

CHAPTER

14

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

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

Chapter summary

In 2019, Part D plans were the primary source of outpatient prescription drug coverage for 45.4 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 12.7 million individuals with low income and assets. In 2018, Part D expenditures totaled \$97.5 billion, accounting for about 13 percent of Medicare spending. Enrollees paid \$14.2 billion of that amount in plan premiums, in addition to \$16.7 billion 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 have eroded the program's competitive incentives. Over time, 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 because patients who use high-priced drugs are more likely to reach Part D's catastrophic phase, in which

In this chapter

- Enrollment and plan choices in 2019 and benefit offerings for 2020
- Plan sponsors and their tools for managing benefits and spending
- Drug pricing
- Program costs
- Beneficiaries' access to prescription drugs
- Quality in Part D

Medicare pays for 80 percent of spending through reinsurance. As of 2019, brand-drug manufacturers provide a 70 percent discount in the coverage gap (an increase from 50 percent provided between 2011 and 2018). This discount effectively makes the relative price of brands cheaper and decreases what plan sponsors must cover in benefits, blunting sponsors' incentives to manage spending. A separate concern is that the design of Part D's basic benefit combined with the LIS creates plan and beneficiary incentives that increase program costs.

Policymakers have taken 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 2019 and benefit offerings for 2020—In 2019, 74.1 percent of Medicare beneficiaries were enrolled in Part D plans. An additional 2.3 percent obtained drug coverage through employer-sponsored plans that received Medicare's retiree drug subsidy. The remaining 23.6 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 2019, enrollment grew faster in MA–PDs compared with stand-alone prescription drug plans (PDPs). In 2019, 44 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 for the other Part D enrollees, and the LIS share fell from 39 percent to 28 percent.

For 2020, beneficiaries have a broad choice of plans. Compared with plan offerings in 2019, sponsors are offering 5 percent more PDPs, 16 percent more MA–PDs open to all beneficiaries, and 20 percent more MA–PDs tailored to specific populations (special needs plans). 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. Most plans use coinsurance for some formulary tiers rather than copayments. For 2020, the total average estimated cost for basic benefits decreased by 1 percent, and the \$32.74 base beneficiary

premium also reflected a 1 percent drop from 2019. However, individual plans' premiums can vary substantially. In 2020, 244 premium-free PDPs are available to enrollees who receive the LIS, a 13 percent increase from 2019. Apart from 1 region (Ohio), all regions have at least 4 and as many as 12 PDPs at no premium for LIS enrollees.

Part D program costs—Between 2007 and 2018, Part D program spending increased from \$46.2 billion to \$83.4 billion (average annual growth of 5.5 percent). Medicare's reinsurance continues to be the fastest growing component of program spending, at an annual average rate of 16 percent. Between 2007 and 2018, the portion of the benefits paid to plans through capitated direct subsidy fell from 56 percent to 19 percent, while the portion paid through Medicare's reinsurance (which is cost based) grew from 25 percent to 60 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 2017, high-cost enrollees accounted for 59 percent of Part D spending, up from about 40 percent before 2011. 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 2017, more than 378,000 enrollees filled a prescription for which a single claim was sufficient to meet the out-of-pocket threshold, up from just 33,000 in 2010. Enrollees without the LIS were more likely to have such a claim, reflecting the fact that they tend to use different drug classes than do LIS enrollees.

Quality in Part D—In 2020, the average star rating among Part D plans increased 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 to 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 the majority of participating plans successfully reduced medical spending by 2 percent or more, qualifying them for a higher premium subsidy. CMS notes that these results are based on a comparison of plans' spending relative to benchmark spending and are not the results from an independent evaluation of the model. 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, plan benefit offerings, market structure, drug pricing, program costs, beneficiaries' access to medications, and quality. In 2019, Part D plans were the primary source of outpatient prescription drug coverage for 45.4 million Medicare beneficiaries. For 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 pays for much of the premiums and cost sharing on behalf of individuals with low income and assets—12.7 million in 2019. In 2018, Part D expenditures totaled \$97.5 billion on an incurred basis, accounting for about 13 percent of Medicare spending (Boards of Trustees 2019). Part D enrollees paid \$14.2 billion of that amount in plan premiums, in addition to \$16.7 billion in cost sharing.

In several ways, Part D has been a success. Since 2006 when it began, the program has improved Medicare beneficiaries' access to prescription drugs; from 2006 to 2018, the share with Part D or drug coverage at least as generous as Part D increased from 75 percent to 88 percent. Stand-alone prescription drug plans (PDPs) and Medicare Advantage–Prescription Drug plans (MA–PDs) are available in every region of the country. Nearly 90 percent of Part D prescriptions filled are for generic drugs, which tend to have lower prices and cost sharing than brand-name drugs. Enrollees' average premiums for basic benefits have remained around \$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* 2019).

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 the program pays to plans as an increasing number of enrollees reach the benefit's 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, a pipeline of new high-cost biopharmaceutical products will continue the trend. Policymakers are taking steps to give plan sponsors new flexibilities to manage Part D benefits. However, the Part D benefit also needs to be restructured to provide plan sponsors with stronger incentives 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. In 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 an 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 2019b). 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	2019	2020	Average annual growth rate 2006-2020
Deductible	\$250.00	\$415.00	\$435.00	4.0%
Initial coverage limit	2,250.00	3,820.00	4,020.00	4.2
Annual out-of-pocket spending threshold	3,600.00	5,100.00 ^a	6,350.00 ^a	4.1
Total covered drug spending at annual out-of-pocket threshold	5,100.00	8,139.54 ^b	9,719.38 ^b	4.7
Minimum cost sharing above annual out-of-pocket threshold: ^c				
Copayment for generic/preferred multisource drugs	2.00	3.40	3.60	4.3
Copayment for other prescription drugs	5.00	8.50	8.95	4.2

Note: ^aThe amount for 2020 is much higher than that for 2019 because the 2019 amount was restrained by a provision in law that limited increases in the out-of-pocket threshold between 2014 and 2019. In 2020, the out-of-pocket threshold reverts to what it otherwise would have been had CMS increased it by the same factor as other benefit parameters (i.e., annual growth in Part D spending per enrollee). Although Part D's out-of-pocket threshold increased significantly in 2020, effects of the increase on beneficiaries are somewhat limited by the fact that manufacturers provide a 70 percent discount on brand-name drugs in the coverage-gap phase, which counts as beneficiary spending toward the threshold.

^bAn individual's total covered drug spending at the annual out-of-pocket threshold depends on the mix of brand and generic drugs filled in the coverage gap. The amounts for 2019 and 2020 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.

^cEnrollees pay the greater of either the amounts shown or 5 percent coinsurance.

Source: Centers for Medicare & Medicaid Services 2019.

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 that will exceed the benchmark and have not chosen a plan other than their assigned PDP, CMS reassigns them randomly to a new benchmark PDP.¹ If sponsors bid at or near the benchmark, they can gain or maintain market share for LIS enrollees without having to incur marketing expenses.² However, over the years many LIS enrollees have chosen a plan themselves 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. In October 2019, CMS expected to reassign randomly only about 100,000 beneficiaries for benefit year 2020—less than 1 percent of LIS enrollees enrolled in PDPs (Liu 2019).

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). (In practice, the defined standard benefit is used primarily to set the average value of basic benefits that plan sponsors must offer under actuarially equivalent benefit structures.) For 2020, the defined standard benefit includes a \$435 deductible and 25 percent coinsurance until the enrollee reaches an OOP threshold. Historically, the standard benefit has included a benefit phase known as the coverage gap or donut hole, with higher cost sharing between an initial coverage limit and the OOP threshold. Although enrollees no longer face higher cost sharing in the coverage gap, Part D plans continue to identify whether a prescription is filled in the coverage-gap phase because manufacturers of brand-name drugs provide a discount (described on the next page) to Part D enrollees (excluding LIS enrollees) who have more than \$4,020 in cumulative drug spending until the individual reaches \$6,350 in combined OOP spending plus brand discounts. Above this OOP threshold, enrollees pay the greater of 5 percent coinsurance or \$3.60 to \$8.95 per prescription. By law, individuals who receive Part D's LIS pay zero or nominal cost sharing. In 2020, most individuals receiving the LIS pay between \$0 and \$3.60 for generic drugs and between \$0 and \$8.95 for brand-name drugs below the OOP threshold. Above the OOP threshold, LIS enrollees pay zero cost sharing.

Most plan sponsors structure their basic benefits in ways that differ from the defined standard benefit, such as setting the deductible lower than \$435 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 a sponsor offers a PDP with basic benefits in a region, it can also offer up to two "enhanced" PDPs that combine basic benefits with supplemental coverage. For 2020, estimated OOP costs in 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 PDPs.

Changes to Part D's coverage gap for enrollees without low-income subsidies

The policymakers who designed Part D wanted to provide both basic coverage for most enrollees who have relatively low drug spending and 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 plan benefits.

However, Part D's designers 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 in the coverage gap. 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 (Figure 14-1, p. 412). A number of studies suggested that higher cost sharing in the coverage gap 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 was unusual because of the coverage gap.

The Affordable Care Act of 2010 (ACA) called for gradually lowering cost sharing in the coverage gap from 100 percent to 25 percent by 2020. To finance much of this expansion of benefits without directly raising enrollee premiums and program spending, the ACA required manufacturers of brand-name drugs, as a condition of Part D coverage beginning in 2011, to provide enrollees (excluding LIS enrollees) with a 50 percent discount on prescriptions filled during the coverage-gap phase, as seen in Figure 14-1. As a result, in 2011, cost sharing in the coverage gap for brand prescriptions immediately fell from 100 percent to 50 percent. The law also directed that the manufacturers' discount be counted as OOP spending for calculating the "true OOP" threshold. That change lowered OOP costs for some enrollees but also increased the number of 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, as seen in Figure 14-1 (p. 412). In 2020, enrollees pay a consistent 25 percent cost sharing for brand-name and generic drugs between the deductible and the OOP threshold. However, many plans that use copayments for prescriptions filled during the initial coverage phase charge coinsurance once the enrollee reaches the coverage-gap phase of the benefit.

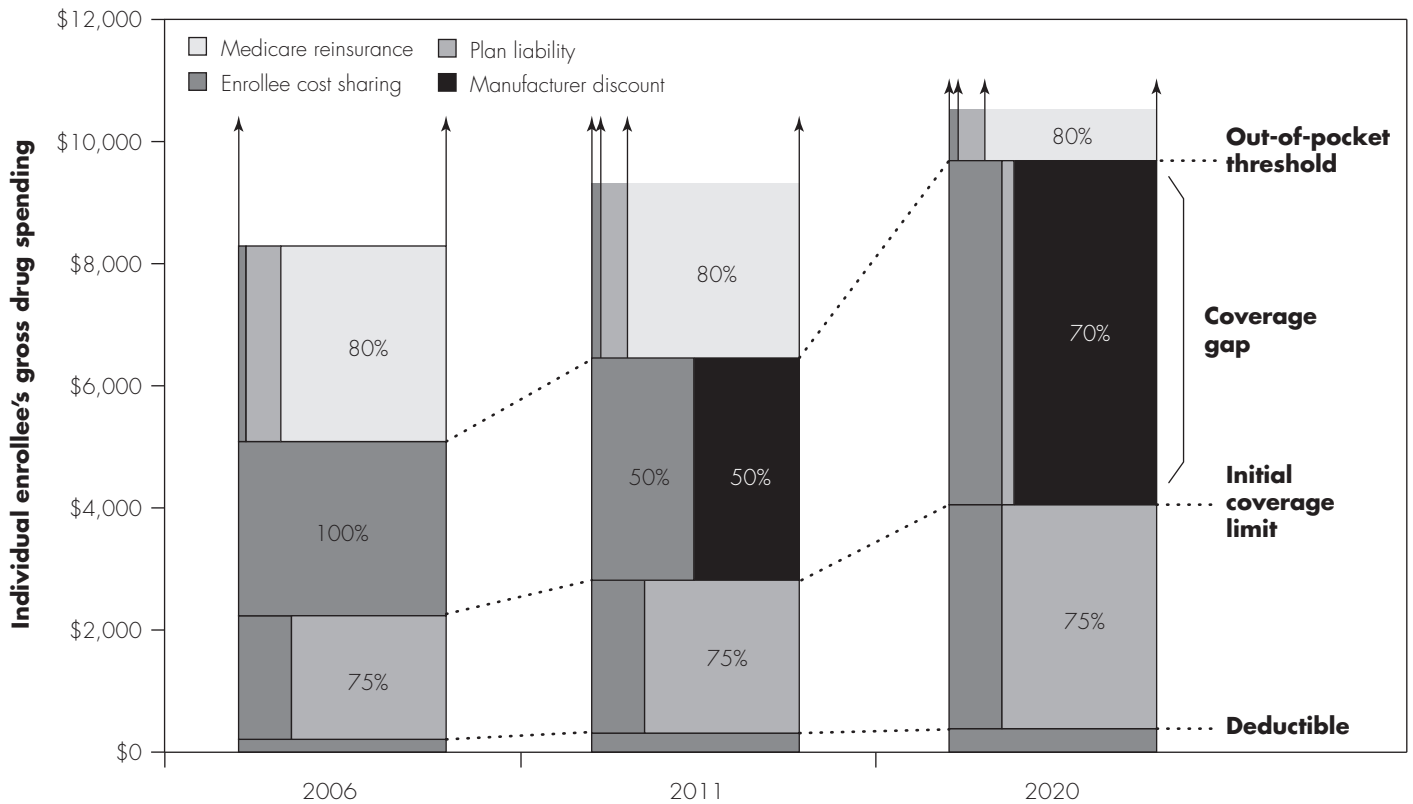
No changes to Part D's coverage gap for low-income subsidy enrollees

Today, the Part D benefit design for LIS enrollees is different from that of the other Part D enrollees, and the sources of financing for prescriptions filled in the coverage gap differ (Figure 14-2, p. 413). Under law, Medicare's low-income cost-sharing subsidy pays for 100 percent of most LIS enrollees' costs during the coverage-gap phase minus their nominal copayments.⁴ 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 in the coverage-gap phase until the LIS enrollee reaches the OOP threshold. In contrast, for enrollees without the LIS, manufacturers of brand-name drugs and plan sponsors are responsible for financing Part D benefits for prescriptions filled in the coverage-gap phase.

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

FIGURE 14-1

Part D's defined standard benefit for enrollees without the LIS has changed over time to include a 70 percent manufacturers' discount on brand-name drugs in the coverage gap



Note: LIS (low-income subsidy). "Gross drug spending" refers to amounts paid at the pharmacy before postsale rebates and discounts. The coverage-gap phase (between the initial coverage limit and out-of-pocket (OOP) threshold) is depicted as it would apply to brand-name drugs for an enrollee who does not receive Part D's LIS. Exclusive of LIS enrollees, enrollees' cost-sharing for generic drugs in the coverage gap was 100 percent in 2006, 93 percent in 2011, and 25 percent in 2020. The amount of drug spending at which an enrollee reaches the OOP threshold depends on the mix of brand-name and generic prescriptions the enrollee fills in the coverage gap.

