

CHAPTER

14

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

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Chapter summary

In 2018, Part D plans were the primary source of outpatient prescription drug coverage for 43.9 million Medicare beneficiaries. 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 12.5 million individuals with low income and assets. In 2017, Part D expenditures totaled \$93.9 billion, accounting for about 13 percent of Medicare spending. Enrollees paid \$14.0 billion of that amount in plan premiums, in addition to what they paid in cost sharing.

Part D has been a success in many respects. It has improved beneficiaries' access to prescription drugs. Generic drugs now account for nearly 90 percent of the prescriptions filled. Enrollees' average premiums for basic benefits have remained around \$30 per month for many years. More than 8 in 10 Part D enrollees report they are satisfied with the program.

However, changes to Part D's coverage gap and manufacturer discounts combined with the expanding role of high-cost medicines may be eroding plans' incentives for and ability to achieve cost control. Over time, as more enrollees have reached the catastrophic phase of the benefit, a growing share of Medicare's payments to plans have taken the form of cost-based reinsurance subsidies rather than capitated payments. This trend is exacerbated by a pipeline of new products that are likely to have high costs. Beginning in

In this chapter

- Enrollment, plan choices in 2018, and benefit offerings for 2019
- Plan sponsors and their tools for managing benefits and spending
- Drug pricing
- Program costs
- Beneficiaries' access to prescription drugs
- Quality in Part D

2019, brand-drug manufacturers must provide a 70 percent discount in the coverage gap (an increase from 50 percent). This change correspondingly decreases what plan sponsors must cover in benefits and likely weakens sponsors' incentives to manage spending. A separate concern is that Part D's LIS may lead to plan and beneficiary incentives that increase program costs.

Policymakers are taking steps to give plan sponsors new flexibilities to manage drug spending. For example, CMS now allows for certain midyear formulary changes without prior approval, and Medicare Advantage–Prescription Drug [plans] (MA–PDs) can use step therapy—a type of management tool that begins treatment with the most preferred drug therapy and progresses to other therapies only if necessary—for Part B drugs under certain circumstances. However, other measures to increase the financial risk that sponsors bear (such as those recommended by the Commission in 2016) are also needed so that plan sponsors have greater incentive to use the new management tools and keep Part D financially sustainable for beneficiaries and taxpayers.

Enrollment in 2018 and benefit offerings for 2019—In 2018, 73.3 percent of Medicare beneficiaries were enrolled in Part D plans. An additional 2.5 percent obtained drug coverage through employer-sponsored plans that received Medicare's retiree drug subsidy. The remaining 24.2 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 2007 and 2018, enrollment grew faster in MA–PDs compared with stand-alone prescription drug plans (PDPs). In 2018, 42 percent of enrollees were in MA–PDs compared with 30 percent in 2007. Over the same period, the number of enrollees who received the LIS grew more slowly than non-LIS enrollees, and the LIS share fell from 39 percent to 28 percent.

For 2019, beneficiaries continue to have a broad choice of plans. Sponsors are offering 15 percent more PDPs and 21 percent more MA–PDs than in 2018. MA–PDs continue to be more likely than PDPs to offer enhanced benefits. Most beneficiaries are in plans with a five-tiered formulary that uses differential cost sharing between preferred and nonpreferred drugs, as well as a specialty tier for high-cost drugs. Use of coinsurance continues to be widespread. For 2019, the total average estimated cost for basic benefits decreased by 5 percent. The higher brand manufacturer discount in the coverage gap and lower covered benefits likely contributed to this decrease. The base beneficiary premium was \$33.19, a 5 percent drop from \$35.02 in 2018. However, individual plans' premiums can vary substantially. In 2019, 215 premium-free PDPs are available to enrollees who receive the LIS, about the same number as in 2018.

With the exception of 1 region (Florida), all regions have at least 3 and as many as 10 PDPs for LIS enrollees at no premium.

Part D program costs—Between 2007 and 2017, Part D program spending increased from about \$46 billion to about \$80 billion (average annual growth of 5.6 percent). Medicare’s reinsurance (which covers 80 percent of enrollees’ spending in the catastrophic phase of the benefit after rebates) continues to be the fastest growing component of program spending, at an average annual rate of nearly 17 percent. Between 2007 and 2017, the portion of the benefits paid to plans through capitated direct subsidy fell from 55 percent to 21 percent, while the portion paid through Medicare’s reinsurance (which is cost based) grew from 25 percent to 54 percent. Enrollees who incur spending high enough to reach the catastrophic phase of the benefit (high-cost enrollees) continued to drive Part D spending. In 2016, high-cost enrollees accounted for 58 percent of all Part D spending, up from about 40 percent before 2011. Generally, prices paid at the pharmacy counter moderated after 2015. However, price growth remained strong in drug classes that have few or no generic or therapeutic alternatives. Among high-cost enrollees, nearly all growth in spending was due to increases in the average price per prescription filled (reflecting both price inflation and changes in the mix of drugs used). In 2016, about 360,000 enrollees filled a prescription for which a single claim would have been sufficient to meet the out-of-pocket threshold, up from just 33,000 in 2010. Non-LIS beneficiaries were more likely to have such a claim, reflecting the fact that they tend to use different drug classes from LIS enrollees.

Quality in Part D—In 2019, the average star rating among Part D plans decreased somewhat for PDPs and remained about the same for MA–PDs. However, the trend among MA–PD sponsors of consolidating contracts to achieve higher star ratings leads us to question the validity of MA–PD ratings and the comparison between PDPs and MA–PDs. 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. Initial results indicate that half of the participating plans (11 out of 22 plans) successfully reduced medical spending by 2 percent or more, qualifying them for a higher premium subsidy in 2019. We are encouraged by the initial results and look forward to learning about the characteristics of MTM programs that enabled PDPs to improve pharmaceutical care and health outcomes for beneficiaries. ■

Background

Each year, the Commission provides a status report on Part D that examines several performance indicators: enrollment patterns, plan benefit offerings, market structure, drug pricing, program costs, beneficiaries' access to medications, and quality. In 2018, Part D plans were the primary source of outpatient prescription drug coverage for 43.9 million Medicare beneficiaries. For each of those 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. Part D also includes a low-income subsidy (LIS) that provides assistance with premiums and cost sharing to 12.5 million individuals with low income and assets. In 2017, Part D expenditures totaled \$93.9 billion on an incurred basis, accounting for about 13 percent of Medicare spending (Boards of Trustees 2018). Part D enrollees paid \$14.0 billion of that amount in plan premiums, in addition to what they paid in cost sharing.

In a number of 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 2017, 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. Enrollees' average premiums for basic benefits have remained flat at or near \$30 per month for many years, and more than 8 in 10 Part D enrollees report they are satisfied with the program and with their plan (*Medicare Today* 2018).

However, changes to Part D's benefit design combined with recent trends in prescription drug spending may be eroding plans' incentives for cost control. 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. Over time, a growing share of Part D subsidies have taken the form of cost-based reimbursements to plans. This trend results from higher drug prices that increase Medicare's liability for the 80 percent reinsurance as an increasing number of enrollees reach a threshold on out-of-pocket (OOP) spending. A growing proportion of total Part D

drug spending is attributable to the relatively few enrollees who reach the catastrophic phase. Going forward, this trend will be exacerbated by a pipeline for new high-cost biopharmaceutical products. Policymakers are taking steps to give plan sponsors new flexibilities to manage Part D benefits. However, other measures to restructure Part D's reinsurance—such as those recommended by the Commission in 2016—are also needed so that plan sponsors have greater incentive to use the new management tools.

Part D's approach

Medicare's payment system for Part D is different from payment systems under Part A and Part B. For Part D, Medicare pays competing private plans to deliver drug benefits to enrollees. Instead of setting prices administratively, Medicare's payments are based on bids submitted by plan sponsors. Part D pays for drug benefits whether beneficiaries enroll in a PDP or MA–PD.

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 (\$33.19 in 2019) plus (or minus) any difference between their plan's bid and the nationwide average bid (Medicare Payment Advisory Commission 2018b). If enrollees pick a plan that includes supplemental coverage, the enrollee must pay the full price for the additional 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.

A second avenue of competition involves keeping plan premiums at or below regional LIS benchmarks. Part D's bidding process determines the maximum premium amount Medicare will pay on behalf of LIS enrollees. This amount is calculated separately for each of the 34 Part D geographic regions as the average premium among plans with basic benefits, weighted by each plan's LIS enrollment in the previous year. The formula ensures that

**TABLE
14-1**

Parameters of the defined standard benefit increase over time

	2006	2018	2019	Average annual growth rate 2006–2019
Deductible	\$250.00	\$405.00	\$415.00	4.0%
Initial coverage limit	2,250.00	3,750.00	3,820.00	4.2
Annual out-of-pocket spending threshold	3,600.00	5,000.00	5,100.00	2.7
Total covered drug spending at annual out-of-pocket threshold	5,100.00	8,417.60*	8,139.54*	3.7
Minimum cost sharing above annual out-of-pocket threshold:**				
Copayment for generic/preferred multisource drugs	2.00	3.35	3.40	4.2
Copayment for other prescription drugs	5.00	8.35	8.50	4.2

Note: *An individual’s total covered drug spending at the annual out-of-pocket threshold depends on each enrollee’s mix of brand-name and generic drugs filled in the coverage gap. The amounts for 2018 and 2019 are estimated by CMS for an individual with an average mix of drugs who does not receive Part D’s low-income subsidy and who has no other supplemental coverage. The amount for 2019 is lower because of a change in law that causes 95 percent of an enrollee’s spending for brand-name drugs in Part D’s coverage-gap phase to count toward the out-of-pocket threshold, compared with 85 percent in 2018.
**Enrollees pay the greater of either the amounts shown or 5 percent coinsurance.

Source: Centers for Medicare & Medicaid Services 2018d.

at least one stand-alone PDP in each region is available to LIS enrollees at no premium.

This approach to setting Part D’s LIS premium subsidy was also intended to provide incentives for plan sponsors to control drug spending and bid low. Each year, there is some turnover in benchmark plans—those that qualify as premium free for LIS enrollees. If LIS enrollees are in a PDP with a premium above the benchmark and do not choose a plan themselves, CMS reassigns them randomly to a new benchmark PDP.¹ If sponsors bid at or near the benchmark, they can win or maintain market share for LIS enrollees without having to incur marketing expenses.² However, over the years many LIS enrollees have chosen a specific plan and are no longer eligible for reassignment. Many of the plans offered by certain large plan sponsors have kept their benchmark status from year to year. For 2018, only about 175,000 beneficiaries—less than 2 percent of all LIS enrollees enrolled in PDPs—were reassigned randomly (Lyons 2018).

The drug benefit

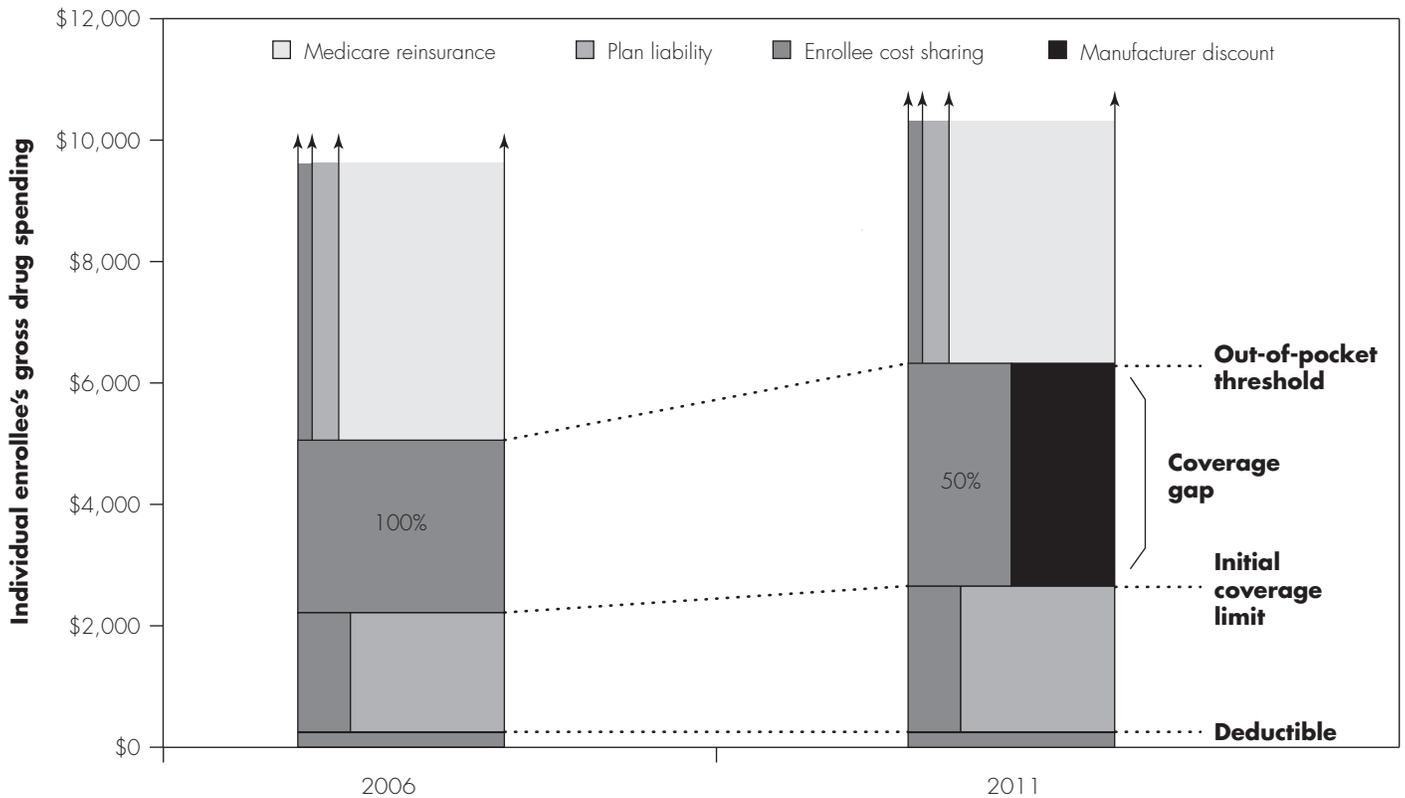
Medicare law describes a defined standard Part D basic benefit. Each year, most of the standard benefit’s parameters change at the same rate as the annual change in beneficiaries’ average drug expenses (Table 14-1).

For 2019, the defined standard benefit includes a \$415 deductible and 25 percent coinsurance until the enrollee reaches \$3,820 in total covered drug spending. Enrollees with spending above that amount (in the so-called coverage gap) pay 25 percent cost sharing for brand-name drugs and 37 percent for generics until they reach a threshold of \$5,100 in OOP spending. Above the OOP threshold, enrollees pay the greater of 5 percent coinsurance or \$3.40 to \$8.50 per prescription. By law, individuals who qualify for and enroll in Part D’s LIS pay zero or nominal cost sharing. In 2019, most individuals receiving the LIS pay between \$0 and \$3.40 for generic drugs and between \$0 and \$8.50 for brand-name drugs.

