the LIS pay between \$0 and \$3.70 per prescription for generic drugs and between \$0 and \$9.20 per prescription for brand-name drugs.<sup>2</sup> If, for example, a plan normally charges a \$40 copayment to fill a brand-name prescription, an LIS enrollee would pay up to \$9.20 and Medicare's LIS would pay \$30.80. Because 100 percent of the costs in the coverage gap count toward the OOP threshold, LIS beneficiaries reach the catastrophic phase at a lower level of spending than other enrollees do. Above the OOP threshold, LIS enrollees pay no cost sharing.

### **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 their basic benefits in ways that differ from the defined standard benefit, such as setting the deductible lower than \$445 or using tiered copayments rather than coinsurance. Some plans also encourage use of lower cost medicines by not applying a deductible when a prescription is filled with certain preferred generics. However, alternative designs must meet requirements for actuarial equivalence, demonstrating that they have the same average value as the defined standard benefit for a beneficiary of average health. CMS also sets maximum

cost-sharing amounts for drug tiers to ensure that a sponsor's plan design is not discriminatory.<sup>3</sup> Once a sponsor offers a PDP with basic benefits in a region, it can also offer up to two "enhanced" PDPs that combine basic benefits with supplemental coverage. For 2021, estimated OOP costs in a sponsor's basic and enhanced plans must differ by at least \$22 per month.

### **Two avenues for premium competition**

The hallmark of Part D is that private plans compete for enrollees based on premiums, formularies, pharmacy networks, and quality of services. There are two pathways through which premium competition takes place: rivalry to attract members and competition to keep premiums at or below benchmarks that reflect the maximum amount Medicare will contribute toward LIS enrollee premiums.

#### **General premium competition**

Part D plan sponsors compete to attract enrollees through low premiums, but sponsors do not set their premiums directly. Instead, sponsors submit bids to CMS that represent their revenue requirements (including administrative costs and profit) for delivering basic benefits to an enrollee of average health. CMS then calculates a nationwide enrollment-weighted average among all the bid submissions. From this average, enrollees pay a portion as a base beneficiary premium (\$33.06 per month in 2021) plus (or minus) any difference between their plan's bid and the nationwide average bid (Medicare Payment Advisory Commission 2020b). If enrollees pick an enhanced plan, the enrollee must pay the full price for the supplemental coverage (i.e., Medicare does not subsidize it). This approach is designed to give sponsors the incentive to control enrollees' spending so that they can bid low and keep premiums attractive. At the same time, sponsors must balance this incentive with beneficiaries' desire to have access to medications. A plan with a very limited number of covered drugs might not attract enrollees.

#### **Competition to keep premiums below LIS benchmarks**

Sponsors also compete to keep the premiums for some plans at or below regional LIS benchmarks. When policymakers developed the premium subsidy for LIS enrollees, they wanted to encourage enrollment in less expensive plans while ensuring that low-income beneficiaries had access to coverage. Policymakers

balanced these goals by creating a subsidy with two key features: (1) a benchmark that limits how much Medicare contributes toward a beneficiary's premium, and (2) automatic enrollment of LIS enrollees in PDPs with premiums at or below the benchmark. CMS calculates separate LIS benchmarks for each of Part D's 34 regions and updates them annually. Each LIS benchmark equals a region's average premium for basic coverage; plans that offer basic coverage and have premiums at or below the benchmark are premium free to LIS enrollees.<sup>4,5</sup>

This approach to setting Part D's LIS premium subsidy was intended to provide incentives for plan sponsors to control drug spending and bid low. LIS enrollees who have not selected a plan themselves are automatically enrolled in a benchmark PDP to which CMS assigns them randomly. Once LIS enrollees select a plan themselves, CMS no longer reassigns them to a new plan. Instead, the agency sends them letters about premium-free plan options. Many plans offered by larger sponsors have kept their benchmark status from year to year or have opted to forgo a de minimis amount of their premium in order to retain LIS enrollees.<sup>6</sup> Nevertheless, each year there is also some turnover in benchmark plans. If LIS enrollees are in a PDP with a premium that will exceed the benchmark and have not chosen a plan other than their assigned PDP, CMS reassigns them randomly to a new benchmark PDP.<sup>7</sup> If sponsors bid at or near the benchmark, they can gain or maintain market share for LIS enrollees without having to incur marketing expenses. Some aspects of how CMS calculates benchmarks and auto-enrolls beneficiaries temper premium competition (see text box on features of the LIS that limit competition, pp. 416–417).

For plan sponsors, auto-enrollees make up an important component of the PDP market. In 2019, 62 percent of the 7.3 million LIS beneficiaries in PDPs had been placed in their plans through the auto-enrollment and reassignment processes. As of November 2020, CMS expected to reassign randomly only about 100,000 LIS beneficiaries for benefit year 2021 (Liu 2020).<sup>8</sup> However, CMS also auto-enrolls LIS beneficiaries who are new to Part D among plans with premiums below regional benchmarks. Between 2015 and 2019, an average of 875,000 beneficiaries were randomly assigned to a benchmark PDP annually; roughly 85 percent were new Part D enrollees who had not yet selected a plan. As LIS enrollees remain in Part D, an increasing share choose a plan themselves and become ineligible for CMS reassignment.

## **Concerns about Part D and recommended changes**

Over time, changes to Part D's benefit design combined with trends in prescription drug pricing and spending have led to concerns about whether plan sponsors have incentives for cost control that are as strong as they were at the start of the program. Factors that have eroded those incentives include brand discounts in the coverage gap, growth in postsale rebates to plans from drug manufacturers, reduced plan liability for drugs filled in the coverage gap and catastrophic phases, and greater use of specialty and other high-priced drugs. As a result, plans' financial risk has declined in recent years. Recently, the Commission recommended major changes to the Part D program that would restructure its defined standard benefit.

### **Brand discounts in the coverage gap distort relative prices**

Changes in law phased out the coverage gap for enrollees who do not receive the LIS. Much of this benefit expansion was financed by requiring manufacturers of brand-name drugs to discount prices in the coverage gap. While those steps lowered OOP costs for some beneficiaries, the manufacturer discount artificially lowers prices for brand-name drugs relative to generics, reducing incentives to use generics. Those incentives are further undermined because the 70 percent discount is treated as though it were the enrollee's own OOP spending. As a result, enrollees without the LIS reach Part D's catastrophic phase more quickly when they use brand-name drugs than when they use generics. Brand manufacturers benefit when enrollees reach the catastrophic phase because they are no longer required to discount prices.

### **Reduced plan liability undermines plans' formulary incentives**

Even though Part D has two distinct benefit structures, plan sponsors bear little liability under either structure for spending in the coverage gap and catastrophic phases. In the coverage gap, sponsors are responsible for just 5 percent of brand spending for enrollees without the LIS and bear no liability for LIS enrollees. Sponsors cover 15 percent of spending in the catastrophic phase. Meanwhile, sponsors receive postsale rebates and discounts that, according to projections by CMS's Office of the Actuary, will average about 29 percent of total drug costs in 2021

## The low-income subsidy has features that limit competition among benchmark plans

In the Part D program, the prescription drug plans (PDPs) that offer basic coverage and have premiums that are lower than or equal to the low-income subsidy (LIS) benchmark are known as *benchmark plans*. These plans play an important role in providing coverage because LIS beneficiaries can enroll without paying a premium (the LIS covers the entire amount on their behalf) and Medicare automatically enrolls in benchmark plans any LIS beneficiaries who do not select a plan on their own. For 2021, there are a total of 246 benchmark plans; most Part D regions (30 of 34) have between 5 and 9 plans.

This approach provides LIS beneficiaries with a stable source of drug coverage, but it also reduces the incentives for benchmark plans to bid competitively. A plan that wants to serve low-income beneficiaries has an incentive to keep its premium below the benchmark to ensure that LIS beneficiaries can enroll without paying a premium and the plan can receive auto-enrollments. However, once a plan has qualified as a benchmark plan in a given year, it does not have an incentive to reduce its premium any further (Congressional Budget Office 2014). If the plan does lower its premium further below the benchmark, it cannot expect to receive any more enrollees in return, for two reasons. First, every benchmark plan in a region typically receives the same number of auto-enrollments. Second, LIS beneficiaries do not have an incentive to switch to the plan because they will not benefit from the lower premium. (Medicare saves money if they enroll in the lower-premium plan instead of another benchmark plan that is more expensive, but the beneficiaries themselves pay no premium in either case.) At the margin, a benchmark plan that lowers its

premium thus receives less Medicare revenue for the same number of enrollees.

As a result, benchmark plans try to keep their premiums just below the benchmark. The top half of Figure 13-2 shows the distribution of the 2021 premiums for basic PDPs, based on the difference between the plan's premium and the benchmark. Almost 90 percent of benchmark plans have premiums that are within \$6 of the benchmark, and only one has a premium that is more than \$10 below the benchmark. The bottom half shows the distribution of the premiums for enhanced PDPs for comparison, using the portion of the plan's premium that reflects the cost of basic coverage. These plans cannot qualify as benchmark plans, and their premiums do not show the same clustering pattern as basic plans. More than 60 percent of enhanced plans have premiums that are more than \$10 below the benchmark, which suggests that benchmark plans do not bid as competitively as they could, and that LIS benchmarks and spending are higher than they need to be.

Policymakers could consider modifying the LIS to encourage plans to submit lower bids, particularly by changing the practice of giving each benchmark plan in a region an equal number of auto-enrollments. For example, benchmark plans that charge lower premiums could receive a larger share of auto-enrollments. Such a change would make the market for benchmark PDPs more competitive—and thus complement the Commission's recommendations to restructure the Part D benefit (Medicare Payment Advisory Commission 2020c)—but it could also reduce the number of benchmark plans and increase the number of LIS beneficiaries who need to switch plans to avoid paying a premium. ■

*(continued next page)*

(Boards of Trustees 2020). For some brand prescriptions filled in the coverage gap and catastrophic phases, the value of rebates and discounts can exceed plan liability. As a result, plan sponsors may reduce their plan liability by including certain brand-name drugs on their formulary and giving that drug preferred status. However, those

formulary placement decisions can also increase costs for enrollees and Medicare (that is, the taxpayers) (Dusetzina et al. 2019).

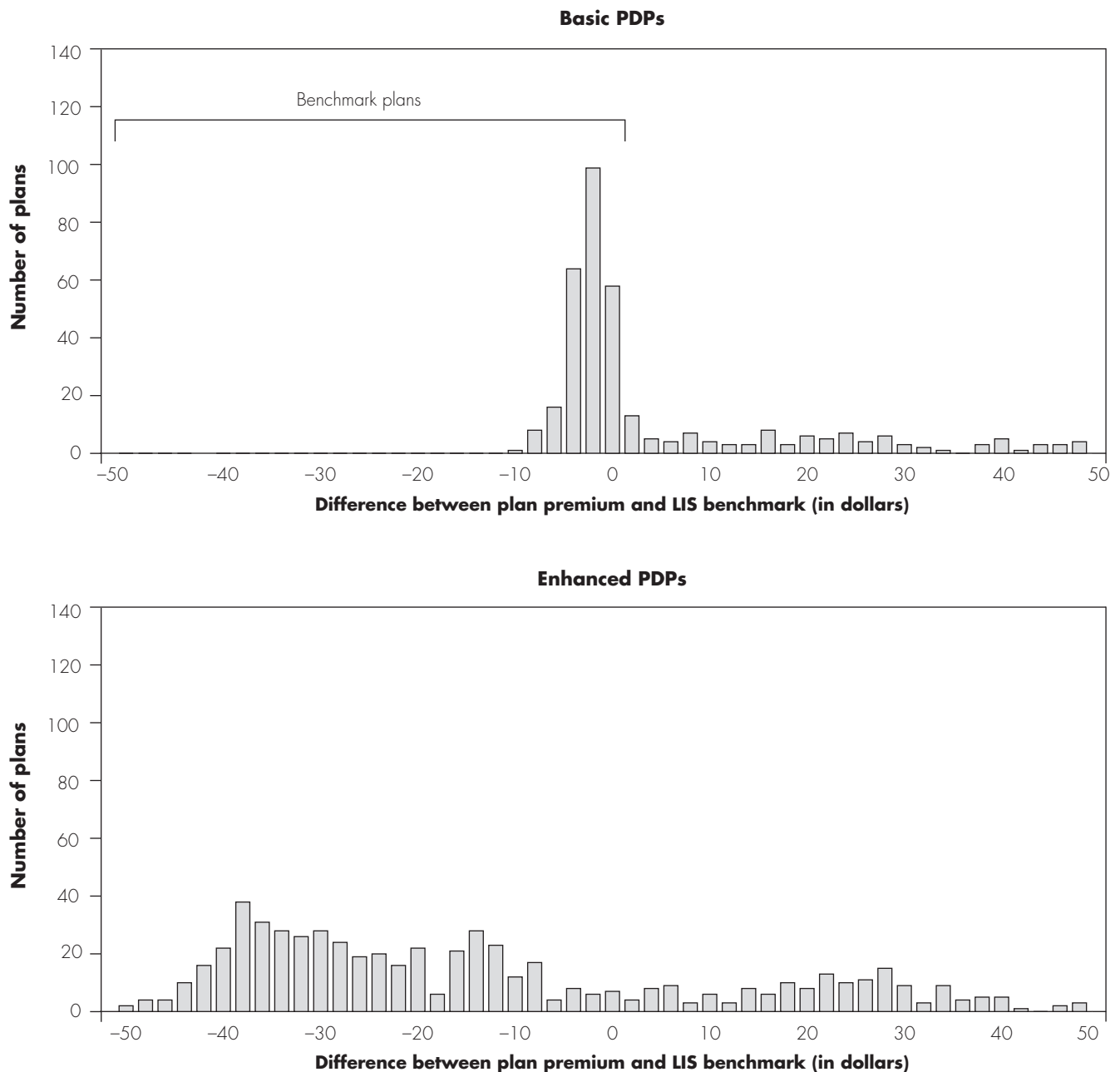
### **Some enrollees have high OOP spending**

In Part D, many plans charge a percentage of a drug's price at the pharmacy for prescriptions on certain

# The low-income subsidy has features that limit competition among benchmark plans (cont.)

**FIGURE 13-2**

**The premiums for most benchmark plans are clustered around the LIS benchmark**



Note: LIS (low-income subsidy), PDP (prescription drug plan). This figure is based on plan premiums and benchmarks for 2021 and does not include plans in the U.S. territories. For enhanced PDPs, we used the portion of the premium that reflects the cost of basic Part D coverage only; we did not include the supplemental premium that those plans charge to finance the cost of their enhanced benefits. This figure does not include plans with premiums that are more than \$50 below the benchmark (8 enhanced PDPs) or more than \$50 above the benchmark (29 basic PDPs and 13 enhanced PDPs).

Source: MedPAC analysis of CMS Part D premium and benchmark data.



formulary tiers or phases of the benefit rather than fixed-dollar copayments. For example, CMS permits plan sponsors to use a specialty tier with coinsurance of 25 percent to 33 percent for expensive therapies. Above Part D's OOP threshold, enrollees without the LIS pay 5 percent coinsurance with no OOP maximum. The share of Medicare Part D spending for specialty drugs and biologics has risen rapidly. At the same time, the gap between brand prices charged at the pharmacy and brand prices net of manufacturers' rebates has widened. When patients use rebated drugs, they pay coinsurance that is effectively higher (as a percentage of a drug's net price) than the stated coinsurance rate of 25 percent to 30 percent. The higher effective coinsurance results from manufacturers providing rebates to plans *after* patients fill their prescriptions, and plans charge coinsurance on the higher "gross" price at the pharmacy. High patient cost sharing can pose a financial hurdle to treatment, potentially affecting certain beneficiaries' decisions to fill their prescriptions.

