

CHAPTER

14

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

R E C O M M E N D A T I O N

- 14** The Congress should change Part D's coverage-gap discount program to:
- require manufacturers of biosimilar products to pay the coverage-gap discount by including biosimilars in the definition of "applicable drugs" and
 - exclude biosimilar manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

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

Chapter summary

In 2016, Medicare spending and enrollee premiums for Part D benefits totaled \$91.6 billion, accounting for over 13 percent of all Medicare outlays. Enrollee premiums made up \$12.7 billion of that total, and enrollees paid additional cost-sharing amounts. In 2017, 42.5 million individuals (72.5 percent of all Medicare beneficiaries) were enrolled in Part D plans; 59 percent were in stand-alone prescription drug plans (PDPs), and 41 percent were in Medicare Advantage–Prescription Drug plans (MA–PDs). In general, Part D plans are available to all Medicare beneficiaries.

Each year, the Commission provides a status report on the Medicare prescription drug benefit established under Part D that describes beneficiaries’ access to prescription drugs: enrollment levels, plan benefit designs, and the quality of Part D services. The report also analyzes changes in plan bids, premiums, and program costs. The Commission makes recommendations as necessary, and this year’s report includes a recommendation related to biosimilars. (See text box on p. 426 for background on biosimilars.)

For the past two years, the Commission has noted its concern that a growing share of program spending has been for high-cost enrollees—beneficiaries who reach the catastrophic phase of Part D’s benefit. This year’s status report provides further evidence that this trend has continued, and we point to factors that contribute to greater catastrophic spending. The Commission’s June

In this chapter

- Enrollment, plan choices in 2017, and benefit offerings for 2018
- Plan sponsors and their tools for managing benefits and spending
- Drug pricing
- Program costs
- Biosimilars in Medicare Part D
- Beneficiaries’ access to prescription drugs
- Quality in Part D

2016 recommendations address concerns about Part D's financial sustainability and affordability for its enrollees while maintaining the program's market-based approach.

Medicare beneficiaries' drug coverage in 2017 and benefit offerings for 2018— Among the 42.5 million individuals enrolled in Part D plans in 2017, 12.2 million received the low-income subsidy (LIS), while 30.3 million were enrolled in plans and did not receive the LIS. Three percent of all Medicare beneficiaries (1.6 million individuals) received drug coverage through employer-sponsored plans that received Medicare's retiree drug subsidy. The nearly 25 percent of Medicare beneficiaries not enrolled in a Part D plan or in an employer plan receiving the retiree drug coverage subsidy were divided roughly equally between those who had creditable drug coverage (i.e., benefits at least as generous as Part D) from other sources and those with no coverage or coverage less generous than Part D.

For 2018, plan sponsors are offering 782 PDPs and 2,003 MA-PDs, about 5 percent and 16 percent, respectively, more plans than in 2017. Beneficiaries continue to have broad choice among plans—between 19 and 26 PDPs to choose from, depending on where they live, as well as typically 10 or more MA options. MA-PDs continue to be more likely than PDPs to offer enhanced benefits, using some of their (non-Part D) MA payments to lower their deductibles and reduce Part D premiums. For 2018, 216 premium-free PDPs are available to enrollees who receive the LIS, a 6 percent decrease from 2017. With the exception of one region (Florida), all regions continue to have at least 3 and as many as 10 PDPs available at no premium to LIS enrollees.

In 2018, the 10 PDPs with the highest 2017 enrollment continue to use a 5-tier formulary with differential cost sharing among preferred generics, other generics, preferred brand-name drugs, nonpreferred drugs, and specialty-tier high-cost drugs. Over time, many plan sponsors have moved from charging fixed-dollar copayments to charging coinsurance for certain tiers. In fact, the top 10 PDPs by enrollment use coinsurance rather than fixed-dollar copayments for medications on nonpreferred tiers.

Part D program costs—Between 2007 and 2016, Part D program spending on an incurred basis increased from \$46 billion to \$79 billion (an average annual growth rate of about 6 percent). Medicare's reinsurance subsidy (which covers 80 percent of spending for enrollees who reach the catastrophic phase of the benefit) became the largest component of program spending in 2014 and has remained the fastest growing component, at an average annual growth rate of nearly 18 percent between 2007 and 2016. In 2016, a higher share of Medicare payments were retrospective,

cost-based reimbursement rather than prospective, risk-based payments—a result not contemplated in the original design of the program. Enrollees who incur spending high enough to reach the catastrophic phase of the benefit (high-cost enrollees) have been driving Part D program costs, accounting for 57 percent of gross spending in 2015, up from about 40 percent before 2011. Spending on a per enrollee basis for high-cost individuals grew by more than 10 percent per year between 2011 and 2015, and that growth was accounted for almost entirely by increases in the average price per prescription filled (reflecting both price inflation and changes in the mix of drugs used). Going forward, the pharmaceutical pipeline is shifting toward greater numbers of biologic products and specialty drugs, many of which have high prices. The use of high-priced drugs by Part D enrollees will likely grow and put significant upward pressure on Medicare spending for reinsurance and the LIS.