Most plan sponsors structure their basic benefits in ways that differ from the defined standard benefit, such as setting the deductible lower than \$415 or using tiered copayments rather than coinsurance. Plans may also encourage use of lower cost medicines by not applying a deductible when a prescription is filled with certain preferred generics. However, those alternative benefit structures must meet requirements for actuarial equivalence, demonstrating that they have the same average basic-benefit 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.³ Once

FIGURE 14-1

Part D's defined standard benefit before and after introduction of the manufacturers' discount on brand-name drugs in the coverage gap



Note: "Gross drug spending" refers to amounts paid at the pharmacy before rebates and discounts. The coverage-gap phase (between the initial coverage limit and out-of-pocket threshold) is depicted as it would apply to brand-name drugs for an enrollee who does not receive Part D's low-income subsidy (LIS). Non-LIS enrollees' cost sharing for generic drugs in the coverage gap was 100 percent in 2006 and 93 percent in 2011.

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

a sponsor offers a PDP with basic benefits in a region, it can also offer up to two "enhanced-alternative" PDPs that combine basic benefits with supplemental coverage. For 2019, estimated OOP costs between a sponsor's basic and enhanced plans must differ by at least \$22 per month. CMS no longer requires plan sponsors to maintain a meaningful difference in OOP costs between two enhanced-alternative PDPs.

Changes to Part D's coverage gap

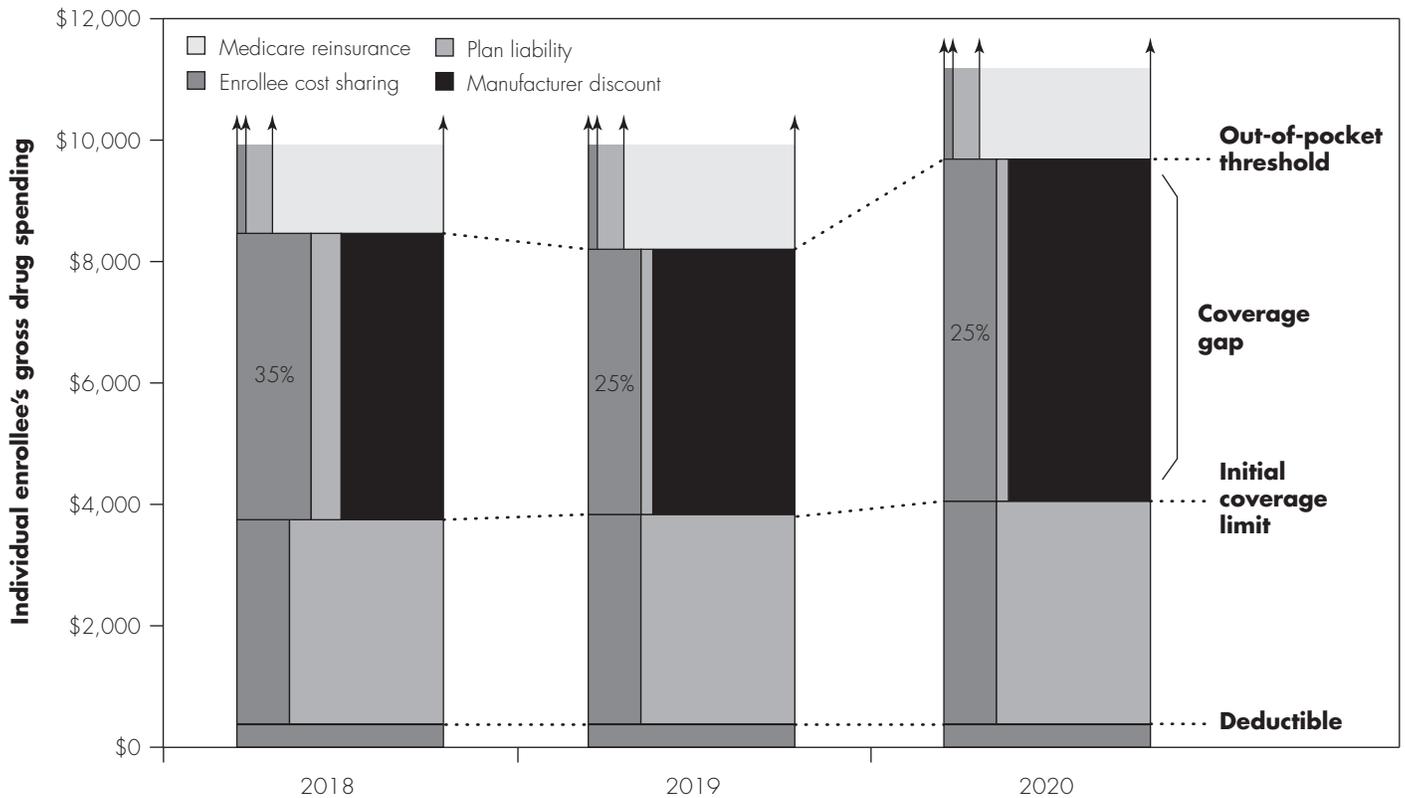
The policymakers who designed Part D wanted to provide both basic coverage for most enrollees who have relatively low drug spending as well as some catastrophic protection for enrollees with high drug costs. For this reason, the defined standard basic benefit initially covers 75 percent

of drug spending above the deductible and all but 5 percent coinsurance once an enrollee reaches the OOP threshold. That threshold is known as "true OOP" because it excludes cost sharing paid on behalf of a beneficiary by most sources of supplemental coverage, such as employer-sponsored policies and enhanced-alternative plan benefits.

However, the policymakers who designed Part D also needed to keep program costs within an agreed-on spending target (Blum 2009). For this reason, before 2011, enrollees with spending that exceeded the initial coverage limit were responsible for paying a prescription's full price at the pharmacy up to the OOP threshold. That is, the enrollee's cost sharing rose from 25 percent in the initial coverage phase to 100 percent until he or she reached the OOP threshold (left-hand side of Figure 14-1). A number

**FIGURE
14-2**

Part D's discount on brand-name drugs in the coverage gap and defined standard benefit structure has changed over time



Note: "Gross drug spending" refers to amounts paid at the pharmacy before postsale rebates and discounts. The amount of drug spending at which a beneficiary reaches the out-of-pocket (OOP) threshold depends on the mix of brand-name and generic prescriptions he or she fills in the coverage gap. The coverage-gap phase (between the initial coverage limit and OOP threshold) is depicted as it would apply to brand-name drugs for an enrollee who does not receive Part D's low-income subsidy (LIS). Non-LIS enrollees' cost sharing for generic drugs in the coverage gap was 44 percent in 2018, is 37 percent in 2019 and will be 25 percent in 2020.

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

of studies suggested that higher cost sharing in this coverage gap (also called the "donut hole") decreased rates of medication adherence, primarily for brand-name drugs (Fung et al. 2010, Yu et al. 2016, Zhang et al. 2013, Zhang et al. 2009). Compared with commercial insurance, Part D's benefit structure is unusual because of the coverage gap.

The coverage gap affects enrollees' OOP spending differently depending on whether the beneficiary receives the LIS. Under law, LIS enrollees experience no coverage gap; Medicare's low-income cost-sharing subsidy pays for 100 percent of most enrollees' costs during the coverage-

gap phase minus their nominal copayments. Manufacturers of brand-name drugs are not required to pay any discount for LIS enrollees during the coverage gap, and plan sponsors are not liable for covered benefits until the LIS enrollee reaches the OOP threshold. Although Part D's cost-sharing assistance offsets the higher burden that LIS enrollees would otherwise face, the current structure of the subsidies may be creating plan and beneficiary incentives that lead to higher program costs (see text box, p. 394).

The Patient Protection and Affordable Care Act of 2010 (PPACA) called for gradually lowering cost sharing in the coverage gap from 100 percent to 25 percent by

2020 and for constraining annual increases in the OOP threshold. To finance much of this expansion of benefits without directly raising enrollee premiums and program spending, PPACA required manufacturers of brand-name drugs, as a condition of Part D coverage, to provide non-LIS enrollees with a 50 percent discount on prescriptions filled during the coverage-gap phase (right-hand side of Figure 14-1, p. 391). As a result, in 2011, cost sharing in the coverage gap for brand prescriptions immediately fell from 100 percent to 50 percent. Over time, plans' liability for benefit spending on brand-name drugs in the coverage gap rose from 0 percent in 2011 to 25 percent by 2020.⁴ The law also required that the manufacturers' discount be counted as though it were the enrollee's own OOP spending for calculating the "true OOP" amount. That change lowered OOP costs for some beneficiaries but also increased the number of non-LIS enrollees who reached the OOP threshold above which Medicare pays 80 percent of spending through reinsurance.

The Bipartisan Budget Act (BBA) of 2018 changed Part D to phase out the coverage gap more quickly by increasing the manufacturers' discount from 50 percent to 70 percent. In 2019, enrollees who reach the coverage gap pay 25 percent cost sharing for brand-name drugs until they reach the OOP threshold compared with 35 percent in 2018 (Figure 14-2). Because the 70 percent discount is counted as though it were the enrollee's own spending, CMS estimates the dollar amount at which a non-LIS enrollee reaches the OOP threshold will be lower in 2019 than it was in 2018. This decrease means that more enrollees are likely to reach Part D's catastrophic phase, in which Medicare pays 80 percent reinsurance. In 2020 and thereafter, beneficiaries enrolled in plans with basic benefits will pay the equivalent of 25 percent cost sharing for all drugs (generics as well as brand name) between the deductible and the OOP threshold.

In the Commission's March 2017 report, we highlighted how Part D's unique benefit design, Medicare's cost-based reinsurance payments, and plan sponsors' focus on premium competition can affect incentives regarding which drugs a plan covers on its formulary (Medicare Payment Advisory Commission 2017). Because plan sponsors are not liable for much benefit spending in the coverage gap, Part D's structure may provide a financial advantage to sponsors when they select certain drugs with high prices and large postsale rebates over lower cost alternatives. The dollar amount of rebates for certain drugs can be larger than a plan sponsor's liability for the associated benefit spending.

Recent changes to the coverage gap heighten those concerns. In 2019, plan sponsors cover just 5 percent of spending for brand prescriptions filled in the gap phase. By comparison, CMS's Office of the Actuary projects that plan sponsors will obtain postsale rebates and discounts worth about 26 percent of total drug costs (Boards of Trustees 2018). In its 2019 call letter to plan sponsors, CMS said it has significant concerns about the effects of the higher coverage-gap discount and low plan liability on Part D drug costs in 2019 and in future years (Centers for Medicare & Medicaid Services 2018d).

In 2020, a PPACA provision will again change Part D's benefit structure: The OOP threshold will increase by more than 20 percent (Figure 14-2). As part of the law's effort to close the coverage gap, PPACA temporarily restrained increases in the OOP threshold. (Between 2006 and 2019, the threshold grew by 2.7 percent compared with 4.0 percent for the deductible and 4.2 percent for the initial coverage limit (Table 14-1, p. 390).) The law requires that in 2020, the OOP threshold revert to what it would have been had it grown at the same rate as other benefit parameters.⁵ While it would appear that enrollees will incur much higher OOP spending before reaching the higher threshold, the increase in the brand manufacturer's discount will absorb a considerable portion of that increase.⁶

Over the past year, CMS has made other regulatory changes to Part D, many of which will broaden plan sponsors' flexibility to manage their enrollees' benefits. However, other measures to increase the financial risk that sponsors bear are also needed so that plan sponsors have greater incentive to use the new management tools. As more of Medicare's subsidy payments to plans have taken the form of cost-based reinsurance, plan premiums do not necessarily reflect sponsors' actual cost of providing Part D benefits or how effective sponsors are at managing drug spending. One recent study found that because of Part D's reinsurance, some plan sponsors are able to charge low premiums even though they expect high drug spending in the catastrophic phase of the benefit (Jung and Feldman 2018).⁷ If lower premiums do not correspond to better management of benefit costs, then the competitive structure of the Part D program may not provide plan sponsors with the incentive to manage spending, particularly for the catastrophic phase of the benefit. Part D's cost-based reinsurance payments reduce plan sponsors' incentive to manage spending in that phase.

How Part D's low-income subsidy affects plan incentives and program costs

Part D's benefit structure is fundamentally different for enrollees who receive the low-income subsidy (LIS). Copayments for LIS enrollees are set by law, and plan sponsors cannot encourage the use of lower cost drugs in the same way that sponsors encourage non-LIS enrollees through differential copayments on cost-sharing tiers. In the coverage-gap phase, a plan's responsibility for paying an LIS enrollee's covered drug benefit costs is reduced to zero. At the same time, plan sponsors likely receive postsale rebates on brand-name prescriptions filled by LIS enrollees. These distinct benefit features for LIS enrollees tend to undermine both plans' ability to manage drug spending and their incentives for cost control.

A plan qualifies as having LIS benchmark status solely on the basis of whether the plan sponsor bids at or below a regional premium threshold. Like other plans, those with benchmark status must demonstrate that their benefit design uses cost sharing that, for a beneficiary of average health, is actuarially equivalent to Part D's defined standard benefit. For example, during the initial coverage phase, beneficiary cost sharing is expected to average about 25 percent of drug costs (before retrospective rebates and discounts). Ideally, sponsors of benchmark plans would want to manage all LIS benefits to keep premium costs down and bid below or near regional premium thresholds.

However, some evidence raises questions about the strength of sponsors' financial incentives to manage LIS drug spending. Research suggests that plan sponsors may bid less competitively for their prescription drug plans (PDPs) that cater to LIS enrollees than their other plans, with premiums clustered at or near the benchmark premiums of sponsors that have the largest LIS market shares

(Congressional Budget Office 2014, Decarolis 2015). One study found that LIS enrollees were, on average, more profitable for plan sponsors compared with enrollees who did not receive the LIS (Gomberg and Hunter 2015). In previous reports, the Commission has found that, relative to other Part D enrollees, a higher proportion of LIS enrollees use brand-name drugs when lower cost alternatives are available (Medicare Payment Advisory Commission 2016a). Given that plan sponsors cannot modify LIS cost sharing, one might expect, as an alternative, tighter formularies in benchmark plans or greater use of tools such as prior authorization. However, when CMS analyzed benchmark plans for 2013 through 2016, the agency found only slightly tighter formularies and similar use of utilization management tools (Centers for Medicare & Medicaid Services 2016).