### **Weak incentives for LIS enrollees to select lower cost medicines**

Although the LIS helps ensure access to medicines for low-income beneficiaries, its limits on cost sharing also give LIS enrollees weaker incentives to use lower cost drugs and make it more difficult for plan sponsors to manage drug spending. For enrollees without the LIS, plan sponsors set tiered cost sharing to provide strong incentives to select lower cost drugs: for example, a \$5 copayment for generics compared with \$40 to fill a prescription for a preferred brand-name drug (or higher amounts for nonpreferred drugs). In this example, for an enrollee without the LIS, the savings associated with choosing a generic would be \$35 (\$40 minus \$5). By comparison, because an LIS enrollee pays a maximum of \$3.70 for a generic prescription and up to \$9.20 for any brand-name drug, their OOP savings from taking a generic over a brand would be just \$5.50 (\$9.20 minus \$3.70). Similarly, LIS enrollees have no incentive to use a plan's preferred brand-name drug rather than nonpreferred ones (or nonformulary ones gotten through an exceptions process) because they would pay the same \$9.20 copayment regardless.

### **Expanded role of high-priced drugs has driven growth in reinsurance**

At the start of Part D in 2006, most spending was attributable to brand prescriptions for widely prevalent conditions such as high cholesterol and depression.

Blockbuster drugs for such conditions lost patent protection toward the end of that decade and many Part D enrollees switched to generic versions of their medicines. As those brand revenues fell, manufacturers turned to developing orphan drugs, biologics, and other high-priced specialty drugs for smaller patient populations. These trends have changed the distribution of Part D spending. Between 2006 and 2018, increased generic use kept growth in average Part D drug expenses to about 4 percent per year, but prices of brand-name drugs and biologics grew by more than 7 percent annually (Medicare Payment Advisory Commission 2019). As a result, an increasing share of Part D spending is in the benefit's catastrophic phase, in which Medicare pays 80 percent of costs through reinsurance. Between 2010 and 2018, the share of Part D spending attributable to the catastrophic phase increased from 20 percent to 41 percent (Medicare Payment Advisory Commission 2020c). Higher prices, reflecting both increases in prices of existing products and the use of new high-priced drugs, have been the primary driver of the growth in catastrophic spending.

### **Marked decline in plan risk over time**

The share of enrollees' benefit spending for which plan sponsors are at risk has declined markedly over time. We estimate that between 2007 and 2017, among enrollees without the LIS, the share of aggregate basic benefit costs for which plan sponsors were responsible declined from 53 percent to 29 percent (Medicare Payment Advisory Commission 2020c). For LIS enrollees, plan liability decreased from 30 percent to 19 percent. Meanwhile, the Medicare program's share of benefits reimbursed through cost-based mechanisms—reinsurance and LIS-paid cost sharing—rose commensurately. This decrease in plans' liability undermines incentives for plan sponsors to manage benefits and negotiate lower drug prices.

### **The Commission's recommendations for improving Part D**

In its June 2020 report to the Congress, the Commission recommended major changes to the Part D program that would restructure its defined standard benefit as follows:

- For spending below the catastrophic threshold, eliminate the manufacturers' coverage-gap discount that currently applies to enrollees without the LIS and remove the coverage gap for LIS enrollees. These changes would create a standard benefit for all enrollees in which plans would become responsible

for 75 percent of spending for benefits between the deductible and the catastrophic threshold, with enrollees responsible for the remaining 25 percent through cost sharing.

- For catastrophic spending, reduce Medicare’s reinsurance by shifting insurance risk to plan sponsors and drug manufacturers. Medicare would provide 20 percent reinsurance rather than the current 80 percent. Manufacturers would become responsible for at least 30 percent of catastrophic spending on high-priced medicines, while plan sponsors would be liable for the remaining 50 percent. The policy would also provide enrollees with greater financial protection by adding an annual cap on beneficiaries’ OOP costs.

The Commission recommended phasing in the reduction in Medicare’s reinsurance payments and increased plan liability for catastrophic spending. Sponsors would incorporate lower expected Medicare reinsurance subsidies and higher expected benefit liability into plan bids. In turn, Medicare’s capitated payments to plans would increase to incorporate their new, higher share of spending below and above the catastrophic threshold.

To help plan sponsors manage overall drug spending more effectively, the Commission recommended that the Congress establish a higher copayment amount under the LIS for nonpreferred and nonformulary drugs. In addition, plan sponsors would be provided with greater formulary flexibility for drugs in the protected classes. The Commission also recommended that plans be allowed to establish preferred and nonpreferred tiers for specialty-tier drugs to encourage their enrollees to use lower priced therapies.

The Commission’s recommended reforms would result in higher capitated payments for all enrollees, with a larger impact, in dollar terms, for LIS beneficiaries. However, given the structure of the risk adjustment model, CMS would need to recalibrate its model to ensure that overall payment rates were adequate for both LIS enrollees and other Part D beneficiaries.

Given plans’ greater insurance risk associated with catastrophic spending under these reforms, policymakers could consider modifying the Part D risk corridors to temporarily provide plan sponsors with greater protection during a transition to the new benefit structure. While the enhanced protection would be available to all plans, in practice, the protection would be particularly valuable

for smaller plans and plan sponsors that do not have the scale to spread the insurance risk or the capital to reinsure themselves.

The Congressional Budget Office estimated that the combined package of Commission recommendations would lead to one-year program savings of more than \$2 billion relative to baseline spending and savings of more than \$10 billion over five years.

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## **Enrollment, plan choices in 2020, and benefit offerings for 2021**

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Over time, a growing proportion of Medicare beneficiaries has enrolled in Part D. An important reason is a shift in enrollment from retiree drug plans to Part D plans set up for employer groups. Enrollment has also grown faster in MA–PDs compared with stand-alone PDPs.

### **In 2020, over three-quarters of Medicare beneficiaries were in Part D plans or employer plans that received the retiree drug subsidy**

In 2020, 47.0 million individuals—74.6 percent of Medicare’s total enrollment—were enrolled in Part D plans (Table 13-1, p. 420). That share is up from 54 percent of Medicare beneficiaries in 2007 (data not shown). An additional 1.9 percent of beneficiaries obtained drug coverage through employer-sponsored plans that received Medicare’s retiree drug subsidy (RDS) for serving as the primary provider. (The RDS is paid from the Part D program.) The remaining 23.5 percent of Medicare beneficiaries were divided roughly equally between those who had creditable drug coverage from other sources and those with no coverage or coverage less generous than Part D (data not shown).

The share of Medicare beneficiaries covered under Part D has grown over time. However, between 2019 and 2020, enrollment in PDPs declined from 25.5 million to 25.1 million (Table 13-2, p. 421). Instead, MA–PD enrollment (including special needs plans (SNPs)) has expanded, as has membership in employer group waiver plans (EGWPs)—Part D plans established for Medicare-eligible retirees of certain employers.<sup>9</sup> EGWPs can take the form of PDPs or MA–PDs. Between 2007 and 2020, enrollment in EGWPs grew by an annual average of 11 percent, reflecting the shift from employers operating

**TABLE  
13-1**

**More than three-quarters of Medicare enrollees received drug coverage through Part D, 2020**

	Beneficiaries	
	In millions	Share of Medicare enrollment
Medicare enrollment	63.0	100%
Part D enrollment*		
In Part D plans	47.0	74.6
In plans receiving RDS	1.2	1.9
Total Part D	48.2	76.5**

Note: RDS (retiree drug subsidy). Enrollment in Part D plans based on data as of April 1, 2020.

\*Excludes federal government and military retirees covered by either the Federal Employees Health Benefits Program or the TRICARE for Life program.

\*\*The remaining 23.5 percent of beneficiaries not enrolled in Part D are divided roughly equally between those who receive comparable drug coverage through other sources (such as the Federal Employees' Health Benefits Program, Tricare for Life, and the Department of Veterans' Affairs), and those who had no drug coverage or had coverage less generous than Part D.

Source: MedPAC based on Table IV.B7 and Table V.B3 of the 2020 annual report of the Boards of Trustees of the Medicare trust funds and CMS Part D enrollment data as of April 1, 2020.

plans that receive the RDS to Part D plans established for their retirees. In 2013, EGWPs accounted for 17 percent of Part D enrollment, but that share declined to 15 percent in 2020.

By 2020, among all Part D plans (including EGWPs), 47 percent of Part D enrollees were in MA-PDs compared with 30 percent in 2007 (Table 13-2). This trend in MA-PD enrollment is consistent generally with more rapid growth in MA enrollment compared with traditional fee-for-service (FFS) Medicare. Over the period from 2007 to 2020, among nonemployer plans, enrollment in MA-PDs grew an average 9 percent annually compared with 2 percent in PDPs.

In 2020, 12.8 million beneficiaries (27 percent of Part D enrollees) received the LIS (data not shown). Of these individuals, approximately 8.3 million were eligible for

both Medicare and full Medicaid benefits (Boards of Trustees 2020). The remainder qualified either because they received benefits through the Medicare Savings Programs or Supplemental Security Income program or because they were eligible after they applied directly to the Social Security Administration. Compared with other Part D enrollees, LIS enrollees are more likely to be female; more than twice as likely to be Black, Hispanic, or Asian or Pacific Islander; and over five times more likely to be under age 65 (Medicare Payment Advisory Commission 2020a).

Between 2007 and 2020, enrollment growth for Part D enrollees without the LIS was faster (7 percent per year) than for LIS enrollees (2 percent per year). This faster growth is partly attributable to the growth of EGWPs, which have few LIS enrollees. Over the same period, the share of Part D enrollees who received the LIS fell from 39 percent to 27 percent. In 2020, about 52 percent (6.7 million) of LIS enrollees were in PDPs; the rest were in MA-PDs. Although most individuals receiving the LIS are enrolled in traditional FFS Medicare rather than MA, since 2016, LIS enrollment in MA-PDs has grown while LIS enrollment in PDPs has declined due to the growth of their enrollment in SNPs (Boards of Trustees 2020).

**Beneficiaries' enrollment decisions in 2020**

Most enrollees are in plans that are actuarially equivalent to Part D's defined standard benefit or are enhanced in some way, rather than being in plans that follow the defined standard benefit. Enrollees in MA-PDs tend to have more generous benefits than beneficiaries enrolled in PDPs—in part because MA-PD plan sponsors are permitted to use a portion of their Medicare Advantage (MA) (Part C) payments to supplement their Part D benefits.

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

In 2020, 55 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copayments (Table 13-3, p. 422). The remaining 45 percent of PDP enrollees had enhanced benefits. No plan sponsors offered a PDP that used the defined standard benefit. Enrollees in MA-PDs, excluding SNPs, were overwhelmingly in enhanced plans. Typically, enhanced plans have no deductible or a lower deductible than that used for Part D's defined standard benefit. In MA-PDs, 49 percent of enrollees had no deductible in



**TABLE  
13-2**

**Part D enrollment trends by plan type, 2007-2020**

	<b>2007</b>	<b>2013</b>	<b>2019</b>	<b>2020</b>	<b>Average annual growth rate 2007-2020</b>
Total Part D enrollment (in millions)	24.2	35.4	45.4	47.0	5%
Share of Medicare beneficiaries	54%	67%	74%	75%	N/A
Enrollment by type (in millions)					
PDP	16.9	22.5	25.5	25.1	3
MA-PD	7.2	12.9	20.0	21.9	9
Share in MA-PD	30%	36%	44%	47%	N/A
Non-employer plan enrollees (in millions)					
PDP	16.2	18.1	20.8	20.4	2
MA-PD	<u>6.2</u>	<u>11.4</u>	<u>17.6</u>	<u>19.4</u>	9
Subtotal	22.4	29.4	38.4	39.8	5
Share in MA-PD	28%	39%	46%	49%	N/A
EGWPs (PDP and MA-PD, in millions)					
	1.8	6.0	7.1	7.2	11
Share in EGWP	7%	17%	16%	15%	N/A

Note: N/A (not applicable), PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), EGWP (employer-group waiver plan). Figures based on enrollment as of April 1 of each year with the exception of 2007 (as of July 1, 2007).

Source: MedPAC based on Part D enrollment data and Table IV.B7 and Table V.B3 of the 2020 annual report of the Boards of Medicare trust funds.

their plan’s benefit design. By comparison, only 15 percent of PDP enrollees and 8 percent of SNP enrollees were in plans with no deductible. However, 56 percent of PDP enrollees and 34 percent of SNP enrollees were in plans that do not apply a deductible to prescriptions filled from certain cost-sharing tiers, such as preferred generic drugs (data not shown). In addition, most SNP enrollees are individuals dually eligible for Medicare and Medicaid who receive Part D’s LIS, which covers most of their premium and cost sharing.

Under the MA payment system, MA-PD plan sponsors may use a portion of their Part C payments to supplement Part D drug benefits (e.g., by lowering deductibles) or to lower Part D premiums.<sup>10</sup> In 2020, MA-PD sponsors applied on average \$35 per month (27 percent) of their Part C rebate dollars to Part D benefits. Of that amount, 43 percent was used to lower Part D premiums for basic

benefits and the rest was used for supplemental drug benefits.

**Average enrollee premiums decreased in 2020**

Despite significant growth in catastrophic benefits, average premiums for basic Part D benefits have remained low for several reasons, including growth in manufacturer rebates and postsale pharmacy fees, a higher coverage-gap discount for brand-name drugs, and the entry of relatively large cohorts of younger enrollees into Part D. In addition, Medicare’s reinsurance subsidy has offset benefit spending that would otherwise have increased enrollee premiums.<sup>11</sup> In 2020, monthly beneficiary premiums averaged about \$27 across all types of plans (basic and enhanced), a 7 percent decline from the prior year. Average premiums have remained around \$30 per month since 2010. However, underlying that average is wide variation in

**TABLE  
13-3**

**MA-PD enrollees more likely to be in enhanced plans, 2020**

	PDP		General MA-PD		SNP	
	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent
Total	20.5	100%	15.3	100%	3.0	100%
Type of benefit						
Defined standard	0.0	0	0.1	<0.5	1.7	54
Actuarially equivalent*	11.3	55	0.2	1	0.4	12
Enhanced	9.2	45	15.0	98	1.0	34
Type of deductible						
Zero	3.0	15	7.4	49	0.2	8
Reduced	5.0	25	7.3	48	0.4	12
Defined standard**	12.4	61	0.5	4	2.5	81

Note: MA-PD (Medicare Advantage-Prescription Drug [plan]), PDP (prescription drug plan), SNP (special needs plan). "General MA-PD" enrollment excludes employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B-only plans. In 2020, 85 percent of SNP enrollees were in plans for dual eligible (Medicare and Medicaid) beneficiaries, 12 percent in plans for beneficiaries with certain chronic conditions, and 3 percent in plans for institutionalized individuals. Totals may not sum due to rounding.

\*Includes actuarially equivalent standard and basic alternative benefits.

\*\*Deductible of \$435 in 2020.

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

premiums, from \$0 for many MA-PDs to \$191 per month for the most expensive PDP offering enhanced coverage.

On average, prescription drug premiums were lower for beneficiaries enrolled in MA-PDs compared with those enrolled in PDPs, in part reflecting plan sponsors' use of Part C rebate dollars. In 2020, the average monthly premium for an MA-PD enrollee's Part D benefit was \$15, with an additional \$35 of premium costs paid through Part C rebates for basic and supplemental drug benefits (Medicare Payment Advisory Commission 2020d). By comparison, PDP enrollees faced an average premium of \$38 per month.

Two other factors affect the premium amounts enrollees pay. First, higher income individuals have a lower federal subsidy of their Part D benefits. As of October 2020, 3.8 million enrollees (about 8 percent) were subject to the income-related premium (Liu 2020). As with the income-related premium for Part B, higher Part D premiums

apply to individuals with an annual adjusted gross income greater than \$88,000 and to couples with an adjusted gross income greater than \$176,000. A beneficiary whose income exceeds these levels pays a monthly adjustment amount in addition to their Part D plan premium. For 2021, adjustments range from \$12.30 to \$77.10 per month, depending on income (Centers for Medicare & Medicaid Services 2020g).