Financial disincentives to use biosimilars in Part D—Biologics make up a fast-growing segment in the biopharmaceutical sector and will continue to grow in importance. Biosimilars are expected to have lower prices than originator biologics. However, the take-up of biosimilars in Part D may be dampened by certain Part D policies. To rectify financial incentives that disadvantage biosimilars, the Commission recommends applying the same discount that manufacturers of originator biologics and brand-name drugs provide in the coverage gap to biosimilar products. Consistent with the Commission’s 2016 recommendations, discounts on biosimilars would not count as though they were an enrollee’s own out-of-pocket (OOP) spending for purposes of determining when an enrollee reached Part D’s catastrophic phase. (Subsequent to the Commission’s vote on this recommendation, the Bipartisan Budget Act of 2018 directed biosimilar manufacturers to, beginning in 2019, provide a discount on their products in the coverage gap. However, unlike the Commission’s recommendation, the discount amount would continue to count as though it were the enrollees’ own OOP spending.) To the extent that the adoption of the Commission’s set of recommendations results in net program savings, the Congress could consider enhancing protections for non-LIS enrollees facing high cost-sharing burdens.

Access to prescription drugs—Giving plans greater flexibility to use management tools could help ensure that prescribed medicines are safe and appropriate for the patient and could potentially reduce overuse or misuse. However, for some beneficiaries, those same tools could also limit access to needed medications. Plan sponsors must strike a balance between providing access to medications while encouraging enrollees to use lower cost therapies through their formulary designs. Medicare requires plan sponsors to establish coverage determination and appeals

processes with the goal of ensuring access to needed medications. Beneficiary advocates, prescribers, plan sponsors, and CMS have all noted frustrations with Part D coverage determinations, exceptions, and appeals processes. A more efficient approach would be to resolve such issues at the point of prescribing through e-prescribing and electronic prior authorization (ePA) rather than at the pharmacy counter, but there are obstacles to their full adoption. Perhaps the most essential requirement for adoption of ePA is clinician acceptance and use, which can require paying fees and embracing practice pattern change.

Quality in Part D—In 2018, the average star rating among Part D plans increased somewhat for PDPs and remained about the same for MA–PDs. 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 Part D prescription drug services is different from the provision of medical services, quality measures used currently for Part D may not help beneficiaries make informed choices among plan options. Part D plans are required to implement medication therapy management (MTM) programs to improve quality. In the past, the Commission has expressed concern about the effectiveness of plans’ MTM programs to improve the quality of pharmaceutical care. This year, program data and the Commission’s focus groups suggest some encouraging trends. For example, information provided by MTM programs helped some doctors address polypharmacy issues. However, we continue to be concerned that sponsors of stand-alone PDPs do not have financial incentives to engage in MTM. In 2017, Medicare began testing enhanced MTM programs by providing incentives for selected stand-alone PDPs to conduct medication reviews and tailor drug benefit designs that encourage adherence to appropriate drug therapies. Six Part D sponsors operating PDPs in five regions of the country are participating in CMS’s enhanced MTM model. ■

**TABLE
14-1**

Parameters of the defined standard benefit increase over time

	2006	2017	2018	Average annual growth rate 2006–2018
Deductible	\$250.00	\$400.00	\$405.00	4.1%
Initial coverage limit	2,250.00	3,700.00	3,750.00	4.3
Annual out-of-pocket spending threshold	3,600.00	4,950.00	5,000.00	2.8
Total covered drug spending at annual out-of-pocket threshold	5,100.00	8,071.16*	8,417.60*	4.3
Minimum cost sharing above annual out-of-pocket threshold:				
Copayment for generic/preferred multisource drugs	2.00	3.30	3.35	4.4
Copayment for other prescription drugs	5.00	8.25	8.35	4.4

Note: *An individual’s total covered drug spending at the annual out-of-pocket threshold depends on each enrollee’s mix of brand-name and generic drugs filled in the coverage gap. The amounts for 2017 and 2018 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.