In addition, our examination of PDP claims shows that, in 2015, plans with higher proportions of LIS enrollees tended to cover a lower share of their enrollees' spending and charged a higher percentage in cost sharing. We divided PDPs into groups depending on the share of their enrollees who received the LIS and then examined cost sharing and covered benefit amounts from prescriptions filled during the initial coverage phase. Among PDPs in which two-thirds or more of their enrollees received the LIS, cost sharing averaged 28 percent, compared with about 24 percent among PDPs with less than 10 percent of plan enrollment made up of LIS beneficiaries. For similar levels of drug spending, Medicare's low-income cost-sharing subsidy paid for a higher share of total drug costs compared with plans that mostly served non-LIS beneficiaries. This pattern deserves further exploration to ensure that sponsors do not structure plan benefits and formularies in ways that routinely shift costs toward Medicare. ■

The Commission's recommendations for improving Part D

In its June 2016 report to the Congress, the Commission recommended certain changes to the Part D program (Medicare Payment Advisory Commission 2016a). To address the concern about growth in Medicare's

reinsurance payments, one set of changes would give plan sponsors greater financial incentives to manage the benefits of enrollees who reach Part D's catastrophic phase (referred to as "high-cost enrollees"), which would require a change in law. Over a transition period, Medicare would significantly lower the amount of reinsurance it

pays plans, from 80 percent of spending above the OOP threshold to 20 percent, and the insurance risk that plan sponsors shoulder for catastrophic spending would rise commensurately, from 15 percent to 80 percent. At the same time that Medicare reduced its reinsurance, the program would make larger capitated payments to plan sponsors. Medicare’s subsidy of basic benefits would remain unchanged at 74.5 percent, but sponsors would receive more of that subsidy through capitated payments instead of open-ended reinsurance (i.e., plan sponsors would submit higher bids and lower estimates for the expected reinsurance costs). Under such a change, Part D’s risk adjusters would become more important as a tool for counterbalancing plan incentives for selection. CMS would need to take steps to recalibrate the risk adjustment system. At the same time, sponsors would be given greater flexibility to use formulary tools.⁸ The combination of those changes would create incentives for plan sponsors to better manage drug spending and would provide them with more tools to do so.

Other parts of the Commission’s recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees’ true OOP spending, but would also provide greater insurance protection to all enrollees not receiving the LIS by eliminating cost sharing above the OOP threshold (although some enrollees would incur higher OOP costs than they do today). To the extent that the adoption of the Commission’s set of recommendations results in net program savings, the Congress could consider enhancing protections for non-LIS enrollees facing high cost-sharing burdens. Because Part D’s nominal cost-sharing amounts provide little financial incentive for LIS enrollees to use lower cost products, the recommended improvements would also direct the Secretary of Health and Human Services to modify some LIS copayments.

In 2016, the Congressional Budget Office estimated that the combined effects of the Commission’s recommendations would lead to one-year program savings of more than \$2 billion relative to baseline spending and to more than \$10 billion in savings over five years.

Enrollment, plan choices in 2018, and benefit offerings for 2019

Over time, a growing proportion of Medicare beneficiaries has enrolled in Part D. An important

**TABLE
14-2**

Three-quarters of Medicare enrollees received drug coverage through Part D, 2018

	Beneficiaries	
	In millions	Share of Medicare enrollment
Medicare enrollment	59.9	100%
Part D enrollment*		
In Part D plans	43.9	73.3
In plans receiving RDS	1.5	2.5
Total Part D	45.4	75.8**

Note: RDS (retiree drug subsidy). Part D plan enrollment figures are based on enrollment as of April 1, 2018.

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

**The remaining 24.2 percent of beneficiaries not enrolled in Part D are divided fairly equally between those who receive 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.B4 of the Medicare Boards of Trustees’ report for 2018 and monthly Part D enrollment data as of April 1, 2018.

reason is a shift in enrollment from retiree drug plans to Part D plans. Enrollment has grown faster in MA-PDs compared with stand-alone PDPs. In 2019, plan sponsors are offering 15 percent more PDPs and 21 percent more MA-PDs than in 2018.

In 2018, over three-quarters of Medicare beneficiaries were in Part D plans or employer plans that received the retiree drug subsidy

In 2018, 43.9 million individuals—73.3 percent of Medicare’s total enrollment—were enrolled in Part D plans (Table 14-2). An additional 2.5 percent of beneficiaries obtained drug coverage through employer-sponsored plans that received Medicare’s retiree drug subsidy (RDS) for being the primary provider.⁹ The remaining 24.2 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.

**TABLE
14-3**

Part D plan enrollment trends, 2007-2018

	2007	2010	2015	2016	2017	2018	Average annual growth rate 2007-2018
Total Part D enrollment (in millions)	24.2	27.6	39.2	41.0	42.5	43.9	6%
Percent of Medicare beneficiaries	54%	58%	71%	72%	73%	73%	N/A
Enrollment by type (in millions)							
PDP	16.9	17.6	24.0	24.7	25.1	25.4	4
MA-PD	7.2	10.0	15.3	16.3	17.4	18.5	9
Percent in MA-PD	30%	36%	39%	40%	41%	42%	N/A

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

Source: MedPAC based on Part D enrollment data and Table IV.B7 and Table V.B4 of the Medicare Boards of Trustees' report for 2018.

The share of Medicare beneficiaries covered under Part D has grown over time, with faster growth in MA-PD enrollment. Between 2007 and 2018, Part D enrollment grew from 54 percent of Medicare beneficiaries to 73 percent, an average growth of 6 percent annually (Table 14-3). Enrollment in MA-PDs grew an average of 9 percent annually compared with 4 percent in PDPs. In 2018, 42 percent of Part D enrollees were in MA-PDs compared with 30 percent in 2007. This trend in MA-PD enrollment is consistent generally with more rapid growth in MA enrollment than in fee-for-service (FFS) Medicare (see Chapter 13 on Medicare Advantage).

In 2018, 12.5 million beneficiaries with income at or below 150 percent of the federal poverty level (28 percent of Part D enrollees) received the LIS (data not shown). Of these individuals, 8 million were eligible for both Medicare and full Medicaid benefits. The remaining LIS enrollees 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 non-LIS enrollees, LIS enrollees are more likely to be female; more than twice as likely to be African American, Hispanic, or Asian; and over four times more likely to be under age 65 (Medicare Payment Advisory Commission 2018a).

Between 2007 and 2018, enrollment growth for Part D enrollees who received the LIS was slower (3 percent

per year) than for non-LIS enrollees (7 percent per year) (data not shown). The faster growth in enrollment of non-LIS enrollees is partly attributable to the recent growth in employer group waiver plans that reflects a shift from employers operating plans that receive the RDS to sponsoring Part D plans for their retirees.¹⁰ Consequently, the share that received the LIS fell from 39 percent to 28 percent. In 2018, about 61 percent (7.6 million) of LIS enrollees were in PDPs; the rest were in MA-PDs (data not shown). Although most individuals receiving the LIS are enrolled in traditional Medicare rather than Medicare Advantage (MA), LIS enrollment in MA-PDs has grown.

Beneficiaries' enrollment decisions in 2018

Most enrollees are in plans that are actuarially equivalent to Part D's defined standard benefit or are enhanced in some way. 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 MA (Part C) payments to supplement their Part D benefits.

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

In 2018, 60 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copayments (Table 14-4). The remaining 40 percent of PDP enrollees had enhanced benefits. No PDP enrollees were in defined standard

**TABLE
14-4**

MA-PD enrollees more likely to be in enhanced plans, 2018

	PDP		MA-PD	
	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent
Total	20.8	100%	12.7	100%
Type of benefit				
Defined standard	0.0	0	0.1	<0.5
Actuarially equivalent*	12.4	60	0.5	4
Enhanced	8.4	40	12.1	96
Type of deductible				
Zero	9.4	45	5.4	43
Reduced	1.9	9	6.9	54
Defined standard**	9.5	46	0.4	3

Note: MA-PD (Medicare Advantage–Prescription Drug [plan]), PDP (prescription drug plan). The MA-PD enrollment described here excludes employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, demonstrations, and Part B–only plans. Components may not sum to stated totals due to rounding.
 *Includes actuarially equivalent standard and basic alternative benefits.
 **Deductible of \$405 in 2018.

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

benefit plans because plan sponsors offered none. MA-PD enrollees were overwhelmingly in enhanced plans. In both plan types, the typical enhancement was having no deductible or a deductible smaller than that used for Part D’s defined standard benefit. In PDPs and MA-PDs, 45 percent and 43 percent of enrollees, respectively, had no deductible in their plans’ benefit designs.

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.¹¹ For 2019, MA-PD plan sponsors applied on average more than \$32 per month (29 percent) of their Part C rebate dollars to Part D benefits. That amount was divided nearly evenly between lowering enrollees’ Part D premiums and supplementing their drug benefits.

Average enrollee premiums remained flat in 2018

Despite significant growth in catastrophic benefits, average premiums for basic Part D benefits have remained low. (Low premiums in part reflect the effects of Medicare’s reinsurance subsidy, which has offset benefit spending

that would otherwise have increased plan sponsors’ bids. See pp. 410–411 for more detail on plan bids and enrollee premiums.) In 2018, monthly beneficiary premiums averaged about \$32 across all types of plans (basic and enhanced), and average premiums have remained around \$30 per month since 2010. However, underlying that average is wide variation in premiums from \$0 for many MA-PDs to \$197 per month for one PDP offering enhanced coverage.

On average, 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 2018, the average monthly premium for an MA-PD enrollee was \$18, with an additional \$16 of premium costs paid through Part C rebates (Medicare Payment Advisory Commission 2018a). By comparison, PDP enrollees paid an average of \$41 per month.

Two other factors affect the premium amounts paid by a given enrollee. First, higher income beneficiaries have a lower federal subsidy of their Part D benefits. In 2018, 2.9 million Part D enrollees (over 6 percent) were subject to the income-related premium (Liu 2018).

**TABLE
14-5**

MA-PDs are more likely to offer enhanced benefits than PDPs, 2019

	PDP		MA-PD	
	Number of plans	Percent	Number of plans	Percent
Total	901	100%	2,414	100%
Type of benefit				
Defined standard	0	0	37	2
Actuarially equivalent*	348	39	83	3
Enhanced	553	61	2,294	95
Type of deductible				
Zero	263	29	1,116	46
Reduced	170	19	1,138	47
Defined standard**	468	52	160	7
Some drugs covered in the coverage gap	191	21	1,005	42

Note: MA-PD (Medicare Advantage–Prescription Drug [plan]), PDP (prescription drug plan). The MA-PD enrollment described here excludes employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, demonstrations, and Part B-only plans. Components may not sum to stated totals due to rounding.
 *Includes actuarially equivalent standard and basic alternative benefits.
 **Deductible of \$415 in 2019.

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

As with the income-related premium for Part B, higher Part D premiums apply to individuals with an annual adjusted gross income greater than \$85,000 and to couples with an adjusted gross income greater than \$170,000. A beneficiary whose income exceeds these levels pays a monthly adjustment amount in addition to the Part D premium paid to a plan. In 2018, the adjustment amount ranged from \$13.00 to \$74.80 per month, depending on income. For 2019, adjustments range from \$12.40 to \$77.40 per month (Centers for Medicare & Medicaid Services 2018d).¹²

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). 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 creditable coverage. In 2018, 2 million Part D enrollees paid the LEP (Liu 2018).

Benefit offerings for 2019

Beneficiaries are encouraged to reexamine plan options each year during an 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 and OOP costs of medications.

Beneficiaries have a variety of plan options

For 2019, plan sponsors are offering 901 PDPs and 2,414 MA-PDs, about 15 percent and 21 percent more plans, respectively, than in 2018. The increase in PDPs is attributable almost entirely to the decision of plan sponsors to offer more enhanced plans that include supplemental drug coverage. Plan sponsors were likely motivated by a change in CMS’s “meaningful difference” policy. In prior years, when a PDP sponsor offered two enhanced plans in a region, it was required to design benefit packages that had a specified difference between the plans’ estimated OOP costs. CMS discontinued that requirement for 2019 (Centers for Medicare & Medicaid Services 2018h).¹³ The

growth in MA–PD offerings likely reflects interest among plan sponsors in gaining a share of expanding enrollment in MA.

In each of the nation’s 34 PDP regions, beneficiaries continue to have broad choice. Options range from 22 PDPs in Alaska to 30 PDPs in the Pennsylvania–West Virginia region, along with MA–PDs in most areas. The number of MA plans available to a beneficiary varies by the county of residence, with an average county having 13 MA plans (23 plans when weighted by Medicare population). A small number of counties have no MA plans available.¹⁴

MA–PDs are much more likely to offer more generous coverage than PDPs. For example, 95 percent of MA–PDs include enhanced coverage beyond basic benefits, compared with 61 percent of PDPs (Table 14-5). Among plans with basic benefits, the 2019 marketplace includes no PDPs and just 2 percent of MA–PDs (excluding special needs plans) with the standard benefit design. A larger share of MA–PDs than PDPs charges no deductible (46 percent vs. 29 percent, respectively), and 52 percent of PDPs use the same \$415 deductible as the defined standard benefit. A larger share of MA–PDs (42 percent) than PDPs (21 percent) includes some additional coverage in the gap phase.

Plan premiums

For 2019, CMS calculated that Part D’s base beneficiary premium—enrollees’ share of the monthly national average expected cost for basic benefits—was \$33.19, a 5 percent drop from \$35.02 in 2018. One key reason the base premium declined was that, for 2019, brand-drug manufacturers must pay a 70 percent discount on drugs filled during the beneficiary’s coverage-gap phase rather than 50 percent, which was the case in 2018.

This change helped reduce the projected cost to Part D plans of providing basic benefits. 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.

Seven of 10 stand-alone PDPs with the highest enrollment in 2018 experienced relatively small increases in their premium for 2019. On average, premiums increased about \$1 per month (Table 14-6, p. 400). The largest changes to monthly premiums were for the top three plans:

SilverScript Choice (17 percent increase to \$30.73), AARP MedicareRx Preferred (11 percent decrease to \$74.76), and Humana Walmart (37 percent increase to \$27.67). One sponsor introduced an option for 2019 (not shown in Table 14-6) designed for beneficiaries who take brand-name drugs; that plan has a much higher premium than its sponsors’ other plans but lower cost sharing on certain brands because the plan applies a portion of rebates at the point of sale (Levy 2018).