Second, individuals enrolling in Part D outside their initial enrollment period must have proof that they had drug coverage as generous as the standard benefit under Part D (i.e., "creditable coverage") to avoid the late enrollment penalty (LEP) that would be added to their premiums for the duration of their Part D enrollment. The LEP amount depends on the length of time an individual goes without creditable coverage 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

**TABLE  
13-4**

**Comparison of PDP, general MA-PD, and SNP offerings, 2021**

	PDP		General MA-PD		SNP	
	Number of plans	Percent	Number of plans	Percent	Number of plans	Percent
Total	996	100%	3,133	100%	949	100%
Type of benefit						
Defined standard	1	<0.5	31	1	307	32
Actuarially equivalent*	377	38	66	2	103	11
Enhanced	618	62	3,036	97	539	57
Type of deductible						
Zero	139	14	1,582	50	194	20
Reduced	192	19	1,317	42	136	14
Defined standard**	665	67	234	7	619	65

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), SNP (special needs plan). The PDPs described here exclude employer-only plans and plans offered in U.S. territories. MA-PD plans exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B-only plans. SNP plans exclude U.S. territories. Among SNPs for 2021, 575 are for beneficiaries dually eligible for Medicare and Medicaid, 200 are for beneficiaries with certain chronic conditions, and 174 are for institutionalized beneficiaries. Totals may not sum due to rounding.

\*Includes actuarially equivalent standard and basic alternative benefits.

\*\*Deductible of \$445 in 2021.

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

creditable coverage. As of October 2020, 2.3 million Part D enrollees (nearly 5 percent) paid the LEP (Liu 2020).

### Benefit offerings for 2021

Beneficiaries are encouraged to reexamine plan options each year during an annual open enrollment period that runs from October 15 until December 7. In addition to changes in plan availability and premiums, most plans make some changes to their benefit offerings—such as deductible amounts and plan formularies—that can affect access to medications and beneficiaries’ OOP costs.

### Beneficiaries have more plan options in 2021

For 2021, plan sponsors are offering 996 PDPs, 3,133 general MA-PDs, and 949 SNPs—5 percent, 12 percent, and 14 percent more plans, respectively, than in 2020. The increase in PDPs reflects a greater number of enhanced plan offerings. Rapid growth in MA-PD offerings likely reflects interest among plan sponsors in gaining a share of MA’s expanding enrollment. At the same time, some MA-PD sponsors have expanded their SNP offerings.

In each of the nation’s 34 PDP regions, beneficiaries continue to have broad choice. Options range from 25 PDPs in Alaska to 35 PDPs in Texas, along with many MA-PDs in most areas. The number of MA plans available to a beneficiary varies by the county of residence, with the average beneficiary having 32 MA plans available.<sup>12</sup>

MA-PDs that are open to all enrollees are much more likely to offer more generous coverage than PDPs. For example, in 2021, 97 percent of MA-PDs include enhanced coverage beyond basic benefits, compared with 62 percent of PDPs (Table 13-4). Among plans with basic benefits, the 2021 marketplace includes just 1 PDP and 31 general MA-PDs (1 percent) with the standard benefit design. A larger share of MA-PDs than PDPs charges no deductible (50 percent vs. 14 percent), and 67 percent of PDPs use the same \$445 deductible as Part D’s defined standard benefit. By comparison, SNPs (i.e., MA-PDs designed for certain groups of beneficiaries) are much more likely to use the defined standard benefit (32 percent of SNPs) or the same deductible amount as the standard

**TABLE  
13-5**

**Change in 2021 premiums for PDPs with high 2020 enrollment**

Plan name in 2021	Benefit type	2020 enrollment (in millions)	Weighted average monthly premium*		
			2020 premium	Projected 2021 premium	Percent change
SilverScript Choice	Basic	3.9	\$29	\$28	-2%
AARP MedicareRx Preferred	Enhanced	2.0	79	89	12
Humana Basic Rx	Basic	1.5	31	31	0
Humana Premier Rx	Enhanced	1.4	58	65	13
AARP MedicareRx Saver Plus	Basic	1.2	32	33	2
WellCare Classic	Basic	1.1	29	28	-4
Humana Walmart Value Rx	Enhanced	0.8	13	17	30
WellCare Medicare Rx Saver	Basic	0.8	30	32	4
Elixir Rx Plus**	Basic	0.8	22	23	6
WellCare Value Script	Enhanced	0.8	17	17	0

Note: PDP (prescription drug plan).

\*Reflects the average of all PDPs offered under the same plan name in each region of the country, weighted by March 2020 enrollment. The projected weighted average premium for 2021 does not reflect any enrollment switching among plans. Percent changes were calculated before rounding.

\*\*Renamed from Envision Rx Plus in 2020.

Source: Cubanski and Damico 2020.

benefit (65 percent of SNPs). In 2021, 61 percent of SNPs are designed for beneficiaries who are dually eligible for Medicare and Medicaid, 21 percent for individuals who have certain chronic conditions, and 18 percent for institutionalized beneficiaries (data not shown). Because most beneficiaries in SNPs are LIS enrollees, those individuals pay nominal copayments rather than the cost sharing in their plan's benefit design.

### Varied changes in plan premiums

For 2021, CMS calculated that Part D's base beneficiary premium—enrollees' share of the monthly national average expected cost for basic benefits—is \$33.06, a 1 percent increase (32 cents) from their share in 2020. However, premiums for individual Part D plans can vary substantially from the base beneficiary premium because they reflect any difference between the sponsor's bid and the national average bid, as well as any enhanced (supplemental) benefits the plan offers. In addition, in 2021, MA-PD sponsors are applying on average \$40 per month of Part C rebate dollars to lower their Part D premiums compared with \$35 per month the prior year (a nearly 16 percent increase). Of the 2021 amount, \$19 pays for basic benefits and \$21 for enhanced benefits.

The 10 stand-alone PDPs with the highest enrollment in 2020 experienced a mixture of premium increases and decreases for 2021 (Table 13-5). Premiums for PDPs that provide basic benefits changed relatively little, with more substantial increases among some popular PDPs that offer enhanced benefits. For example, members of SilverScript Choice, a basic PDP with 3.9 million enrollees in 2020, saw a \$1 decrease in their monthly premiums for 2021. However, the 2 million individuals enrolled during 2020 in AARP MedicareRx Preferred (an enhanced PDP) faced a \$10 increase in their premium, now \$89 per month.

### More zero-premium PDPs available for LIS enrollees

In 2021, monthly premium benchmarks that reflect the maximum amount Medicare will pay on behalf of LIS beneficiaries range from \$22 in Texas to \$42 in New York. Compared with 2020 levels, the number of zero-premium PDPs available to LIS enrollees in 2021 increased by 6 percent to 259 plans.<sup>13</sup> All regions have at least 5 zero-premium PDPs available, while 3 regions (Arizona, Illinois, and Pennsylvania–West Virginia) have 10 such

PDPs. The number of zero-premium PDPs in Ohio expanded from two in 2020 to five for 2021.

About 0.6 million LIS enrollees (10 percent of LIS enrollees in PDPs) were enrolled in plans in 2020 that, in 2021, have premiums higher than regional benchmarks (Cubanski and Damico 2020). Unless they changed plans, those LIS enrollees would be responsible for paying some of the 2021 premium, which averages \$33 per month.

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

The top 10 PDPs (ranked by 2020 enrollment) tend to use 5-tiered formularies with differential cost sharing among drugs listed on preferred generic, other generic, preferred brand, and nonpreferred drug tiers, as well as a specialty tier for high-cost drugs. For 2021, PDPs that were available nationwide generally kept generic copays very low: Median copays are zero for preferred generics and \$5 for prescriptions filled from the other-generics tier (Cubanski and Damico 2020). The top 10 PDPs had a mix of cost-sharing increases and decreases for preferred brand-name drugs, generally on the order of a \$40 copayment, and a median coinsurance rate of 40 percent for nonpreferred drugs.

### **Demonstration models in Part D**

CMS's Center for Medicare & Medicaid Innovation (CMMI) is testing several models that aim to provide stronger incentives to sponsors for improving the quality of pharmacy services, increasing adherence to treatments that may reduce medical spending, and managing benefits.

- **Enhanced Medication Therapy Management (MTM) model.** MTM includes services such as medication reviews and adherence education that aim to uncover or prevent problems related to prescriptions (Center for Medicare & Medicaid Innovation 2020b). Although Part D requires all sponsors to offer MTM services, for years the Commission has had concern about the effectiveness of these efforts, particularly in stand-alone PDPs. In 2017, CMS began testing an Enhanced MTM model to see whether payment incentives and regulatory flexibility could improve enrollee therapeutic outcomes and reduce Medicare spending. Six Part D sponsors operating 22 PDPs in 5 regions of the country are participating over a 5-year period. About 1.3 million PDP enrollees in those plans were targeted for enhanced MTM services and 30 percent to 40 percent received services. Over the first

two years of the program, CMS found no significant reductions in Medicare spending for Part A and Part B services among enrollees in enhanced MTM plans (Acumen LLC 2020). In both years, plan payments under the model were slightly larger than observable decreases in spending, resulting in net costs to Medicare.

- **Part D payment modernization model.** In 2020, CMMI launched a model that aims to address rising Medicare reinsurance subsidy costs in Part D while preserving or improving quality of care (Center for Medicare & Medicaid Innovation 2020c). Participating plan sponsors accept two-sided (but asymmetric) risk and are eligible for performance-based payments or losses based on plans' actual reinsurance spending relative to predetermined benchmarks.<sup>14</sup> The model gives plans regulatory flexibilities to help manage enrollees' drug spending and permits plans to use rewards and incentives as tools for encouraging enrollees to use clinically equivalent lower-cost drugs. Two plan sponsors have participated so far, but CMMI has not yet provided details about their interventions or results.
- **MA value-based insurance design (VBID) model.** Encompassing both medical and drug offerings, the VBID model gives MA–PD sponsors flexibility to vary their supplemental benefits to encourage enrollees with certain chronic conditions to use high-value care.<sup>15</sup> Such benefits may include lowering or eliminating cost sharing for certain classes of prescription medicines such as antihypertensives. For 2021, 19 sponsors are offering VBID plans that include tailored rewards and incentives to a projected 1.6 million enrollees. An evaluation of the model's first three years (2017 through 2019) found small but statistically significant increases in prescription fills for certain targeted drugs, no significant changes to Medicare or MA costs, and lower Part D bids associated with the model in 2018 and 2019 (Center for Medicare & Medicaid Innovation 2020a).
- **Part D Senior Savings Model.** CMMI's newest Part D model lets participating enhanced drug plans include coverage of certain insulins at cost sharing of no more than \$35 per one-month supply. The model is intended to provide diabetics who do not receive Part D's LIS better access to insulin through more predictable cost sharing (see text box on the Senior Savings Model, pp. 426–427).



## Part D Senior Savings Model for insulin

**B**efore 2021, as beneficiaries reached the coverage-gap phase of Part D's benefit, most plans set their cost sharing at 25 percent coinsurance—even when the plan charged fixed-dollar copayments in the initial coverage phase of the benefit (Cubanski et al. 2020, Dusetzina et al. 2020a, Verma 2020). Plan sponsors used coinsurance in the coverage gap because of differences in how brand manufacturers' discounts are applied to basic versus enhanced plans. For beneficiaries without the low-income subsidy (LIS), manufacturers are required to offer a 70 percent discount on prescriptions filled in the coverage gap. However, when an enhanced plan charges lower cost sharing in the coverage gap than does the defined standard benefit, prices are not discounted until after supplemental benefits are covered (Center for Medicare & Medicaid Innovation 2020d). That lowers the amount of manufacturer discounts while increasing plans' benefit costs and enrollee premiums. According to CMS, this financial disincentive for

offering supplemental benefits during the coverage gap has resulted in “virtually no enhanced plans lowering beneficiary cost sharing in this phase for insulin or other brand drugs, biologics, or biosimilars” (Verma 2020). Under the Center for Medicare & Medicaid Innovation's (CMMI's) Senior Savings Model, participating insulin manufacturers pay the 70 percent discount before the application of supplemental benefits (Centers for Medicare & Medicaid Services 2020j).

At 2019 list prices for insulin, 25 percent coinsurance would amount to median out-of-pocket (OOP) costs ranging from \$70 to \$236 per month (Dusetzina et al. 2020a). By comparison, in 2019 many plans charged about \$45 per prescription in the initial coverage phase. To provide diabetics without the LIS better access to insulin through more predictable cost sharing, CMMI's Part D Senior Savings Model lets participating enhanced drug plans include coverage of certain insulins at cost sharing of no more than \$35 per

*(continued next page)*

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### Plan sponsors and their tools for managing benefits and spending

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Nearly 300 organizations sponsor Part D plans, but most beneficiaries are enrolled in plans sponsored by a handful of large health insurers. In addition to their role as insurers, plan sponsors carry out marketing, enrollment, customer support, claims processing, coverage determinations, and exceptions and appeals processes. Other key functions are performed by plans' pharmacy benefit managers (PBMs): developing formularies, establishing pharmacy networks, and negotiating with manufacturers and pharmacies for postsale rebates and discounts. Most large plan sponsors are vertically integrated with their own PBMs and many also operate mail-order and specialty pharmacies. Smaller plan sponsors typically contract for PBM services. By law, the Medicare program is prohibited from becoming involved in negotiations among sponsors, drug manufacturers, and pharmacies.

For the delivery of outpatient drug benefits, PBMs do not take physical possession of prescription medicines; pharmacies do. Pharmacies typically buy drugs from wholesalers and specialty drug distributors, dispense prescriptions to plan members, and are paid by PBMs for the difference between a negotiated amount and the member's cost sharing.

Final prices that plan sponsors pay for prescription drugs are usually lower than manufacturers' list prices, and the size of the discount sponsors obtain varies depending on negotiations for postsale rebates. Sponsors and their PBMs gain bargaining leverage with manufacturers through the relative size of their market shares of enrollees and by influencing market shares of drug products through their formularies. In drug classes that have competing therapies, PBMs negotiate with brand manufacturers for rebates that the manufacturers pay after each prescription has been filled. In this way, final prices that manufacturers

## Part D Senior Savings Model for insulin (cont.)

one-month supply. Plans participating in the model are not required to cover all insulins, but they must offer enrollees access to at least one of each type of insulin (e.g., short-acting insulin in a vial form) marketed by participating pharmaceutical manufacturers. CMS actuaries estimate that premium increases for participating plans associated with the model will be on the order of \$1 per month (Centers for Medicare & Medicaid Services 2020j). Beneficiaries in enhanced plans who take insulin could see their average annual OOP spending for insulins decrease from \$675 to \$229 (Verma 2020).

The agency notes that over 3.3 million Medicare beneficiaries who took insulin were enrolled in Part D plans. Of that total, 2 million were LIS enrollees who paid nominal copayments or were enrolled in an employer group waiver plan, which may have offered more generous coverage. Of the remaining 1.3 million beneficiaries, over 0.9 million (73 percent) were enrolled in enhanced plans.

Participation in the model by insulin manufacturers and plan sponsors is voluntary. For 2021, all three major manufacturers (Eli Lilly, Novo Nordisk, and Sanofi-Aventis) agreed to participate (Centers for Medicare & Medicaid Services 2020j). Over 1,600 plans are also participating, with 8 to 10 PDP options available in each region, in addition to multiple MA–PDs (Cubanski and Damico 2020).<sup>16</sup> Participating plans were identified in the Medicare Plan Finder tool on Medicare.gov so that beneficiaries could search for and select them during the fall 2020 open enrollment period.

The Senior Savings Model reduces cost sharing for insulin-dependent diabetics and may help their adherence to this important treatment. Nevertheless, beneficiaries with other conditions continue to face high OOP costs. Moreover, underlying structural features of Part D’s benefit design and subsidies that may have contributed to rapid growth in insulin prices remain unaddressed. ■

obtain for their drugs are individualized by payer. PBMs (and manufacturers) consider rebates highly confidential because broader knowledge about the magnitude of discount could affect what competitors demand in their own negotiations with manufacturers, compressing (and for some payers, reducing) rebates.

### Concentrated enrollment among plan sponsors

Most of the largest sponsors are insurers whose core business function has been to offer commercial and MA health plans with combined medical and pharmacy benefits. However, because some 60 percent of Medicare beneficiaries are in FFS Medicare, if those individuals choose to enroll in Part D, they obtain benefits through stand-alone PDPs. For this reason, PDPs remain an important market opportunity and many MA plan sponsors also offer PDPs.

Since the start of Part D in 2006, many large sponsors have horizontally merged or acquired other sponsors, thereby expanding enrollment and market shares. In 2020, the top seven sponsors ranked by enrollment and a group of Blue Cross and Blue Shield companies that collectively own Prime Therapeutics (a PBM) together accounted for 84 percent of Part D enrollment. In 2007, those same organizations accounted for 61 percent of enrollment.