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

which drugs a plan covers on its formulary (Medicare Payment Advisory Commission 2017). In the coverage-gap phase, plan sponsors bear just 5 percent liability on brand-name drugs for enrollees without the LIS and 0 percent for LIS enrollees. Likewise, above Part D's OOP threshold, plan sponsors are responsible for only 15 percent of benefit spending for enrollees both with and without the LIS. Yet in both of those benefit phases, plan sponsors obtain rebates on brand-name prescriptions which, at times, may be larger than the plan's benefit liability. Thus, Part D's benefit design can create incentives for sponsors to include certain high-cost, high-rebate drugs on their formulary over others. Such behavior, in turn,

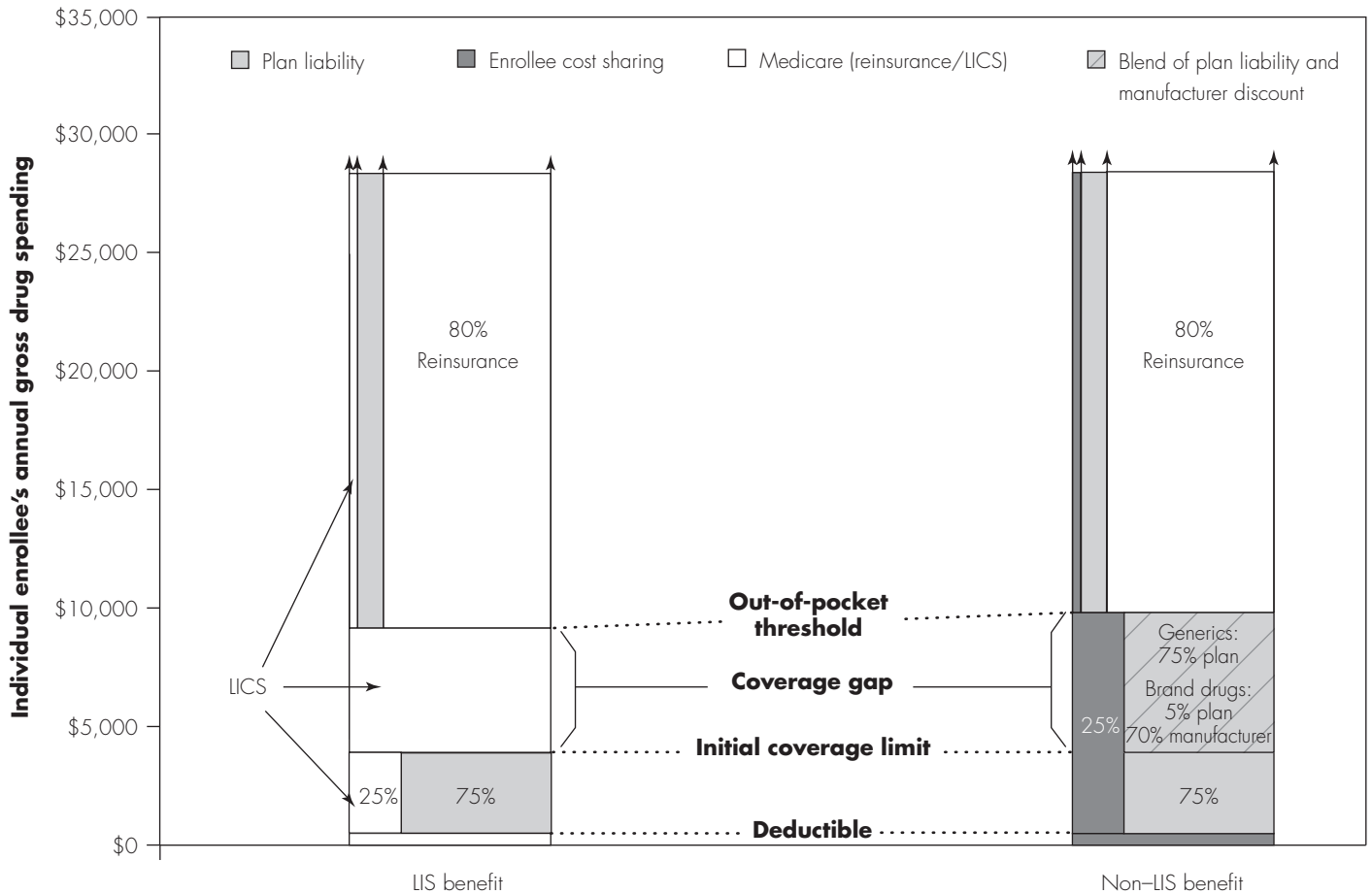
can increase beneficiary cost sharing as well as Medicare spending for reinsurance and low-income cost-sharing subsidies. At the same time, manufacturers may find that, for some products, higher prices allow them to offer larger rebates than their competitors' rebates and gain market share through favorable formulary placement. In this sense, Part D's benefit design can contribute to the inflationary trend in drug pricing.

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

FIGURE 14-2

Part D's basic benefit is different for beneficiaries with and without the LIS, 2020



Note: LIS (low-income subsidy), LICS (low-income cost-sharing subsidy). LICS pays for most or all cost-sharing liabilities for LIS enrollees. LIS enrollees pay nominal copayments (set in law) until they reach the out-of-pocket threshold.

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

(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). 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. While 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 favorable risk selection. CMS would need to take steps to recalibrate the

**TABLE
14-2**

More than three-quarters of Medicare enrollees received drug coverage through Part D, 2019

	Beneficiaries	
	In millions	Share of Medicare enrollment
Medicare enrollment	61.3	100%
Part D enrollment*		
In Part D plans	45.4	74.1
In plans receiving RDS	<u>1.4</u>	<u>2.3</u>
Total Part D	46.8	76.4**

Note: RDS (retiree drug subsidy). Part D plan enrollment figures are based on enrollment as of April 1, 2019.
 *Excludes federal government and military retirees covered by either the Federal Employees Health Benefits Program or the TRICARE for Life program.
 **The remaining 23.6 percent of beneficiaries not enrolled in Part D are divided equally between those who receive comparable drug coverage through other sources (such as the Federal Employees' Health Benefits Program, TRICARE for Life, and the Department of Veterans Affairs) and those who had no drug coverage or had coverage less generous than Part D.

Source: MedPAC based on Table IV.B7 and Table V.B3 of Boards of Trustees 2019 and CMS Part D enrollment data as of April 1, 2019.

risk adjustment system. At the same time, sponsors would be given greater flexibility to use formulary tools.⁵ The combination of these 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 enrollees without 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 enrollees without the LIS who face 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 LIS copayments for certain drug classes.

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.

The Commission's 2016 recommendations would give plan sponsors greater financial incentives to include lower priced drugs on their formularies. Because plan sponsors would be responsible for a greater share of insurance risk in the catastrophic phase, the recommendations would reduce the financial benefits of including high-price, highly rebated products on their formularies. Part D enrollees would also benefit from lower cost sharing if they chose to use lower priced drugs. To the extent that sponsors move away from preferring high-price, highly rebated products, there may be some effect on manufacturers' pricing strategies. However, any effect of our 2016 recommendations on pricing would be indirect, and our recommendations would not address our concern about the structure of the LIS benefit. For this reason, the Commission has begun examining further changes to Part D's benefit design (Medicare Payment Advisory Commission 2019c).

Enrollment and plan choices in 2019 and benefit offerings for 2020

Over time, a growing proportion of Medicare beneficiaries has enrolled in Part D. An important reason is a shift in enrollment from retiree drug plans to Part D plans set up for employer groups. Enrollment has grown faster in MA-PDs compared with stand-alone PDPs. In 2020, plan sponsors are offering 5 percent more PDPs, 16 percent more general MA-PDs, and 20 percent more MA-PDs tailored to specific populations (special needs plans, or SNPs) than in 2019.

In 2019, over three-quarters of Medicare beneficiaries were in Part D plans or employer plans that received the retiree drug subsidy

In 2019, 45.4 million individuals—74.1 percent of Medicare's total enrollment—were enrolled in Part D plans (Table 14-2). That share is up from 54 percent of

**TABLE
14-3**

Part D enrollment trends by plan type, 2007-2019

	2007	2013	2018	2019	Average annual growth rate 2007-2019
Total Part D enrollment (in millions)	24.2	35.4	43.9	45.4	5%
Share of Medicare beneficiaries	54%	67%	73%	74%	N/A
Enrollment by type (in millions)					
PDP	16.9	22.5	25.4	25.5	3
MA-PD	7.2	12.9	18.5	20.0	9
Share in MA-PD	30%	36%	42%	44%	N/A
Non-employer plan enrollees					
PDP	16.2	18.1	20.8	20.8	2
MA-PD	<u>6.2</u>	<u>11.4</u>	<u>16.1</u>	<u>17.6</u>	9
Subtotal	22.4	29.4	36.9	38.4	5
Share in MA-PD	28%	39%	44%	46%	N/A
EGWPs (PDP and MA-PD)	1.8	6.0	6.9	7.1	12
Share in EGWP	7%	17%	16%	16%	N/A

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

Source: MedPAC based on Part D enrollment data and Table IV.B7 and Table V.B3 of Boards of Trustees 2019.

Medicare beneficiaries in 2007 (data not shown). An additional 2.3 percent of beneficiaries obtained drug coverage through employer-sponsored plans that received Medicare’s retiree drug subsidy (RDS) for serving as the primary provider. The remaining 23.6 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.

The share of Medicare beneficiaries covered under Part D has grown over time, with faster growth in MA-PD enrollment (including SNPs) and in employer group waiver plans (EGWPs), which are Part D plans established for Medicare-eligible retirees of certain employers. EGWPs can take the form of PDPs or MA-PDs. Enrollment in EGWPs grew by an annual average of 12 percent, reflecting the shift from employers operating

plans that receive the RDS to Part D plans established for their retirees. By 2013, 17 percent of Part D enrollees were enrolled in EGWPs (see text box on employer groups in Part D, pp. 416-417).

By 2019, among all Part D plans (including EGWPs), 44 percent of Part D enrollees were in MA-PDs compared with 30 percent in 2007 (Table 14-3). This trend in MA-PD enrollment is consistent generally with more rapid growth in Medicare Advantage (MA) enrollment compared with traditional fee-for-service (FFS) Medicare. Over the period from 2007 to 2019, among non-employer plans, MA-PDs grew an average 9 percent annually compared with 2 percent in PDPs.

In 2019, 12.7 million beneficiaries with income at or below 150 percent of the federal poverty level (28 percent of Part D enrollees) received the LIS. Of these individuals,

Employer groups in Part D

There are several ways in which the Part D program subsidizes employers' pharmacy benefits for their retirees who are Medicare beneficiaries. At the start of Part D, the most popular approach was through Medicare's retiree drug subsidy (RDS). Under the RDS, if an employer agrees to provide primary drug coverage to retirees with an average benefit value equal to or greater than Part D's defined standard benefit ("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. In 2007, Part D paid \$3.9 billion through the RDS to former employers of 7.1 million Medicare beneficiaries.

However, by 2019, RDS payments fell to just \$0.8 billion toward the prescription coverage of 1.4 million retirees and dependents.

Over the same period that the RDS declined, employer group waiver plans (EGWPs) expanded, covering 16 percent of Part D enrollees (7.1 million) by 2019 (see Table 14-3, p. 415). EGWPs are sponsored by employers that contract directly with CMS or on a group basis with an insurer or pharmacy benefit manager to administer the Part D benefit. They differ from employer plans that receive the RDS in that Medicare Part D is the primary payer rather than the employer. The employer typically provides secondary

(continued next page)

**TABLE
14-4**

Comparison of EGWPs and other Part D plans, 2018

	EGWPs	Other Part D plans	All Part D plans
Enrollment (in millions)	6.9	36.9	43.9
Share of total	16%	84%	100%
Share of category's enrollment:			
LIS enrollees	2%	34%	28%
PDP enrollees	67%	56%	58%
High-cost enrollees	5%	9%	8%
Gross Part D spending (in billions of dollars)	\$28.4	\$139.7	\$168.1
Share of total	17%	83%	100%
Share of category's enrollment:			
Below the OOP threshold	78%	55%	59%
Above the OOP threshold	22%	44%	41%
Coverage-gap discounts (in billions of dollars)	\$3.1	\$3.8	\$6.9
Share of total	45%	55%	100%
Average annual gross spending per enrollee	\$4,095	\$3,783	\$3,832

Note: EGWP (employer group waiver plan), LIS (low-income subsidy), PDP (prescription drug plan), OOP (out-of-pocket). "High-cost enrollees" are those with OOP spending high enough to reach the catastrophic phase. Gross Part D spending reflects prescription spending at the pharmacy before postsale rebates and discounts. Components may not sum to totals due to rounding.

Source: MedPAC based on Part D enrollment and prescription drug event Tap data.

Employer groups in Part D (cont.)

coverage that supplements the defined standard benefit. EGWPs must follow many of the same regulations as other Part D plans, such as having their formularies approved by CMS. However, one key difference is they do not submit bids. Instead, Medicare pays EGWPs a direct subsidy based on the national average of bids from Part D plans with open enrollment.⁶ EGWPs receive Medicare’s reinsurance for enrollees who reach the out-of-pocket threshold and low-income subsidies for qualifying beneficiaries. EGWPs are not eligible for risk-corridor payments.⁷

The shift from the RDS to becoming a Part D plan reflects changes in law and regulation that made EGWPs more financially attractive to many employers. In 2010, the Affordable Care Act (ACA) altered the tax treatment of drug expenses covered by the RDS and increased the generosity of the standard Part D benefit by gradually eliminating the coverage gap. Under the ACA, employers still receive the RDS tax free, but after 2013, they could no longer deduct drug expenses for which they received the subsidy as a cost of doing business. However, they can still deduct prescription drug (and other health) expenses not covered by the subsidy. The ACA also requires manufacturers of brand-name drugs to provide sizable discounts (initially 50 percent, today 70 percent) for Part D enrollees in the coverage gap, including EGWP enrollees. That discount is not available under the RDS (Angeloni and Margiott 2016, Express Scripts 2015). CMS guidance permits EGWPs to apply the manufacturers’ discount to coverage-gap spending before applying the employer’s supplemental coverage, thereby reducing the employer’s cost of providing wraparound benefits

(Centers for Medicare & Medicaid Services 2013, Centers for Medicare & Medicaid Services 2010).⁸

In 2018, EGWPs accounted for 6.9 million, or 16 percent, of Part D enrollees and 17 percent of gross Part D spending (Table 14-4). EGWPs have distinctly different characteristics from other Part D plans. In 2018, only 2 percent of EGWP enrollees received the low-income subsidy, compared with 34 percent of enrollees in other plans. Two-thirds of EGWP enrollees were in stand-alone prescription drug plans rather than Medicare Advantage–Prescription Drug plans, compared with 56 percent of other Part D enrollees. EGWP plans tend to offer more generous benefits that supplements the standard Part D benefit and may charge enrollees different premiums for the same plan. Their formularies tend to use fewer tiers than other plans, and EGWP enrollees use mail-order pharmacies more extensively. Because of their wraparound benefits, EGWP enrollees had annual average spending that was higher than spending by enrollees in other plans in 2018. However, under Part D’s “true out-of-pocket” provision, supplemental benefits such as those provided by EGWPs do not count toward an enrollee’s out-of-pocket threshold. For this reason, EGWP enrollees with spending beyond the initial coverage phase tend to stay in the coverage gap longer than would an enrollee without supplemental coverage. In 2018, less than 5 percent of EGWP enrollees reached Part D’s catastrophic phase compared with 9 percent in other Part D plans. Because disproportionately more EGWP enrollees reached the coverage gap, 45 percent of all manufacturer discounts on brand-name drugs provided in Part D accrued to the 16 percent of enrollees in EGWPs. ■

8 million were eligible for both Medicare and full Medicaid benefits. The remainder qualified either because they received benefits through the Medicare Savings Programs or Supplemental Security Income program or because they were eligible after they applied directly to the Social Security Administration. Compared with the majority of Part D 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 2018).