Source: Centers for Medicare & Medicaid Services 2017c.

Background

In 2017, 42.5 million Medicare beneficiaries were enrolled in Part D plans. Since 2006 (the year Part D began), the share of beneficiaries with drug coverage increased from 75 percent to 88 percent.¹ Part D generally has improved beneficiaries’ access to prescription drugs, with plans available to all. Surveys indicate that Medicare beneficiaries enrolled in Part D continue to be satisfied with the Part D program and their plans (Healthcare Leadership Council 2017, Healthcare Leadership Council 2015).

Medicare subsidizes nearly three-quarters of the cost of a defined standard benefit or benefits with the same average value for Part D enrollees. (For additional background, see Part D payment basics (Medicare Payment Advisory Commission 2017b).) In 2016, Part D expenditures totaled \$91.6 billion on an incurred basis, accounting for over 13 percent of Medicare spending (Boards of Trustees 2017).² Part D enrollees paid \$12.7 billion of that amount in plan premiums, in addition to cost-sharing amounts. Each year, the Commission provides a status report on Part D that examines several performance indicators: enrollment patterns, plan benefit offerings, market structure, drug pricing, program costs, beneficiaries’ access to medications, and quality. The Commission also makes recommendations as necessary, and this year’s report includes a recommendation related

to biosimilars. (See text box on p. 426 for background on biosimilars.)

Part D’s approach

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

The design of the program is intended to give plan sponsors incentives to offer beneficiaries attractive prescription drug coverage while controlling growth in drug spending. Policymakers envisioned that plans would compete for enrollees based on premiums, benefit structure (e.g., deductible amounts), formularies, quality of services, and networks of pharmacies.

The drug benefit

Medicare defines a standard Part D benefit with most parameters changing at the same rate as the annual change in beneficiaries’ average drug expenses (Table 14-1). For 2018, the defined standard basic benefit includes a \$405 deductible and 25 percent coinsurance until the enrollee reaches \$3,750 in total covered drug spending. Enrollees

**TABLE
14-2****Three-quarters of Medicare enrollees received drug coverage through Part D, 2017**

	Beneficiaries	
	In millions	Percent of Medicare enrollment
Medicare enrollment	58.6	100%
Part D enrollment*		
In Part D plans	42.5	72.5
In plans receiving RDS	<u>1.6</u>	<u>2.7</u>
Total Part D	44.1	75.2**

Note: RDS (retiree drug subsidy). Part D plan enrollment figures are based on enrollment as of April 1, 2017.
 *Excludes federal government and military retirees covered by either the Federal Employees Health Benefits Program or the TRICARE for Life program.
 **The remaining 24.8 percent of beneficiaries not enrolled in Part D were divided roughly equally between those who had creditable drug coverage from other sources (such as the Federal Employees Health Benefits Program, TRICARE for Life, and the Department of Veterans Affairs) and those with no coverage or coverage less generous than Part D.

Source: MedPAC based on Table IV.B7 and Table V.B4 of the Medicare Boards of Trustees' report for 2017 and monthly Part D enrollment data as of April 1, 2017.

with spending above that amount pay cost sharing higher than 25 percent in the so-called coverage gap until they reach a threshold of \$5,000 in out-of-pocket (OOP) spending. That amount excludes cost sharing paid by most sources of supplemental coverage such as employer-sponsored policies. Above the OOP threshold, enrollees pay the greater of 5 percent coinsurance or \$3.35 to \$8.35 per prescription.

Part D includes a low-income subsidy (LIS) that provides assistance with premiums and cost sharing for individuals with low incomes and assets. Individuals who qualify for this subsidy pay zero or nominal cost sharing set by statute. In 2018, most individuals receiving the LIS pay between \$0 and \$3.35 for generic drugs and between \$0 and \$8.35 for brand-name drugs.

Before 2011, enrollees exceeding the initial coverage limit were responsible for paying the full negotiated price of covered drugs (usually not reflecting manufacturers'

rebates) up to the annual OOP threshold. Part D's OOP threshold is also known as a "true OOP" cap because it excludes cost sharing paid on behalf of a beneficiary by most sources of supplemental coverage, such as employer-sponsored policies and enhanced benefits provided by Part D plans. The Patient Protection and Affordable Care Act of 2010 (PPACA) directed CMS to phase out the coverage gap between 2011 and 2020. In 2018, cost sharing for prescriptions filled during the gap phase is 35 percent for brand-name drugs and 44 percent for generic drugs.³ An individual with no other source of drug coverage is estimated to reach the \$5,000 limit at just over \$8,400 in total drug expenses.⁴ In 2020 and thereafter, in the defined standard benefit, beneficiaries will pay 25 percent cost sharing for all drugs between the deductible and the OOP threshold. Manufacturers of brand-name drugs and originator biologics must provide a 50 percent discount during the coverage-gap phase of the benefit as a condition for Part D to cover their drugs.⁵ In addition, that discount is added to the enrollee's own spending for purposes of determining whether the enrollee has reached the OOP threshold.