Part D sponsors differ in competitive strategies and tend to focus on certain subsectors of enrollees. For example, in 2020, UnitedHealth Group plans accounted for 25 percent to 30 percent of national MA–PD enrollment and 22 percent of PDP enrollees without the LIS, but a comparatively smaller 12 percent of LIS enrollees in PDPs (Table 13-6, p. 428). Conversely, CVS Health (which owns insurer Aetna) had their highest market share among LIS enrollees in PDPs but a comparatively smaller share of the MA–PD market.

**TABLE  
13-6**

**Part D enrollment is more concentrated among PDP and employer group plan sponsors than MA-PD sponsors, 2020**

Stand-alone PDPs				MA-PDs				Employer group plans	
Without LIS		With LIS		Without LIS		With LIS		All enrollees	
Parent organization	Market share	Parent organization	Market share	Parent organization	Market share	Parent organization	Market share	Parent organization	Market share
UnitedHealth Group	22%	CVS Health	31%	UnitedHealth Group	25%	UnitedHealth Group	30%	Cigna	24%
CVS Health	19	Centene	22	Humana	19	Humana	17	UnitedHealth Group	24
Centene	16	Humana	16	CVS Health	9	Anthem	8	CVS Health	24
Humana	15	UnitedHealth Group	12	Kaiser Foundation	9	Centene	8	Kaiser Foundation	7
Cigna	14	Cigna	11	Anthem	4	CVS Health	5	Humana	5
Top 5	86	Top 5	92	Top 5	67	Top 5	69	Top 5	84

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy). Enrollees in each group total: PDP enrollees without LIS (18.4 million), PDP enrollees with LIS (6.7 million), MA-PD enrollees without LIS (15.9 million), MA-PD enrollees with LIS (6.1 million), and employer group plans enrollees (7.2 million). Components may not sum to totals due to rounding.

Source: MedPAC analysis based on April 2020 enrollment data from CMS.

Nationally, MA-PD enrollment is less concentrated than that for PDPs and employer-group plans. In 2020, the top five MA-PD sponsors enrolled 67 percent of enrollees without the LIS and 69 percent of LIS enrollees (Table 13-6). In addition to large health plans, MA-PD sponsors include a broader variety of companies, such as smaller regional organizations, religiously affiliated groups, and integrated delivery systems. By comparison, the top five PDP sponsors accounted for 86 percent of enrollees without the LIS and 92 percent of LIS enrollees.<sup>17</sup> Among employer-group plans, 84 percent of enrollees were in plans offered by the top five sponsors. Because some smaller sponsors contract for services with PBMs owned by large plan sponsors, PBMs' market concentration is higher than that shown for plan sponsors.

**Formulary management and manufacturer rebates**

Formularies remain plan sponsors' most important tool for managing drug benefits. Sponsors and their PBMs decide

which drugs to include and 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 while encouraging enrollees to use preferred therapies.

CMS requires plan sponsors to cover the types of drugs commonly needed by Part D enrollees as recognized in national treatment guidelines, and the agency reviews each plan's formulary as part of the process of deciding whether to approve its 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.

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. For example, a manufacturer might pay a base rebate for including the product on a plan's formulary but might pay larger rebates if the drug is on a preferred tier or if prior authorization requirements are waived. Producers of brand-name drugs with no therapeutic substitutes might not provide any rebates. An analysis of 2016 data provided by a group of Part D plan sponsors found that only about a third of brand-name drugs had more than nominal manufacturer rebates (Johnson et al. 2018). Rebates were largest in drug classes in which brand-name drugs competed directly with one another or when the brand drug faced competition from three or more generics. Payers and PBMs also negotiate "price-protection" provisions under which manufacturers rebate a drug's midyear price increases above a specified threshold.

Medicare policy can affect rebates. The Part D requirement to cover all protected-class drugs likely reduces plan sponsors' bargaining leverage with manufacturers; rebates are less easily obtained and smaller, on average, for brand-name drugs in protected classes. In the study described above, of 124 brand-name drugs in protected classes, only 16 received rebates, and among those drugs, rebates averaged 14 percent of point-of-sale (POS) prices compared with 30 percent for all brand-name drugs (Johnson et al. 2018).

### **Pharmacy networks and postsale fees**

Plan sponsors try to encourage enrollees to use pharmacies that dispense prescriptions at lower cost. For example, enrollees in some (non-Medicare) employer plans are required to fill prescriptions within an exclusive network of retail pharmacies, refill prescriptions by mail rather than through community pharmacies, and fill prescriptions with a 90-day rather than a 30-day supply. Likewise, in the commercial sector, vertically integrated plan sponsors often encourage their clients to dispense specialty drugs exclusively through their own specialty pharmacies.

Part D law and CMS guidance limit plan sponsors' ability to use those approaches. Most notably, 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.<sup>18</sup> Plan sponsors must also demonstrate that their network of pharmacies meets access standards. Nor can plan sponsors set up a narrower network of specialty pharmacies. With

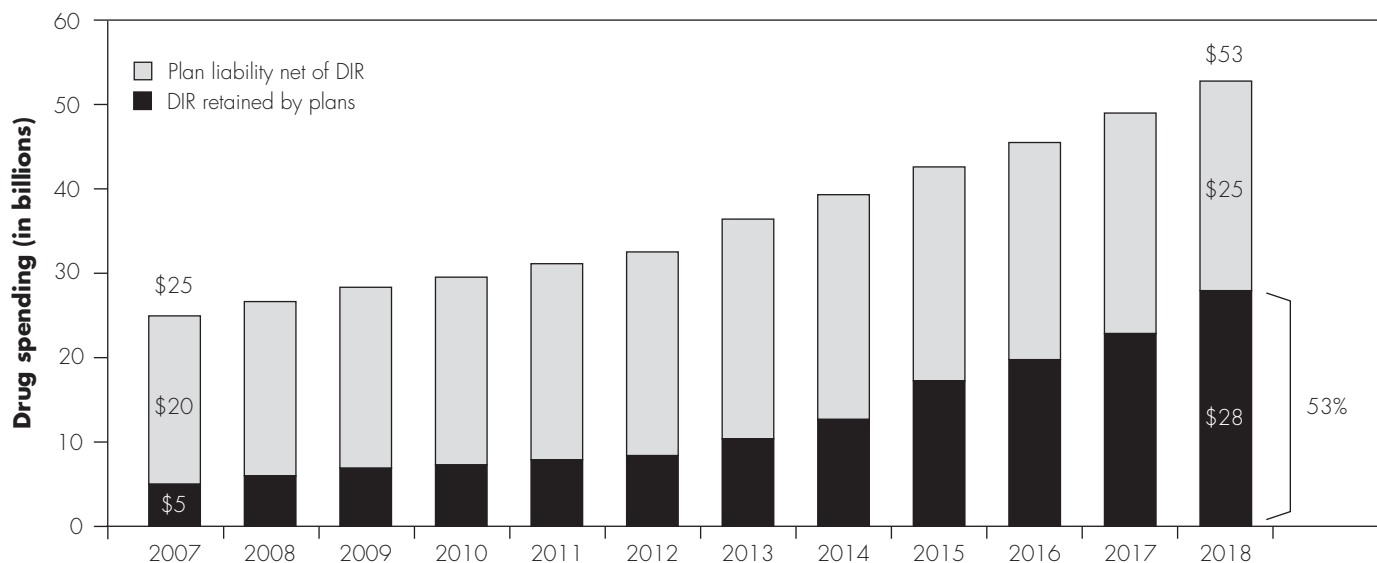
a few exceptions, Part D's convenient-access standards apply to the dispensing of all types of drugs, including specialty drugs.<sup>19</sup> However, traditional access standards may be less applicable to specialty pharmacies because typically they fill prescriptions primarily through home delivery.

Sponsors can, however, designate a subset of network pharmacies that offer preferred (lower) cost sharing. In 2021, 98 percent of PDPs use preferred cost-sharing pharmacies (Fein 2020b). 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, may be more effective at encouraging generic drug use. However, in previous years, tiered pharmacy networks have been controversial because of concerns that some Part D members have less access to preferred pharmacies. If LIS enrollees have less opportunity to use preferred pharmacy networks, the tiered network strategy could lead to higher Medicare spending because Medicare pays for most or all of LIS enrollees' cost sharing.

Although Part D sponsors cannot set up exclusive pharmacy networks, they can include other network contract terms that try to achieve the same aims—terms that have largely led to postsale payments from pharmacies to plans. The terms can include fees that are a condition for participating as a preferred cost-sharing pharmacy, periodic payment reconciliations related to drug reimbursement rates, or performance-based fees that are assessed on quality measures (Fein 2016). While participants in preferred networks gain more prescription volume, the pharmacies are essentially agreeing to lower and less predictable reimbursements from plans, which for some pharmacies has made participation in preferred networks much less desirable. For example, in 2021, some groups of independent pharmacies have chosen not to participate (Fein 2020a).

### **Aggregate postsale rebates and discounts have grown over time**

When Part D began in 2006, postsale rebates and discounts, referred to collectively as direct and indirect remuneration (DIR), offset a relatively small share of Part D's spending. However, DIR has grown rapidly in subsequent years. Manufacturer rebates make up the vast majority of DIR; in 2017, manufacturer rebates made up more than 80 percent of the \$35 billion in total Part D DIR

**FIGURE  
13-3****Rebates and discounts offset over 50 percent of plan liability  
in 2018, up from about 20 percent in 2007**

Note: DIR (direct and indirect remuneration). Gross plan liability (\$53 billion in 2018) is calculated as the difference between gross spending for Part D's basic benefit costs and the portion of the benefit costs paid by Medicare's reinsurance (80 percent of gross spending above the annual out-of-pocket threshold) before postsale rebates and discounts.

Source: MedPAC analysis based on Part D aggregate payment data from CMS Office of the Actuary and Part D's prescription drug event data.

obtained by plan sponsors (Fein 2018b).<sup>20</sup> In 2018, plan sponsors' share of DIR totaled \$28 billion and offset over 50 percent of the sponsors' benefit liability, up from about 20 percent in 2007 (Figure 13-3).<sup>21</sup> The widening gap between prescription prices at the pharmacy and prices net of rebates and discounts has led to concerns about the accuracy of Part D's risk-adjustment system, among other issues (see text box on the rapid growth in pharmaceutical manufacturer rebates).

### Recent regulatory issues in Part D

High prices of prescription drugs have been the focus of the administration for the last several years. In 2020 alone, there have been multiple executive orders and policy proposals aimed at addressing high drug prices. Two executive orders released in the summer of 2020 would have eliminated postsale pharmaceutical manufacturer rebates in Part D ("the rebate rule") and tied the payments for certain drugs covered under Part B and Part D to prices

paid in other countries (the "most favored nation" (MFN) pricing rule") (Executive Office of the President 2020a, Executive Office of the President 2020b). On November 20, 2020, the administration finalized the rebate rule and published an interim final rule for the MFN pricing rule that applied only to drugs covered under Part B (Centers for Medicare & Medicaid Services 2020h, Department of Health and Human Services 2020c).

Unlike most policies affecting Part D that are promulgated by CMS, the rebate rule is under the purview of the Department of Health and Human Services (HHS) Office of Inspector General. The final rule would modify the federal health care program's anti-kickback statute (AKS) safe harbor rule to disallow postsale rebates from manufacturers in Part D. The sunset of this safe harbor would have become effective on January 1, 2022, but has been delayed by a year (until January 1, 2023) as the new administration and stakeholders decide how to proceed.

## Rapid growth in pharmaceutical manufacturer rebates undermines the accuracy of Part D's risk adjustment

CMS risk adjusts Medicare's monthly capitated payments to plans using the prescription drug hierarchical condition category (RxHCC) model. The model predicts plan liability for Part D's basic benefit costs based on medical diagnoses and demographic factors.<sup>22</sup> The model is calibrated so that coefficients for condition categories reflect average drug costs associated with specific disease groups as reflected in Part D's prescription drug event (PDE) data.

In the early years of the program, Part D's risk adjustment system, estimated using gross prices (before deducting direct and indirect remuneration (DIR)), provided a reasonable approximation of the relative costliness of disease conditions. Because manufacturer rebates are typically tied to the sales of specific drugs, DIR's increasing role and variability across therapeutic classes raises concerns about the accuracy of the RxHCC model (Johnson et al. 2018, Langreth et al. 2016). When prediction inaccuracies occur systematically, risk adjustment may no longer be effective in mitigating risk-selection incentives (i.e., plans attracting enrollees with certain conditions and avoid enrollees with other conditions).

We examined how manufacturer rebates can affect Part D's risk adjustment by comparing the risk-adjustment factors estimated with and without rebates

for two categories of drugs—insulins used for the treatment of diabetes and tumor necrosis factor (TNF) inhibitors used to treat inflammatory conditions such as rheumatoid arthritis, ulcerative colitis, and Crohn's disease. We chose these two categories of drugs because we were able to obtain information on rebates and discounts from published studies and reports.<sup>23</sup> We also focused on these classes because they represented two very different types of drugs used by Part D enrollees: one, a widely used therapy with monthly costs in the hundreds of dollars per user; the other, a specialty drug used by a small number of beneficiaries with monthly costs in the thousands of dollars per user.

For simplicity, we used a single community segment model.<sup>24</sup> The base case was calibrated using 2017 diagnoses to predict 2018 gross plan liability, as reflected in the 2018 Part D prescription drug event data. Then we re-estimated the model using plan costs net of rebates for insulins and TNF inhibitors (net-cost model). Both models included the identical set of 76 RxHCCs and demographic variables (the same explanatory variables included in the current version of the RxHCC model).

### Using costs net of rebates reduced risk-adjustment factors by up to 75 percent

We found that using net costs lowered the risk-adjustment factors for conditions affected by insulins

*(continued next page)*

While eliminating the safe harbor for rebates, the final rule also would create two new safe harbor protections for:

- price reductions (discounts) given by drug manufacturers that are set in advance through a written agreement and are passed through to beneficiaries at the point of sale.
- service fees that a manufacturer pays to a PBM in exchange for a service provided by the PBM when the payments are based on fixed-dollar amounts (i.e., not related to the sales or prices of drug products).

The change to the AKS safe harbor rule is subject to review by the new administration and to legal challenge (Pharmaceutical Care Management Association 2021). One challenge relates to whether the proposed version of the rule had been officially withdrawn; if so, finalizing the rule may violate the Administrative Procedures Act (Ropes & Gray 2020).<sup>25</sup> Another point of contention is that the executive order on rebates mandated that the rule not increase federal spending, premiums, or patient out-of-pocket costs. There are a variety of ways in which

## Rapid growth in pharmaceutical manufacturer rebates undermines the accuracy of Part D's risk adjustment (cont.)

and TNF inhibitors.<sup>26</sup> Among the conditions affected by insulins, the reduction in risk-adjustment factors ranged from just over 10 percent for diabetes without complications (RxHCC31) to 75 percent for diabetic retinopathy (RxHCC241). For conditions affected by TNF inhibitors, the reduction in the risk-adjustment factors ranged from 13 percent for inflammatory bowel disease (RxHCC67) to 30 percent for rheumatoid arthritis and other inflammatory polyarthropathy (RxHCC83). The potential financial impact of incorporating rebates would vary depending on the individual plan bid. For a hypothetical plan with a bid equal to the national average bid in 2018 (\$57.93, or \$695 for 12 months), the use of net insulin costs would have lowered Medicare's annual payments for an enrollee who has diabetic retinopathy by \$214.

### Changes in the relative costs of conditions affect risk scores for all beneficiaries

A decrease in the relative costliness of a specific condition (e.g., diabetes) means that other conditions, not affected by the change in costs, are by definition

more costly relative to that condition. To illustrate this, we compared the changes in average risk scores for beneficiaries with a diagnosis of diabetes to those without the diagnosis. Under the net-cost model, risk scores averaged 1.39 among beneficiaries with diabetes compared with 1.53 in the base case (Table 13-7). That is, using net costs for insulins reduced the average risk scores by 0.14, or by 9 percent. The risk scores for other beneficiaries (i.e., without diabetes), on the other hand, increased by 0.06, or by 8 percent, on average.