Between 2007 and 2019, enrollment growth for Part D enrollees who did not receive the LIS was faster (7 percent per year) than for LIS enrollees (3 percent per year) (data not shown). The faster growth in enrollment

**TABLE
14-5**

MA-PD enrollees more likely to be in enhanced plans, 2019

	PDP		General MA-PD		SNP	
	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent
Total	20.8	100%	13.8	100%	2.6	100%
Type of benefit						
Defined standard	0.0	0	0.1	<0.5	1.4	54
Actuarially equivalent*	12.1	58	0.2	2	0.4	15
Enhanced	8.7	42	13.5	98	0.8	31
Type of deductible						
Zero	8.1	39	6.4	46	0.2	7
Reduced	3.3	16	7.0	50	0.2	11
Defined standard**	9.4	45	0.5	3	2.1	81

Note: MA-PD (Medicare Advantage-Prescription Drug [plan]), PDP (prescription drug plan), SNP (special needs plan). "General MA-PD" enrollment excludes employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B-only plans. In 2019, 84 percent of SNP enrollees were in plans for dual-eligible (Medicare and Medicaid) beneficiaries (D-SNPs), 13 percent in chronic condition special needs plans (C-SNPs) for beneficiaries with certain chronic conditions, and 3 percent in institutional special needs plans (I-SNPs). Totals may not sum 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.

of these enrollees is partly attributable to the growth of EGWPs, which have few LIS enrollees. Consequently, on net, the share of Part D enrollees who received the LIS fell from 39 percent to 28 percent. About 57 percent (7.3 million) of LIS enrollees were in PDPs; the rest were in MA-PDs. Although most individuals receiving the LIS are enrolled in traditional FFS Medicare rather than MA, LIS enrollment in MA-PDs has grown. Medicare Trustees attribute this pattern to growth, since 2016, in sponsor offerings of SNPs for dual-eligible beneficiaries (Boards of Trustees 2019).

Beneficiaries' enrollment decisions in 2019

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

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

In 2019, 58 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copayments (Table 14-5). The remaining 42 percent of PDP enrollees had enhanced benefits. No PDP enrollees were in defined standard benefit plans because plan sponsors offered none. Enrollees in MA-PDs, excluding SNPs, were overwhelmingly in enhanced plans. Typically, enhanced plans have no deductible or a lower deductible than that used for Part D's defined standard benefit. In PDPs and MA-PDs, 39 percent and 46 percent of enrollees, respectively, had no deductible in their plan's benefit design. By comparison, a far larger share of SNP enrollees (54 percent) were in defined standard plans, and a large proportion of all SNP enrollees (81 percent) were in plans that used the defined standard benefit's deductible. However, most SNP enrollees are individuals dually eligible for Medicare and Medicaid who receive Part D's LIS, which covers most of their premiums and cost sharing.

Under the MA payment system, MA–PD plan sponsors may use a portion of their Part C payments to supplement Part D drug benefits (e.g., by lowering deductibles) or to lower Part D premiums.⁹ For 2020, MA–PD sponsors have applied on average nearly \$35 per month (28 percent) of their Part C rebate dollars to Part D benefits. Of that amount, 43 percent is used to lower Part D premiums and the rest is used for supplemental drug benefits.

Average enrollee premiums decreased in 2019

Despite significant growth in catastrophic benefits, average premiums for basic Part D benefits have remained low, partly due to the effects of Medicare’s reinsurance subsidy, which has offset benefit spending that would otherwise have increased enrollee premiums.¹⁰ Growth in manufacturer rebates and postsale pharmacy fees, the increase in the coverage-gap discount for brand-name drugs, and the entry of relatively large cohorts of younger enrollees into Part D are other reasons that average premiums have remained stable. In 2019, monthly beneficiary premiums averaged about \$29 across all types of plans (basic and enhanced), a 7 percent decline from the prior year. Average premiums have remained around \$30 per month since 2010. However, underlying that average is wide variation in premiums, from \$0 for many MA–PDs to \$156 per month for one PDP offering enhanced coverage.

On average, prescription drug premiums were lower for beneficiaries enrolled in MA–PDs compared with those enrolled in PDPs, in part reflecting plan sponsors’ use of Part C rebate dollars. In 2019, the average monthly premium for an MA–PD enrollee was \$16, with an additional \$17 of premium costs paid through Part C rebates (Medicare Payment Advisory Commission 2019a). By comparison, PDP enrollees paid an average premium of \$40 per month.

Two other factors affect the premium amounts enrollees pay. First, higher income individuals have a lower federal subsidy of their Part D benefits. As of October 2019, 3.5 million enrollees (7.6 percent) were subject to the income-related premium (Liu 2019). As with the income-related premium for Part B, higher Part D premiums apply to individuals with an annual adjusted gross income greater than \$87,000 and to couples with an adjusted gross income greater than \$174,000. A beneficiary whose income exceeds these levels pays a monthly adjustment amount in addition to their Part D plan premium. For 2020, adjustments range from \$12.20 to \$76.40 per month,

depending on income (Centers for Medicare & Medicaid Services 2019h).

Second, individuals enrolling in Part D outside their initial enrollment period must have proof that they had drug coverage as generous as the standard benefit under Part D (i.e., “creditable coverage”) to avoid the late enrollment penalty (LEP) that would be added to their premiums for the duration of their Part D enrollment. The LEP amount depends on the length of time an individual goes without creditable coverage and is calculated by multiplying 1 percent of the base beneficiary premium by the number of full, uncovered months an individual was eligible but was not enrolled in a Part D plan and went without other creditable coverage. As of October 2019, 2.1 million Part D enrollees paid the LEP (Liu 2019).

Benefit offerings for 2020

Beneficiaries are encouraged to reexamine plan options each year during an annual open enrollment period that runs from October 15 until December 7. In addition to changes in plan availability and premiums, most plans make some changes to their benefit offerings—such as deductible amounts and plan formularies—that can affect access to medications and beneficiaries’ OOP costs. CMS operates an online decision-support tool (Medicare Plan Finder) to help beneficiaries evaluate plan options. The agency updated the tool before the open enrollment season for 2020, but the new version met some criticisms.

Beneficiaries have more plan options in 2020

For 2020, plan sponsors are offering 948 PDPs, 2,799 general MA–PDs, and 832 SNPs—5 percent, 16 percent, and 20 percent more plans, respectively, than in 2019. In recent years, plan sponsors have offered more enhanced PDPs that include supplemental drug coverage, 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 2018b).¹¹ Rapid growth in MA–PD offerings likely reflects interest among plan sponsors in gaining a share of MA’s expanding enrollment. At the same time, some MA–PD sponsors have expanded their SNP offerings, particularly for beneficiaries who are dually eligible for Medicare and Medicaid.

**TABLE
14-6**

Comparison of PDP, general MA-PD, and SNP offerings, 2020

	PDP		General MA-PD		SNP	
	Number of plans	Percent	Number of plans	Percent	Number of plans	Percent
Total	948	100%	2,799	100%	832	100%
Type of benefit						
Defined standard	0	0	43	2	286	34
Actuarially equivalent*	382	40	81	3	106	13
Enhanced	566	60	2,675	96	440	53
Type of deductible						
Zero	133	14	1,349	48	156	19
Reduced	161	17	1,244	44	140	17
Defined standard**	654	69	206	7	536	64

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), SNP (special needs plan). The PDPs described here exclude employer-only plans and plans offered in U.S. territories. MA-PD plans exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B-only plans. SNP plans exclude U.S. territories. Among SNPs for 2020, 520 are for beneficiaries dually eligible for Medicare and Medicaid, 162 are for beneficiaries with certain chronic conditions, and 150 are for institutionalized beneficiaries. Totals may not sum due to rounding.

*Includes actuarially equivalent standard and basic alternative benefits.

**Deductible of \$435 in 2020.

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

In each of the nation’s 34 PDP regions, beneficiaries continue to have broad choice. Options range from 24 PDPs in Alaska to 32 PDPs in California, 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 27 MA plans (when weighted by Medicare population). A small number of counties have no MA plans available.¹²

MA-PDs that are open to all enrollees (general MA-PDs) are much more likely to offer more generous coverage than PDPs. For example, in 2020, 96 percent of MA-PDs include enhanced coverage beyond basic benefits, compared with 60 percent of PDPs (Table 14-6). Among plans with basic benefits, the 2020 marketplace includes no PDPs and just 2 percent of MA-PDs (excluding SNPs) with the standard benefit design. A larger share of MA-PDs than PDPs charges no deductible (48 percent vs. 14 percent, respectively), and 69 percent of PDPs use the same \$435 deductible as Part D’s defined standard benefit.

By comparison, SNPs (i.e., MA-PDs designed for certain groups of beneficiaries) are much more likely to use the defined standard benefit (34 percent of SNPs) or the same deductible amount as in the standard benefit (64 percent of SNPs). In 2020, 63 percent of SNPs are designed for beneficiaries who are dually eligible for Medicare and Medicaid, 19 percent for individuals who have certain chronic conditions, and 18 percent for institutionalized beneficiaries (data not shown).

Varied changes in plan premiums and cost sharing

For 2020, CMS calculated that Part D’s base beneficiary premium—enrollees’ share of the monthly national average expected cost for basic benefits—was \$32.74, a 1 percent decrease from \$33.19 in 2019. 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.

**TABLE
14-7**

Change in 2020 premiums for PDPs with the highest 2019 enrollment

Plan name in 2020	Benefit type	2019 enrollment (in millions)	Weighted average monthly premium ^a		
			2019 premium	Projected 2020 premium	Percent change
SilverScript Choice	Basic	4.4	\$31	\$29	-7%
Humana Premier Rx ^b	Enhanced	2.6	N/A	57	N/A
AARP MedicareRx Preferred	Enhanced	2.2	75	79	6
Humana Basic Rx ^c	Basic	1.6	31	31	0
AARP MedicareRx Saver Plus	Basic	1.3	34	32	-4
WellCare Medicare Rx Saver ^d	Basic	1.2	29	31	6
WellCare Classic	Basic	1.0	32	29	-9
AARP MedicareRx Walgreens	Enhanced	0.7	28	34	23
WellCare Medicare Rx Select ^d	Enhanced	0.7	17	21	23
WellCare Medicare Rx Value Plus ^d	Enhanced	0.5	60	72	20
Top 10 PDPs		16.1	40	42	6
All PDPs		20.5	39	42	7

Note: PDP (prescription drug plan), N/A (not available). Components may not sum to stated totals due to rounding.

^aThese data reflect the average of all PDPs offered under the same plan name in each region of the country, weighted by 2019 enrollment. The projected weighted average premium for 2020 does not reflect any enrollment switching among plans. Percent changes calculated before rounding.

^bReflects the combination of two plans offered in 2019—Humana Walmart Rx (at an average monthly premium of \$28) and Humana Enhanced (at an average premium of \$76).

^cRenamed from Humana Preferred Rx in 2019.

^dWellCare purchased Aetna’s PDPs in 2018 and rebranded them under WellCare with otherwise the same plan name for 2020.

Source: Cubanski and Damico 2019.

The 10 stand-alone PDPs with the highest enrollment in 2019 experienced a mixture of premium increases and decreases in 2020. Across all PDPs weighted by their 2019 enrollment, the average projected premium for 2020 rose to \$42 from \$39 per month (Table 14-7). However, the final average change in PDP premiums could be lower because the \$3 per month (7 percent) projected increase does not reflect movement of enrollees to plans with lower premiums.

Although the top 10 PDPs experienced an average monthly premium increase of about \$2, plan sponsors revised some of their offerings, and annual changes to premiums for individual plans varied. For 2020, Humana combined an enhanced PDP that had relatively low premiums in 2019 with another plan that had much higher premiums into Humana Premier Rx. For beneficiaries who had been enrolled in the lower premium plan,

their premiums more than doubled unless they changed plans.¹³ In 2018, WellCare acquired Aetna’s PDPs.¹⁴ For 2020, enrollees who remained in a divested plan (such as WellCare Medicare Rx Select or WellCare Medicare Rx Value Plus) saw average monthly premiums increase by 20 percent or more. Premiums for United HealthCare’s AARP MedicareRx Walgreens PDP increased by 23 percent for 2020. However, other basic PDPs such as SilverScript Choice, AARP MedicareRx Saver Plus, and WellCare Classic each saw average premiums decline for 2020.

The top 10 PDPs (ranked by 2019 enrollment) tend to use five-tiered formularies with differential cost sharing among drugs listed on preferred generic, other generic, preferred brand, and nonpreferred drug tiers, as well as a specialty tier for high-cost drugs. Although cost-sharing requirements in Part D plans have generally risen over time, for 2020, PDPs with the highest enrollment held

steady or lowered generic copays: Median copays are zero for preferred generics and \$3 for prescriptions filled from the other-generics tier (Cubanski and Damico 2019). In 2020, the top 10 PDPs had a mix of cost-sharing increases and decreases for preferred brand-name drugs.

Over time, many plan sponsors have moved from charging copayments (predetermined fixed amounts) to coinsurance for certain tiers. For 2020, the top 10 PDPs shown in Table 14-7 (p. 421) all use coinsurance for medications on nonpreferred drug tiers, charging 32 percent to 50 percent of each prescription's negotiated price (Cubanski and Damico 2019). By charging enrollees a percentage of the price of their prescriptions rather than a flat copayment, some of manufacturers' price increases are reflected in beneficiaries' cost sharing. One reason for the move to coinsurance is that some plan sponsors have combined certain brand and generic drugs on the same cost-sharing tier, such as a single tier 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 average benefit.

Greater numbers of benchmark PDPs

Compared with 2019 levels, the number of PDPs available to LIS enrollees at no premium ("benchmark PDPs") in 2020 increased by 13 percent to 244 plans.¹⁵ In one region, Ohio, the number of benchmark PDPs dropped from seven in 2019 to two for 2020. However, all other regions have at least 4 benchmark PDPs available, while the Arizona region has 12 such PDPs. The number of benchmark PDPs in Florida expanded from two in 2019 to four for 2020.