Although cost-sharing requirements in Part D plans have generally risen over the years, for 2019, PDPs with the highest enrollment have a mix of cost-sharing increases and decreases (data not shown). The top 10 PDPs (ranked by 2018 enrollment) continue to use a five-tiered formulary with differential cost sharing between preferred and nonpreferred drugs, as well as a specialty tier for high-cost drugs. Over time, many plan sponsors have moved from charging copayments (predetermined fixed amounts) to coinsurance (calculated as a percentage of cost) for certain tiers. In fact, for 2019, the top 10 PDPs shown in Table 14-6 all charge coinsurance rather than copayments for medications on nonpreferred drug tiers, charging 32 percent to 50 percent of each prescription’s negotiated price (Cubanski et al. 2018). By charging enrollees a share of the price of their prescriptions rather than a flat copayment, some of the price increases are reflected in beneficiaries’ cost sharing. Another reason for the move to coinsurance is that some plan sponsors have combined certain brand and generic drugs on the same cost-sharing tier (e.g., for all nonpreferred drugs). When the same tier includes both low-priced and high-priced drugs, plan sponsors may find it difficult to set a copayment amount that provides a comparable value of benefit.

Benchmark PDPs

Compared to 2018 levels, the number of PDPs available to LIS enrollees at no premium (“benchmark PDPs”) in 2019 remained essentially flat at 215 plans.¹⁵ One region, Florida, has two qualifying PDPs available. However, all other regions have at least 3 qualifying PDPs available, while the Arizona region has 10 such PDPs.

About 0.9 million LIS enrollees (about 1 in 10 LIS enrollees in PDPs) were enrolled in plans in 2018 that, in 2019, have premiums higher than regional benchmarks (Cubanski et al. 2018). However, many of those beneficiaries paid a premium in 2018, meaning they selected a plan rather than accepting Medicare’s random assignment to a benchmark plan. Once an LIS

**TABLE
14-6**

Change in 2019 premiums for PDPs with high 2018 enrollment

Plan name	Benefit type	2018 enrollment (in millions)	Weighted average monthly premium*		Change in weighted average monthly premium	
			2018 premium	Projected 2019 premium	Dollar	Percent
SilverScript Choice	Basic	4.6	\$26.34	\$30.73	\$4.39	17%
AARP MedicareRx Preferred	Enhanced	2.5	83.56	74.76	-8.80	-11
Humana Walmart	Enhanced	2.4	20.20	27.67	7.47	37
Humana Preferred	Basic	1.6	31.16	31.10	-0.06	<-0.5
Aetna Medicare Rx Saver Plus	Basic	1.4	35.49	34.06	1.43	-4
AARP MedicareRx Saver	Basic	1.2	29.61	29.20	-0.41	-1
WellCare Classic	Basic	1.0	30.41	31.65	1.24	4
Humana Enhanced	Enhanced	0.8	75.83	75.89	0.06	<0.5
AARP MedicareRx Walgreens	Enhanced	0.7	26.99	28.07	1.08	4
Aetna Medicare Rx Value Plus	Enhanced	0.6	57.46	60.16	2.70	5
Top 10 PDPs combined		16.6	38.97	40.02	1.05	3
All PDPs		20.6	40.57	41.21	0.64	2

Note: PDP (prescription drug plan). Components may not sum to stated totals due to rounding.

*Reflects the average of all PDPs offered under the same plan name in each region of the country, weighted by 2018 enrollment. The projected weighted average premium for 2019 does not reflect any enrollment switching among plans.

Source: Cubanski et al. 2018.

enrollee selects a plan, the enrollee is no longer eligible for reassignment.¹⁶ For 2019, CMS estimated that the agency randomly reassigned only about 100,000 individuals to new plans (Lyons 2018).

Plan sponsors and their tools for managing benefits and spending

Nearly 300 organizations sponsor Part D plans. In addition to insuring outpatient drug benefits, plan sponsors carry out marketing, enrollment, customer support, claims processing, coverage determinations, and exceptions and appeals processes. Sponsors also either contract with a pharmacy benefit manager (PBM) or perform those functions themselves through an in-house PBM.

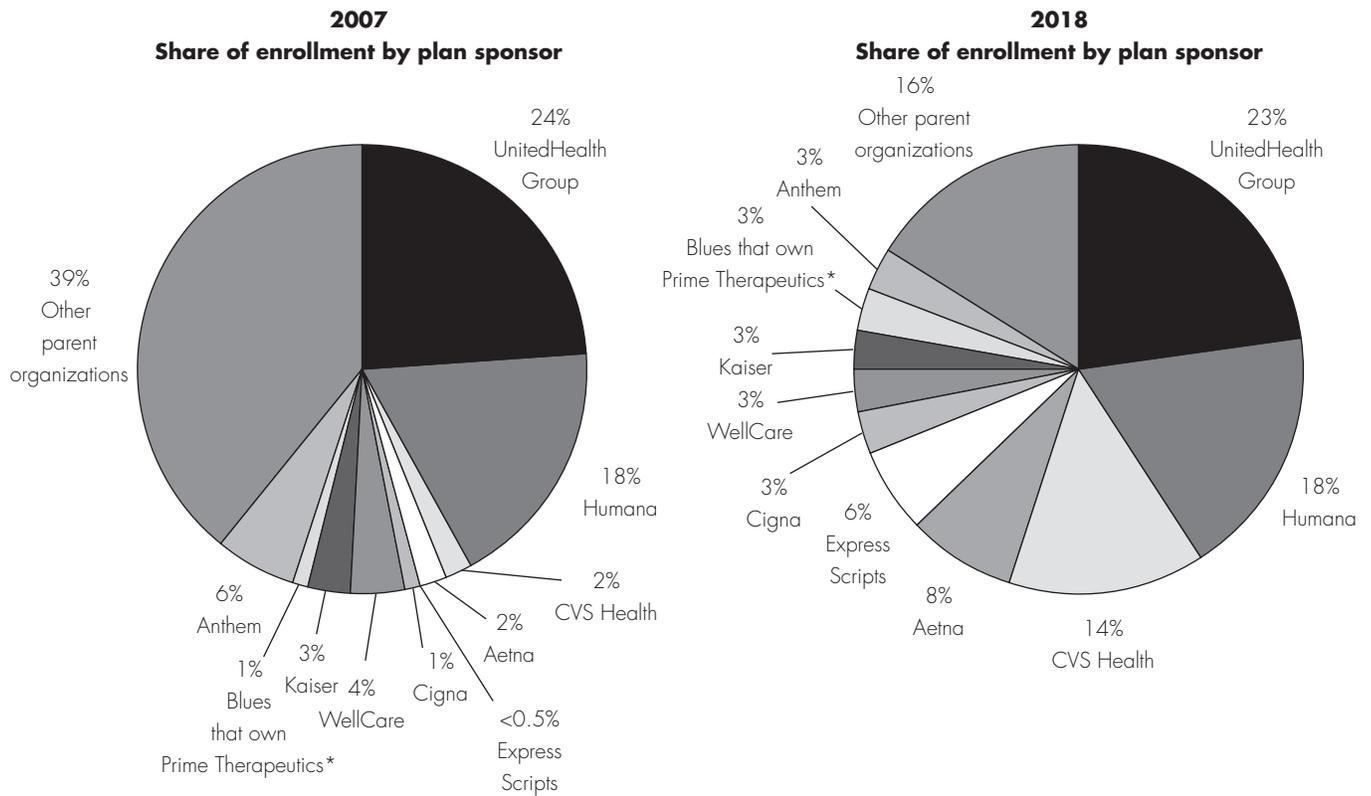
Most sponsoring organizations also operate health plans or manage pharmacy benefits for commercial clients, and they use a similar set of approaches—involving formularies, manufacturer rebates, and pharmacy networks—for their Medicare and non-Medicare business. The market structure of plan sponsors has changed dramatically and continues to do so. By law, the Medicare program is prohibited from becoming involved in negotiations among sponsors, drug manufacturers, and pharmacies.

Concentrated enrollment among plan sponsors

Sponsors and PBMs exert bargaining leverage with drug manufacturers and pharmacies by winning large market shares of clients and by influencing the market shares of

**FIGURE
14-3**

A number of plan sponsors have gained Part D market share over time



Note: Market shares are based on Part D enrollment, including both stand-alone prescription drug plans and Medicare Advantage–Prescription Drug plans. Employer group waiver plans are also included. In 2018, CIGNA finalized its purchase of Express Scripts, and a merger between CVS Health and Aetna is near completion. *Prime Therapeutics is a pharmacy benefit manager that in 2018 served 22 Blue Cross/Blue Shield plans. Components may not sum to stated totals due to rounding.

Source: MedPAC based on enrollment data from CMS.

drug products through the structures of their formularies and tiered cost sharing. High enrollment levels can also provide sponsors with economies of scale that lower other costs. Part D enrollment is concentrated among a small number of sponsoring organizations. Combined, the two largest plan sponsors, UnitedHealth Group and Humana, have accounted for about 40 percent of the Part D market each year since 2007 (Figure 14-3). Over time, other sponsors have expanded their enrollment and market shares. In 2018, the top nine organizations ranked by enrollment and a group of Blue Cross and Blue Shield companies that collectively own or are serviced by Prime Therapeutics (a PBM) together accounted for 84 percent

of Part D enrollment. In 2007, those same organizations accounted for 61 percent of enrollment.

Plan sponsors’ organizational structures differ in the degree to which each company integrates clinical and health plan services, PBM services, and dispensing. Most of the largest sponsors are insurers whose core business function is to offer commercial and MA health plans with combined medical and pharmacy benefits. However, more than 60 percent of Medicare beneficiaries remain in the FFS program and thus obtain Part D benefits through stand-alone PDPs (if they choose to enroll). Because PDPs remain an important market opportunity, the insurers serving as MA sponsors also offer PDPs in

many or all regions. Other sponsors—Express Scripts and CVS Health—have had core business models that focused primarily on pharmacy benefit management and dispensing and have offered only PDPs. However, both organizations are merging with insurers, thereby becoming more vertically integrated.¹⁷ Both also serve as PBMs under contract to other Part D sponsors. Most top sponsors also offer employer group waiver plans, which can take the form of MA-PDs or PDPs.

Enrollment among beneficiaries who receive Part D's LIS is also concentrated. In 2018, CVS Health had more LIS enrollees than any other sponsor: a total of 2.5 million, or 20 percent of LIS enrollees. Once a sponsor has a sizable number of LIS enrollees, its bid can influence LIS benchmarks because the benchmarks are calculated as a regional average premium weighted by LIS enrollment. At the same time, should the sponsor miss a regional benchmark by bidding too high, it would stand to lose potentially sizable numbers of LIS enrollees and market share.

Tools for managing benefits and spending

Over the first decade of Part D, the use of pharmacy management tools and fortuitous timing of patent expirations led to the expanded use of generics. By 2016, about 87 percent of prescriptions filled by Part D enrollees were for generics, compared with 61 percent in 2007. Today, generic substitutions in both Part D and among commercial populations may have reached a saturation point. For their commercial clients, plan sponsors increasingly focus on managing the use of specialty drugs and biologics for conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. Spending for specialty drugs used by Part D enrollees is also expanding quickly. Many of these treatments are often injectable or infusible products. Dispensing specialty drugs can raise challenging logistical issues, and patients who take them may require closer clinical management. Specialty drugs also have very high prices, with annual costs of treatment per person of tens of thousands of dollars or more.

Sponsors use several general approaches to manage pharmacy benefits for both commercial and Part D plans. However, law and regulations limit how sponsors may manage their Part D populations compared with how the same organizations manage their commercial populations. Recently, policymakers have taken steps to expand the management tools available to Part D plan sponsors. However, as yet there have been no changes to Part D's

risk-sharing provisions that would give plan sponsors financial incentives to fully utilize those new tools in practice as they do with their commercial population.¹⁸

Formulary design and management

Formularies remain plan sponsors' most important tool for managing drug benefits. Sponsors decide which drugs to list on their formulary, which cost-sharing tier is appropriate for each drug, and whether a drug will be subject to prior authorization or other forms of utilization management. Those decisions require that plan sponsors strike a balance between providing access to medications while encouraging enrollees to use preferred therapies. Greater flexibility to use such tools also affects plan sponsors' bargaining leverage with manufacturers over rebates.

Within constraints, plan sponsors have tightened formularies modestly in recent years. Similarly, the use of utilization management tools in Part D—quantity limits, step therapy, and prior authorization—has grown.¹⁹ Sponsors apply such tools for drugs that are expensive, potentially risky, or subject to abuse, misuse, and experimental use. These tools are also intended to encourage the use of lower cost therapies.

Manufacturer rebates

In drug classes that have competing drug therapies, sponsors and their PBMs negotiate with brand manufacturers for rebates that are paid after a prescription has been filled. Individual negotiations can vary. For example, producers of brand-name drugs with no therapeutic substitutes may not provide any rebates.

Generally, manufacturers pay larger rebates when plan sponsors position a drug on their formulary in ways that increase the likelihood that the manufacturer will win market share over competitors. For example, a manufacturer might pay a rebate for placing its product on a plan's formulary (versus excluding the drug) but might pay somewhat larger rebates for putting the drug on a preferred cost-sharing tier or for not applying prior authorization requirements. Data on manufacturers' rebate amounts for individual drug products are highly proprietary.

The share of a drug product's gross price rebated to PBMs and payers can be high when there are close substitutes in the product's drug class. For example, across all payers for Sanofi's insulin product Lantus, the implied

rebate—the share of gross drug sales offset by rebates and other discounts—grew from around 10 percent in 2009 to nearly 60 percent by the second quarter of 2016 (*Indianapolis Business Journal* 2016). The extent to which rebates and discounts offset price increases varies across manufacturers, driven primarily by the mix of products in their portfolios and the competitive pressures they face (Credit Suisse 2015).

Pharmacy networks and postsale fees

Plan sponsors try to encourage enrollees to use pharmacies that dispense prescriptions at lower cost. For example, for some non-Medicare employer plans, enrollees are required to fill prescriptions within an exclusive network of retail pharmacies, refill prescriptions by mail rather than through retail pharmacies, and fill prescriptions with a 90-day rather than a 30-day supply.

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.²⁰ Plan sponsors must also demonstrate that their network of pharmacies meets access standards.

Sponsors can, however, designate a subset of network pharmacies that offer preferred (lower) cost sharing. The strategy of designating certain “preferred cost-sharing pharmacies” has the potential to lower costs for Medicare and enrollees if it encourages enrollees to fill prescriptions at more efficient pharmacies. Differences between cost sharing at preferred pharmacies and other network pharmacies can vary substantially among plans (Medicare Payment Advisory Commission 2016b). In 2019, about 88 percent of beneficiaries enrolled in PDPs are in plans with preferred cost-sharing pharmacies, down from over 99 percent of plans in 2018 (Fein 2019).

Tiered networks as a management tool have been controversial because of past concerns that some enrollees do not have adequate access to preferred pharmacies with lower cost sharing. In addition, 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. Out of these concerns, CMS guidance permits plans to offer lower cost sharing at preferred pharmacies only if the approach does not raise Medicare

payments (Centers for Medicare & Medicaid Services 2015a, Centers for Medicare & Medicaid Services 2014b).