The effects of using costs net of rebates on risk scores of beneficiaries with inflammatory conditions were similar (a decrease by 0.13, or 7 percent). However, the effects on other beneficiaries (i.e., without inflammatory conditions) were relatively small—an increase in the average risk scores of 0.01, or 1 percent. The impact on other beneficiaries, in this case, is much smaller than in the case of insulins because TNF inhibitors, while significantly more costly per patient than insulins, are used by less than 1 percent of Part D beneficiaries.

(continued next page)

**TABLE  
13-7**

**Changes in the relative costs of specific conditions affect risk scores for all beneficiaries**

	Risk score		Change in average risk score	
	Base case	Net costs	Value	Percent
Beneficiaries with diabetes	1.53	1.39	-0.14	-9%
Beneficiaries without diabetes	0.77	0.83	0.06	8
Beneficiaries with inflammatory conditions	1.75	1.63	-0.13	-7
Beneficiaries without inflammatory conditions	0.95	0.96	0.01	1

Note: The "base case" model was calibrated using 2017 diagnoses to predict 2018 gross plan liability, as reflected in the 2018 Part D prescription drug event data. Then we re-estimated the model using plan costs net of rebates for insulins and tumor necrosis factor inhibitors ("net-costs" model). "Beneficiaries with diabetes" includes all individuals who had an indication for prescription drug hierarchical condition category (RxHCC)30 (diabetes with complications) or RxHCC31 (diabetes without complications). "Beneficiaries with inflammatory conditions" includes all individuals who had an indication for RxHCC67 (inflammatory bowel disease), RxHCC82 (psoriatic arthropathy and systemic sclerosis), RxHCC83 (rheumatoid arthritis and other inflammatory polyarthropathy), or RxHCC316 (psoriasis other than arthropathy).

Source: MedPAC analysis of 2018 Part D prescription drug event data and Part D risk score file.

## Rapid growth in pharmaceutical manufacturer rebates undermines the accuracy of Part D's risk adjustment (cont.)

### Risk scores would vary less for plans than for individual beneficiaries

While the effects on risk scores of using net, rather than gross, costs in the risk-adjustment model on risk scores could be large for individual beneficiaries, plan payments are ultimately determined by the average of risk scores of all of their enrollees. As a result, the impact on an individual plan would depend on the plan's mix of RxHCCs indicated for its enrollees.

We found that, under the net-cost model, plan-level average risk scores increased for PDPs by 0.7 percent, on average, and decreased for MA-PDs by 1.5 percent (these averages are calculated using plan weights, not weighted by enrollment) (Table 13-8). Because inflammatory conditions affect only 6 percent of Part D enrollees, the effects on plan-level risk scores were relatively small (a reduction of less than 0.5 percent) (data not shown). Instead, most of the effects appear to be driven by change in the cost of insulins. Risk scores tended to decline among MA-PDs likely because a higher share of MA-PD enrollees with diabetes had an indication for RxHCC30 (diabetes with complications), a condition category for which using net insulin costs had a greater impact compared with RxHCC31 (diabetes without complications).

There were, however, wide variations around these averages. For example, average risk scores would have declined by 5.4 percent or more for 10 percent of MA-

PDs and increased by 2.1 percent or more for at least 10 percent of MA-PDs compared with the base case.

Our findings are specific to insulin and TNF inhibitors and therefore are not generalizable to other therapies or broader classes of therapies. However, there are several general implications for the program. First, the existence of manufacturer rebates on some, but not all brand-name drugs, likely results in overpayments for some conditions and inadequate payments for others. Second, Part D's risk adjustment may no longer provide adequate adjustment to mitigate against plan sponsors' incentives to engage in risk selection. The opportunity for financial gains could also encourage the use of formulary structures that favor high-price, high-rebate drugs even when lower-cost alternatives are available (Antos and Capretta 2019, Arambadjis et al. 2020, Dusetzina et al. 2019). This situation could worsen, particularly if manufacturer rebates continue to grow in tandem with higher prices. The findings also imply that both the magnitude of rebates and the prevalence of the condition(s) treated by the medication contribute to greater inequity across plans in their average risk scores, and therefore, their payments. Finally, using net, rather than gross, costs in the risk-adjustment model would improve the adequacy and accuracy of payments across plans. This change would be particularly important under the Commission's recent recommendations to restructure the Part D benefit that would increase the capitated payments' share of plan sponsors' revenues to cover Part D's benefit costs. ■

**TABLE  
13-8**

### Effects on plan-level average risk scores would be muted by the averaging of risk scores across enrollees

	Number of plans	Change in plan-level average risk score		
		Mean	10th percentile	90th percentile
PDPs	890	0.7%	-1.5%	2.7%
MA-PDs	3,171	-1.5	-5.4	2.1

Note: PDP ([stand-alone] prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]).

Source: MedPAC analysis of 2018 Part D prescription drug event data and Part D risk score file.



**TABLE  
13-9**

**Part D prices grew more slowly in 2019 compared with prior years**

	Price index as of December		Average annual percent change	
	2018	2019	2006-2018	2018-2019
All drugs and biologics	1.86	1.91	5.3%	2.6%
Single-source brand-name drugs and biologics	3.36	3.55	10.6	5.7
Generic drugs	0.17	0.15	-13.7	-11.0
After accounting for generic substitution	1.14	1.11	1.1	-2.1

Note: Chain-weighted Fisher price indexes. Prices reflect total amounts paid to pharmacies before rebates or discounts from manufacturers and pharmacies. Indexes are measured at the median of the distribution relative to prices as of January 2006. Price indexes shown are rounded; the change between 2018 and 2019 were calculated using unrounded data.

Source: Acumen LLC analysis for MedPAC.

manufacturers, plan sponsors, and PBMs could react to such a policy change, and consultants have estimated potential effects that range from higher to lower spending (Department of Health and Human Services 2020a). However, estimates by CMS’s Office of the Actuary and others suggest the policy would result in higher federal spending, and in some cases, higher beneficiary premiums (Department of Health and Human Services 2020a). CMS’s Office of the Actuary estimated that the policy would cost \$186 billion over 10 years, while the Congressional Budget Office estimated that it would cost \$177 billion over the same period. However, in November 2020, the HHS Secretary asserted that the implementation of the final rule would not increase federal spending, Medicare beneficiary premiums, or patients’ total OOP costs (Department of Health and Human Services 2020b).

**Drug pricing**

Growth in gross or POS prices—prices at the pharmacy counter—has been the focus of much recent attention. Most Part D enrollees primarily use generic drugs, and many (but not all) generic prices remain low. However, enrollees without the LIS who use brand-name drugs often feel the effects of rising POS prices when they pay coinsurance.

As policymakers have debated what to do about drug price growth, they have examined not only the market power of manufacturers in setting and raising prices but also the drug supply and distribution chains and benefits management. At all levels, incentives exist that drive prices higher. For one, payments for pharmaceuticals or services provided in conjunction with drug distribution are often based on a percentage of prices (Diplomat Specialty Pharmacy 2017, Fein 2018a, Feldman 2018, Garthwaite and Morton 2017). For another, some participants in the drug supply chain have tended to rely on drug price inflation for revenue growth (Cahn 2017, Fein 2017, Lopez 2016, Sell 2015). At the same time, manufacturers have shifted their development pipelines toward higher cost drugs and biologics, products that may not have direct therapeutic competitors. Over time, these factors, combined with the increasing market concentration of supply chain participants, have put upward pressure on both POS prices and rebates.

While some analysts contend that growth in prices net of rebates is the primary measure of importance, changes in POS and net prices are both important to monitor. Especially for drugs and biologics that are subject to coinsurance, prices paid at the pharmacy are an important indicator of Part D’s costs, since POS prices affect beneficiary cost sharing and the rate at which beneficiaries reach Part D’s catastrophic phase. At the same time, net

drug prices affect the premiums paid by Part D enrollees and subsidized by the Medicare program. Until recently, POS prices have grown aggressively. Although the Commission does not have data on rebates for individual drugs, Medicare Trustees report that average rebates have grown significantly.<sup>27</sup> Because, on average, rebates have grown even faster than POS prices, there has been a widening divergence between gross and net drug prices. As a result, a growing share of drug costs net of rebates have shifted to beneficiaries and the Medicare program.

### **Prices paid at the point of sale**

To examine growth in POS 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 price indexes reflect POS prices before retrospective rebates and discounts paid by pharmaceutical manufacturers and pharmacies and are measured at the median of the distribution unless otherwise noted.

### **In 2019, average prices decreased owing to new and existing generic competitors**

Between 2006 and 2019, drug prices, measured by individual national drug codes (NDCs), rose by an average of 91 percent (an index value of 1.91) (Table 13-9).<sup>28</sup> Overall, prices for Part D drugs and biologics grew more slowly in 2019 (2.6 percent) compared with an average annual increase of 5.3 percent before 2019.

Prices of generics are often a small fraction of the prices of their brand-name counterparts (Government Accountability Office 2016, Schondelmeyer and Purvis 2019). As a result, the use of generic drugs can provide significant savings to beneficiaries and the Medicare program. When measured by prices that take generic substitution into account, Part D prices decreased by 2.1 percent in 2019, a reversal of the inflationary trend that began after the 2012 “patent cliff.”<sup>29</sup>

### **“Deflation” was limited to specific therapeutic classes that experienced new or increased generic competition**

Price deflation, however, did not occur uniformly across therapeutic classes. Changes in price indexes between 2018 and 2019 varied widely, ranging from a drop of nearly 30 percentage points for anticonvulsants to an increase of about 10 percentage points for anti-

inflammatory drugs used for the treatment of conditions such as rheumatoid arthritis (annual changes are measured as the difference in cumulative price indexes as of December of respective years) (Table 13-10, p. 436).

New and increased generic competition for selected therapeutic classes played an important role in the decline in the overall Part D price index. Market entry of generic competitors to the anticonvulsant Lyrica (pregabalin) and a prostate cancer drug, Zytiga (abiraterone acetate), in late 2018 and 2019 likely accounted for most, if not all, of the decrease in price indexes for anticonvulsants (–29.9 percentage points) and antineoplastics (–2.6 percentage points).

For therapies to treat multiple sclerosis, the decrease in the price index in 2019 (by 6.5 percentage points) was likely due to the increased competition from the generic versions of Copaxone (glatiramer acetate) (Weintraub 2019) (Table 13-10, p. 436). With total Part D spending of nearly \$1.5 billion at its peak sales in 2017, Copaxone was considered one of the “blockbuster” drugs for the treatment of multiple sclerosis (Centers for Medicare & Medicaid Services 2019b, Weintraub 2019). Despite the availability of generics since 2015, its Part D market share was not materially affected until a court ruling invalidated Teva’s dosing patents for Copaxone in late 2018 (Elvidge 2018). Between 2017 and 2019, Copaxone’s share of all prescriptions for glatiramer acetate in Part D fell from 93 percent to 62 percent. Because generic versions of glatiramer acetate cost less than half that of Copaxone, the shift in market shares resulted in a lower average price.<sup>30</sup>

For other therapeutic classes that are dominated by brand-name drugs or biologics such as anti-inflammatory drugs and antidiabetic therapies including insulins, prices continued to rise. As a result, between 2018 and 2019, price indexes for high-priced specialty drugs and biologics also continued to increase.

With the share of generic prescriptions nearing 90 percent, there is less opportunity for generic substitutions.<sup>31</sup> Meanwhile, rapid growth in prices of single-source brand-name drugs and biologics will put upward pressure on Part D prices and program spending. Of particular concern is the increasing role of high-priced drugs and biologics. Between 2006 and 2019, our price index for biologics grew by a cumulative 266 percent (an index value of 3.66) (Table 13-10, p. 436). Accounting for generic (biosimilar) substitutions had almost no effect on

**TABLE  
13-10**

**Prices declined in some therapeutic classes but increased in others, 2018–2019**

	Price index as of December 2019 (relative to prices in January 2006)	Change from December 2018	
		Percentage points	Percent
Part D (after accounting for generic substitution)	1.11	-2.4%	-2.1%
Specialty-tier drugs*	2.58	1.8	0.7
Biologics	3.66	8.6	2.4
Selected therapeutic classes			
Antidepressant	0.24	-1.0	-4.0
Antipsychotic	0.61	1.1	1.9
Anticonvulsant	0.37	-29.9	-44.7
Immunosuppressant	0.41	1.2	2.9
Antiretroviral	1.89	7.3	4.0
Antineoplastic	2.17	-2.6	-1.2
Multiple sclerosis therapy	3.82	-6.5	-1.7
Anti-inflammatory	3.27	10.1	3.2
Antidiabetics**	2.86	8.7	3.1
Insulin	4.14	9.5	2.4

Note: Chain-weighted Fisher price indexes. Prices account for generic substitution and reflect total amounts paid to pharmacies before rebates or discounts from manufacturers and pharmacies.  
 \*Because there was no specialty tier defined for Part D plans until 2007, the price index for specialty-tier drugs is measured relative to prices as of January 2007 rather than January 2006 (i.e., set to 1.0 in January 2007).  
 \*\*Antidiabetics include both oral antidiabetic medications and insulins.

Source: Acumen LLC analysis for MedPAC.

the prices of biologics because competitive tactics among manufacturers and regulatory hurdles have so far worked to thwart entry of and price competition from biosimilars in Part D (see text box on lack of biosimilar competition, addressed in the March 2020 report to the Congress, pp. 430–431). High-priced drugs and biologics will pose a considerable challenge for the financing of the program as plan sponsors have little to no leverage to negotiate prices for many of these products.

**Program costs**

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

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

Combined, the direct subsidy and expected reinsurance payments aim to cover 74.5 percent of the expected cost of basic benefits. Today, a much larger share of Medicare’s payments takes the form of reinsurance (cost-based reimbursement) rather than the direct subsidy (capitated



**TABLE  
13-11**

**Medicare’s reimbursement amounts for Part D**

	Calendar year							Average annual growth rate	
	2007	2010	2015	2016	2017	2018	2019	2007–2018	2018–2019
Reimbursement amount (in billions):									
Direct subsidy*	\$17.6	\$19.6	\$18.1	\$17.1	\$14.6	\$13.5	\$11.6	-2.4%	-14.1%
Reinsurance	<u>8.0</u>	<u>11.2</u>	<u>33.2</u>	<u>35.5</u>	<u>37.6</u>	<u>40.6</u>	<u>46.3</u>	15.9	14.0
Subtotal, basic benefits	25.6	30.8	51.3	52.6	52.2	54.1	57.9	7.0	7.0
Low-income subsidy	16.7	21.1	25.6	26.4	27.3	28.5	29.8	5.0	4.6
Retiree drug subsidy	<u>3.9</u>	<u>3.9</u>	<u>1.1</u>	<u>1.0</u>	<u>0.8</u>	<u>0.8</u>	<u>0.7</u>	-13.4	-12.5
Total Part D	46.2	55.8	78.0	80.0	80.3	83.4	88.4	5.5	6.0
Enrollee premiums**	4.1	6.7	11.5	12.7	14.0	14.2	13.9	12.0	-2.1

Note: The numbers presented reflect reconciliation. Components may not sum to stated totals due to rounding.

\*Net of risk-sharing payments using Part D’s risk corridors.

\*\*For basic benefits, excluding low-income premium subsidies.

Source: MedPAC analysis based on Table IV.B10 of 2020 annual report of the Boards of Trustees of the Medicare trust funds.

payments). In addition to reinsurance, Medicare shares financial risk with plan sponsors by risk adjusting direct-subsidy payments to reflect the expected costliness of a plan’s enrollees and by limiting each plan’s overall losses or profits through risk corridors if actual benefit spending, excluding reinsurance, is much higher or lower than the plan sponsor anticipated in its bid.