About 1.3 million LIS enrollees (18 percent of LIS enrollees in PDPs) were enrolled in plans in 2019 that, in 2020, have premiums higher than regional benchmarks (Cubanski and Damico 2019). However, many of those enrollees paid a premium in 2019, meaning they selected a plan rather than accepting Medicare's random assignment to a benchmark plan. Once an LIS enrollee selects a plan, the enrollee is no longer eligible for reassignment.¹⁶ For 2020, CMS estimated that the agency randomly reassigned only about 100,000 individuals to new plans (Liu 2019).

Updated Medicare Plan Finder

Part D's competitive design presumes that enrollees review their options periodically and are willing to switch plans when a competitor offers a better alternative. However, many Part D enrollees remain in the same plan from year

to year, even in the face of premium and cost-sharing increases. Some individuals may simply be satisfied with their plan, or the time costs associated with searching for information to compare plans may not be worth the potential savings. Others may be overwhelmed by the complexity of the task of comparing options.

Much of the published literature on Part D suggests that when beneficiaries select a plan, they often make suboptimal choices, and the complexity and broad availability of plan options may lead to consumer inertia (Abaluck and Gruber 2016, Cummings et al. 2009, Zhou and Zhang 2012). Other literature suggests that in the presence of such inertia, premiums for Part D plans that have been on the market for longer periods of time tend to rise (Ho et al. 2017, Marzilli Ericson 2014).

Research has found that in the early years of Part D, about 13 percent of enrollees without the LIS switched plans during any given open enrollment period (Hoadley et al. 2013, Suzuki 2013). A more recent study of these enrollees had similar results: Over the period from 2007 to 2016, 6 percent to 11 percent of MA-PD enrollees and 10 percent to 13 percent of PDP enrollees switched plans in any given year (Koma et al. 2019). Over Part D's first four or five years, researchers estimated that 30 percent to 50 percent of PDP enrollees changed plans at least once (Hoadley et al. 2013, Ketcham et al. 2015). PDP enrollees who faced relatively large premium increases (such as \$20 per month) were more likely to switch plans, but most individuals with large premium increases remained in the same plan (Hoadley et al. 2013).

Displaying plan options in a clear manner could help Part D enrollees evaluate whether it is worthwhile to switch plans. CMS has operated a decision-support tool, Medicare Plan Finder (www.medicare.gov), for many years to serve this function.¹⁷ Plan Finder allows beneficiaries to enter their personal list of prescription medications and select among local pharmacies in their ZIP code. The tool then displays PDP or MA-PD options for the beneficiary to compare and evaluate in more detail, such as by looking at plan premiums, whether each plan's formulary covers the individual's medications, and estimated cost-sharing amounts. It also contains direct links so that beneficiaries can enroll in their selected plan. However, beneficiary advocates have criticized Plan Finder for adding to confusion rather than helping to overcome choice overload. For example, Plan Finder has been criticized for using language that is not user friendly,

making it difficult to find information about preferred cost-sharing pharmacies, and for ambiguity in the meaning of star ratings, among other issues (Clear Choices Campaign and National Council on Aging 2018, Government Accountability Office 2019). Until recently, Plan Finder sorted the beneficiary’s plan options from lowest to highest total cost (i.e., premiums plus cost sharing) side by side with considerable detail about cost-sharing requirements. One recent experiment showed that beneficiaries would be better able to select lower cost plans if total cost was displayed alone, or total cost side by side with premiums and total cost sharing, rather than more complicated financial details (McGarry et al. 2018).

In 2019, CMS introduced a new version of Plan Finder that reduced some of the previous version’s complexity. Beneficiaries can use the redesigned version on smartphones and tablets as well as desktop computers. If a Part D enrollee chooses to enter his or her Medicare ID number, Plan Finder now autoloads their list of medications based on past claims. It also includes a webchat option for additional support. Despite these improvements, the new version of Plan Finder met immediate criticism because, unlike the previous version, it displays plan options ranked by lowest to highest premiums rather than by total costs. CMS subsequently added a prompt to encourage beneficiaries to sort plans by total cost but did not revert to sorting by total cost as the tool’s default display (McGarry et al. 2019). CMS may provide beneficiaries with a special enrollment period if they had problems with Plan Finder and felt they had inaccurate information for their enrollment decision (Alonso-Zalvidar 2019).

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 businesses. The market structure of plan sponsors has consolidated and become more vertically integrated. By law, the Medicare program is prohibited from becoming involved in negotiations among sponsors, drug manufacturers, and pharmacies.

Concentrated enrollment among plan sponsors

Plan sponsors and their PBMs exert bargaining leverage with drug manufacturers and pharmacies by winning large market shares of enrollees and by influencing the market shares of drug products through their formularies and tiered cost sharing. High enrollment levels can also provide sponsors with economies of scale that lower other costs.

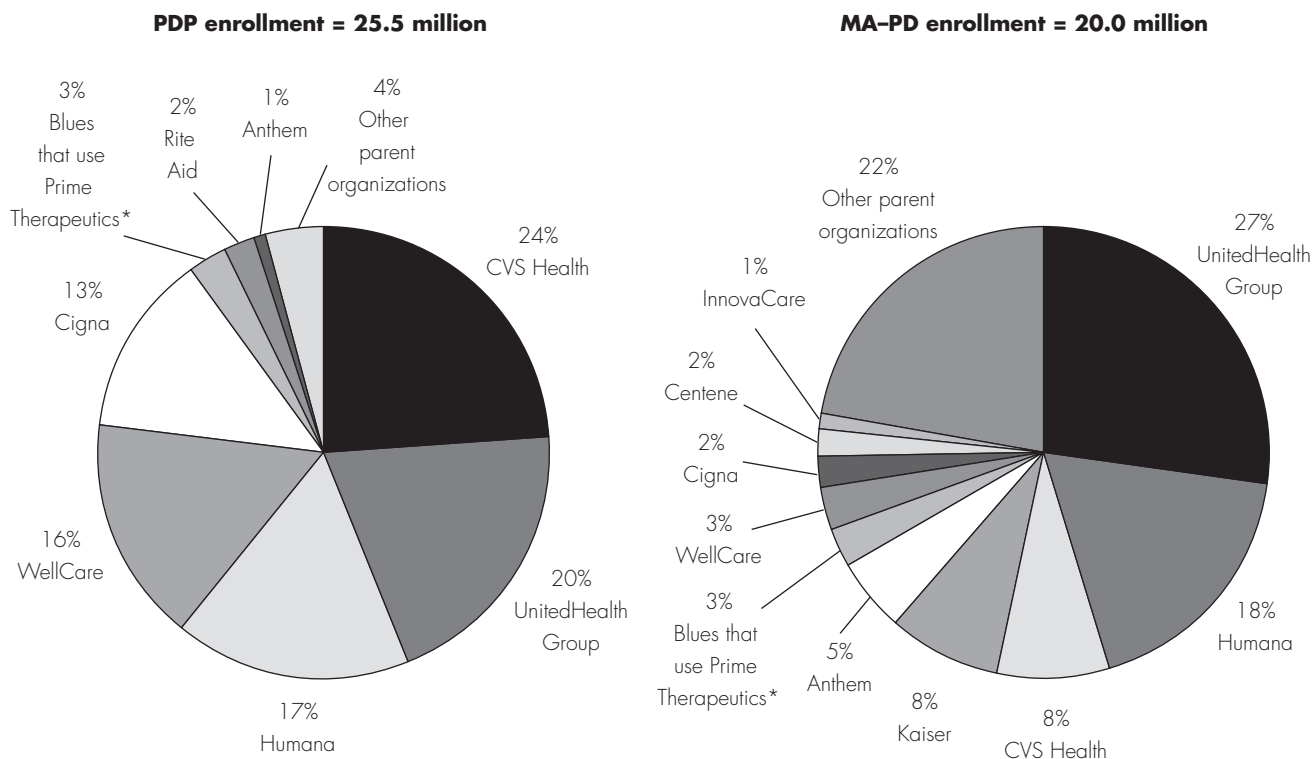
Although plan sponsors’ organizational structures differ, the general trend in recent years has been toward more vertical integration among managed care organizations, PBMs, and pharmacies. Most of the largest sponsors are insurers whose core business function has been to offer commercial and MA health plans with combined medical and pharmacy benefits. However, because more than 60 percent of Medicare beneficiaries are in traditional FFS Medicare, if they choose to enroll in Part D, they obtain benefits through stand-alone PDPs. For this reason, PDPs remain an important market opportunity, and insurers serving as MA sponsors also offer PDPs in many regions. Recently, two major PDP sponsors with core business models that focused on pharmacy benefit management and dispensing merged with major health plans.¹⁸

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. Over time, other sponsors have expanded their enrollment and market shares. In 2019, the top seven 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 85 percent of Part D enrollment. In 2007, those same organizations accounted for 61 percent of enrollment.

Enrollment in PDPs is highly concentrated among a small number of plan sponsors. Nationally, in 2019, the top five PDP sponsors—CVS Health, UnitedHealth Group, Humana, WellCare, and Cigna (including its subsidiary Express Scripts)—collectively enrolled 90 percent of beneficiaries in PDPs (Figure 14-3, p. 424). Enrollment

FIGURE 14-3

PDP enrollment is more concentrated than MA-PD enrollment among a small number of plan sponsors, 2019



Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). Market shares are based on Part D enrollment, including employer group waiver plans. Components may not sum to totals due to rounding.
 *Prime Therapeutics is a pharmacy benefits manager that, in 2019, served 18 Blue Cross/Blue Shield plans.

Source: MedPAC based on enrollment data from CMS.

among beneficiaries in FFS Medicare who receive Part D’s LIS is also concentrated. PDPs offered by those same five companies accounted for 95 percent of LIS beneficiaries enrolled in PDPs (data not shown).¹⁹

MA-PD enrollment is less concentrated than that for PDPs. As shown in Figure 14-3, the top five MA-PD sponsors in 2019 enrolled 65 percent of MA-PD enrollees. Similarly, 62 percent of LIS beneficiaries in MA-PDs were enrolled in plans offered by the same top five sponsors (data not shown). In addition to large, vertically integrated health plans, MA plan sponsors include a broader variety of companies, such as smaller regional organizations, religiously affiliated groups, and integrated delivery systems.

Most large sponsors also offer EGWPs, and the market for EGWPs is highly concentrated. In 2019, the top five sponsors of EGWPs—Cigna, UnitedHealth Group, CVS Health, Kaiser Permanente, and Humana—accounted for 82 percent of EGWP enrollment.

Tools for managing benefits and spending

Over the first decade of Part D, the use of pharmacy management tools and the fortuitous timing of patent expirations led to the expanded use of generics. By 2017, 88 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.²⁰ Instead, for their commercial clients, plan sponsors focus increasingly on managing the use of specialty drugs and biologics for conditions such as cancer, HIV, hepatitis C, rheumatoid arthritis, and multiple sclerosis. Spending for specialty drugs used by Part D enrollees is also expanding quickly. Many of these treatments are self-injectable products. Dispensing certain 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 reaching 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. This year, CMS's Center for Medicare & Medicaid Innovation launched a demonstration program called the Part D Payment Modernization Model that provides "new incentives for plans, patients, and providers to choose drugs with lower list prices to address rising federal reinsurance subsidy costs in Part D" (Centers for Medicare & Medicaid Services 2019j).²¹ To date, however, there have been no large-scale changes to risk-sharing provisions that would give plan sponsors financial incentives to fully use those new tools in practice as they may do with their commercial population.

Formulary management and manufacturer rebates

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 forms of utilization management—quantity limits, step therapy, and prior authorization. Those decisions require that plan sponsors strike a balance between providing access to medications while encouraging enrollees to use preferred therapies. Greater flexibility to use such tools also affects plan sponsors' bargaining leverage with manufacturers over rebates.

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

process of deciding whether to approve its bid. For most drug classes, plans must cover at least two distinct drugs that are not therapeutically equivalent or bioequivalent, as well as "all or substantially all drugs" in six protected classes—anticonvulsants, antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

Within those constraints, plan sponsors have tightened formularies modestly in recent years. Similarly, the use of utilization management tools in Part D has grown. 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.

Manufacturers use rebates to provide discounts on brand-name drugs that are individualized for different purchasers, including Part D plan sponsors. In 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. Generally, manufacturers pay larger rebates when a sponsor positions a drug on its formulary in a way that increases the likelihood that the manufacturer will win market share over competitors. For example, a manufacturer might pay a base rebate for including the product on a plan's formulary but might pay larger rebates if the drug is on a preferred tier or if prior authorization requirements are waived. Producers of brand-name drugs with no therapeutic substitutes may not provide any rebates. One recent Milliman analysis of 2016 data provided by a group of Part D plan sponsors found that only 36 percent of brand-name drugs had more than nominal manufacturer rebates (Johnson et al. 2018). In recent years, payers and PBMs have also negotiated "price-protection" provisions under which the manufacturer agrees to rebate a drug's midyear price increases above a specified threshold.

Data on manufacturers' rebate amounts for individual drugs are highly proprietary. The Milliman study found that as a share of point of sale (POS) prices, rebates were largest (averaging 39 percent) in drug classes in which brand-name drugs competed directly with one another or when the brand drug faced competition from three or more generics (34 percent). The share of a drug product's POS 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 about 60 percent by the second quarter of 2016 due to heightened competition among insulins (*Indianapolis Business Journal* 2016).

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

Formularies have been an effective tool for encouraging beneficiaries to use certain drugs over others. However, the Commission is concerned that in Part D, plan sponsors' relatively small liability for spending in the coverage gap and catastrophic phases, combined with Medicare's reinsurance subsidies and manufacturers' rebates, can affect plans' formulary decisions in ways that may be at odds with beneficiary and program interests. For some drugs, plan sponsors have incentives to give preferable formulary placement to high-price, high-rebate products over alternatives with lower list prices.²² In turn, enrollees who are charged coinsurance pay more in cost sharing, and Medicare reinsurance and low-income cost-sharing subsidies are higher.

Pharmacy networks and postsale fees

Plan sponsors try to encourage enrollees to use pharmacies that dispense prescriptions at lower cost. For example, in the commercial insurance sector, enrollees in some (non-Medicare) employer plans are required to fill prescriptions within an exclusive network of retail pharmacies, refill prescriptions by mail rather than through 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.²³ 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. In

2020, 95 percent of PDPs use preferred cost-sharing pharmacies compared with 92 percent of PDPs in 2019 (Fein 2019c). 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 pharmacies that, for example, may be more effective at encouraging generic drug use. Differences between cost sharing at preferred pharmacies and other network pharmacies can vary substantially among plans (Medicare Payment Advisory Commission 2016b).

Tiered networks 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 fees that are a condition for participating as a preferred cost-sharing pharmacy, periodic payment reconciliations related to drug reimbursement rates, or performance-based fees that are assessed on quality measures (Fein 2016).²⁴ While participants in preferred networks gain more prescription volume, the pharmacies are essentially agreeing to lower and less predictable reimbursements from plans, which for some pharmacies has made participation in plan sponsors' preferred networks much less desirable. For example, in 2020, fewer independent pharmacies are participating in PDP preferred cost-sharing networks (Fein 2019a).