Although Part D plan 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 amounts 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).²¹ For some pharmacies, postsale fees have made participation in plan sponsors' networks much less desirable because the pharmacies have not been able to predict their ultimate amount of reimbursement from plans.

Plan sponsors must report postsale pharmacy fees to CMS in the same way they report manufacturers' rebates. According to CMS, pharmacy price concessions and fees grew dramatically between 2013 and 2017, from \$229 million to \$4 billion (Centers for Medicare & Medicaid Services 2018l). Critics point out that when Part D enrollees pay cost sharing in the deductible phase or based on a percentage coinsurance at the pharmacy before such fees are assessed, those cost-sharing amounts are too high.

Specialty pharmacies

Commercial plan sponsors often try to dispense high-cost specialty drugs through an exclusive network of specialty pharmacies. Many of the largest insurers and PBMs own specialty pharmacies, and some encourage their clients to dispense exclusively through that company. In Part D, plan sponsors cannot 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.²² As with general retail pharmacies, some Part D plan sponsors include terms in their contracts with specialty pharmacies that include postsale price concessions and fees.

Most specialty pharmacies fill prescriptions through home delivery or deliveries to a convenient location. Specialty pharmacies can help ensure that patients meet specific clinical criteria through plans' prior authorization processes before dispensing prescriptions. They can also reduce waste by, for example, initially dispensing a 7- or 14-day supply and observing the patient for side effects, treatment effectiveness, and adherence before providing

a 30-day supply. Specialty pharmacies also play a role in patient education, monitoring, and data reporting. They often employ nurses to provide counseling by telephone about side effects and to monitor adherence. Specialty pharmacies may also facilitate outreach to patient assistance programs.²³

A variety of ownership types have evolved to dispense specialty drugs. Owners of specialty pharmacies include pharmacy chains, PBMs, health plans, drug wholesalers, hospital systems, and prescriber practices, or the pharmacy can operate as an independent business. Although most manufacturers do not own specialty pharmacies, a number of drug makers pay fees to specialty pharmacies and have contracts that limit which ones may dispense their drug. These relationships can result in specialty pharmacies with financial incentives that align with manufacturers.

Recent regulatory changes to Part D

In 2018, CMS finalized a number of regulatory changes in Part D and proposed other steps for stakeholder review and comment. Many of those measures were designed to make the tools that plan sponsors use in Part D more similar to those already available for managing pharmacy benefits in commercial populations.

For example, CMS now allows plan sponsors to add a newly approved generic to their formularies and remove or change the tier status of a therapeutically equivalent brand-name drug at any point during the benefit year without prior approval. The new generic would have to be offered at the same or lower cost sharing and with the same or less restrictive utilization management criteria, and beneficiaries must receive notification. This is consistent with the Commission's 2016 recommendation that CMS streamline the agency's process for reviewing formulary changes (Medicare Payment Advisory Commission 2016a).

In July 2018, CMS issued guidance for the 2019 benefit year allowing plan sponsors to use different utilization management requirements for a drug depending on a patient's indication (Centers for Medicare & Medicaid Services 2018j). As an example, some tumor necrosis factor (TNF) blockers have been licensed by the Food and Drug Administration (FDA) for a broader range of indications than others. Previously, the manufacturer of the product with more indications would have greater leverage in negotiations for plan formulary placement and rebates. Under indication-specific criteria, however, plan sponsors may require a patient with, for example, Crohn's disease to try a different TNF blocker that is approved for

fewer indications (but includes Crohn's) before covering the other agent. That approach gives sponsors leverage to encourage more price competition among drug therapies. CMS also noted that beginning with benefit year 2020, the agency will allow plan sponsors to limit on-formulary coverage of certain drugs by indication (Centers for Medicare & Medicaid Services 2018i).

Alternative therapies that can be used to treat the same condition sometimes fall across medical and pharmacy benefits. As health plans have expanded their pharmacy benefit management capabilities and acquired large warehouses of member data, those organizations have begun looking to manage specialty drugs across pharmacy and medical benefits. Some entities contend that by doing so, they can introduce greater price competition among manufacturers in certain drug classes. In August 2018, CMS issued guidance that, for 2019 and subsequent years, allows MA-PDs to use step therapy for managing Part B drugs, under which plan sponsors can require enrollees to try a drug covered under either Part B or Part D before using a Part B therapy for the same indication (Centers for Medicare & Medicaid Services 2018f).

Drug pricing

At all levels of the drug supply and distribution channels, there are incentives that drive prices higher because payments for pharmaceutical products or other services that are provided in conjunction with the distribution of pharmaceutical products are often based on a percentage of the drugs' prices (Diplomat Specialty Pharmacy 2017, Fein 2018, Feldman 2018, Garthwaite and Morton 2017). Over the past decade, manufacturers have shifted their development pipelines toward higher cost drugs and biologics. Meanwhile, participants in drug supply and distribution channels grew to rely on price inflation for revenue growth (Cahn 2017, Fein 2017, Lopez 2016, Sell 2015). Those factors combined with the increasing market concentration among participants in the drug supply and distribution channels put upward pressure on both prices and rebates. Until recently, the result was aggressive growth in drug prices at the point of sale (POS), which determines gross Part D spending (i.e., aggregate amounts paid at the pharmacy). There has also been a growing divergence between POS prices and net prices (net of postsale rebates and discounts from manufacturers and pharmacies (see text box on the effects of rebates, pp. 406–407)). This

**TABLE
14-7**

Overall price growth moderated in 2016 and 2017, but prices for single-source brand-name drugs continued to grow aggressively

Year-over-year price change (in December)

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Cumulative 2006–2017
All drugs and biologics	5.9%	4.7%	5.2%	5.5%	4.9%	3.8%	8.6%	7.8%	5.7%	4.0%	4.3%	80%
Single-source brand-name drugs	8.2	10.3	9.2	10.5	11.3	12.5	12.8	13.9	11.2	8.0	8.7	216
Generic drugs	-16.4	-12.3	-8.1	-11.5	-17.3	-22.8	-4.1	-9.3	-13.0	-12.3	-4.1	-80
After accounting for generic substitution	-0.7	1.9	2.8	1.1	1.3	-8.2	6.7	6.0	2.7	-0.2	1.6	12

Note: Prices are measured by chain-weighted Fisher price indexes that reflect total amounts paid to pharmacies (i.e., do not reflect retrospective rebates or discounts from manufacturers and pharmacies).

Source: Acumen LLC analysis for MedPAC.

divergence means that Medicare and its beneficiaries pay a greater share of actual drug costs (net of rebates).

The aggregate amount of rebates in Part D has been growing. Using plan sponsors’ assumptions about rebates from their 2019 bids, the Medicare Trustees estimated that direct and indirect remuneration (DIR)—consisting predominantly of manufacturers’ rebates—amounted to 26 percent of total drug costs (averaged across all drugs, including those for which plans do not receive any rebates) (Boards of Trustees 2018). This amount is a significant increase from DIR of about 9.6 percent in 2007, and even from 2015, when the intensified competition in the hepatitis C drug market resulted in higher DIR (18.2 percent) than expected. This phenomenon is not limited to the Part D program. According to one estimate, in 2016, net prices for all pharmaceutical products sold in the U.S. were 28 percent below total spending based on invoice (list) prices (IQVIA Institute for Human Data Science 2017).²⁴

POS prices and net prices that reflect rebates and discounts both affect the costs of the Part D benefit. The former affects beneficiary cost sharing and the rate at which beneficiaries reach the catastrophic phase of the benefit, the point after which Medicare pays 80 percent of the

costs in individual reinsurance. For this reason, from beneficiaries’ and Medicare’s perspectives, prices paid at the pharmacy are an important indicator of Part D’s costs. The latter—net prices—affects premiums and plan profits (see text box on prices, pp. 406–407).

Prices paid at the point of sale

The Commission has contracted with Acumen LLC for many years to construct a series of volume-weighted price indexes. The indexes do not reflect retrospective rebates or discounts from manufacturers and pharmacies; rather, they reflect POS prices—total amounts paid to the pharmacies, including ingredient costs and dispensing fees.

Overall price increases moderated in 2016 and 2017

Price increases for Part D drugs and biologics moderated in 2016 and 2017. Measured by individual national drug codes (NDCs) and excluding manufacturers’ rebates, annual increases averaged about 4 percent in both years, compared with year-over-year increases of between 8.6 percent and 5.7 percent from 2013 through 2015 (Table 14-7).²⁵ This pattern is heavily influenced by the growth in prices of single-source brand-name drugs, which grew at a double-digit rate between 2010 and 2015 before returning to high single-digit growth rates in 2016 and 2017.

Effects on the Part D program of growing rebates and the divergence between point-of-sale prices and net prices

The role of rebates in drug pricing has garnered attention because of its implications for beneficiary cost sharing and for Medicare's program costs. For the past several decades, manufacturers have used rebates to charge different prices depending on each payer's market power (i.e., negotiating leverage) and its ability to deliver a certain market-share goal. In recent years, the gap between pharmacy prices (or point of sale (POS) prices) and net prices reflecting postsale rebates has widened considerably.

In theory, plan sponsors could apply manufacturer rebates in one of two ways. They could:

- reduce the price of the prescription that generated the rebate at the POS or
- offset aggregate benefit costs with the aggregate amount of rebate payments.

Under the first approach, enrollees who use drugs for which a rebate is negotiated would benefit from the

price discount. This approach is not always practical if, for example, the amount of rebate payment is determined retroactively based on performance goals or the magnitude of price increases. Under the second approach, the aggregate amount of rebate payments would be used to lower a plan's premium for all enrollees.

Part D plans overwhelmingly use the second approach because beneficiaries evaluate premiums closely when comparing plan options, and premiums are the basis on which plans qualify as low-income subsidy (LIS) benchmark plans. Using rebates to reduce plan premiums lowers Medicare program spending because (1) Medicare retains a portion of aggregate rebates to offset a share of program payments for individual reinsurance and (2) the rebates lower the subsidies Medicare pays for a portion of plan premiums for all enrollees. However, an opposite effect is that a higher proportion of enrollees reach Part D's out-of-pocket threshold—the point at which Medicare pays for 80 percent of benefits. At the same time, CMS has noted

(continued next page)

On average, prices of generic drugs are 75 percent to 90 percent lower than their brand-name counterparts, and generic prices tend to decline over time (Government Accountability Office 2016). While certain generic medications have experienced sharp price increases in recent years, primarily due to decreases in market competition, the prices of generic drugs between 2006 and 2017 generally declined (Berndt et al. 2017, Dave et al. 2017, Joyce et al. 2018, Loftus 2017, Thomas 2016).

Measured by a price index that takes generic substitution into account, Part D prices decreased slightly (0.2 percent) in 2016 and increased by 1.6 percent in 2017.²⁶ These rates contrast with the uptick we observed between 2013 and 2015, when price increases for brand-name drugs overwhelmed the effects of using lower priced generics. As a result, between December 2006 and December

2017, despite the 80 percent increase in average prices for individual NDCs, when generic substitution is taken into account, prices grew by just a cumulative 12 percent.

Brand price growth remained strong in many therapeutic classes

Over the past decade, prices have grown rapidly for brand-name drugs and biologics with few or no generic or biosimilar alternatives. Between 2007 and 2017, prices of single-source, brand-name products (that have no generic or biosimilar substitutes but may have generic alternatives in the same therapeutic class) grew by a cumulative 195 percent (index value of 2.95) (Figure 14-4, p. 408). Although brand-name products only account for a small share of prescriptions (about 13 percent in 2016; data not shown), their price increases can overwhelm the effects of using lower priced generics.

Effects on the Part D program of growing rebates and the divergence between point-of-sale prices and net prices (cont.)

that the increase in rebates and the resulting disparity between POS prices and net prices lower costs for plan sponsors while increasing costs for beneficiaries who pay coinsurance (calculated as a share of undiscounted POS prices) and for Medicare, in higher payments for reinsurance and low-income cost-sharing subsidies (Centers for Medicare & Medicaid Services 2017b).

Part D's unique benefit design may also distort formulary incentives for plan sponsors. For example, the Commission has raised concerns that the existence of manufacturers' coverage-gap discount and Medicare reinsurance payments that reduce plan liability for the benefit may create a situation in which there is a financial advantage to plan sponsors when they select high-cost, high-rebate drugs over lower cost alternatives (Medicare Payment Advisory Commission 2017). Such a financial benefit could accrue to plan sponsors because, under Part D's risk corridors, any rebates received above the projected amount contribute primarily to plan profits (Centers for Medicare & Medicaid Services 2017b).

In recent years, plan sponsors have negotiated additional "price-protection" provisions. Under these agreements, if a drug's list price increases above a specified threshold, the manufacturer rebates any incremental increase above the threshold to the plan sponsor (Kaczmarek 2015, Pharmacy Benefit Management Institute 2017). Sponsors negotiate ceiling prices because manufacturers' midyear price increases may result in benefit costs that are higher than they expected. While price-protection rebates give more predictability to sponsors, that protection could allow manufacturers to increase their POS prices with less resistance from plan sponsors. (In addition, it does not protect sponsors from annual price increases as the price protection only applies to price increases that occur during a given benefit year.) In turn, it could contribute to the greater divergence between POS and net prices, worsening the shift in costs toward beneficiaries and taxpayers who finance the Medicare program. ■

While drug prices have continued to rise in many classes, there has been a notable deceleration for some classes. For example, in 2017, our price index for therapies to treat rheumatoid arthritis and multiple sclerosis remained flat. However, previous increases had already raised prices for these therapies to three or more times those observed at the beginning of 2007.