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

**Trends in program subsidies and costs**

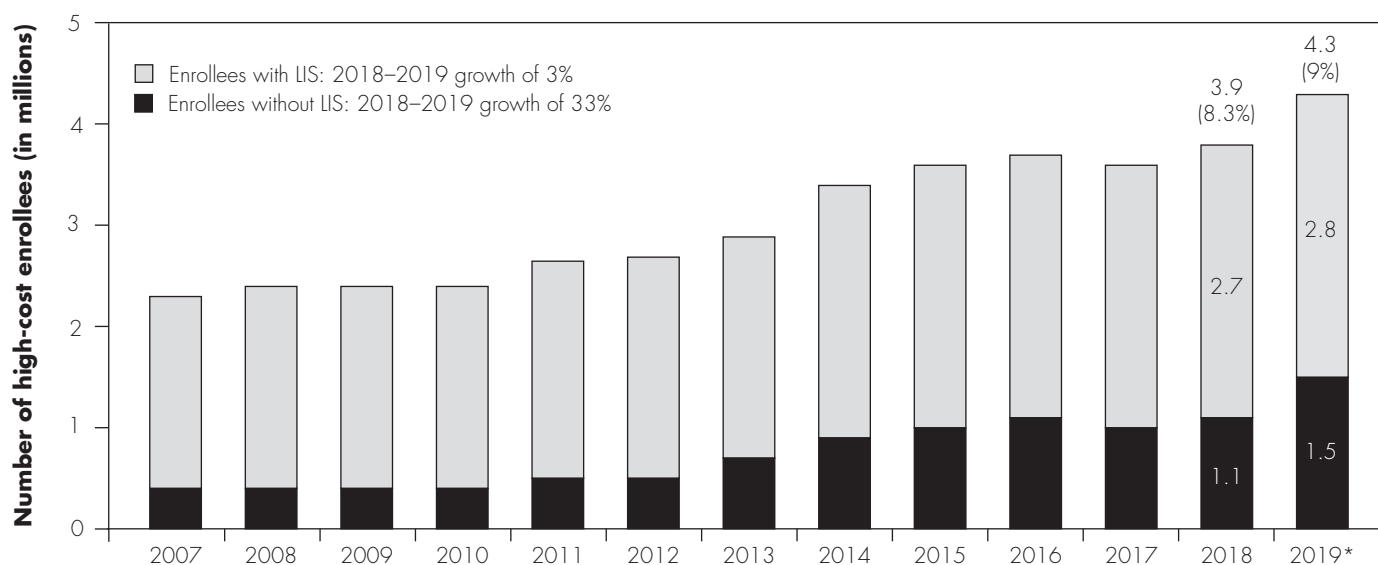
Between 2007 and 2019, program spending (including expenditures for the RDS) rose from \$46.2 billion to \$88.4 billion (Table 13-11), or an average 5.5 percent per year. In 2019, Medicare paid \$11.6 billion for direct subsidies, \$46.3 billion for individual reinsurance, \$29.8 billion for the LIS, and \$0.7 billion for the RDS. Medicare payments for individual reinsurance have grown faster than other

components of Part D spending. Between 2018 and 2019, reinsurance payments rose by 14 percent, compared with a decline of 14.1 percent for the capitated direct subsidy payments (Table 13-11).

In 2019, premiums paid by Part D enrollees for basic benefits (not including the premiums paid by Medicare on behalf of LIS enrollees) totaled \$13.9 billion, a decrease of 2.1 percent from \$14.2 billion in 2018. Before 2019, premiums paid by enrollees grew by an average of 12 percent per year, reflecting primarily growth in enrollment by beneficiaries who do not receive the low-income subsidy and some increase in benefit costs.<sup>32</sup> Despite significant growth in the catastrophic benefit (paid mostly by Medicare’s reinsurance), average premiums for basic Part D benefits have remained low, in part because plans tend to underestimate the amount of reinsurance they will need when they submit their bids. This behavior reduces beneficiary premiums because projected program spending is too low and results in Medicare subsidizing more than the 74.5 percent of program spending set in law.

**FIGURE  
13-4**

**Part D enrollees reaching the benefit's catastrophic phase, 2007-2019**



Note: LIS (low-income subsidy). Growth rates were calculated using figures before rounding was applied. Components may not sum to stated totals due to rounding.  
\*Preliminary figure based on Part D TAP prescription drug event data.

Source: Enrollee counts from 2007 are based on published figures from CMS. Enrollee counts for 2010 to 2019 are based on MedPAC analysis of Part D prescription drug event data.

### 2019 saw the largest ever increase in the number of beneficiaries without the LIS reaching the catastrophic phase

In 2019, 9.0 percent of Part D enrollees had spending high enough to reach the catastrophic phase of the benefit (high-cost enrollees), up from 8.3 percent in 2018 (Figure 13-4). In 2019, the number of beneficiaries reaching the catastrophic phase grew 12 percent to 4.3 million. The growth was driven by the largest-ever increase in the number of beneficiaries without the LIS reaching the catastrophic phase, which rose by 33 percent.

Medicare's spending for reinsurance grew correspondingly. Since 2010, changes in law coupled with rapid growth in POS prices and high take-up of new hepatitis C treatments led to a double-digit increase in the number of enrollees without the LIS who incurred spending high enough to reach the catastrophic phase (Hartman et al. 2018). This rate of increase in 2019 is unprecedented, likely reflecting recent changes in law that accelerated the closure of the coverage gap by increasing

the manufacturer coverage-gap discount on brand-name drugs (and biologics) from 50 percent to 70 percent. Because the manufacturer coverage-gap discount is treated as though it were the enrollee's own spending, a larger discount amount contributing toward the annual OOP threshold means that enrollees without the LIS reach the catastrophic phase more quickly.

### In 2019, more enrollees reached the catastrophic phase with lower levels of spending than in 2018

From the perspective of beneficiaries without the LIS, the higher manufacturer discount (70 percent) meant that (1) their cost-sharing liability for brand-name drugs and biologics was lower, and (2) a higher percentage of each prescription's price was counted toward the beneficiary's annual OOP threshold. As a result, when beneficiaries filled prescriptions for brand-name drugs or biologics in the coverage gap, the total amount of drug spending and OOP cost sharing needed to reach the annual OOP threshold was lower.

**TABLE  
13-12**

**In 2019, most high-cost enrollees without the LIS had lower levels of spending than in 2018**

	2018	2019*	Change 2018-2019
Annual OOP threshold	\$5,000	\$5,100	\$100
Median gross spending per high-cost beneficiary			
With LIS	14,108	14,621	513
Without LIS	17,073	15,641	-1,432
Median OOP spending per high-cost beneficiary**			
With LIS	60	56	-4
Without LIS	2,852	2,168	-684

Note: LIS (low-income subsidy), OOP (out-of-pocket). An individual's total gross drug spending at the annual OOP threshold depends on each beneficiary's mix of brand-name and generic drugs filled in the coverage gap.

\*Preliminary figures based on Part D TAP prescription drug event data.

\*\*Typically OOP spending paid by high-cost beneficiaries is lower than the annual OOP threshold because both Medicare's low-income cost-sharing subsidy and the coverage-gap discount paid by pharmaceutical manufacturers are counted toward the annual OOP threshold as if it were incurred by the beneficiary.

Source: MedPAC analysis of Part D prescription drug event data.

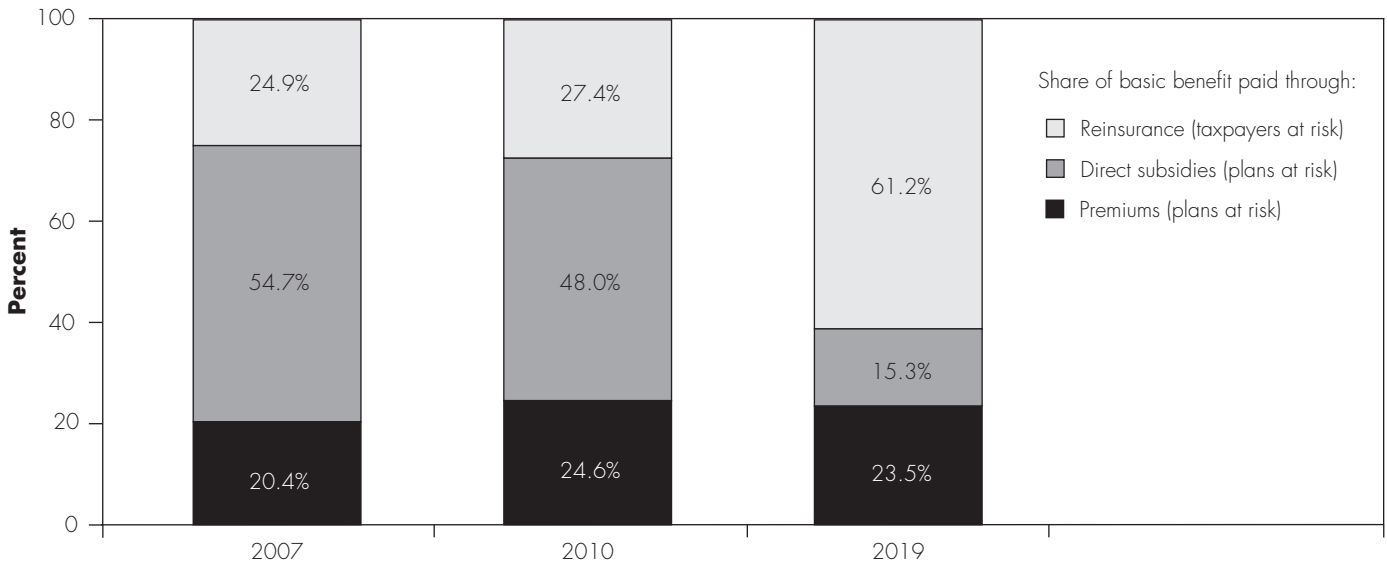
In 2019, the annual OOP threshold was set at \$5,100, up \$100 from \$5,000 in 2018 (based on a statutory formula) (Table 13-12). CMS's estimates for total (gross) spending at annual OOP thresholds in 2018 and 2019 were \$8,417.60 and \$8,139.54, respectively (Centers for Medicare & Medicaid Services 2018a).<sup>33</sup> The estimate for 2019 was lower because the changes made by the Bipartisan Budget Act of 2018 increased the coverage gap discount from 50 percent to 70 percent, and as a result, 95 percent of an enrollee's spending for brand-name drugs and biologics filled in the coverage gap counted toward the OOP threshold, compared with 85 percent in 2018.

In 2019, average levels of spending incurred by high-cost enrollees without the LIS were lower than in 2018 (Table 13-12). In 2019, median gross spending for high-cost enrollees without the LIS was over \$1,400 lower (\$15,641 compared with \$17,073 in 2018.) Correspondingly, these enrollees' OOP cost sharing fell—median OOP costs of \$2,168 in 2019 compared with \$2,852 in 2018. In contrast, for high-cost LIS enrollees, median gross spending rose by about \$500 while OOP cost sharing amounts fell slightly.

The surge in number of beneficiaries reaching the catastrophic phase of the benefit in 2019 pushed up the share of high-cost enrollees' aggregate spending (i.e., including catastrophic and noncatastrophic spending) to 64 percent of Part D spending from 61 percent in 2018. Despite the deceleration in the per capita spending for high-cost enrollees in 2019, the rapid growth in the average price of prescriptions filled will likely continue to drive spending for high-cost enrollees. Moreover, the number of beneficiaries filling a single prescription for a high-priced drug that was sufficient to meet the OOP threshold continued to grow. In 2019, more than 483,000 enrollees (about 11 percent of high-cost enrollees) filled such a prescription, up from just 33,000 in 2010.<sup>34</sup> The increase in the number of beneficiaries with such claims has accelerated in recent years, rising by more than 100,000 since 2017.

**Taxpayers bear an increasing share of the risk for Part D spending**

In nearly every year since 2007, the portion of basic benefits paid through enrollee premiums has been below the 25.5 percent objective specified in law. In

**FIGURE  
13-5****Taxpayers bear increasing share of the risk for Part D benefit spending**

Note: Figures represent aggregate values for incurred basic benefits net of risk corridor payments. Figures for enrollee premiums include amounts paid to Part D plans by enrollees and by Medicare on behalf of enrollees who receive the low-income subsidy.

Source: MedPAC analysis based on Table IV.B10 of 2020 annual report of the Boards of Trustees of the Medicare trust funds.

2019, premiums paid by enrollees or by Medicare’s LIS accounted for 23.5 percent of basic benefit costs (Figure 13-5). According to the Boards of Trustees, for 2019, enrollees’ share of the basic benefit costs were below the 25.5 percent set in statute because plan bids assumed higher DIR and slow reinsurance growth, and as a result, “reinsurance amounts in the 2019 [plan] bids were significantly underestimated” (Boards of Trustees 2020).

Insurance risk provides an incentive for plan sponsors to offer attractive benefits while managing their enrollees’ spending through formularies and other tools. However, data from the Boards of Trustees show that between 2007 and 2019, the portion of the average basic benefit paid to plans through Medicare’s capitated direct subsidy fell from 54.7 percent to 15.3 percent (Figure 13-5). Correspondingly, in 2019, the portion for which plans are at risk (direct subsidy payments plus enrollee premiums) accounted for less than 40 percent of benefit costs (23.5 percent plus 15.3 percent), down from about 75 percent in 2007 (20.4 percent plus 54.7 percent). Over the same

period, the portion paid through Medicare’s reinsurance subsidies (for which taxpayers are at risk) grew from about 25 percent to just over 61 percent. The Commission has been concerned that the shift of risk from plan sponsors to Medicare has eroded plans’ incentives to manage spending.

**Beneficiaries’ access to prescription drugs**

Formulary management is the most important tool used by plan sponsors. Greater flexibility to use formulary tools could help plan sponsors manage spending while ensuring that prescribed medicines are safe and appropriate for the patient, potentially reducing overuse and misuse. However, for some Part D enrollees, those same tools could limit access to needed medications. To ensure access, CMS reviews each plan’s formulary to check that it includes medicines in a wide range of therapeutic

classes used by the Medicare population and applies utilization management tools in appropriate ways. Further, Part D law requires sponsors to have a transition process to ensure that new enrollees, as well as current members whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.<sup>35</sup>

Medicare also requires plan sponsors to establish a process for coverage determination and appeals. Part D requires quicker adjudication times than for most medical benefits covered by Medicare Advantage (MA) plans.<sup>36</sup> If an enrollee is dissatisfied with a plan's final coverage decision (redetermination), he or she may appeal the decision to an independent review entity (IRE) and then to higher levels of appeal.

Measuring access is inherently complicated because clinical appropriateness can vary across patients. In reviewing beneficiaries' access to Part D drugs, we examined general program-wide indicators of access using data from CMS audits and Part D's appeals process, as well as recent research focused on Part D beneficiary access.

### **Audit results suggest improvements in formulary administration, coverage determinations, and appeals**

CMS audits a selection of sponsoring organizations each year for compliance with program requirements, ultimately covering most plan sponsors over its multiyear work cycle. Each year, CMS selects different plan sponsors to audit, and as a result, comparison across years is not always straightforward. In 2019, the audit covered 12 plan sponsors and about 71 percent of beneficiaries enrolled in the MA and Part D programs, up from 2 percent of beneficiaries in 2018 (Centers for Medicare & Medicaid Services 2020a).<sup>37</sup> Because of this seeming difference, CMS cautions against reading too much into the changes in audit performance from year to year.

Between 2017 and 2019, CMS found “no particular trend” in plan sponsors' performance for Part D formulary and benefit administration (FA) (e.g., accuracy of claims processing and appropriateness of utilization management applied) while over the same period observing improvements in coverage determinations, appeals, and grievances (CDAG) (Centers for Medicare & Medicaid Services 2020a). CMS noted, however, that the performance for formulary administration remained consistently strong during this period, with better than

average scores in all three years, compared with the audit results in 2015 and 2016 (Centers for Medicare & Medicaid Services 2020a).