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 2018e). Critics point out that Part D enrollees pay coinsurance at the pharmacy before such fees are assessed, which means 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. All of the largest insurers and PBMs own specialty pharmacies, and most 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.²⁵ 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-day or 15-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. Some specialty pharmacies also facilitate outreach to patient assistance programs.²⁶

A variety of ownership types have evolved to dispense specialty drugs, including insurers, wholesalers, hospital systems, pharmacy chains, independent specialty pharmacies, and prescriber practices. Recently, however, the industry has grown more vertically integrated—dominated by specialty pharmacies owned by PBMs and health plans (Fein 2019b). Although most manufacturers do not own specialty pharmacies, drug makers pay fees to specialty pharmacies and have contracts that limit which ones may dispense their drug. For some specialty pharmacies, these relationships can result in financial incentives that are aligned with drug manufacturers. However, in a vertically integrated entity, a specialty pharmacy's incentives more closely align with those of its affiliated PBM and health plan. Lack of transparency into postsale discounts and fees received by specialty pharmacies means we are unable to assess how different ownership arrangements may affect Medicare's spending for Part D drugs.

Recent regulatory issues in Part D

In 2018, CMS made several regulatory changes designed to make the tools that plan sponsors use in Part D more like those already available for managing pharmacy benefits in commercial populations. Consistent with the Commission's 2016 recommendation to streamline CMS's process for reviewing formulary changes, the agency now permits 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. CMS also allows plan sponsors to use different utilization management requirements for a drug depending on a patient's indication, and plans may limit on-formulary coverage of certain drugs by indication (Centers for Medicare & Medicaid Services 2018c, Centers for Medicare & Medicaid Services 2018d). MA-PDs may now use step therapy to manage Part B drugs: 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 2018a).

In 2019, the Department of Health and Human Services (HHS) and CMS withdrew from consideration other major regulatory proposals. Most notably, HHS's Office of Inspector General (OIG) had proposed removing the safe-harbor protection that manufacturers' rebates receive from liability under the federal anti-kickback statute. In its place, OIG proposed permitting rebate arrangements between Part D plans, their PBMs, and manufacturers only if the full rebate amount was reflected in prescription prices at the point of sale.²⁷ Drug manufacturers and certain patient assistance groups supported OIG's proposal on the grounds that it would reduce beneficiary cost sharing on rebated drugs. However, other organizations raised concerns that the regulatory change would lead to higher Part D premiums for all enrollees and raise Medicare program spending. Ultimately, HHS withdrew the proposal.

A second regulatory proposal that CMS withdrew in 2019 relates to Part D's protected classes. CMS proposed allowing sponsors to use prior authorization and step therapy more broadly to determine whether use of a drug was for a protected-class indication (Centers for Medicare & Medicaid Services 2019i). Under the proposal, plan sponsors would have been able to exclude a protected-class drug from a formulary if (1) the drug was a new

formulation of an existing single-source drug or biological product, regardless of whether the older formulation remained on the market, or (2) the price of the drug increased beyond a certain threshold over a specified period. These exceptions from the protected-class policy would not have superseded sponsors' obligation to cover two distinct drugs in each drug class. Following stakeholder concerns and opposition to the proposed policy, CMS chose not to finalize the provisions (Centers for Medicare & Medicaid Services 2019i). Instead, CMS codified existing policy under which plan sponsors are permitted to apply prior authorization or step therapy only for beneficiaries initiating therapy (i.e., new starts) in five of the six protected classes. For antiretrovirals, no prior authorization or step therapy is allowed at all.

Drug pricing

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

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

While some analysts contend that growth in prices net of rebates is the primary measure of importance, changes in POS and net prices are both important to monitor. Until

recently, POS prices have grown aggressively. Because POS prices affect beneficiary cost sharing and the rate at which beneficiaries reach Part D's catastrophic phase, prices paid at the pharmacy are an important indicator of Part D's costs. At the same time, net drug prices affect the premiums that are paid by Part D enrollees and subsidized by the Medicare program. Although the Commission does not have data on rebates for individual drugs, Medicare Trustees report that average rebates have grown significantly (Boards of Trustees 2019).²⁸ Because rebates have grown even faster than POS prices, there has been a widening divergence between gross and net drug prices. Over time, Medicare and beneficiaries have paid an increasing share of drug costs net of rebates.

Prices paid at the point of sale

To examine growth in POS prices, the Commission contracted with Acumen LLC to construct a series of volume-weighted price indexes that reflect total amounts paid to pharmacies for Part D prescriptions, including ingredient costs and dispensing fees.

In 2018, modest price growth overall, but strong increases in brand prices

Overall, prices for Part D drugs and biologics grew modestly in 2018. Measured by individual national drug codes (NDCs) and excluding retrospective rebates and pharmacy discounts, annual increases averaged 3.4 percent (Table 14-8).²⁹ Growth in the overall Part D index is influenced heavily by pricing for single-source brand-name drugs. Our index for brand prices grew at double-digit rates in most years until 2015, when growth decelerated to mid-to-high single-digit rates. In 2018, the index for single-source brand-name drugs grew by 6.9 percent.

Use of generic drugs tends to provide significant savings to beneficiaries and the Medicare program. On average, prices of generics can be 75 percent to 90 percent lower than their brand-name counterparts (Government Accountability Office 2016). Generics enter the market at substantially lower prices than the brand-name drugs they replace, and generic prices tend to decline over time with entry of additional producers (Dave et al. 2017a, QuintilesIMS Institute 2016). In recent years, certain generic medications have experienced sharp price increases, primarily due to decreases in market competition (Berndt et al. 2017). There have also been allegations that certain generic prices have been artificially high due to price fixing among some suppliers (Bartz and

**TABLE
14-8**

Price increases for brand-name drugs continue to overwhelm the effects of using lower priced generics

**Average annual change in Part D price indexes
(December over December)**

	Average annual change in Part D price indexes (December over December)			Cumulative change 2006-2018
	2006-2015	2015-2017	2018	
All drugs and biologics	5.8%	4.1%	3.4%	86%
Single-source brand-name drugs	11.1	8.0	6.9	236
Generic drugs	-12.9	-11.0	-9.1	-83
After accounting for generic substitution	1.4	0.7	1.7	14

Note: Prices are measured by chain-weighted Fisher price indexes.

Source: Acumen LLC analysis for MedPAC.

Chiacu 2019). Nevertheless, between 2006 and 2018, prices of most generic drugs generally declined (Dave et al. 2017b, Schondelmeyer and Purvis 2019).

Consistent with this general trend, our index of generic prices has declined since the start of the Part D program and fell by 9.1 percent in 2018 (Table 14-8). In that same year, generic prices were a cumulative 83 percent below the index value observed in 2006.

When measured by an index that reflects both brand-name drugs and generic substitution, Part D prices increased by 1.7 percent in 2018—a higher rate of growth than rates observed between 2015 and 2017 (Table 14-8).³⁰ Although brand-name drugs accounted for only about 13 percent of prescriptions in 2018, brand-name drugs made up 80 percent of all Part D spending. As a result, price increases for brand-name drugs overwhelmed the effects of using lower priced generics.

Manufacturers’ ability to raise prices varies across therapeutic classes

Over the past decade, prices have grown rapidly for brand-name drugs and biologics that have few competing therapies. Between 2007 and 2018, prices of single-source brand-name products that have no generic or biosimilar substitutes (but that may have generic alternatives in the same therapeutic class) grew by a cumulative 236 percent

(Table 14-8). Over the same period, prices of biologics grew by a cumulative 257 percent (data not shown). Competitive tactics among manufacturers, regulatory hurdles, and slow acceptance among providers have so far worked to thwart entry of and price competition from biosimilars in Part D (see text box on lack of biosimilar competition, pp. 430–431).

In general, the extent to which a manufacturer can raise the price of its product depends on market dynamics, such as whether there are generics or brand alternatives, and on the regulatory environment in which it operates (Borges dos Santos et al. 2019). One example of how regulations can affect pricing power in Part D is the protected-class policy that requires plan sponsors to include on their formularies “all or substantially all” drugs in six categories. CMS has noted that the inability of plan sponsors to manage drugs in protected classes has “allowed the pharmaceutical industry to command high prices on protected class drugs in Part D” (Azar and Verma 2018).

In four of the six protected classes, prices of brand-name drugs have grown more rapidly than the overall average for single-source brand-name drugs (Figure 14-4, p. 432). Between 2006 and 2018, prices of brand antipsychotics grew by 286 percent, while prices of brand anticonvulsants and antidepressants more than quadrupled. Prices of

Lack of biosimilar competition in Part D

B iologics are medicines derived from living organisms, such as human insulin, recombinant hormones, growth factors, and monoclonal antibodies. Because biologics are injected or infused into the patient and often require individualized dosing, many are administered in clinician offices or hospital outpatient departments and covered under Part B. However, an increasing number of biologics are expected to be self-injectable, dispensed through pharmacies, and paid under Part D. Whether covered under Part B or Part D, most biologics have very high prices.

Biosimilars are follow-on products to an originator biologic. They are analogous to generics in the sense that they compete with the originator product on price once the originator's period of market protection has expired. As with generics, use of biosimilars may be an important means for improving access to medicines and restraining growth in Medicare spending through lower prices. However, unlike generics, due to their molecular complexity and the effects of differing production processes, biosimilars are not exact chemical replicas of the originator biologic. As of January 2020, the Food and Drug Administration (FDA) had approved 26 biosimilars, 19 of which are provider administered and fall under Part B.³¹

Federal law provides for two designations: *biosimilar* or *interchangeable biosimilar*.³² An interchangeable

designation has additional importance for Part D medicines because pharmacists may substitute the interchangeable biosimilar for the originator biologic without the prescriber's intervention. In addition, some state laws require not only interchangeability but also other measures, such as prescriber and patient notification, before a pharmacy can automatically substitute a biosimilar (Cauchi 2016, Stevenson 2015).

None of the seven FDA-approved biosimilars that would fall under Part D has yet been launched in the U.S. The seven are biosimilars to two originator biologics—Enbrel (made by Amgen) and Humira (made by AbbVie).³³ Although not used for all the same indications, both products are self-administered treatments for autoimmune diseases such as rheumatoid arthritis. In 2017, they had Part D sales of \$1.8 billion and \$2.6 billion, respectively (Centers for Medicare & Medicaid Services 2019g). In recent years, manufacturers of the two treatments have increased their list prices in lockstep, and both have extended their market protection by amassing patents (Ross 2018).³⁴ Because producers of biosimilars need to challenge the patents before launching in the United States, building a “patent thicket” effectively fends off price competition.³⁵ Rather than fight extensively in court, some biosimilar producers have made agreements with manufacturers of originator products to delay entry. For example, in return for earlier entry into Europe, AbbVie signed agreements with the

(continued next page)

certain brand-name drugs in protected classes sometimes continue to grow aggressively even after the entry of generic competition. For example, between 2013 and 2017, the average price of Wellbutrin XL (bupropion XL), an antidepressant with about a dozen generic competitors, grew by over 40 percent per year on average (Centers for Medicare & Medicaid Services 2019g). Between 2013 and 2017, the average annual spending per patient taking Wellbutrin XL increased from about \$2,700 to over \$14,000.

Manufacturers may have greater ability to raise prices of protected-class drugs when these medications are used widely by beneficiaries who receive Part D's LIS. Part D plans that include larger percentages of LIS enrollees have incentives to keep their premium below the regional LIS benchmark and, for MA-PDs, avoid having to use Part C rebate dollars to pay for Part D premiums. Nevertheless, because Medicare's LIS pays for most of the enrollees' OOP costs, plan sponsors do not bear the effects of price increases as much as they might otherwise, and they may

Lack of biosimilar competition in Part D (cont.)

producers of biosimilars to Humira that delay their launches in the U.S. until 2023 (Watral 2019).

Once launched, biosimilars might not gain market share quickly if prescribers and patients have apprehensions about using the new products. Because small changes to manufacturing processes can alter the structure of biologics, manufacturers of originator biologics argue that the immunogenicity of biosimilars could differ from originators.³⁶ They contend that expensive clinical testing is the only way to evaluate differences between the effects of biosimilars and originator products in patients (Biotechnology Innovation Organization 2016). The FDA's designation of interchangeability is due, in part, to such concerns. However, biosimilar producers counter that even for a given originator product, changes in the manufacturing process can alter the final structure and function of therapeutic proteins (Madsen 2016, Stevenson 2015). Moreover, countries in the European Union have been using biosimilars about a decade longer than the U.S., and their use has led to substantial savings and no safety recalls (Scott Morton et al. 2016).

FDA naming conventions may be a regulatory hurdle that hinders acceptance of biosimilars. As part of the product's nonproprietary name, biosimilars are randomly assigned a four-letter suffix to identify the manufacturer. For example, Amgen's product Amjevita (an approved biosimilar for Humira) has the name

adalimumab-atto. The Federal Trade Commission (FTC) opposes the use of a suffix because it "may cause physicians to believe mistakenly that the products necessarily have clinically meaningful differences" and could reduce competition among biologics with the same active ingredient (Jex 2016). The FTC also argues that unique naming is not necessary because products can be tracked by alternative mechanisms such as national drug codes.

General conservatism about switching patients to a biosimilar has led to a pricing tactic known as a "rebate trap" (Hakim and Ross 2017). Specifically, manufacturers of originator products may withhold rebates on their biologic if a pharmacy benefit manager (PBM) or payer places a competing biosimilar on its formulary. Even if the biosimilar's producer offers a large rebate, the fact that prescribers are generally unwilling to switch patients from one product to the other means that the biosimilar producer could potentially gain market share only for new patients. However, PBMs and payers are likely unwilling to include a biosimilar on their formulary if it means losing rebates for the originator product's larger patient population. Under a similar pricing tactic, originator manufacturers tie their willingness to provide rebates across their portfolio of drugs to the exclusion of biosimilars from a plan's formulary (Balto 2018). ■

have less incentive to thwart or avoid the increases. In some cases, higher prices can even provide a financial advantage to the plan in the form of higher rebates. In addition, manufacturers face little to no resistance from LIS patients when they raise the prices of their products.