Under current law, Part D's OOP threshold will increase by more in future years than it has in recent years. Because of a provision in PPACA that was intended to help close the coverage gap, Part D's OOP threshold has grown more slowly than the deductible and initial coverage limit (2.8 percent, compared with 4.1 percent and 4.3 percent, respectively (Table 14-1, p. 401)). As of 2018, cumulative growth in the OOP threshold was about 20 percentage points lower than the growth in the deductible and initial coverage limit. The law requires that, in 2020, the OOP threshold reverts to what it would have been had it grown at the same rate as other benefit parameters, meaning that, in 2020, Part D's OOP threshold will increase significantly and enrollees will remain in the coverage gap longer and could incur higher OOP costs. In their 2017 report, the Medicare Trustees projected that the OOP threshold would increase from \$5,250 in 2019 to \$6,650 in 2020 (Boards of Trustees 2017). In each year thereafter, the OOP threshold will increase by the rate of growth in per capita Part D spending—the same as for the deductible and initial coverage limit.

Most plan sponsors offer alternative benefit designs, such as a deductible lower than \$405 or tiered copayments rather than coinsurance. However, the alternative benefit must meet requirements for actuarial equivalence to demonstrate that they have the same average benefit value.

Once a plan sponsor offers a plan with basic benefits in a region, it can also offer up to two plans with additional drug coverage that supplements the standard benefit, called enhanced plans. Under current CMS guidance, plans must be “meaningfully different” from one another.⁶

Two avenues of competition in Part D

Part D plan sponsors compete to attract enrollees through low premiums, but sponsors do not set their premiums directly. Instead, plan sponsors submit to CMS bids 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 must pay a portion as a base beneficiary premium (\$35.02 in 2018) plus (or minus) any difference between their plan’s bid and the nationwide average bid (Medicare Payment Advisory Commission 2017b). 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. For example, 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.⁷ 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 at least one stand-alone PDP in each region is available to LIS enrollees at no premium.

This approach to subsidizing LIS enrollees also provides incentives for plan sponsors to control drug spending and bid low. If sponsors do so, they can win or maintain market share without having to incur marketing expenses for LIS enrollees. Each year, there is some turnover in benchmark plans—plans that qualify as premium free for LIS enrollees. If LIS enrollees are in a plan with a premium above the benchmark and do not choose a plan themselves, CMS reassigns these enrollees randomly

to a new benchmark plan. Instead of accepting the new assignment, LIS enrollees may choose a plan themselves. However, if their selected plan has a premium higher than the benchmark, they must pay the difference between the plan’s premium and the benchmark amount. Once LIS enrollees select a plan themselves, CMS no longer reassigns them to a new plan. Instead, the agency sends beneficiaries letters about premium-free plan options in the enrollee’s region.

Much of Part D’s original structure from 2006 reflects a system of federal subsidies and regulations designed to encourage broad participation of enrollees and private plan sponsors. Today, participation in the market for prescription drug plans is healthy, but the financial sustainability of Part D is a growing concern because of sizable increases in program expenditures for high-cost enrollees (those who reach Part D’s OOP threshold). In June 2016, the Commission recommended a combination of changes designed to address concerns and improve Part D for the future while maintaining the program’s market-based approach (see text box on the Commission’s 2016 recommendations, pp. 404–405). In this chapter, the Commission’s recommendation would add to prior recommendations by removing financial disincentives that may keep plan sponsors from placing biosimilars on their formularies.

Enrollment, plan choices in 2017, and benefit offerings for 2018

Over time, a growing proportion of Medicare beneficiaries has chosen to enroll in Part D partly because enrollment has shifted from retiree drug plans to Part D plans. Further, enrollment has grown faster in MA–PDs compared with stand-alone PDPs. In 2018, plan sponsors are offering 5 percent more PDPs and 16 percent more MA–PDs.