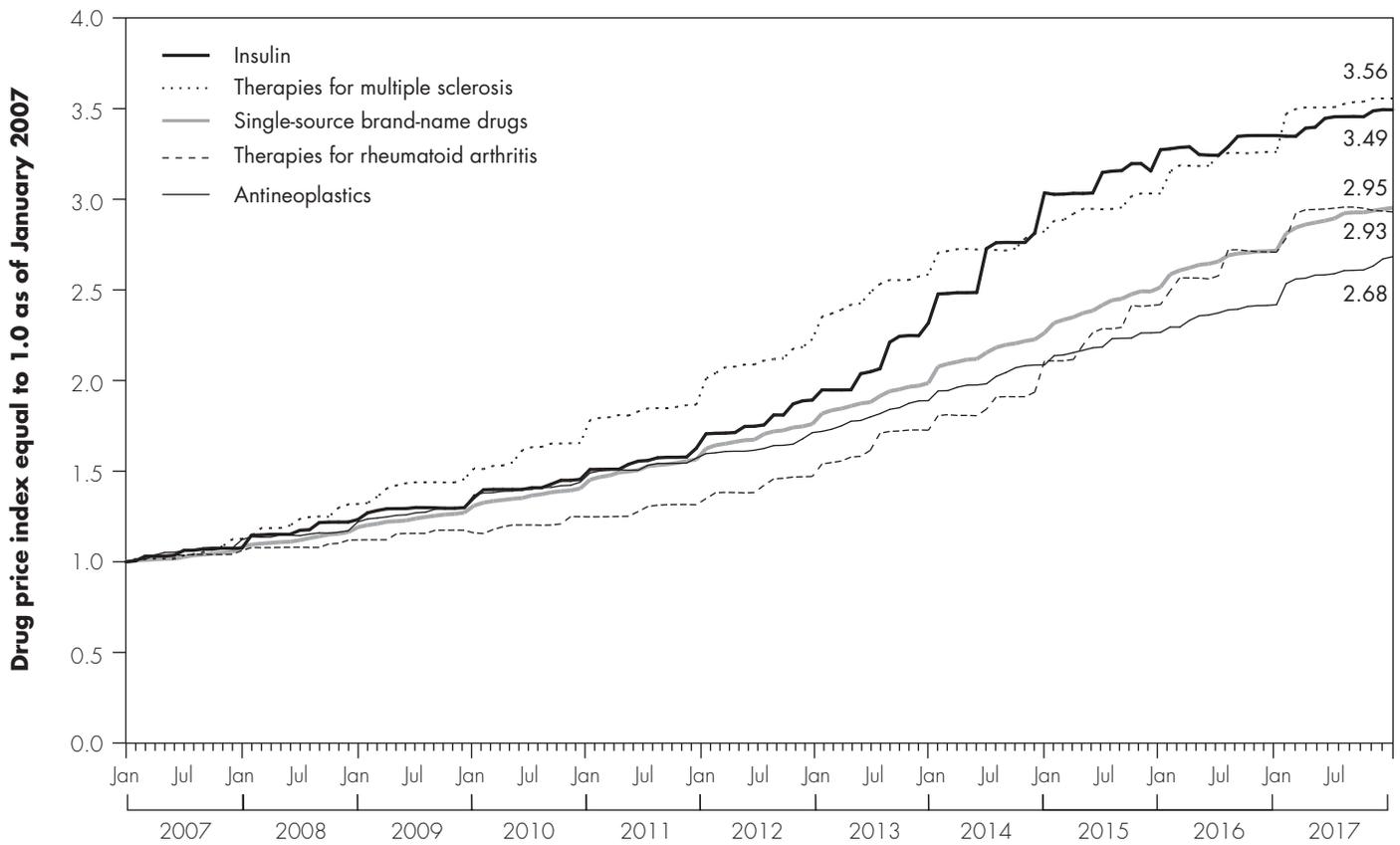
POS prices for brand-name drugs, however, are rarely the actual prices paid by plan sponsors because manufacturer rebates and other discounts can offset substantial amounts. For example, between 2007 and 2016, insulin prices grew by a cumulative 249 percent (index value of 3.49) (Figure 14-4, p. 408). However, because multiple manufacturers compete to produce insulin products, payers have been able to extract substantial price concessions from manufacturers (*Indianapolis Business Journal* 2016, Sagonowsky 2018). Thus, the trend for net prices for

insulin would show slower growth than for POS prices (Langreth et al. 2016).

Antineoplastics saw slower growth in prices compared with other drug classes dominated by single-source brand-name drugs (a cumulative 168 percent). The observed lower trend is heavily influenced by generic antineoplastics, which account for nearly 90 percent of prescriptions in this class. At the same time, antineoplastics still under patent protection command extremely high prices and tend to have lower rebates because these products have few or no therapeutic substitutes (Langreth et al. 2016). That is, rebates, if available, likely do not affect net prices of antineoplastics to the extent they do for some other classes where manufacturers provide larger rebates. As a result, the POS price trend shown by our index likely provides a reasonable approximation of the growth in net prices of antineoplastics.

**FIGURE
14-4**

Aggressive growth in prices of brand-name drugs reflects both price inflation and a shift toward more expensive products



Note: Chain-weighted Fisher price indexes.

Source: Acumen LLC analysis for MedPAC.

In general, the extent to which a manufacturer of a specific drug can raise its price depends on many factors—for example, whether there are generics or brand therapeutic alternatives, how many competitors there are in the given market, and whether their competitors cover all the same indications. Competition within a therapeutic class can result in restraint in list-price growth or in higher postsale rebates and discounts.

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.

**TABLE
14-8****Medicare's reimbursement amounts for Part D**

	2007	2010	2013	2014	2015	2016	2017	Average annual growth rate 2007-2017
Reimbursement amount (in billions):								
Direct subsidy*	\$17.6	\$19.6	\$19.6	\$18.5	\$18.1	\$17.1	\$14.2	-1.8%
Reinsurance	<u>8.0</u>	<u>11.2</u>	<u>19.2</u>	<u>27.2</u>	<u>33.2</u>	<u>35.5</u>	<u>37.4</u>	16.7
Subtotal, basic benefits	25.6	30.8	38.8	45.7	51.3	52.6	51.6	7.3
Low-income subsidy	16.7	21.1	23.2	24.3	25.6	26.4	27.5	5.1
Retiree drug subsidy	<u>3.9</u>	<u>3.9</u>	<u>1.7</u>	<u>1.3</u>	<u>1.1</u>	<u>1.0</u>	<u>0.8</u>	-14.7
Total Part D	46.2	55.8	63.7	71.3	78.0	80.0	79.9	5.6
Enrollee premiums**	4.1	6.7	9.3	10.5	11.5	12.7	14.0	13.1

Note: N/A (not applicable). 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 based on Table IV.B10 of the 2018 annual report of the Boards of Trustees of the Medicare trust funds.

Combined, the direct subsidy and reinsurance payments aim to cover 74.5 percent of the expected cost of basic benefits. Today, a much larger share of this overall subsidy takes the form of reinsurance (cost-based reimbursement) rather than the direct subsidy (capitated payments). In addition to reinsurance, Medicare shares risk with plan sponsors by 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. (Part D's low-income cost-sharing subsidy pays for the difference between cost sharing set by plan sponsors and the nominal amounts set in law.)

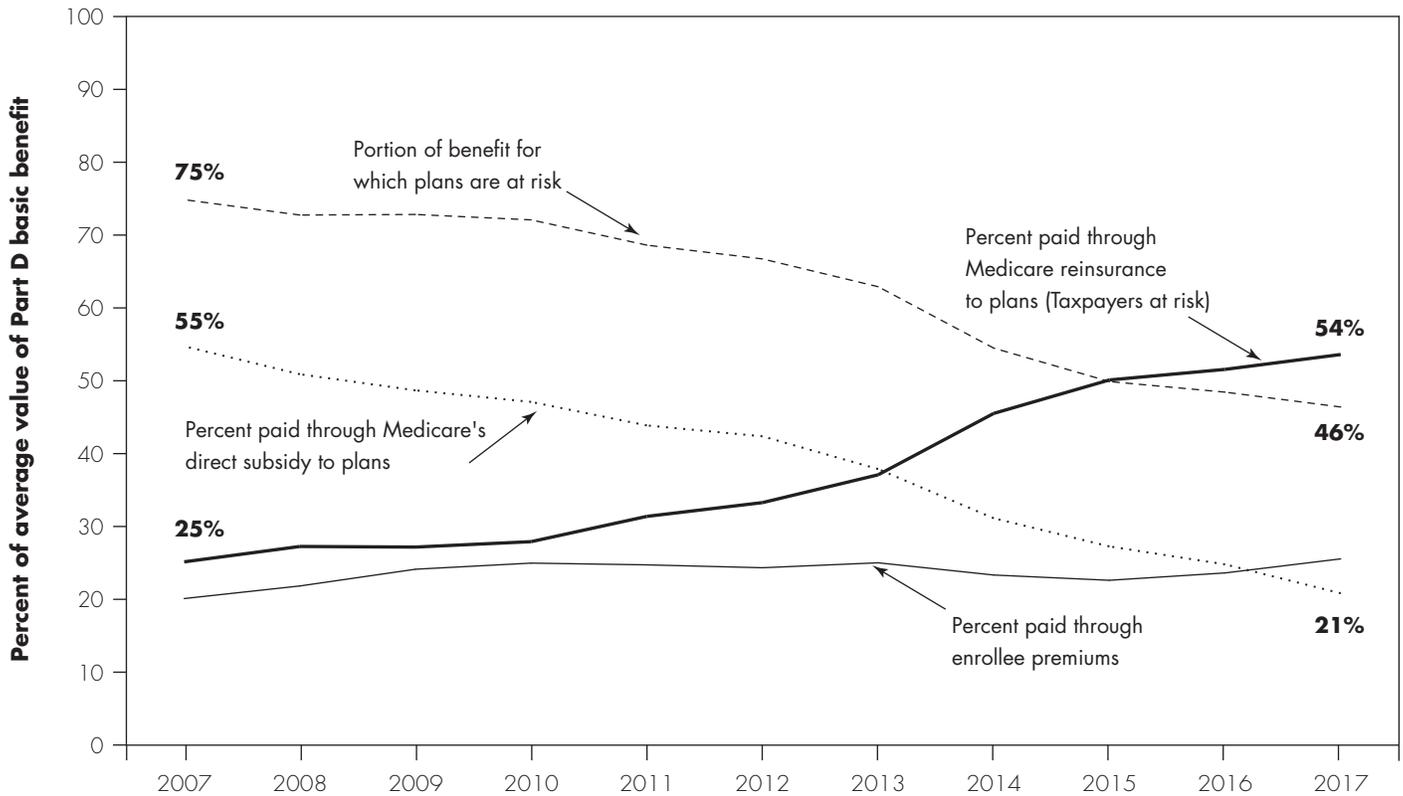
Trends in program subsidies and costs

Between 2007 and 2017, program spending (including expenditures for the RDS) rose from \$46.2 billion to \$79.9

billion (Table 14-8), or an average 5.6 percent per year. In 2017, Medicare paid \$14.2 billion for direct subsidies, \$37.4 billion for individual reinsurance, \$27.5 billion for the LIS, and \$0.8 billion for the RDS.

Medicare payments for individual reinsurance have grown faster than other components of Part D spending. Between 2007 and 2017, reinsurance payments increased at an average annual rate of 16.7 percent, compared with a decrease of 1.8 percent per year for the capitated direct subsidy payments (Table 14-8).

Compared with Medicare spending for reinsurance at the start of the program, growth accelerated between 2010 and 2015 due to a combination of factors. POS prices grew rapidly for brand-name drugs, and launch prices for new medicines such as hepatitis C treatments were extremely high (Hartman et al. 2018). The rapid growth in POS prices resulted in more enrollees reaching the OOP threshold. Changes made by PPACA to close the coverage gap also contributed to reinsurance growth by increasing the number of non-LIS enrollees who reached the OOP threshold. Between 2010 and 2015, Part D experienced a double-digit increase in the number of non-LIS enrollees

**FIGURE
14-5****Taxpayers bear increasing share of the risk for Part D benefit spending, 2007–2016**

Note: Figures represent the Commission's estimate of average values for incurred basic benefits net of risk corridor payments. "Portion of benefit for which plans are at risk" is calculated as the sum of the percent paid through direct subsidy and the percent paid through enrollee premiums. "Enrollee premiums" includes amounts paid by Medicare on behalf of beneficiaries who receive Part D's low-income subsidy.

Source: MedPAC based on Part D aggregate payment data from CMS Office of the Actuary.

who incur high costs and correspondingly rapid growth in Medicare spending for reinsurance.

Most recently, growth in Medicare's reinsurance to plans has slowed. In 2017, spending for hepatitis C and diabetes drugs slowed at the same time that manufacturer rebates rose as a whole. Those factors combined led to reinsurance spending that grew 6 percent annually between 2015 and 2017 (Boards of Trustees 2018, Cuckler et al. 2018, Hartman et al. 2018).

Going forward, analysts expect rebates to level off as a larger share of spending will be for relatively more costly specialty drugs (Cuckler et al. 2018). At the same time, changes made by the BBA of 2018 will further increase the number of beneficiaries reaching the OOP

threshold (see p. 393). As a result, reinsurance is expected to continue to grow as a share of total spending, shifting an even higher proportion of Medicare payments toward cost-based reimbursement. The most recent report by the Medicare Trustees projects that reinsurance payments will account for nearly 80 percent of subsidy payments to plans by 2027 (Boards of Trustees 2018).

Taxpayers bear increasing share of the risk for Part D spending

In 2017, premiums paid by Part D enrollees for basic benefits (not including the premiums paid by Medicare on behalf of LIS enrollees) totaled \$14 billion. That amount has grown by an average of 13 percent per year since 2007, reflecting both growth in enrollment and increases in benefit costs.

Despite significant growth in catastrophic benefits, average premiums for basic Part D benefits have remained low, in part reflecting the effects of Medicare’s reinsurance subsidy, which has offset benefit spending that would otherwise have increased plan premiums. In the Commission’s June 2015 report to the Congress, we noted regular patterns in spending that may suggest a bidding strategy that provides a financial advantage to plan sponsors (Medicare Payment Advisory Commission 2015). When plans underestimate catastrophic spending in their bids, they are able to charge lower premiums to enrollees and then later get reimbursed by Medicare for 80 percent of actual catastrophic claims (net of postsale rebates and discounts) through additional reinsurance at reconciliation. Because premiums are lower than they would have been had they reflected actual catastrophic claims costs, 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 (Figure 14-5).

At the same time, plan sponsors have bid too high on benefit spending other than catastrophic benefits. To the extent that actual costs for the basic benefits (excluding Medicare’s reinsurance payments) are lower than what was estimated in plan bids, the structure of Part D’s risk corridors allows plan sponsors to keep most of the difference as profits (Centers for Medicare & Medicaid Services 2017b). Between 2009 and 2015 (the latest year for which we have reconciled payment data by plan), the majority of plan sponsors returned a portion of their prospective payments to Medicare through risk corridors, meaning that they had profits above and beyond those assumed in their bids.

Part D was designed so that plan sponsors bear insurance risk on their enrollees’ drug spending. Insurance risk provides an incentive for plan sponsors to offer attractive benefits while managing their enrollees’ drug spending through formularies and other tools. However, data from CMS’s Office of the Actuary show that the portion of benefits paid to plans through Medicare’s capitated direct subsidy payments between 2007 and 2017 fell from 55 percent to 21 percent (Figure 14-5). Correspondingly, the portion for which plans are at risk (direct subsidy payments plus enrollee premiums) accounted for only 46 percent of the benefit costs in 2017, down from 75 percent in 2007. The portion paid through Medicare’s reinsurance subsidies

(for which taxpayers are at risk) grew from 25 percent to 54 percent over the same period.