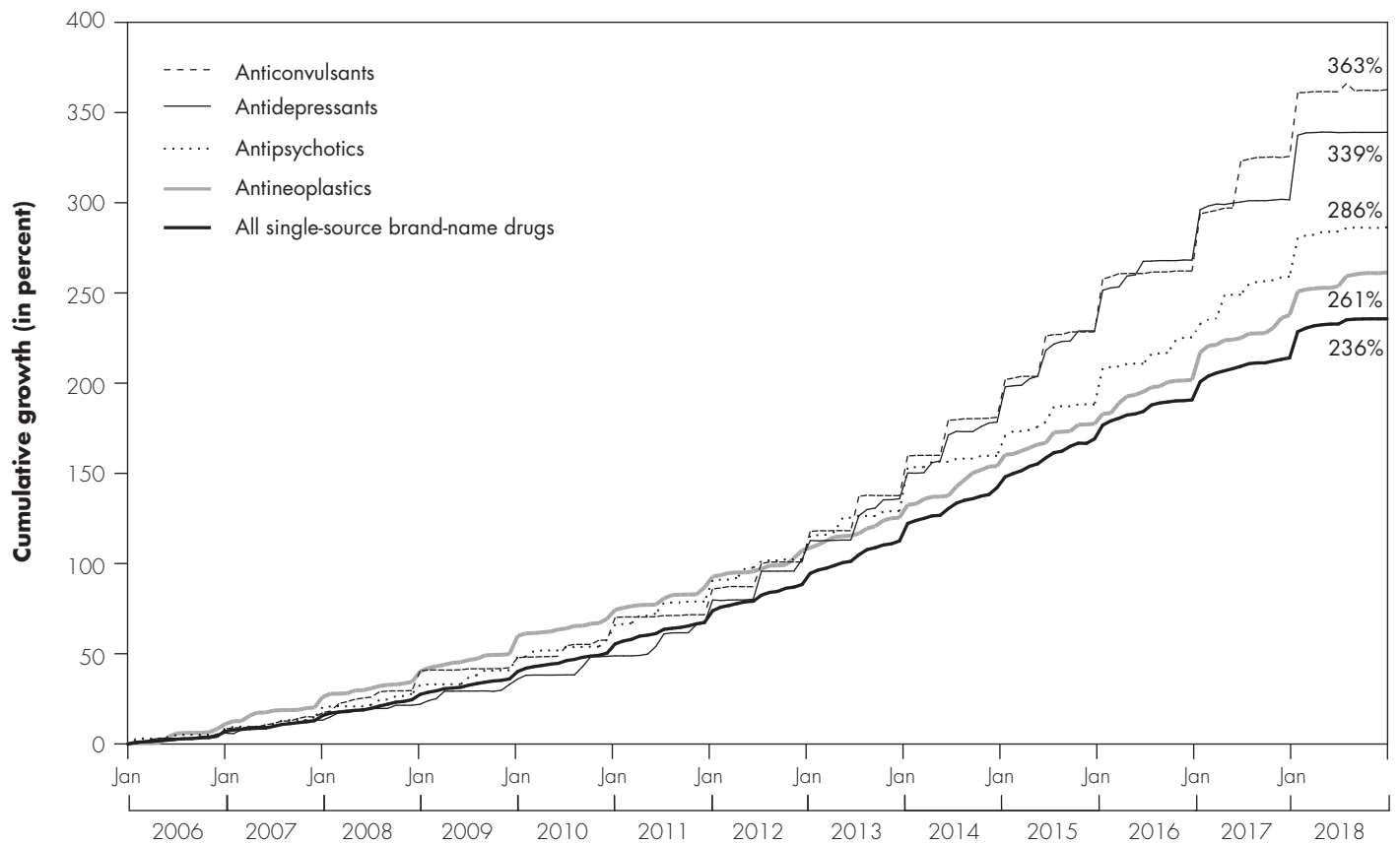
Average prices of drugs used by LIS enrollees grew more rapidly than for other Part D enrollees

LIS enrollees tend to use a different mix of drugs than other Part D enrollees do. Although they make up 28 percent of all Part D enrollees, in 2017, LIS beneficiaries accounted

for disproportionate shares of prescriptions in 13 of the top 15 therapeutic classes used by all Part D enrollees (Table 14-9, p. 433). Most notably, LIS enrollees filled 75 percent of antipsychotic prescriptions in Part D, 53 percent of anticonvulsants, 51 percent of multiple sclerosis agents, and 49 percent of prescriptions for the antiviral class, agents for asthma and chronic obstructive pulmonary disease, and narcotic analgesics. While the differences between rates of generic dispensing between LIS enrollees and enrollees without the LIS vary by therapeutic class, LIS enrollees tended to use fewer generics.

**FIGURE
14-4**

Prices of brand-name drugs in four of the six protected classes grew faster than overall prices of single-source brand-name drugs



Note: Chain-weighted Fisher price indexes. Prices are measured at the individual national drug codes that reflect total amounts paid to pharmacies (i.e., they do not reflect rebates or discounts from manufacturers and pharmacies).

Source: Acumen LLC analysis for MedPAC.

Price indexes that separately reflect the mix of drugs used by LIS enrollees and enrollees without the LIS show that over time, prescriptions filled by LIS enrollees experienced more rapid price growth (Figure 14-5, p. 434). In 2010, the market basket of medicines taken by LIS enrollees had an index value that was just 4 percentage points higher than that of enrollees without the LIS. However, by 2018, the difference grew to 21 percentage points, which likely reflects use of medications that are subject to less price competition as well as greater use of brand-name drugs rather than generics. While there may be clinical reasons for some LIS enrollees to use brand-name drugs rather than generics, the limited financial

incentives they face also play a role. Because LIS cost sharing is limited to nominal copays (or zero for some beneficiaries), plan sponsors have less ability to encourage LIS enrollees to use generic drugs or preferred brand-name drugs.

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:

**TABLE
14-9**

LIS enrollees accounted for a disproportionate share of prescriptions in top therapeutic classes and tended to use fewer generics, 2017

Top 15 drug classes ranked by spending	Spending (in billions)	Prescriptions (in millions)	LIS share	Generic dispensing rate (in percent)	
				LIS	Without LIS
Diabetic therapy	\$23.3	155.4	39%	53%	71%
Asthma/COPD therapy agents	11.0	64.9	49	26	33
Antivirals	10.4	9.9	49	45	83
Antineoplastic—systemic enzyme inhibitors	8.1	0.8	30	13	9
Anticoagulants	6.8	41.6	30	52	51
Analgesic, anti-inflammatory—non-narcotic	6.6	42.3	41	95	97
Antihyperlipidemics	5.5	241.2	27	96	97
Antipsychotics (neuroleptics)	5.5	30.9	75	88	97
Anticonvulsants	5.4	90.8	53	89	93
Antihypertensive therapy agents	5.0	240.2	28	99	99
Antineoplastic—immunomodulators	4.0	0.3	22	1	<1
Analgesics—narcotic	3.4	77.6	49	96	97
Peptic ulcer therapy	3.0	118.4	40	93	98
Calcium and bone metabolism regulators	2.7	20.7	35	79	93
Multiple sclerosis agent—others	2.6	0.4	51	1	1

Note: LIS (low-income subsidy), COPD (chronic obstructive pulmonary disease).

Source: MedPAC analysis based on Part D prescription drug event data.

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

Combined, the direct subsidy and expected reinsurance payments aim to cover 74.5 percent of the expected cost of basic benefits. Today, a much larger share of Medicare’s payments takes the form of reinsurance (cost-based reimbursement) rather than the direct subsidy (capitated payments). In addition to reinsurance, Medicare shares financial risk with plan sponsors by risk adjusting direct-subsidy payments to reflect the expected costliness of a plan’s enrollees and by limiting each plan’s overall losses

or profits through risk corridors if actual benefit spending, excluding reinsurance, is much higher or lower than the plan sponsor anticipated in its bid.

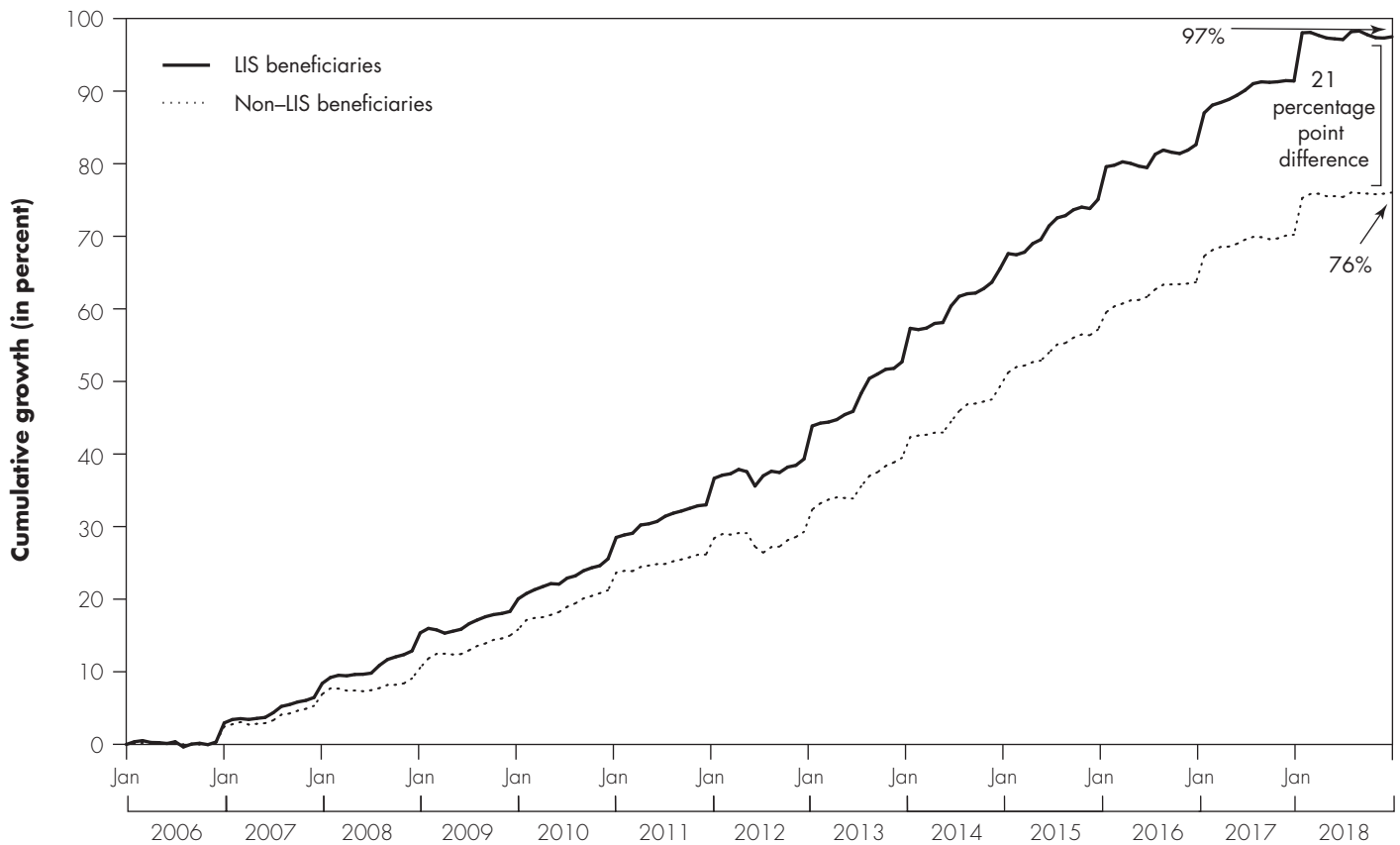
Beneficiary premiums are designed to cover the remaining 25.5 percent of the expected cost of basic benefits. In addition to monthly premiums, Part D enrollees also pay any cost sharing required by plan sponsors or, in the case of LIS enrollees, cost-sharing amounts set in law. (Part D’s low-income cost-sharing 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 2018, program spending (including expenditures for the RDS) rose from \$46.2 billion to \$83.4 billion (Table 14-10, p. 435), or an average 5.5 percent per year. In 2018, Medicare paid \$13.1 billion for direct subsidies, \$40.9 billion for individual reinsurance, \$28.6 billion for the LIS, and \$0.8 billion for the RDS.

**FIGURE
14-5**

Prices of drugs used by enrollees with the LIS, on average, grew more rapidly than for other enrollees, 2006-2018



Note: LIS (low-income subsidy). Chain-weighted Fisher price indexes. Prices are measured at the individual national drug codes that reflect total amounts paid to pharmacies (i.e., they do not reflect rebates or discounts from manufacturers and pharmacies).

Source: Acumen LLC analysis for MedPAC.

Medicare payments for individual reinsurance have grown faster than other components of Part D spending. Between 2007 and 2018, reinsurance payments rose at an average annual rate of 16.0 percent, compared with a decline of 2.6 percent per year for the capitated direct subsidy payments (Table 14-10).

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 were extremely high (Hartman et al. 2018). Rapid growth in POS prices and the high take-up of new high-priced hepatitis C treatments resulted in more enrollees reaching the OOP threshold. Changes made

by the ACA to close the coverage gap also contributed to reinsurance growth. Between 2010 and 2015, Part D experienced a double-digit increase in the number of enrollees without the LIS who reached the catastrophic phase, and Medicare spending for reinsurance grew correspondingly.

Medicare's reinsurance payments grew at a slower pace in 2016 and 2017 but ticked up in 2018. Unlike the period from 2010 to 2015, in 2016 and 2017, reinsurance grew annually at a more moderate 6.4 percent, due largely to deceleration in spending for hepatitis C drugs (Boards of Trustees 2019). In 2018, higher spending for specialty drugs led to 8.8 percent growth in reinsurance.

**TABLE
14-10**

Medicare’s reimbursement amounts for Part D

	2007	2010	2014	2015	2016	2017	2018	Average annual growth rate 2007–2018
Reimbursement amount (in billions):								
Direct subsidy*	\$17.6	\$19.6	\$18.5	\$18.1	\$17.1	\$14.6	\$13.1	-2.6%
Reinsurance	<u>8.0</u>	<u>11.2</u>	<u>27.2</u>	<u>33.2</u>	<u>35.5</u>	<u>37.6</u>	<u>40.9</u>	16.0
Subtotal, basic benefits	25.6	30.8	45.7	51.3	52.6	52.2	54.0	7.0
Low-income subsidy	16.7	21.1	24.3	25.6	26.4	27.3	28.6	5.0
Retiree drug subsidy	<u>3.9</u>	<u>3.9</u>	<u>1.3</u>	<u>1.1</u>	<u>1.0</u>	<u>0.9</u>	<u>0.8</u>	-13.4
Total Part D	46.2	55.8	71.3	78.0	80.0	80.4	83.4	5.5
Enrollee premiums**	4.1	6.7	10.5	11.5	12.7	14.0	14.2	12.0

Note: The numbers presented reflect reconciliation.
 *Net of risk-sharing payments using Part D’s risk corridors.
 **For basic benefits, excluding low-income premium subsidies.

Source: MedPAC analysis based on Table IV.B10 of the 2019 annual report of the Boards of Trustees of the Medicare trust funds.

Taxpayers bear increasing share of the risk for Part D spending

In 2018, premiums paid by Part D enrollees for basic benefits (not including the premiums paid by Medicare on behalf of LIS enrollees) totaled \$14.2 billion. That amount has grown by an average of 12 percent per year since 2007, reflecting primarily growth in enrollment and some increase in benefit costs.

Despite significant growth in catastrophic benefits, average premiums for basic Part D benefits have remained low, in part because Medicare’s reinsurance subsidy has offset benefit spending that would otherwise have increased plan premiums.³⁷ 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 14-6, p. 436).

Insurance risk provides an incentive for plan sponsors to offer attractive benefits while managing their enrollees’ spending through formularies and other tools. However, data from CMS’s Office of the Actuary show that between 2007 and 2018, the portion of the average basic benefit paid to plans through Medicare’s capitated direct subsidy fell from 56 percent to 19 percent (Figure 14-6, p. 436).