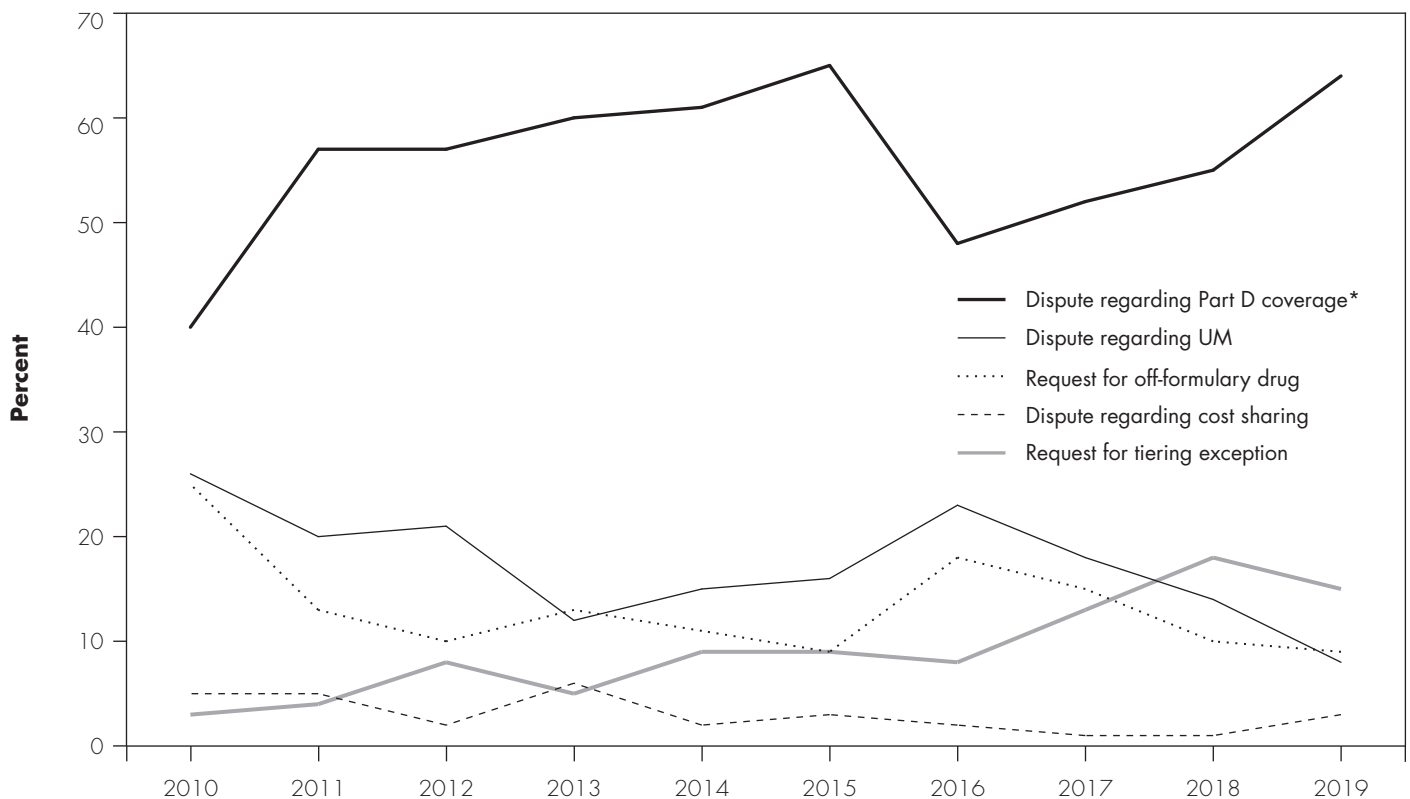
At the same time, plan sponsors' performance varied widely. For example, in 2019, for half of plan sponsors, CMS audits found no FA issues, but among other sponsors, the number and the severity of noncompliant actions led to audit scores ranging from 0.5 to 2.5 (lower scores are better) (Centers for Medicare & Medicaid Services 2020a).<sup>38</sup> Similar variation was observed for CDAG. The two plan sponsors that used a single formulary across all plans performed substantially better on both FA and CDAG than sponsors that used multiple formularies.

### **Independent reviewers were more likely to agree with plans' coverage decisions than in previous years**

Assessing how well Part D's exceptions and appeals processes work can be a challenge.<sup>39</sup> Currently, the IRE reports information about cases in the IRE step of the appeals process to CMS, which uses these data for measures in Part D plans' star ratings. Typically, only a small share of redeterminations is appealed or automatically forwarded to an IRE.<sup>40</sup> In 2019, the number of cases appealed or forwarded to an IRE totaled 36,227, or about 0.8 cases per 1,000 enrollees. The number of cases has fluctuated over the years, ranging from 0.4 cases per 1,000 enrollees to 0.9 per 1,000 enrollees.

The IRE hears Part D cases related to cost sharing, plans' application of utilization management tools, requests for formulary and tiering exceptions, and sponsors' decisions regarding plan coverage of a drug. Between 2010 and 2019, appeals related to drug coverage accounted for the largest share of the cases, ranging from 40 percent to 65 percent (Figure 13-6, p. 442). These cases typically relate to disputes about whether a prescription was written for a medically accepted indication or whether the drug meets the statutory definition of a Part D-covered drug (Centers for Medicare & Medicaid Services 2020i).

Between 2010 and 2019, appeals related to utilization management tools such as prior authorization and requests for coverage of a drug not on formulary generally declined, with the exception of an uptick in 2016, when many plan sponsors used prior authorization and quantity limits or limited formulary coverage to manage the use of new hepatitis C treatments (Hoadley et al. 2015, Jung et al. 2016).

**FIGURE  
13-6****Changes in the types of appeals that reach IRE, 2010–2019**

Note: IRE (independent review entity), UM (utilization management). UM tools used by plan sponsors include prior authorization, step therapy, and quantity limits.  
\*Part D coverage issues may arise, for example, from disputes about whether a prescription was written for a medically accepted indication or whether the drug meets the statutory definition of a Part D-covered drug.

Source: Part D reconsideration and appeals data from CMS for 2010 through 2019.

Between 2010 and 2019, the share of all appeals that were reversed by the IRE declined over time, from 47 percent to 11 percent (Figure 13-7). Despite fluctuations from year to year, all categories of appeals exhibited this general downward trend. These trends suggest that plans have improved their compliance with Part D’s formulary rules and have applied rules consistently in their coverage determinations (Office of Inspector General 2018b).

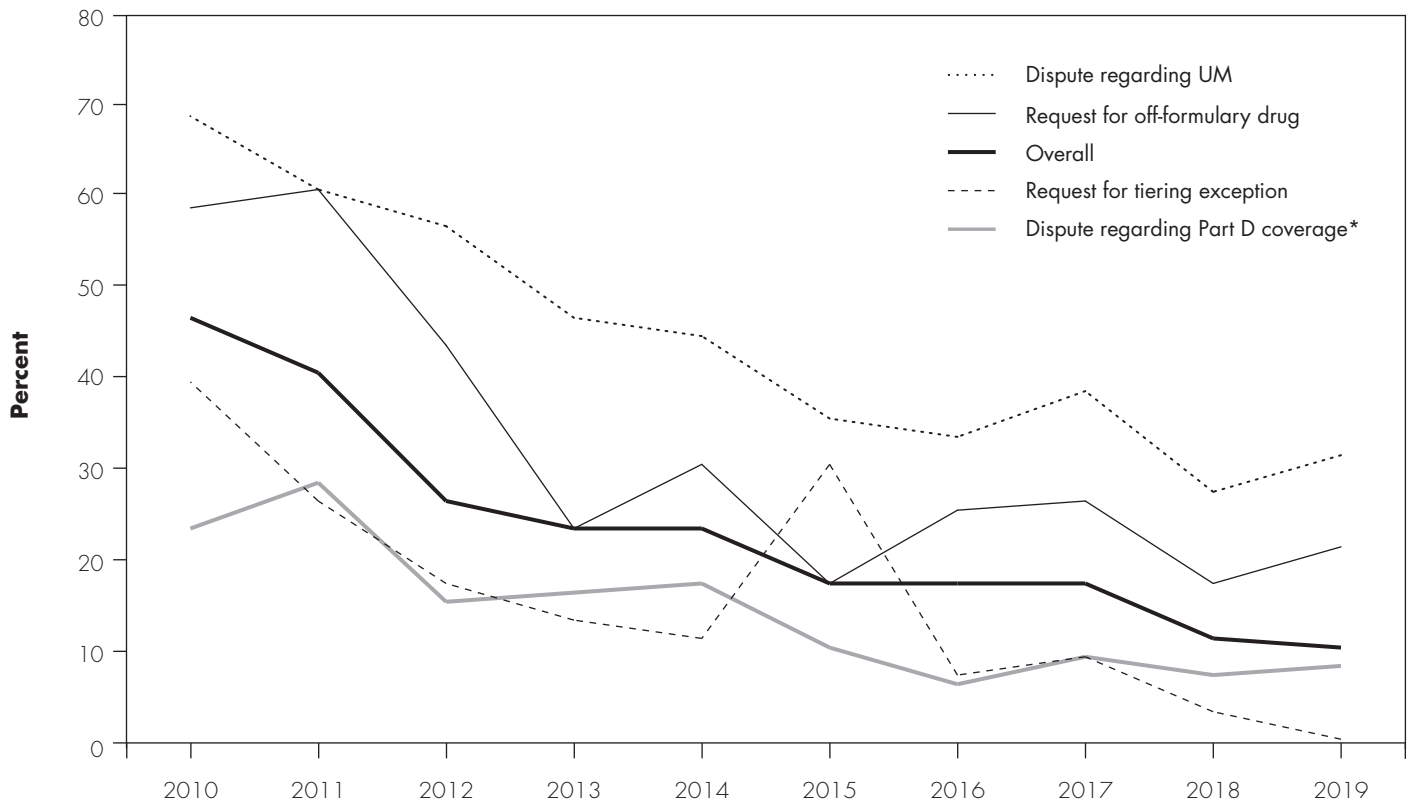
Despite these improvements, some beneficiaries still face difficulty obtaining prescribed medicines. Each year, millions of prescriptions are rejected at pharmacies. Many of these pharmacy rejections may be appropriate, such as when the beneficiary has not met prior authorization requirements to ensure safe use. However, the Office of Inspector General found that some rejections were

inappropriate and avoidable, potentially delaying or deterring beneficiaries’ access to needed medications (Office of Inspector General 2019).

**Need to improve electronic communication between Part D plans and prescribers**

A more constructive approach toward ensuring appropriate access would be to provide enrollees and prescribers with real-time information about formulary coverage and utilization management requirements in ways that fit into providers’ workflow at the point of prescribing. Rather than relying on the exceptions and appeals process, a better approach would be to resolve questions about coverage with electronic tools, such as real-time benefit tools (RTBT) and electronic prior authorization (ePA).



**FIGURE  
13-7****Reversal of plan coverage decisions by IRE has generally declined over time, 2010–2019**

Note: IRE (independent review entity), UM (utilization management). UM tools used by plan sponsors include prior authorization, step therapy, and quantity limits.  
\*Part D coverage issues may arise, for example, from disputes about whether a prescription was written for a medically accepted indication or whether the drug meets the statutory definition of a Part D–covered drug.

Source: Part D reconsideration and appeals data from CMS.

If built into the prescriber’s workflow, standardized approaches to ePA and automated coverage determinations could save patients and providers significant time and resources and speed up delivery of care (American Medical Association-convened workgroup of 17 state and specialty medical societies 2019). In 2019, CMS finalized a rule requiring Part D sponsors to implement one or more RTBC tools capable of integrating with at least one prescriber’s electronic health record system by January 1, 2021 (Centers for Medicare & Medicaid Services 2019c). However, the extent to which this requirement increases the use of RTBCs in Part D will depend on the degree to which clinicians—who face no requirements under this rule—adopt them when prescribing for their Medicare patients. In 2020, CMS issued a final rule that requires

Part D plan sponsors to implement real-time comparison tools for enrollees by January 1, 2023 (Centers for Medicare & Medicaid Services 2021).

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

More than 80 percent of Part D enrollees report that their Part D plans provide good value and that their OOP costs are reasonable (Medicare Today 2020). At the same time, in focus groups convened for the Commission, physicians and beneficiaries were acutely aware of high drug costs and reported having frequent discussions about ways to lower costs (Catterson et al. 2020). These seemingly conflicting results reflect the dichotomy between the majority of beneficiaries who take generic drugs for

common conditions and the relatively small number of beneficiaries who use many brand-name drugs or high-cost specialty drugs.

For an individual enrollee without the LIS, the cost-sharing burden for high-cost specialty drugs can be substantial, totaling thousands of dollars in the catastrophic phase of the benefit alone (Cubanski et al. 2019). (Most enrollees who receive Part D's LIS do not face a large financial hurdle because their cost sharing is limited to nominal copayments.) In recent years, even as Part D's coverage gap was closing, OOP costs incurred by beneficiaries who used specialty drugs rose because those individuals paid coinsurance on medicines with list prices that rose rapidly (Cubanski et al. 2019).

For many reasons, when generic specialty drugs have entered the market, beneficiaries have not always benefited from lower prices (Dusetzina et al. 2020b). For example, the list price differential between a generic and its brand counterpart may be relatively small. As a result, sponsors may continue to prefer the brand version that has lower costs for the plan owing to the coverage-gap discount and rebates paid by the manufacturer. Even when entries of multiple generic competitors result in substantially lower prices and plan sponsors adjust their formularies to prefer the generic version, beneficiaries may still pay relatively high OOP costs because the coverage-gap discount does not apply to generic drugs (Dusetzina et al. 2020b).

High cost sharing can result in beneficiaries not initiating therapy or abandoning prescriptions at the pharmacy (Doshi et al. 2018, Dusetzina et al. 2020b).<sup>41</sup> For drugs placed on specialty tiers, beneficiaries have little recourse as they may not request a tiering exception to obtain the specialty-tier drugs at lower (preferred) cost sharing.<sup>42</sup> It is not possible to measure the extent to which high prices are impeding access to needed medications. However, increases in the number of therapies that command very high prices is likely to increase the number of beneficiaries who face affordability issues (Dusetzina et al. 2020b, Park and Look 2020).

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## Quality in Part D

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CMS collects quality and performance data to monitor sponsors' operations. A subset of data is used to rate plans in a 5-star system, from which CMS determines MA quality bonus payments. (Although both MA-PDs

and stand-alone PDPs are evaluated for quality with star ratings, only MA-PDs are eligible for quality bonus payments in the Part C payment system.) Quality data are also made available to the public to help beneficiaries evaluate their plan options during Part D's annual open enrollment period. Additionally, CMS requires plan sponsors to carry out medication therapy management (MTM) programs to improve the quality of pharmaceutical care for high-risk beneficiaries. Although the Commission supports CMS's goal of improving medication management, we have ongoing concerns about the effectiveness of plans' MTM programs. In 2017, CMS began a new, enhanced MTM model.

## Measuring plan performance

CMS collects Part D quality and performance data at the contract level from several sources—the Consumer Assessment of Health Providers and Systems<sup>®</sup> (CAHPS<sup>®</sup>) survey, agency monitoring of plans, data furnished by plan sponsors, and claims information (Centers for Medicare & Medicaid Services 2020d).<sup>43</sup> Selected performance measures are available on the Plan Finder at [www.medicare.gov](http://www.medicare.gov) to help beneficiaries evaluate their plan options during Part D's annual open enrollment period. The lowest rated plans are flagged to caution beneficiaries about choosing those plans. The highest rated plans can enroll beneficiaries outside the annual open enrollment period. In addition, for MA-PDs, Part D performance data affect the MA program's overall plan ratings used to determine the amount of bonus payment.

For 2021, Part D plan ratings are based on up to 14 metrics that measure plan performance on intermediate outcomes, patient experience and access, and process (Centers for Medicare & Medicaid Services 2020d). Intermediate outcome measures (four metrics, including adherence to selected classes of medications) typically each receive a weight of 3, but one (statin use in persons with diabetes) received a weight of 1 because it was a new measure. Weights for the seven measures related to patient experience and access (e.g., CAHPS survey results on ease with which plan members get needed medicines) were increased to 2.0 (from 1.5 for 2020). Two process measures (e.g., accuracy of drug prices posted on the Plan Finder) receive a weight of 1. Finally, drug plan quality improvement, a measure reflecting changes in drug plans' performance from one year to the next, is assigned the highest weight, which is 5 (Centers for Medicare & Medicaid Services 2020d). Most MA-PDs are rated on up to 44 measures that assess the quality of plan services



provided under the MA program, including 14 measures used to assess the quality of prescription drug (Part D) services provided. PDPs are evaluated only on scores for the 14 Part D measures.