High-cost enrollees drive overall Part D spending growth

In 2016, 3.6 million Part D enrollees (about 8 percent) had spending high enough to reach the catastrophic phase of the benefit (beneficiaries known as “high-cost enrollees”) (Table 14-9, p. 412). Between 2010 and 2016, the number of high-cost enrollees rose at an annual rate of 7 percent, compared with 1 percent annually before 2010. During this period, the share of high-cost non-LIS enrollees grew more rapidly than the share of high-cost LIS enrollees: 18 percent annually versus 5 percent annually. Still, in 2016, LIS enrollees accounted for 71 percent of all high-cost enrollees (calculated on unrounded numbers).

Aggregate spending for high-cost enrollees (i.e., including catastrophic and non-catastrophic spending) grew from about 40 percent of Part D spending before 2011, to 44 percent in 2011, to 58 percent in 2016. That growth reflects an annual 10 percent increase in per capita spending for high-cost enrollees compared with an annual 0.7 percent decrease in per capita spending for enrollees who did not reach the OOP threshold between 2010 and 2016 (data not shown).

Most spending growth for high-cost enrollees was due to higher prices

Rapid growth in the average price of prescriptions filled by high-cost enrollees explains most of the overall growth in their spending. That growth reflects inflation of the existing products’ prices, greater availability of higher priced drugs and biologics, and other changes in the mix of medications prescribed.

Between 2010 and 2016, the average price per standardized, 30-day prescription for high-cost enrollees grew at an annual rate of 10 percent, while the number of prescriptions filled per enrollee per month remained flat. This pattern is in stark contrast to enrollees who did not reach the OOP threshold. The average price of their prescriptions fell 3.2 percent annually, while the number of prescriptions they used grew by 2.5 percent annually.

High-cost enrollees tend to use more brand-name drugs. For example, in 2016, their average generic dispensing rate was just under 75 percent, or about 12 percentage points below the overall Part D average. Some of this difference reflects situations in which brand-name

**TABLE
14-9**

Part D enrollees reaching the benefit's catastrophic phase, 2007–2016

	2007	2010	2012	2013	2014	2015	2016	Average annual growth rate	
								2007–2010	2010–2016
In millions									
LIS	1.9	2.0	2.1	2.2	2.5	2.6	2.6	1%	5%
Non-LIS	0.4	0.4	0.5	0.7	0.9	1.0	1.1	–2	18
All	2.3	2.4	2.6	2.9	3.4	3.6	3.6	1	7
Share of all									
Part D enrollees	8.8%	7.9%	7.7%	7.6%	8.6%	8.7%	8.3%	N/A	N/A

Note: LIS (low-income subsidy), N/A (not applicable). Growth rates were calculated using figures before rounding was applied. Components may not sum to stated totals due to rounding.

Source: Enrollee counts from 2007 are based on published figures from CMS. Enrollee counts from 2010 to 2016 are based on MedPAC analysis of Part D prescription drug event data.

medications are the dominant standard of care within a therapeutic class. However, we have consistently found that high-cost enrollees tend to use more brand-name drugs even in classes with generic alternatives (Medicare Payment Advisory Commission 2016a). For example, in 2016, nearly a quarter of high-cost LIS enrollees filled prescriptions for Nexium, a proton pump inhibitor in a therapeutic class with generic alternatives and over-the-counter products.

Part D's cost-sharing subsidy for LIS beneficiaries likely increases their propensity to use brand-name medications when generics are available. While the subsidy helps beneficiaries afford medications, it also minimizes or eliminates the financial incentives plans create to encourage use of lower cost drugs. Part of the Commission's June 2016 recommendation would moderately change LIS cost sharing to encourage the use of lower cost alternatives when they are available (see section on the Commission's recommendations, pp. 394–395).

Patterns of spending differ between high-cost enrollees with and without the LIS

Patterns of drug spending differ between LIS and non-LIS enrollees with high costs, and spending for non-LIS beneficiaries has grown faster. Between 2007 and 2016,

average annual spending increased by 190 percent for non-LIS beneficiaries compared with 100 percent for LIS beneficiaries. By 2016, high-cost enrollees without the LIS had spending of \$29,797 per year compared with \$20,899 per year for high-cost LIS enrollees.

Overall, 1 in 10 high-cost enrollees filled at least one prescription in which a single claim would have been sufficient to reach Part D's catastrophic phase.²⁷ Among non-LIS beneficiaries, about 18 percent had such a prescription compared with over 6 percent of LIS beneficiaries.

Differences in patterns of spending are largely attributable to the drug classes used by these two groups. One study found that, in 2015, non-LIS beneficiaries were more likely to use drugs to treat cancer, multiple sclerosis, rheumatoid arthritis, and pulmonary hypertension, while LIS beneficiaries were more likely to use medications for mental health, diabetes, HIV/AIDS, and pain (Trish et al. 2018). Hepatitis C treatments represented a considerable portion of spending for both groups. Our own analysis corroborates these patterns. In 2016, among high-cost enrollees, spending on cancer drugs accounted for over a quarter of all spending by non-LIS beneficiaries, compared with about 6 percent for LIS beneficiaries. Drugs to treat mental health conditions, on the other hand, accounted

**TABLE
14-10**

Examples of drugs used by high-cost enrollees, 2016

	Aggregate amount (in billions)		Average per beneficiary			
	Gross spending	Manufacturer gap discount	Annual cost	Annual total OOP cost	Annual OOP cost in catastrophic phase	Manufacturer gap discount
High-cost non-LIS enrollees						
Revlimid (multiple myeloma)	\$2.0	\$0.06	\$33,681	\$2,055	\$1,195	\$923
Imbruvica (leukemia)	0.8	0.03	30,096	1,999	1,085	965
Copaxone (multiple sclerosis)	0.8	0.03	20,362	1,492	745	761
Enbrel (inflammatory conditions)	0.7	0.05	12,599	638	249	907
Letairis (pulmonary arterial hypertension)	0.3	0.01	35,049	2,129	1,273	937
						Low-income cost-sharing subsidy
High-cost LIS enrollees						
Invega Sustenna (antipsychotic)	\$0.7	N/A	\$3,884	\$5	\$0	\$980
Lantus SoloStar (insulin)	0.9	N/A	1,135	7	0	389
Truvada (antiviral for HIV/AIDS)	0.5	N/A	3,996	8	0	783
Oxycontin (opioid analgesic)	0.5	N/A	1,795	11	0	515

Note: OOP (out-of-pocket), LIS (low-income subsidy), N/A (not applicable). Components may not sum to totals due to rounding. A beneficiary is classified as "LIS" if that individual received Part D's LIS at some point during the year.

Source: MedPAC analysis of Part D prescription drug event data and denominator file from CMS.

for 10 percent of spending for high-cost LIS beneficiaries, compared with about 2 percent for high-cost non-LIS beneficiaries.

Drug classes used more heavily by non-LIS beneficiaries tended to have therapies with higher prices than drugs in therapeutic classes used more heavily by LIS beneficiaries (Table 14-10). For example, in 2016, the annual cost of drugs to treat cancer and pulmonary hypertension, conditions more prevalent among non-LIS beneficiaries, ranged from just above \$30,000 to over \$35,000 per beneficiary. In comparison, for conditions more prevalent among LIS beneficiaries, annual costs ranged from \$1,135 for insulin to just under \$4,000 for an antiviral medication.

For selected medications used to treat prevalent conditions, annual cost-sharing amounts paid by high-cost enrollees without the LIS averaged between \$638 and \$2,129 (5 percent to 7 percent of the total annual medication costs).

For all but one of these selected medications, 50 percent or more of OOP costs were incurred in the catastrophic phase of the benefit. Manufacturers paid, on average, between \$761 and \$965 in coverage-gap discounts (amounts are calculated as an average per high-cost enrollee who used the medications shown in the table). These discounts, on average, offset about one-third of beneficiaries' total cost-sharing liability. One exception was Enbrel, for which the discount offset, on average, nearly 60 percent of beneficiaries' cost-sharing liability.

High-cost LIS enrollees pay much lower cost sharing out of pocket than those without the LIS. In 2016, average annual OOP spending for high-cost LIS enrollees for the selected medications averaged between \$5 and \$11 because Part D's LIS paid nearly all of the cost-sharing liability on their behalf. Medicare's low-income cost-sharing subsidy paid \$389 to \$980 for the selected

**TABLE
14-11**

Use of drugs and biologics placed on specialty tiers, 2007-2017

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Average annual growth rate 2007-2017
Use of specialty-tier drugs												
Spending (in billions)	\$3.4	\$4.1	\$5.3	\$6.1	\$8.0	\$10.1	\$14.1	\$20.6	\$30.2	\$35.5	\$37.1	27%
Claims (in millions)	3.0	2.8	3.1	3.2	3.8	4.1	5.3	6.7	7.7	8.7	8.3	11
Dollars per claim	\$1,151	\$1,490	\$1,713	\$1,939	\$2,076	\$2,462	\$2,648	\$3,065	\$3,907	\$4,068	\$4,455	14
Specialty-tier drugs as share of total Part D spending and use												
Spending	6%	6%	7%	8%	9%	11%	14%	17%	22%	24%	25%	
Claims	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.5	0.5	0.6	0.6	

Note: A specialty-tier drug is a drug that meets CMS's cost threshold per month (\$670 in 2017) and is identified based on a plan's placement of a product on its specialty tier. Which products are placed on a specialty tier varies across plans.

Source: Acumen LLC analysis for MedPAC.

medications (Table 14-10, p. 413), accounting for between 20 percent and over one-third of each medication's total cost.

Use of higher cost drugs poses challenges for Part D

FDA approvals of innovative medicines in the last few years have included an increasing number of biologics and specialty drugs, with new medicines focused on treatments for a range of cancers, viral infections, and autoimmune diseases, among other categories (Blair and Cox 2016, Frey 2017).²⁸ Many of these new entrants command higher prices than existing therapies and generally have few or no lower cost alternatives.

This shift in biopharmaceutical research and development has resulted in a rapid growth in the use of higher cost specialty drugs and biologics. Between 2007 and 2017, gross Part D spending for specialty-tier drugs (which, by definition, have high prices) grew an average 27 percent per year (Table 14-11).²⁹ (While some of the growth

in spending for specialty-tier drugs may be attributable to increased use of specialty tiers by plan sponsors, the pipeline effects are likely larger because most sponsors had a formulary tier structure that included a specialty tier by 2008, and nearly all plan sponsors had specialty tiers by 2010.) As a result, specialty-tier drugs now account for 25 percent of overall gross spending in Part D, up from about 6 percent to 7 percent before 2010.

Drugs with very high prices pose a particular challenge for Part D because most of their costs fall in the catastrophic phase of the benefit, for which Medicare takes most of the insurance risk. An increasing number of beneficiaries are meeting the OOP threshold with a single claim. In 2010, just 33,000 beneficiaries filled a prescription in which a single claim would have been sufficient to meet the OOP threshold. By 2016, that number rose more than 10-fold to over 360,000. Coinsurance on high-priced medicines is increasingly burdensome for enrollees without the LIS as well as for Medicare's LIS, which pays most or all of the cost-sharing liability on behalf of LIS beneficiaries.

To ensure the Part D program remains affordable for beneficiaries and taxpayers, there is an urgent need to address the current risk-sharing structure to better align plan incentives with those of Medicare and its beneficiaries. Commission recommendations to alter how plans are paid—through larger capitated payments and less open-ended reinsurance, combined with greater flexibility to use formulary tools—would strengthen plan sponsors’ incentives to manage drug spending for high-cost enrollees (see section on the Commission’s recommendations, pp. 394–395).

Beneficiaries’ access to prescription drugs

The overarching goal for the Part D program is to provide Medicare beneficiaries with good access to clinically appropriate medications while remaining financially sustainable to taxpayers. That goal involves finding a balance between managing medication therapies to encourage adherence to drugs with good therapeutic value while being judicious about whether the overall number and mix of medicines prescribed is beneficial to a particular patient (Medicare Payment Advisory Commission 2016a). Formulary management is the most important set of tools used by plan sponsors to strike this balance.

Greater flexibility to use formulary tools could help ensure that prescribed medicines are safe and appropriate for the patient, potentially reducing overuse and misuse. However, for some beneficiaries, those same tools could potentially limit access to needed medications. To ensure beneficiary access, CMS reviews and approves each plan’s formulary to check that it provides access to a wide range of therapeutic classes used by the Medicare population. Part D law also 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.³⁰ Medicare also requires plan sponsors to establish a process for coverage determination and appeals.

Part D’s exceptions and appeals process

Part D’s exceptions and appeals process begins when an enrollee’s prescription is rejected at the pharmacy because the drug is not listed on the formulary or because of

utilization management requirements. The pharmacy is required to provide the enrollee with written information on how to obtain a detailed notice from his or her plan about why the benefit was denied and the right to appeal. The enrollee must contact the plan for the basis of the denial of benefits and initiate a request for a coverage determination with supporting justification from the prescriber.

Part D requires quicker adjudication time frames than for most Medicare Advantage medical benefits: Plan sponsors must make a decision about exceptions and coverage determinations within 72 hours of a request or within 24 hours for expedited requests. Because of the importance of the prescriber’s supporting statement in making a decision, the adjudication time frame for exceptions begins at the point at which the plan receives supporting justification from the prescriber. If the plan contacts the prescriber but is not able to obtain the supporting information needed to make a determination within a reasonable period of time, the plan must issue a denial and process any subsequent information it receives as a redetermination.³¹ If the enrollee is dissatisfied with the outcomes of those steps, he or she may appeal the decision to an independent review entity (IRE) and potentially to higher levels of appeal.

Part D plan sponsors report to CMS certain data on pharmacy claims that are rejected at the point of sale, as well as outcomes of coverage determinations and redeterminations. In 2016, only about 4 percent of prescriptions were rejected at the pharmacy for reported reasons—most commonly because the drug was not on the plan’s formulary, followed by plan requirements for prior authorization, quantity limits, or step therapy (Centers for Medicare & Medicaid Services 2018c). In that same year, only about 7 percent of reported rejections proceeded to a plan coverage determination, and, further, 7 percent of these determinations were subsequently appealed or sent on automatically for plan redeterminations. Although outcomes vary considerably among plans, in 2016, 65 percent and 71 percent of determination and redetermination decisions, respectively, were fully favorable to the enrollee (Centers for Medicare & Medicaid Services 2018c). Rates per 1,000 enrollees at which individuals sought coverage determinations and redeterminations have generally increased in recent years. This trend may indicate that enrollees and prescribers have become more aware of or willing to make use of the appeals process or that their prescriptions were increasingly subject to utilization management requirements.³² In 2016, rates of coverage

determinations per 1,000 enrollees declined by 3.5 percent and redeterminations rose by 2.3 percent.