Correspondingly, the portion for which plans are at risk (direct subsidy payments plus enrollee premiums) accounted for only 40 percent of benefit costs in 2018, 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 60 percent over the same period.

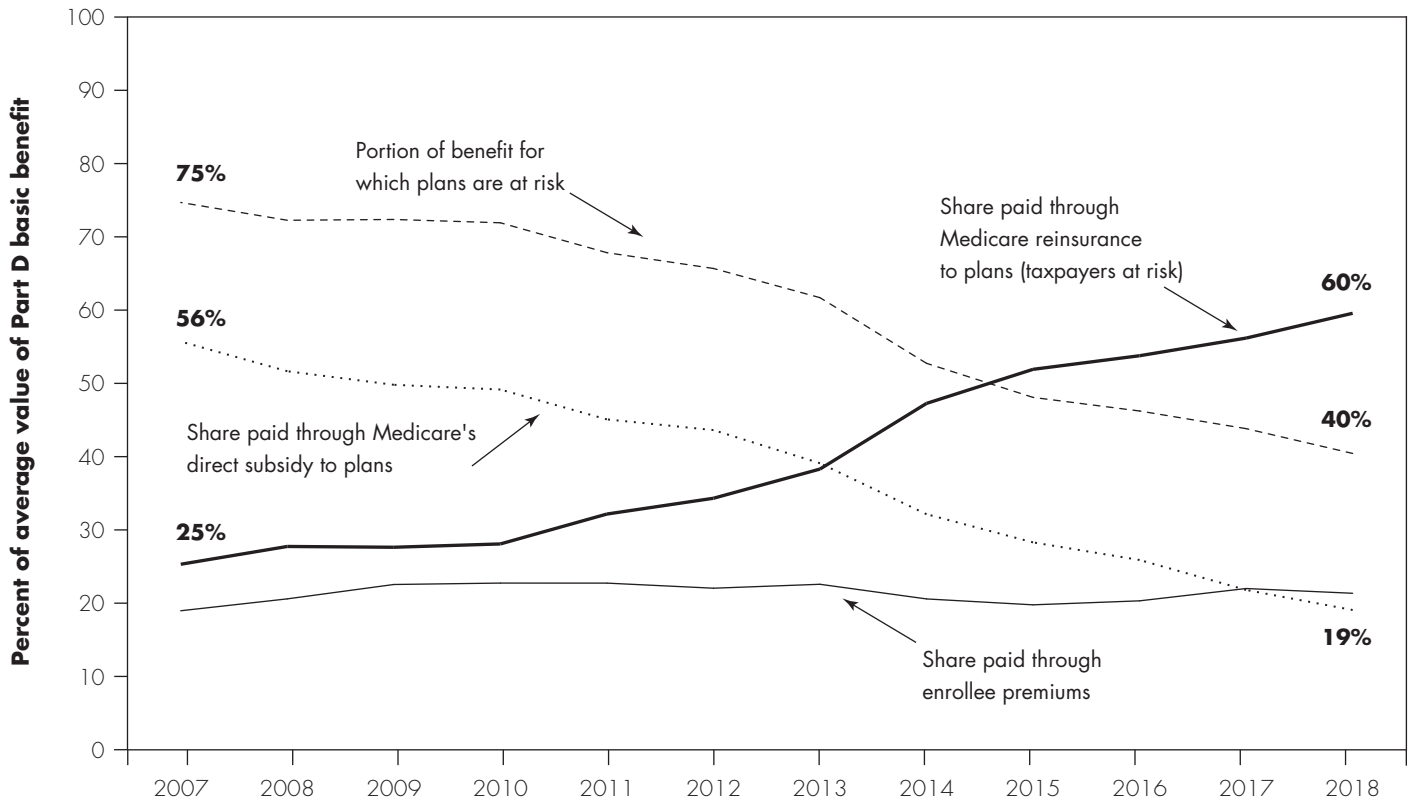
High-cost enrollees drive overall Part D spending growth

In 2017, 3.6 million (8 percent) of Part D enrollees had spending high enough to reach the catastrophic phase of the benefit, thus defining them as high-cost enrollees (Table 14-11, p. 437). Between 2010 and 2017, the number of high-cost enrollees rose at an annual rate of 6 percent, compared with 1 percent annually before 2010. After 2010, the share of high-cost enrollees without the LIS grew more rapidly than the share with the LIS—15 percent versus 4 percent annually. Nevertheless, in 2017, LIS enrollees accounted for 71 percent of high-cost enrollees (calculated on unrounded numbers).

Aggregate spending for high-cost enrollees (i.e., including catastrophic and noncatastrophic spending) grew from

**FIGURE
14-6**

Taxpayers bear increasing share of the risk for Part D benefit spending, 2007-2018



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 share paid through direct subsidy and the share 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.

about 40 percent of Part D spending before 2011 to 59 percent in 2017 (data not shown). That growth reflects a nearly 10 percent annual increase in per capita spending for high-cost enrollees compared with an annual 1.6 percent decrease in per capita spending between 2010 and 2017 for enrollees who did not reach the OOP threshold.

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 2017, the average price per standardized, 30-day prescription for high-cost enrollees grew at an annual rate of 9.4 percent, while the number of prescriptions filled per enrollee per month grew by just 0.3 percent. This pattern is in stark contrast to enrollees who did not reach the OOP threshold. The average price of their prescriptions fell 2.9 percent annually, while the number of prescriptions they used grew by 1.3 percent annually.

High-cost enrollees tend to use more brand-name drugs. For example, in 2017, their average generic dispensing rate was just under 75 percent, or about 13 percentage points below the overall Part D average. Some of this difference reflects situations in which brand-name

**TABLE
14-11**

Part D enrollees reaching the benefit's catastrophic phase, 2007-2017

	2007	2010	2012	2014	2015	2016	2017	Average annual growth rate	
								2007-2010	2010-2017
In millions									
LIS	1.9	2.0	2.1	2.5	2.6	2.6	2.6	1%	4%
Without LIS	0.4	0.4	0.5	0.9	1.0	1.1	1.0	-2	15
All	2.3	2.4	2.6	3.4	3.6	3.6	3.6	1	6
Share of all									
Part D enrollees	8.8%	7.9%	7.7%	8.6%	8.7%	8.3%	8.0%	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 2017 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.

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

Among high-cost enrollees, patterns of drug spending differ between enrollees with and without the LIS; specifically, spending for enrollees without the LIS has grown faster. Between 2007 and 2017, average annual spending rose a cumulative 218 percent for enrollees

without the LIS compared with 113 percent for LIS enrollees. By 2017, high-cost enrollees without the LIS had spending of \$32,597 per year compared with \$22,318 per year for those with the LIS.

In 2017, more than 378,000 enrollees (1 in 10 high-cost enrollees) had a single prescription that was sufficient to meet the out-of-pocket threshold, up from just 33,000 in 2010.³⁸ Among high-cost enrollees without the LIS, about 19 percent had such a prescription, compared with nearly 7 percent of high-cost LIS enrollees.

Differences in spending patterns are largely attributable to differences in the drug classes used by the two groups. One study found that, in 2015, enrollees without the LIS were more likely to use drugs to treat cancer, multiple sclerosis, rheumatoid arthritis, and pulmonary hypertension, while LIS enrollees 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 2017, among high-cost enrollees, spending on cancer drugs accounted for over 28 percent of spending by enrollees without the LIS, compared with under 7 percent for LIS enrollees. Drugs to treat mental health conditions, on the other hand, accounted for nearly 13 percent of spending for high-cost

**TABLE
14-12**

Examples of drugs used by high-cost enrollees for the treatment of prevalent conditions, 2017

	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 enrollees without LIS						
Revlimid (multiple myeloma)	\$2.5	\$0.06	\$39,222	\$2,236	\$1,387	\$974
Imbruvica (leukemia)	1.1	0.03	32,246	2,027	1,143	991
Ibrance (breast cancer)	0.9	0.03	32,200	2,036	1,092	1,053
Copaxone (multiple sclerosis)	0.8	0.03	21,532	1,546	795	789
						Low-income cost-sharing subsidy
High-cost LIS enrollees						
Harvoni (hepatitis C)	\$1.7	N/A	\$44,796	\$51	\$21	\$4,274
Humira Pen (inflammatory conditions)	1.2	N/A	17,052	7	1	2,213
Lyrica (anticonvulsant)	1.1	N/A	1,191	7	0	402
Lantus SoloStar (insulin)	0.9	N/A	1,138	7	0	378
Latuda (antipsychotic)	0.9	N/A	2,655	5	0	764

Note: OOP (out-of-pocket), LIS (low-income subsidy), N/A (not applicable). 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.

LIS enrollees, compared with less than 3 percent for high-cost enrollees without the LIS.

Drug classes used more heavily by high-cost enrollees without the LIS tended to have higher prices than the drug classes used more heavily by high-cost LIS enrollees (Table 14-12). For example, in 2017, the annual cost of drugs to treat cancers such as multiple myeloma and leukemia, which were used more heavily by high-cost enrollees without the LIS, averaged over \$30,000 per person. With some exceptions such as treatments for hepatitis C and anti-inflammatory drugs, medicines used by larger numbers of LIS enrollees tended to have lower annual costs per beneficiary.

For selected medications used to treat prevalent conditions, annual cost-sharing amounts paid by high-cost enrollees

without the LIS averaged between \$1,546 and \$2,236 (6 percent to 7 percent of the total annual costs of those medications). For all medications, 50 percent or more of OOP costs were incurred in the catastrophic phase of the benefit. Manufacturers paid, on average, between \$789 and \$1,053 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 enrollees' total cost-sharing liability.

High-cost LIS enrollees pay much lower cost sharing out of pocket than those without the LIS. In 2017, average annual OOP spending for high-cost LIS enrollees for the selected medications averaged between \$5 and \$51 because Part D's LIS pays nearly all of the cost-sharing liability on their behalf. Medicare's low-income cost-

sharing subsidy paid \$378 to \$4,274 for the selected medications (Table 14-12), accounting for between 10 percent and about one-third of each medication's total cost.

Use of higher cost drugs poses challenges for Part D

Food and Drug Administration 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).³⁹ 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 (Medicare Payment Advisory Commission 2019c).⁴⁰ (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 since most sponsors had a formulary that included a specialty tier by 2008, and nearly all plan sponsors had a specialty tier by 2010.) As a result, in 2017, specialty-tier drugs accounted for 25 percent of gross spending in Part D, up from about 6 percent to 7 percent before 2010.

Drugs with very high prices pose a challenge for Part D because most of their costs fall in the catastrophic phase of the benefit, where Medicare takes most of the insurance risk. Coinsurance on high-priced medicines is increasingly burdensome for both enrollees with and without the LIS, but Medicare (and thus taxpayers) pays most or all of the cost-sharing liability for LIS enrollees.

To ensure that the Part D program remains affordable for enrollees 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 Part D enrollees. The Commission's 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.

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 tool used by plan sponsors to strike this balance.

Greater flexibility to use formulary tools could help plan sponsors manage spending while ensuring that prescribed medicines are safe and appropriate for the patient, potentially reducing overuse and misuse. However, for some Part D enrollees, those same tools could potentially limit access to needed medications. To ensure access, CMS reviews each plan's formulary to check that it includes medicines in a wide range of therapeutic classes used by the Medicare population and applies utilization management tools in appropriate ways. Further, Part D law requires sponsors to have a transition process to ensure that new enrollees, as well as current members whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.⁴¹ Medicare also requires plan sponsors to establish a process for coverage determination and appeals.

For some enrollees, certain structural factors in Part D lead to coverage denials at the pharmacy or delays in filling prescriptions (Office of Inspector General 2019). Even with plan notifications and online information, prescribers and beneficiaries can become confused about whether a plan covers certain medicines when formularies change from year to year. CMS requires plan sponsors to make coverage determinations in a relatively short time frame; otherwise, the request is automatically denied and advanced to the plans' redetermination or appeals processes. There are limits as to what available data can tell us about how well Part D's exceptions and appeals processes work. A more constructive approach toward ensuring appropriate access would be to provide enrollees and prescribers with real-time information about formulary coverage and utilization management

requirements in ways that fit into providers' workflow at the point of prescribing.

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 his or her plan's formulary or because more information is needed from the prescriber under the plan's utilization management requirements. Pharmacies must provide the enrollee with written information on how to obtain a detailed notice from his or her plan about the reason the benefit was denied and the right to appeal. The enrollee must contact the plan for the basis of the denial and engage his or her prescriber to initiate a request for a coverage determination with supporting justification from the prescriber.

Part D requires quicker adjudication times than for most medical benefits covered by Medicare Advantage plans: Sponsors must make coverage determination and exception decisions within 72 hours of a request or within 24 hours for expedited requests. The adjudication time frame begins at the point the plan receives a formulary or tiering exceptions request. If the initial exceptions request does not include the necessary supporting statement, the plan has up to 14 calendar days to obtain the information. If the plan does not receive a supporting statement within 14 calendar days, it must notify the enrollee of its decision within 72 hours (24 hours for expedited cases) from the end of the 14 calendar days. If the enrollee is dissatisfied with the outcome of those steps, he or she may appeal the decision to an independent review entity (IRE) and then to higher levels of appeal.

Until recently, CMS required Part D plan sponsors to report data on rejected pharmacy claims. However, that information provides only limited insight into the exceptions and coverage determination process because counts of pharmacy claims and rejections often contain duplicate records.⁴² Moreover, data are not available on what happens once a plan rejects a claim—whether the beneficiary was ultimately able to fill the original prescription and whether he or she paid cash for the original drug, took home an alternative therapy, or abandoned the prescription.

With those limitations in mind, CMS data show that in 2017, 83.8 million (3.5 percent) of 2.4 billion Part D transactions were rejected at the pharmacy because the drug was not on the plan's formulary or because of plan requirements for prior authorization, quantity limits, or

step therapy (Centers for Medicare & Medicaid Services 2019c, Office of Inspector General 2019). Of those reported rejections, 8.1 million claims proceeded to a plan coverage determination and more than 70 percent were ultimately approved. Plan sponsors approved 5.3 million (65 percent) of the requests and denied 2.8 million (35 percent) (Office of Inspector General 2019).⁴³ About 745,000 of the denied determinations were subsequently appealed or sent on automatically for plan redetermination, and sponsors overturned nearly 539,000 (73 percent) of their own drug coverage denials.

Currently, the IRE reports information about cases in the IRE step of the appeals process to CMS, which uses these data for measures in Part D plans' star ratings. In 2017, nearly 35,000 cases (less than 5 percent of redeterminations) were appealed or automatically forwarded to an IRE (Office of Inspector General 2019). In 2018, the number of cases appealed or forwarded to an IRE was much lower—less than 29,000 (Centers for Medicare & Medicaid Services 2019k). CMS has noted gaps in data on IRE appeals, but when data were reported and validated, the IRE agreed with the plans' redetermination decisions most of the time. Going forward, the agency has decided to discontinue use of these data in star ratings as of 2022 due to concerns about data reliability (Centers for Medicare & Medicaid Services 2019d).