CMS aggregates individual scores for each measure on the Plan Finder in a 5-star system; a 5-star rating reflects excellent performance, and 1 star reflects poor performance. Among PDPs, the average star rating for 2021 (weighted by 2020 enrollment) increased to 3.58 from 3.50 a year earlier (Centers for Medicare & Medicaid Services 2020b). About 42 percent of PDP enrollees (based on 2020 enrollment) are in 2021 contracts (covering one or more plans) with 4 or more stars, and another 35 percent are in contracts with 3.5 stars. Among MA-PDs offered for 2021, the average star rating decreased from 4.16 to 4.06. Based on 2020 enrollment, CMS estimated that just under 49 percent of MA-PD enrollees were in contracts rated 4 or more stars for 2021. However, as we noted in our chapter about the MA program, the current state of quality reporting in MA is such that we continue to question the reliability of the quality ratings for MA-PDs. Further, the MA-PD results are averaged across a much broader set of measures than the 14 metrics specific to Part D services. When comparing just Part D measures, MA-PDs had the same or lower values than PDPs on 8 of the 14 measures.

Star ratings are intended to provide useful information when enrollees are choosing among plan options with similar costs or when plan sponsors are evaluating certain areas for improvement. However, none of the beneficiaries who participated in the Commission's 2019 focus groups mentioned using Medicare's star ratings as information for choosing a health plan (Catterson et al. 2020). Instead, beneficiaries tended to choose a plan that had the lowest costs.

The Commission supports the use of quality measurements that are patient oriented, encourage coordination across providers, and promote positive change in the delivery system. Because the provision of prescription drug services is different from the provision of medical services, quality measures currently used for Part D may not help beneficiaries make informed choices among plan options.

For example, three intermediate outcome measures rate plans based on member adherence to select classes of medications. Because outcome measures are weighted more heavily than patient access and process measures, the three adherence measures have a disproportionate

impact on plan ratings. However, for prospective enrollees, medication adherence of current members is not likely an important factor when choosing among plan options. Additionally, plans are not in the best position to assess whether the prescribed medications were clinically appropriate. At the same time, measuring plans on member adherence to medications could encourage plans to structure benefits in a way to provide better access.

## **Medication therapy management programs**

Part D plans are required to implement MTM programs to optimize therapeutic outcomes and reduce adverse drug events through improved medication use among beneficiaries who have multiple chronic conditions, take multiple medications, and are likely to have drug spending that exceeds an annual cost threshold (\$4,376 for 2021).

Plan sponsors are required to enroll, with opt-out provisions, all eligible enrollees in their MTM programs. At a minimum, MTM programs must offer a comprehensive medication review (CMR) at least annually and a targeted medication review (TMR) at least quarterly for ongoing monitoring and follow-up of any medication-related issues.<sup>44</sup> CMS has changed the criteria for MTM programs over time to broaden eligibility. Our earlier review of MTM programs revealed wide variations in eligibility criteria and the kinds of interventions provided to enrollees (Medicare Payment Advisory Commission 2009). Today, plan sponsors can no longer set eligibility criteria narrower than requiring beneficiaries to have more than three chronic conditions or use more than eight medications.<sup>45</sup>

In focus groups convened for the Commission in 2020, clinicians and beneficiaries both reported having routine reviews of their medications (Catterson et al. 2020). Some beneficiaries believed they were on too many medications while clinicians described frequently managing patient requests for more drugs (Catterson et al. 2020). In previous focus groups, several primary care doctors gave examples of cases in which an insurer had caught polypharmacy problems. However, many clinicians reported that obtaining a complete list of medications taken by their patients continues to be a challenge (Catterson et al. 2020).

We continue to be concerned that sponsors of stand-alone PDPs do not have financial incentives to engage in MTM or other activities that, for example, reduce unnecessary medical expenditures. CMS's analysis of the data found lower rates of medication reviews among MTM enrollees in PDPs compared with those in MA-PDs. Further, the

effectiveness of the current MTM services in improving the quality of overall patient care is unclear (Centers for Medicare & Medicaid Services 2016, Marrufo et al. 2013).

In 2017, CMS implemented an enhanced MTM model to test whether payment incentives and greater regulatory flexibility in designing MTM programs would lead to “improved therapeutic outcomes, while reducing net Medicare expenditures” (Center for Medicare & Medicaid Innovation 2015). However, as noted earlier, the evaluation of the first two years of the five-year demonstration program found no significant reductions in Medicare

spending for Part A and Part B services among enrollees in enhanced MTM plans.

The Commission is generally supportive of providing Part D plan sponsors with regulatory flexibility combined with appropriate financial incentives to improve the pharmaceutical services provided under the program. We encourage the agency to continue to explore the kinds of intervention strategies that may be effective in improving pharmaceutical care and health outcomes for beneficiaries, as well as how MTM or other services could improve health outcomes and lower medical spending. ■

## Endnotes

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- 1 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, with copayments for generics and preferred drugs initially, but 25 percent coinsurance in the coverage gap.
- 2 A small share of LIS enrollees (about 3 percent) with slightly higher levels of income or assets receive a partial subsidy. In 2021, those individuals pay a \$92 deductible and 15 percent coinsurance on prescriptions up to the OOP threshold. Above the OOP threshold, those LIS enrollees pay \$3.70 for each generic prescription and \$9.20 for brand prescriptions.
- 3 For example, in 2021, generic tiers must have a per prescription copayment of \$20 or less or charge coinsurance of 25 percent or less 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 (Centers for Medicare and Medicaid Services 2020).
- 4 CMS calculates benchmarks using a weighted average of both PDP and MA–PD premiums. For plans that offer enhanced coverage, CMS uses the portion of the plan’s premium that reflects the cost of basic coverage. For MA–PDs, CMS uses plans’ premiums for basic coverage before plan sponsors have applied any MA rebates (a portion of the difference between the MA payment rate and plans’ bids to provide Part A and Part B services) to reduce or eliminate the premium. The weight for each plan equals its share of LIS enrollment.
- 5 The small share of LIS enrollees who receive a partial subsidy pay a portion of the premium for most PDPs, including those with premiums below the LIS benchmark.
- 6 Under CMS’s de minimis policy, plan sponsors may voluntarily waive the portion of the monthly adjusted basic beneficiary premium that is above the LIS benchmark for a subsidy-eligible individual, up to a de minimis amount. The de minimis amount for 2021 is \$2.
- 7 Instead of accepting the new assignment, LIS enrollees may choose a plan themselves. However, if their selected plan has a premium higher than the benchmark, the LIS enrollee must pay the difference between the plan’s premium and the benchmark amount.
- 8 Beneficiaries who are current or former Part D enrollees can be auto-enrolled for a variety of reasons, such as losing and then regaining their LIS and Part D coverage, moving out of their plan’s service area, asking to disenroll from their current plan without selecting a new plan, or failing to pay the premium for their current plan.
- 9 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.
- 10 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, Part B, or MA premiums for supplemental benefits.
- 11 After the end of each benefit year, CMS reconciles what plans expected to receive in reinsurance subsidies from Medicare with reinsurance due based on 80 percent of their enrollees’ actual catastrophic spending net of rebates. On net, Medicare has made additional payments to plans for individual reinsurance at reconciliation in nearly every year except 2017, meaning that actual costs were higher than plans’ expected reinsurance costs that were used to calculate enrollee premiums. This effectively results in a higher overall Medicare subsidy rate than the 74.5 percent target set in law.
- 12 Most MA plans are MA–PDs, offering combined medical and outpatient drug benefits. However, a small share of MA plans (including Medicare Savings Account plans) do not offer prescription drug coverage.
- 13 That number includes 13 plans that had premiums within \$2 of their regional LIS threshold. The plan sponsors chose to waive the de minimis premium amount so that LIS enrollees would pay no premium in those plans.
- 14 CMS will pay participating plans 30 percent of any savings up to 3 percent of the difference between actual reinsurance and the plan’s benchmark, and 50 percent of savings beyond 3 percent. If reinsurance costs are higher than the plan’s benchmark, the plan pays 10 percent of that difference.
- 15 Conditions targeted by participating plans include coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, diabetes, and hypertension.
- 16 For 2021, the over 1,600 participating plans are offered by 76 plan sponsors, including 5 plan sponsors offering stand-alone PDP options nationwide (Centers for Medicare & Medicaid Services 2020j).

- 17 Among stand-alone PDPs, market concentration at the level of a PDP region (one of 34 states or combinations of states) can be high. Using the Herfindahl-Hirschman Index, a measure of market concentration used by the Department of Justice and Federal Trade Commission to evaluate mergers, in 2020, 33 of 34 PDP regions had moderately concentrated PDP enrollment and one region (Hawaii) was highly concentrated. When focusing on LIS enrollment in PDPs, 22 regions were moderately concentrated and 11 were highly concentrated.
- 18 Some pharmacies choose not to contract with certain plans because they do not like the terms and conditions the plans offer. Plan sponsors are not obligated to cover prescriptions at an out-of-network pharmacy, except under certain circumstances.
- 19 Plan sponsors cannot restrict access to a subset of network pharmacies unless dispensing a drug requires “extraordinary specialty handling, provider coordination, or patient education that cannot be met by a network pharmacy” (Centers for Medicare & Medicaid Services 2011). An exception is made if a manufacturer uses a limited distribution network. In this situation, the Part D enrollee would be able to fill that prescription at only one of the designated specialty pharmacies.
- 20 Postsale pharmacy fees and discounts made up the remaining \$4 billion (Centers for Medicare & Medicaid Services 2018b).
- 21 DIR is shared between Medicare and Part D plan sponsors to offset their respective benefit liabilities. Medicare retains a portion of the DIR equal to 80 percent of gross spending above Part D’s OOP threshold divided by total gross spending (i.e., gross reinsurance as a share of total gross spending) and plan sponsors retain the remainder.
- 22 The predicted spending excludes the value of Medicare’s individual reinsurance subsidies because that risk is borne by Medicare rather than by the plan.
- 23 For our analysis, we assumed that, in 2018, Part D sponsors received manufacturer rebates for insulin and tumor necrosis factor (TNF) inhibitors that averaged 50 percent and 20 percent, respectively, of their corresponding gross Part D sales. Both figures are below the average rebates and discounts manufacturers paid to participants in the drug supply chain (Herman 2020, Hernandez et al. 2020, Indianapolis Business Journal 2016, Kakani et al. 2020, Langreth et al. 2016). To be conservative, we also assumed that manufacturers would include the amount they would owe in coverage gap discount as part of the overall rebates they would pay to plan sponsors. These assumptions resulted in effective discount rates of 43 percent for insulins and 17 percent for TNF inhibitors.
- 24 The current version of the RxHCC model estimates five sets of model coefficients for long-term institutional enrollees, aged low-income enrollees, aged non-low-income enrollees, disabled low-income enrollees, and disabled non-low-income enrollees. The use of a single community segment model is a divergence from the method used by CMS. However, our model structures and methods (linear regression with restrictions imposed to ensure hierarchy among RxHCCs) are consistent with the current version of the RxHCC model that has been in use since 2018.
- 25 While there has not been a formal *Federal Register* publication of withdrawal of the proposed rule, if being listed as withdrawn on the OMB website qualifies as an official withdrawal, HHS would have to start over with a new notice of proposed rulemaking.
- 26 Specifically, we compared the risk-adjustment factors with and without rebates for the following condition categories: RxHCC30 (diabetes with complications), RxHCC31 (diabetes without complications), RxHCC241 (diabetic retinopathy), RxHCC311 (chronic ulcer of skin, except pressure), RxHCC67 (inflammatory bowel disease), RxHCC82 (psoriatic arthropathy and systemic sclerosis), RxHCC83 (rheumatoid arthritis and other inflammatory polyarthropathy), and RxHCC316 (psoriasis other than arthropathy).
- 27 Using plan sponsors’ assumptions about rebates from their 2020 bids, the Medicare Trustees estimated that direct and indirect remuneration (DIR)—consisting predominantly of manufacturers’ rebates, but also pharmacy concessions after the point of sale—amounted to 28.4 percent of total drug costs (averaged across all drugs, including those for which plans do not receive any rebates) (Boards of Trustees 2020, Weintraub 2019). This amount is a significant increase from DIR in 2007 of about 9.6 percent, and even from 2015, when the intensified competition in the hepatitis C drug market resulted in higher DIR (18.3 percent) than expected.
- 28 An individual NDC uniquely identifies the drug’s labeler, drug, dosage form, strength, and package size.
- 29 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. The “patent cliff” refers to a year in which manufacturers of widely used brand-name drugs lost market power over pricing because of expirations of patents and periods of exclusivity.
- 30 In 2018, relative to the average per beneficiary cost of Copaxone, the costs of the generic versions were about 63

- percent lower for glatiramer acetate by Mylan N.V. and 53 percent lower for Glatopa by Sandoz Pharmaceuticals owned by Novartis A.G. (Centers for Medicare & Medicaid Services 2019b).
- 31 In 2019, generic drugs accounted for about 87 percent of all Part D drugs dispensed and 21 percent of total Part D spending (Boards of Trustees 2020).
  - 32 Between 2007 and 2019, the number of Part D beneficiaries without the low-income subsidy grew, on average, by just over 7 percent annually.
  - 33 The amounts reflect an average mix of drugs for a beneficiary who does not receive Part D's low-income subsidy and who has no other supplemental coverage.
  - 34 Examples of medications in which a single claim was sufficient to reach the catastrophic phase of the benefit include newer antivirals for the treatment of hepatitis C, antineoplastics, and certain medications used for the treatment of pulmonary hypertension.
  - 35 The transition fill is a temporary one-time supply provided within the first 90 days of coverage in a new plan or the new contract year for existing enrollees.
  - 36 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 exceptions request does not include the necessary supporting statement, the plan has up to 14 calendar days to obtain the information. See March 2020 Report to the Congress for more detail (Medicare Payment Advisory Commission 2020d).
  - 37 CMS audits a selection of sponsoring organizations each year for compliance with program requirements, ultimately covering most plan sponsors over its several-year work cycle. 2018 was the fourth year of the four-year audit cycle, and sponsors selected from those not yet audited for the work cycle that tended to be smaller sponsors. The addition of the approximately 2 percent of beneficiaries enrolled in the MA and Part D programs in 2018 brought the total percentage of beneficiaries covered during the audit cycle to 95 percent (Centers for Medicare & Medicaid Services 2019a).
  - 38 Because the calculated audit score uses the number of noncompliant conditions discovered, the maximum audit score is unlimited. For most of the program areas, the highest score obtained by any plan sponsor was less than 3.0 (Centers for Medicare & Medicaid Services 2020a).
  - 39 Until recently, CMS required Part D plan sponsors to report data on rejected pharmacy claims. However, that information provided only limited insight into the exceptions and coverage determination process because counts of pharmacy claims and rejections often contain duplicate records. Moreover, data are not available on what happens once a plan rejects a claim—for example, whether the beneficiary was ultimately able to fill the original prescription, obtained an alternative therapy, or abandoned the prescription. As of 2019, sponsors are no longer required to submit rejected pharmacy claims unless under audit.
  - 40 For example, in 2017, less than 5 percent of redeterminations were appealed or automatically forwarded to an IRE (Office of Inspector General 2019).
  - 41 The relationship between higher cost sharing and adherence, treatment initiation, or the rate of prescription abandonment is likely to vary widely across therapeutic classes. For example, patients may be less sensitive to higher cost sharing for certain cancer treatments compared with therapies for chronic conditions such as rheumatoid arthritis (Medicare Payment Advisory Commission 2019).
  - 42 Part D enrollees can apply to bona fide independent charity patient assistance programs (PAPs) for help with cost sharing. Pharmaceutical manufacturers can provide cash donations to independent charity PAPs without invoking anti-kickback concerns if the charity is structured properly. However, recent enforcement actions regarding manufacturer donations to charities suggests some PAPs may be in violation of the anti-kickback statute (Office of Inspector General 2018a, Sagonowsky 2017).
  - 43 Due to concerns related to the COVID-19 public health emergency, CMS eliminated the requirement to submit Healthcare Effectiveness Data and Information Set (HEDIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data for the 2021 star ratings. The 2021 Part D star rating measures calculated based on CAHPS data were replaced with earlier values from the 2020 star ratings (Centers for Medicare & Medicaid Services 2020e).
  - 44 CMRs must include an interactive 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 interventions can be delivered by mail or faxed to the beneficiary or the prescriber, as appropriate (Centers for Medicare & Medicaid Services 2014).
  - 45 42 CFR section 423.153(d).



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