CMS also reports on the decisions in the IRE step of the appeals process and uses these data for one measure in Part D plans' star ratings. In 2016, about 35,000 cases (9 percent of redeterminations) were appealed or automatically forwarded to an IRE. CMS has noted considerable gaps in data reporting for IRE appeals for the majority of plans.³³ However, when data were reported and validated, the IRE agreed with the plans' redetermination decisions most of the time.

Although plan sponsors' audit performances generally improved in 2017, CMS continues to find that a significant share of audited plans had difficulties in the areas of Part D coverage determinations, appeals, and grievances. For example, a common shortfall was that many plans misclassified coverage determination or redetermination requests as grievances or customer service inquiries (Centers for Medicare & Medicaid Services 2018a). In 2017 and early 2018, CMS took three enforcement actions against Part D plan sponsors (including civil and monetary penalties) for failure to make timely decisions related to coverage determinations, appeals, and grievances (Centers for Medicare & Medicaid Services 2018a). However, CMS did not impose any intermediate sanctions on plans.

Resolving coverage issues at the point of prescribing

A more efficient approach would be to resolve any issues at the point of prescribing rather than at the pharmacy counter through real-time formulary checks, e-prescribing, and electronic prior authorization. Such tools could reduce the need for coverage determinations and appeals and increase the likelihood that beneficiaries receive an appropriate medicine at the pharmacy. Automated processes could also lower the administrative burden and lead to a more uniform approach for beneficiaries, prescribers, and plans (American Medical Association 2015). Part D plan sponsors are required to support electronic prescribing, but e-prescribing and electronic prior authorization are optional for physicians and pharmacies.³⁴ While beneficiary advocates are generally supportive of such steps, some contend that they would not be sufficient to address persistent challenges (Medicare Rights Center 2016). Perhaps the most essential requirement for adoption of electronic prior authorization is clinician acceptance and use, which can require paying fees to the vendors and embracing practice-pattern change.

Quality in Part D

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. CMS also requires plan sponsors to carry out medication therapy management (MTM) programs to improve the quality of the 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[®] (CAHPS[®]) survey, agency monitoring of plans, data furnished by plan sponsors, and claims information (Centers for Medicare & Medicaid Services 2017a). Selected performance measures are available on the Plan Finder at www.medicare.gov to help beneficiaries evaluate their plan options during Part D's annual open enrollment. 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 to determine the amount of bonus payment.

For 2019, 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 2018b). Intermediate outcome measures (four metrics, including adherence to selected classes of medications) typically each receive a weight of 3, while the seven measures related to patient experience and access (e.g., CAHPS survey results on ease with which plan members get needed medicines) each receive a weight of 1.5.³⁵ 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 2018e). Most MA-PDs are rated on up to 46 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 2019 (weighted by 2018 enrollment) decreased to 3.34 from 3.62 a year earlier (Centers for Medicare & Medicaid Services 2018b). Nearly 69 percent of PDP enrollees (based on 2018 enrollment) are in 2019 contracts with 3.5 stars, and just 3 percent are in contracts with 4 or more stars. Among MA-PDs offered for 2019, the average star rating remained stable at just over 4. Based on 2018 enrollment, CMS estimated that 75 percent of MA-PD enrollees were in contracts rated 4 or more stars for 2019. However, 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 higher values than PDPs on 11 of the 14. Nevertheless, as we noted in our chapter about the MA program, the trend among MA-PD sponsors of consolidating contracts to achieve higher star ratings leads us to question the validity of the MA-PD ratings and the comparison between PDPs and MA-PDs. As noted in Chapter 13, effective 2020, the Bipartisan Budget Act of 2018 changes the policy on plan consolidations.

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 2017 focus groups mentioned using the Medicare star ratings as a source of information to choose a health plan (Summer et al. 2017). Instead, beneficiaries tended to consult with insurance brokers, friends, or family. 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, current members' medication adherence may not be an important factor when choosing among plan options. Additionally, plans may not be 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 the annual cost threshold (\$4,044 for 2019).

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.³⁶ CMS has changed the criteria for plans' 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 narrower eligibility criteria than requiring beneficiaries to have more than three chronic conditions or use more than eight medications (Centers for Medicare & Medicaid Services 2018m).

In focus groups convened for the Commission, the physicians we spoke with were more aware of medication management conducted by the plans, particularly the CMRs, compared with previous years (Summer et al. 2017). Some physicians reported receiving notices stemming from CMRs. A couple of primary care doctors gave examples of cases in which an insurer had caught polypharmacy problems. Multiple physicians talked

about the importance of care coordinators for medication reconciliation after a hospital stay.

At the same time, 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 MTM data found lower rates of CMRs 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 2015b, 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 will lead to "improved therapeutic outcomes, while reducing net Medicare expenditures" (Center for Medicare & Medicaid Innovation 2015). Six Part D sponsors operating 22 PDPs in 5 regions of the country are participating in the enhanced MTM model over a 5-year period that began on January 1, 2017.³⁷

In November 2018, CMS released the performance results for 2017, the first year of the enhanced MTM model (Centers for Medicare & Medicaid Services 2018m). CMS estimates that, in 2017, expected FFS (Part A and Part B) spending for the 1.7 million beneficiaries enrolled in participating plans was reduced by approximately \$325 million (net of prospective payments made to plans to cover the cost of the enhanced MTM programs).

Participating plans that achieve a spending reduction of at least 2 percent qualify for a performance payment in the form of an increased beneficiary premium subsidy (in a future year). According to CMS, among the 22 participating plans:

- 11 plans (50 percent) reduced medical spending by 2 percent or more;
- 7 plans (32 percent) reduced medical spending by less than 2 percent; and
- 4 plans (18 percent) increased medical spending.

As a result, half of the participating plans will receive a higher premium subsidy (an additional \$2 in premium subsidy per member per month) in 2019. CMS expects to release an additional evaluation of plan performance results in the first half of 2019, with estimates of financial impact to be included in subsequent reports.

We are encouraged by the initial performance results. 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 hope to learn from the forthcoming evaluation reports the characteristics of MTM programs and the kinds of intervention strategies that have been more effective in improving pharmaceutical care and health outcomes for beneficiaries, as well as how (and which specific) MTM services improve health outcomes and lower medical spending. ■

Endnotes

- 1 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, they must pay the difference between the plan's premium and the benchmark amount. Once LIS enrollees select a plan themselves, CMS no longer reassigns them to a new plan. Instead, the agency sends beneficiaries letters about premium-free plan options in the enrollee's region.
- 2 Under CMS's de minimus 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 minimus amount. The de minimus amount for 2019 is \$2.
- 3 For example, in 2019, 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 & Medicaid Services 2018d).
- 4 Plans' responsibility for spending on generic prescriptions filled in the coverage gap is rising from 7 percent in 2011 to 75 percent by 2020.
- 5 In each year thereafter, the OOP threshold will increase by the rate of growth in per capita Part D spending—the same as for the deductible and initial coverage limit.
- 6 In 2019, the manufacturer discount increased from 50 percent to 70 percent of brand-drug spending in the coverage gap. Because that discount is counted as though it were an enrollee's own OOP spending, for beneficiaries who use mostly or all brand-name drugs, it offsets much of the increase in the OOP threshold scheduled in the law for 2020.
- 7 The study used monthly prospective reinsurance payments in excess of the reinsurance costs that would be expected based on the risk profile of each plan's enrollees to examine how the "unpredictable" reinsurance costs relate to the premiums plans charged their enrollees.
- 8 The Commission recommended removing protected status from two of the six drug classes for which plan sponsors must now cover all drugs on their formularies (antidepressants and immunosuppressants for transplant rejection), streamlining the process for formulary changes, requiring prescribers to provide supporting justifications with more clinical rigor when applying for exceptions, and permitting plan sponsors to use selected tools to manage specialty-drug costs while maintaining appropriate access to needed medications.
- 9 If an employer agrees to provide primary drug coverage to retirees with an average benefit value equal to or greater than Part D (called "creditable coverage"), Medicare provides a tax-free subsidy to the employer for 28 percent of each eligible retiree's drug costs that fall within a specified range of spending.
- 10 Employer group waiver plans are sponsored by employers that contract directly with CMS or with an insurer or a pharmacy benefit manager to administer a drug benefit. They differ from employer plans that receive the RDS in that they are considered Part D plans—Medicare Part D is the primary payer rather than the employer. However, employer group waiver plans are offered only to Medicare-eligible retirees of a particular employer (i.e., Medicare waives the requirement that most Part D plans allow anyone to enroll).
- 11 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 premiums for services provided under MA or Part D.
- 12 The Bipartisan Budget Act of 2018 modified the income-related premium, reducing federal subsidies further for individuals with incomes between \$133,500 and \$160,000 (or between \$267,000 and \$320,000 for couples). The law also created an income category at \$500,000 for individuals and \$750,000 for couples with an even lower federal subsidy (Social Security Administration 2018).
- 13 However, the agency maintained a meaningful-difference requirement between a sponsor's basic and enhanced benefit packages.
- 14 Most MA plans are MA-PDs, offering combined medical and outpatient drug benefits. However, a small share of MA plans (including Medicare Medical Savings Account plans) do not offer prescription drug coverage.
- 15 The 215 PDP plans available to LIS enrollees at no premium include 29 plans that had premiums within \$2 of their regional LIS threshold. The plan sponsors chose to waive the "de minimus" premium amount so that LIS enrollees would pay no premium in those plans.
- 16 An LIS enrollee who is no longer eligible for reassignment may select another plan during the year, including during the annual open enrollment period. In 2010, among LIS enrollees who were not eligible for reassignment by CMS and whose plans lost benchmark status for 2010, a relatively small share (14 percent) voluntarily switched plans during the annual enrollment period (Hoadley et al. 2015).

- 17 In 2018, CIGNA’s purchase of Express Scripts was finalized. Regulators approved CVS Health’s merger with Aetna after Aetna agreed to divest its PDPs, which it plans to sell to WellCare (Mathews and Prang 2018). Once the mergers are finalized and Aetna’s divestiture is completed, the top four plan sponsors will account for about 66 percent of Part D enrollment, an increase from about 63 percent.
- 18 On January 18, 2019, CMS’s Center for Medicare & Medicaid Innovation announced a new demonstration program that begins in January 2020, called the Part D Payment Modernization model, that would provide “new incentives for plans, patients, and providers to choose drugs with lower list prices in order to address rising federal reinsurance subsidy costs in Part D” (Centers for Medicare & Medicaid Services 2019). Participating plan sponsors would be eligible for performance-based payments based on realized savings (or costs) relative to a predetermined benchmark.
- 19 Step therapy is a type of management tool for drugs that begins a medication treatment regimen for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary.
- 20 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.
- 21 Critics contend that the way in which plan sponsors and their PBMs calculate pharmacy direct and indirect remuneration (DIR) fees is not transparent and that plan sponsors ignore or understate DIR fees when preparing Part D bids, leading to enrollee premiums that are too high (National Community Pharmacists Association 2016). PBMs and sponsors that support the use of pharmacy DIR fees counter that they are a means to encourage greater use of generics and reduce enrollees’ premiums and OOP spending (Holtz-Eakin 2014). To the extent that beneficiaries select plans with tiered networks and use preferred pharmacies that are more efficient, the approach may also lower Medicare spending (Kaczmarek et al. 2013).
- 22 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.
- 23 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. Guidance from the Department of Health and Human Services Office of Inspector General (OIG) states that independent charity PAPs must provide assistance to broad rather than narrow disease groups, manufacturers must not exert direct or indirect control over the charity, and the PAP must not limit assistance to a subset of available products (Office of Inspector General 2014). The Internal Revenue Service is investigating the relationship between certain patient assistance charities and several major pharmaceutical manufacturers (Sagonowsky 2017). OIG has rescinded its advisory opinion for at least one major PAP on the grounds that the PAP did not fully disclose all relevant facts in OIG’s investigation (Office of Inspector General 2018).
- 24 IQVIA Institute (formerly IMS) defines invoice prices as the amounts paid to distributors by their pharmacy or hospital customers, which is different from gross spending reflected in Part D’s prescription drug event data (total payments to pharmacies before accounting for any rebates or discounts pharmacies retain). Net prices measure the amount received by pharmaceutical manufacturers and therefore reflect rebates, off-invoice discounts, and other price concessions made by manufacturers to distributors, health plans, and intermediaries.
- 25 An individual NDC uniquely identifies the drug’s labeler, drug, dosage form, strength, and package size.
- 26 For this index, Acumen grouped 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.
- 27 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.
- 28 Although there is no consistent definition of specialty drugs, they tend to be characterized as high cost and are used to treat a rare condition, require special handling, use a limited distribution network, or require ongoing clinical assessment. Most biologics are a subset of specialty drugs (*American Journal of Managed Care* 2013).
- 29 These figures are based on the Acumen analysis for the Commission of Part D prescription drug event data. Beginning

- in 2007, CMS began setting a cost threshold per month (\$670 since 2017) for drug and biological products that may be placed on a specialty tier. A specialty-tier drug is identified based on a plan's placement of a product on its specialty tier. Which products are placed on a specialty tier varies across plans. Typically, plans charge enrollees coinsurance of 25 percent to 33 percent for products placed on specialty tiers.
- 30 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. Each year since 2012, CMS has conducted a transition monitoring program analysis to evaluate whether plan sponsors are following Part D transition requirements. In 2017, under 6 percent of Part D contracts exceeded CMS's thresholds of noncompliance (Centers for Medicare & Medicaid Services 2018k).
 - 31 In November 2018, CMS proposed limiting to 14 days the amount of time an exception request may be held in open status while the plan sponsor attempts to get a supporting statement from the prescriber. Under the proposal, if the sponsor had not heard from the prescriber, the sponsor would make a decision based on the information it had and notify the beneficiary no later than 14 days from the request (Centers for Medicare & Medicaid Services 2018g).
 - 32 The use of utilization management by Part D plans has increased over time (Medicare Payment Advisory Commission 2018a). The increase may reflect plan sponsors' increased reliance on utilization management to ensure prescriptions are used for clinically appropriate indication(s) (e.g., opioid analgesics) and to manage the use of expensive medications (e.g., hepatitis C therapies).
 - 33 For 2019 and going forward, CMS applies scaled reductions to appeals measures that are components of star ratings based on the completeness of IRE data (Centers for Medicare & Medicaid Services 2018h).
 - 34 The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 requires mandatory electronic prescribing for controlled substances. The exception is New York, which mandates electronic prescribing of all medications.
 - 35 A new intermediate outcome measure was added for 2019—statin use in persons with diabetes. All measures receive a weight of 1 in their first year of use.
 - 36 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 2014a).
 - 37 CMS is testing the Enhanced Medication Therapy Management model across five Part D regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona). CMS selected regions based on variation in market competition and other characteristics as well as variation in Part A and Part B spending and is intended to allow for comparisons across regions and to (in aggregate) be broadly representative of national market characteristics (Centers for Medicare & Medicaid Services 2018m).

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