In past years, CMS analyzed pharmacy rejections data to see whether sponsors administered formularies and transition policies in ways consistent with Part D requirements and displayed the results on CMS.gov. However, as of 2019, sponsors are no longer required to submit rejected pharmacy claims unless under audit. The agency contends that by 2018, failure rates were low: Only 3 percent of contracts exceeded CMS's threshold of noncompliance for transition fills, and 1 percent exceeded its formulary administration threshold. CMS also considered the reporting requirement burdensome to plans and duplicative of audits (Centers for Medicare & Medicaid Services 2019d).⁴⁴ OIG notes, however, that a sponsor would need to reject more than one in five pharmacy claims inappropriately to reach the threshold that CMS used to evaluate formulary administration (Office of Inspector General 2019). OIG found that 17 percent of Part D contracts had at least one inappropriate rejection in 2017.

CMS audits a selection of sponsoring organizations each year for compliance with program requirements,

ultimately covering most plan sponsors over its several-year work cycle. Because the agency had already audited most larger plans previously, in 2018, two-thirds of audited sponsors had 15,000 or fewer enrollees (Centers for Medicare & Medicaid Services 2019a). Compared with audits conducted in 2017, sponsors' audit performances were better for formulary and benefit administration, but slightly worse for coverage determinations, appeals, and grievances.

Rather than relying on the exceptions and appeals process, a better approach would be to resolve questions about coverage with electronic tools such as real-time benefit check (RTBC) and electronic prior authorization (ePA). These tools could reduce the need for appeals and increase the likelihood that beneficiaries receive an appropriate medicine in a timely manner. If built into the prescriber's workflow, standardized approaches to ePA and automated coverage determinations could also save patients and providers significant time and resources and speed up delivery of care (American Medical Association–convened workgroup of 17 state and specialty medical societies 2019). In 2019, CMS finalized a rule requiring Part D sponsors to implement one or more RTBC tools capable of integrating with at least one prescriber's electronic health record system by January 1, 2021 (Centers for Medicare & Medicaid Services 2019i). However, the extent to which this requirement increases the use of RTBCs in Part D will depend on the degree to which clinicians—who face no requirements under this rule—adopt them when prescribing for their Medicare patients.

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 period. CMS also requires plan sponsors to carry out medication therapy management (MTM) programs to improve the quality of pharmaceutical care for high-risk beneficiaries. Although the Commission supports CMS's goal of improving medication management, we

have ongoing concerns about the effectiveness of plans' MTM programs. In 2017, CMS began a new, enhanced MTM model.

Measuring plan performance

CMS collects Part D quality and performance data at the contract level from several sources—the Consumer Assessment of Health Providers and Systems® (CAHPS®) survey, agency monitoring of plans, data furnished by plan sponsors, and claims information (Centers for Medicare & Medicaid Services 2019f). 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 period. The lowest rated plans are flagged to caution beneficiaries about choosing those plans. The highest rated plans can enroll beneficiaries outside the annual open enrollment period. In addition, for MA–PDs, Part D performance data affect the MA program's overall plan ratings used to determine the amount of bonus payment.

For 2020, 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 2019f). Intermediate outcome measures (four metrics, including adherence to selected classes of medications) typically each receive a weight of 3, but one (statin use in persons with diabetes) received a weight of one because it was a new measure. 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. Two process measures (pertaining to drug price accuracy and medication management) receive a weight of 1.0. 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 2019b). Most MA–PDs are rated on up to 47 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 2020 (weighted by 2019 enrollment) increased to 3.50 from 3.34 a year earlier (Centers for Medicare &

Medicaid Services 2019b). About 42 percent of PDP enrollees (based on 2019 enrollment) are in 2020 contracts (covering one or more plans) with 3.5 stars, and another 28 percent are in contracts with 4 or more stars. Among MA–PDs offered for 2020, the average star rating increased to 4.16 from 4.06 for 2019. Based on 2019 enrollment, CMS estimated that 81 percent of MA–PD enrollees were in contracts rated 4 or more stars for 2020. 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 10 of the 14 measures. 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 ratings and the comparison between PDPs and MA–PDs.⁴⁵

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

Medication therapy management programs

Part D plans are required to implement MTM programs to optimize therapeutic outcomes and reduce adverse drug events through improved medication use among beneficiaries who have multiple chronic conditions, take multiple medications, and are likely to have drug spending that exceeds an annual cost threshold (\$4,255 for 2020).

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.⁴⁶ CMS has changed the criteria for MTM programs over time to broaden eligibility. Our earlier review of MTM programs revealed wide variations in eligibility criteria and the kinds of interventions provided to enrollees (Medicare Payment Advisory Commission 2009). Today, plan sponsors can no longer set narrower eligibility criteria than requiring beneficiaries to have more than three chronic conditions or use more than eight medications (Centers for Medicare & Medicaid Services 2019e).

In focus groups convened for the Commission in 2017, the physicians we spoke with were more aware of plans’ medication management efforts, 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 data found lower rates of medication reviews among MTM enrollees in PDPs compared with those in MA–PDs. Further, the effectiveness of the current MTM services in improving the quality of overall patient care is unclear (Centers for Medicare & Medicaid Services 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 would 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, 2017.⁴⁷

In November 2018, CMS released the performance results for 2017, the first year of the enhanced MTM model (Centers for Medicare & Medicaid Services 2018f). However, CMS notes that these results are based on a comparison of plans’ spending relative to benchmark spending and are not results from an independent evaluation of the model. 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 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 subsequent year. During the second year of the model (2018), more plans were eligible to receive the performance-based payments. CMS estimates that, across all plans participating in the model, Part D expenditures were \$684 million (3.5 percent) lower than the anticipated benchmark. This reduction is net of the added cost of the enhanced MTM programs. CMS expects that both enrollment and savings increased in 2019.

According to CMS, in 2018 (the second performance year), among the 22 participating plans:

- 14 plans (64 percent) reduced medical spending by 2 percent or more;
- 6 plans (27 percent) reduced medical spending by less than 2 percent; and
- 2 plans (9 percent) increased medical spending.

As a result, half of the participating plans will receive a higher premium subsidy (an additional \$2 per member per month) in 2020. Forthcoming evaluation reports will provide more thorough estimates of the model’s effects.

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 about the characteristics of MTM programs and the kinds of intervention strategies that have been 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, the LIS enrollee must pay the difference between the plan's premium and the benchmark amount. In 2019, 1 million LIS enrollees (8 percent) paid some of their plan's premium, averaging \$24 per month (Cubanski et al. 2019). 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.
- 2 Under CMS's de minimis policy, plan sponsors may voluntarily waive the portion of the monthly adjusted basic beneficiary premium that is above the LIS benchmark for a subsidy-eligible individual, up to a de minimis amount. The de minimis amount for 2020 is \$2.
- 3 For example, in 2020, 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 2019d).
- 4 Part D's low-income subsidy (LIS) has two components: low-income premium subsidies and low-income cost-sharing subsidies. The latter makes up more than 85 percent of combined LIS spending.
- 5 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 plans sponsors to use selected tools to manage specialty drug costs while maintaining appropriate access to needed medications.
- 6 Specifically, the EGWP direct subsidy is calculated as the Part D national average monthly bid amount adjusted by each enrollee's risk score minus the national base beneficiary premium.
- 7 If a plan's benefit spending, excluding reinsurance, is substantially higher or lower than the plan sponsor anticipated in its bid, Medicare limits each plan's overall losses or profits through risk corridors.
- 8 However, CMS also clarified rules for adjudicating EGWP claims that straddle the coverage gap and the out-of-pocket threshold in a way that delays the point at which the beneficiary reaches the catastrophic phase, which reduced the amount of discount EGWPs receive relative to the previous method of adjudicating claims (Angeloni and Margiott 2016).
- 9 A portion of the difference between an MA plan's payment benchmark and its bid for providing Part A and Part B services is referred to as "MA rebate dollars." Plan sponsors can use MA rebate dollars to supplement benefits or lower Part D or MA premiums.
- 10 After the end of each benefit year, CMS reconciles what plans expected to receive in reinsurance subsidies from Medicare with reinsurance due based on 80 percent of their enrollees' actual catastrophic spending net of rebates. On net, Medicare has made additional payments to plans for individual reinsurance at reconciliation in nearly every year through 2017, meaning that actual costs were higher than plans' expected reinsurance costs that were used to calculate enrollee premiums. These additional payments effectively result in a higher overall Medicare subsidy rate than the 74.5 percent target set in law (see discussion on Medicare's subsidy rate on p. 435).
- 11 However, the agency maintained a meaningful-difference requirement between a sponsor's basic and enhanced benefit packages.
- 12 Most MA plans are MA-PDs, offering combined medical and outpatient drug benefits. However, a small share of MA plans (including Medicare Savings Account plans) do not offer prescription drug coverage.
- 13 In 2019, Humana Walmart Rx had an average monthly premium of \$28, while the Humana Enhanced plan's premium averaged \$76. For 2020, enrollees in Humana Premier Rx pay an average of about \$57 per month.
- 14 Aetna agreed to sell its PDP business to obtain regulatory approval of CVS Health's purchase of Aetna.
- 15 That number includes 51 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, 14 percent voluntarily switched plans during the annual enrollment period (Hoadley et al. 2015).

- 17 Medicare Plan Finder also provides information about FFS Medicare, Medigap supplemental policy options, and Part A and Part B coverage provided through Medicare Advantage plans.
- 18 In 2018, Cigna’s purchase of Express Scripts was finalized. Regulators approved CVS Health’s merger with Aetna in 2019 after Aetna agreed to divest its PDPs, which it sold to WellCare.
- 19 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.
- 20 Generic substitution can lead to substantial savings. By one estimate, if Part D enrollees had substituted generics for brand-name drugs that have the same active ingredient, the Medicare program and beneficiaries would have saved \$2.8 billion in 2016 (Assistant Secretary for Planning and Evaluation 2018).
- 21 Participating plan sponsors are eligible for performance-based payments based on realized savings (or costs) relative to a predetermined benchmark. Few details about the arrangements are available publicly at this point.
- 22 For example, a recent study examined 57 PDP formularies offered in the Part D marketplace in 2016. Researchers found that for drugs that had both brand and generic versions available (multisource drugs), 72 percent of the formularies placed at least one branded drug on a lower cost-sharing tier than the generic. Thirty percent of the formularies placed fewer utilization management requirements on at least one of the branded products than its generic version (Socal et al. 2019).
- 23 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.
- 24 Critics contend that the way in which plan sponsors and their PBMs calculate these postsale payments, known as 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 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).
- 25 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.
- 26 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).
- 27 This provision would have applied also to Medicaid managed care plans. Additionally, the proposal would have required that manufacturers’ payments to PBMs take the form of flat fees that reflect the fair market value for services rather than a share of sales or sales based on volume.
- 28 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, but also pharmacy concessions after the point of sale—amounted to 27.3 percent of total drug costs (averaged across all drugs, including those for which plans do not receive any rebates) (Boards of Trustees 2019). 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.

- 29 An individual NDC uniquely identifies the drug’s labeler, drug, dosage form, strength, and package size.
- 30 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.
- 31 Under a separate regulatory pathway that uses a new drug application approach, the FDA has also approved follow-on biologics reimbursable under Part D such as Basaglar, a recombinant human insulin analog similar to Lantus.
- 32 According to the FDA, a biosimilar product is “highly similar to the reference product notwithstanding minor differences in clinically inactive components” and “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product” (Food and Drug Administration 2015). An interchangeable product is an approved biosimilar that (1) can be expected to produce the same clinical result as the reference product in any given patient and (2) has no higher risk than the reference product in terms of safety or diminished efficacy when the patient switches between the biosimilar and the reference product. To demonstrate interchangeability, applicants must show that the product can be expected to produce the same clinical result as the originator biologic for *all* of the originator’s licensed conditions of use. In many cases, the FDA expects to see evidence from additional clinical studies on variation in treatment effectiveness when patients switch between therapies, as well as additional studies of immunogenicity. However, the FDA acknowledged recently that because the structure of insulin molecules is well understood, approval of follow-on insulins would require lower regulatory hurdles for an interchangeable designation than other types of biosimilars (Food and Drug Administration 2019). The European Medicines Agency, which evaluates and monitors pharmaceuticals for use in the European Union, grants designations only of biosimilarity rather than interchangeability (substitutability).
- 33 Enbrel was approved and launched in 1998. Humira was approved in 2002 and launched in 2003.
- 34 For example, 247 patent applications have been filed for Humira in the U.S. and 57 for Enbrel (I-MAK 2017a, I-MAK 2017b).
- 35 Relative to generic drugs, the process for resolving patent litigation around biologics is more complex. Under the law that guides generic entry, manufacturers of brand-name, small-molecule drugs must list all patents related to the drug in the FDA’s Orange Book. This requirement defines the scope of patent litigation for generic applicants as they decide when to launch products. Because of the intricacies of manufacturing biologics, there is no parallel requirement for manufacturers of originator biologics. Instead, biologics law lays out a so-called patent dance—a procedure with strict sequencing and timing that involves an exchange of information between the originator’s sponsor and the biosimilar applicant to identify patents that might be infringed (Chen et al. 2017).
- 36 The propensity of a therapeutic protein product to generate an immune response to itself or to related proteins is called *immunogenicity*. As in the case of vaccines, some immune responses are intentional. Others are not, and although many are benign, reactions can be clinically significant and range from loss of efficacy to anaphylaxis to neutralization of the body’s own endogenous proteins. Both patient-specific factors and product-specific factors can affect immunogenicity.
- 37 Growth in manufacturer rebates and postsale pharmacy fees, the increase in the coverage-gap discount for brand-name drugs, and the entry of relatively large cohorts of younger enrollees into Part D are other reasons that average premiums have remained stable.
- 38 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.
- 39 Although there is no consistent definition of specialty drugs, they tend to be characterized as high cost, are used to treat a rare condition, require special handling, are provided by a limited distribution network, or require ongoing clinical assessment. Most biologics are a subset of specialty drugs (*American Journal of Managed Care* 2013).
- 40 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.

- 41 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.
- 42 Claims processing between pharmacies and PBMs is highly automated. Duplicates can arise, for example, when a physician writes multiple prescriptions to test the beneficiary's plan coverage or when a pharmacist submits a claim multiple times while waiting for an approval decision (Office of Inspector General 2019).
- 43 The numbers of coverage determinations and appeals exclude cases that were dismissed or withdrawn.
- 44 The agency still evaluates some contracts annually to see whether the formularies posted on plan websites are consistent with agency-approved formularies. CMS also continues to monitor the timeliness of coverage determinations and redeterminations by plan sponsors.
- 45 As noted in Chapter 13, a recent legislative change has made it more difficult for plan sponsors to benefit from consolidating plans that have lower star ratings with another plan that has a higher star rating. However, consolidations that took place prior to the law change may continue to benefit plan sponsors.
- 46 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).
- 47 CMS is testing the Enhanced Medication Therapy Management model in 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 these regions based on variation in market competition and other characteristics, such as variation in Part A and Part B spending. CMS also wants to generate results that can be compared across regions and that are (in aggregate) broadly representative of national market characteristics (Centers for Medicare & Medicaid Services 2018f).

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