In 2017, three-quarters of Medicare beneficiaries were in Part D plans or employer plans that received Medicare’s retiree drug subsidy

In 2017, 42.5 million individuals—72.5 percent of 58.6 million total Medicare beneficiaries—were enrolled in Part D plans (Table 14-2). An additional 2.7 percent of beneficiaries obtained drug coverage through employer-sponsored plans that received Medicare’s retiree drug subsidy (RDS) for being the primary provider.⁸ The

The Commission's 2016 recommendations to improve Part D

In our June 2016 report to the Congress, the Commission recommended changes to prepare the Part D program for the future (Medicare Payment Advisory Commission 2016a). Many new biopharmaceutical products in the development pipeline will have substantially higher prices than previous treatments, even when alternative therapeutic products are available. This trend will exert strong upward pressure on premiums, cost sharing, and program costs.

One set of changes would give plan sponsors greater financial incentives to manage the benefits of 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 out-of-pocket (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. Because plan sponsors would anticipate lower reinsurance payments from Medicare, they would submit higher bids. However, at the same time that Medicare reduced its reinsurance, the program would make larger capitated payments to plan sponsors. Medicare's subsidy of basic Part D benefits would remain unchanged at 74.5 percent, but plan sponsors would receive more of that subsidy through capitated payments instead of open-ended reinsurance. Because Part D's risk adjusters would become more important

as a tool for counterbalancing plan incentives for selection, CMS would need to take steps to recalibrate the risk adjustment system.

At the same time, sponsors would be given greater flexibility to use formulary tools. The Commission recommended removing protected status from two out of the six drug classes in which plan sponsors must now cover all drugs on their formularies (antidepressants and immunosuppressants for transplant rejection), streamlining the process for formulary changes, requiring prescribers to provide supporting justifications with more clinical rigor when applying for exceptions, and permitting plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications (Medicare Payment Advisory Commission 2016a).

Other parts of the Commission's recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true OOP spending, but would also provide greater insurance protection to all enrollees not receiving the low income subsidy (LIS) by eliminating cost sharing above the OOP cap (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

(continued next page)

remaining 24.8 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.⁹

In recent years, enrollment has shifted into Part D plans from employer plans that had previously received the RDS (Figure 14-1, p. 406). This shift reflects changes made by PPACA that increased the relative generosity of the Part D benefit by eliminating the coverage gap and by altering the tax treatment of drug expenses covered by the RDS. Between 2010 and 2017, the number of beneficiaries whose employers received the RDS fell from 6.8 million

to 1.6 million. Over the same period, enrollment in Part D plans operated for employers and their retirees (employer group waiver plans, or EGWPs) grew from 2.4 million to 6.8 million.¹⁰

The share of Medicare beneficiaries covered under Part D has grown over time, as has the share of enrollees in plans that combine prescription coverage with medical benefits (MA-PDs). Between 2007 and 2017, the share of Medicare beneficiaries enrolled in Part D plans grew from about 54 percent to over 72 percent, an average rate of 6 percent annually (Table 14-3, p. 407). Enrollment in MA-PDs grew more rapidly than in PDPs (respectively, 9 percent vs.

The Commission's 2016 recommendations to improve Part D (cont.)

enhancing protections for non-LIS enrollees facing high cost-sharing burdens. Because enrollees who receive the LIS pay nominal cost-sharing amounts that provide little incentive to use lower cost drugs and biologics, the recommended improvements would also moderately increase financial incentives by directing the Secretary of Health and Human Services to modify some LIS copayments. The Commission's 2016 recommendations concerning Part D are as follows:

The Congress should change Part D to:

- **transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits,**
- **exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending, and**
- **eliminate enrollee cost sharing above the out-of-pocket threshold.**

The Congress should change Part D's low-income subsidy to:

- **modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred**

multisource drugs, or biosimilars when available in selected therapeutic classes;

- **direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars; and**
- **direct the Secretary to determine appropriate therapeutic classifications for the purpose of implementing this policy and review the therapeutic classes at least every three years.**

The Secretary should change Part D to:

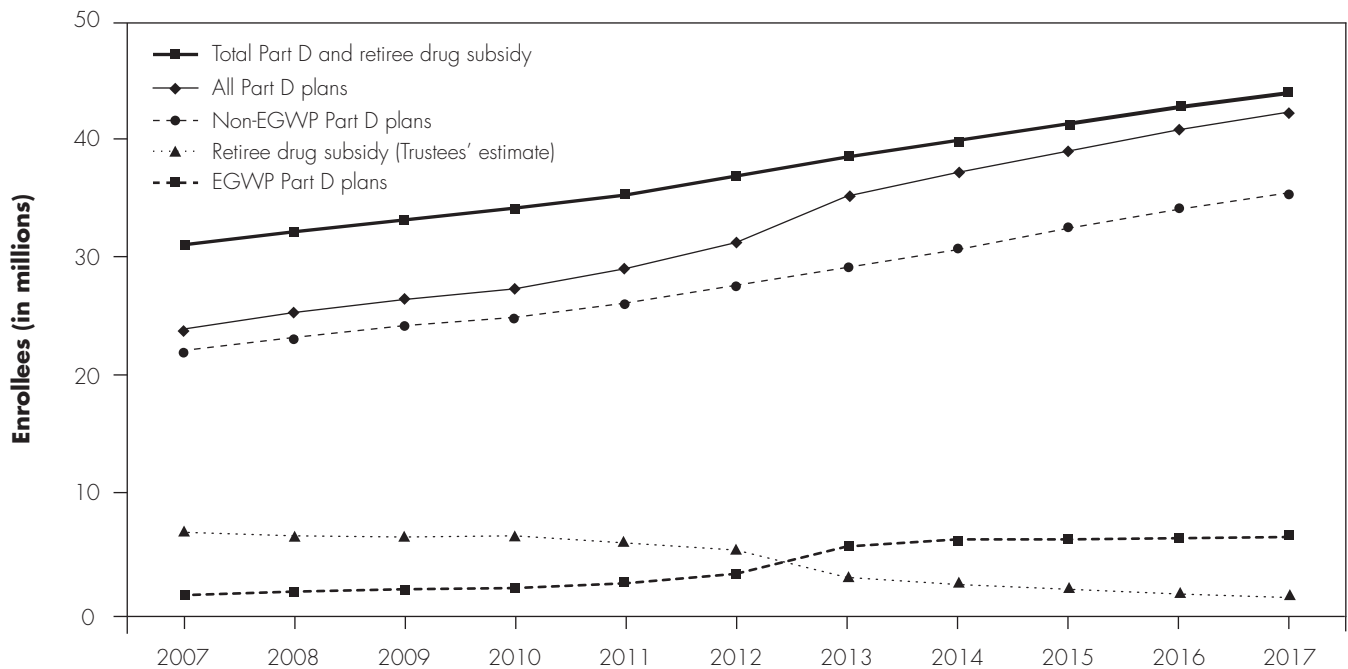
- **remove antidepressants and immunosuppressants for transplant rejection from the classes of clinical concern,**
- **streamline the process for formulary changes,**
- **require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions, and**
- **permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications. ■**

4 percent annually). In 2017, 41 percent of Part D enrollees were in MA-PDs compared with 30 percent in 2007. This trend in MA-PD enrollment is consistent generally with more rapid growth in MA enrollment than in fee-for-service (FFS) Medicare (see Chapter 13).

In 2017, 12.2 million beneficiaries with incomes at or below 150 percent of the federal poverty level (29 percent of Part D enrollees) received the LIS (data not shown). Of these individuals, nearly 8 million were dually eligible for Medicare and Medicaid. The remaining LIS enrollees qualified either because they received benefits through the Medicare Savings Programs or Supplemental Security

Income program or because they were eligible after they applied directly to the Social Security Administration. Compared with non-LIS enrollees, LIS enrollees are more likely to be female; more than twice as likely to be African American, Hispanic, or Asian; and over four times more likely to be under age 65 (Medicare Payment Advisory Commission 2017a).

Between 2007 and 2017, enrollment growth for Part D enrollees who received the LIS was slower (3 percent per year) than for non-LIS enrollees (7 percent per year) (data not shown). The faster growth in enrollment of non-LIS enrollees is partly attributable to the recent growth

**FIGURE
14-1****Enrollment in Part D plans has increased over time, with fewer employers receiving Medicare's retiree drug subsidy**

Note: EGWP (employer group waiver plan).

Source: MedPAC based on CMS Part D enrollment data and Table IV.B7 of the 2017 annual report of the Boards of Trustees of the Medicare trust funds.

in EGWPs that shifted beneficiaries to Part D plans from employer plans that had previously received the RDS. Consequently, the share that received the LIS fell from 39 percent to 29 percent. About 64 percent of LIS enrollees (7.8 million) were in PDPs; the rest were in MA-PDs (data not shown). Most individuals receiving the LIS are enrolled in traditional Medicare rather than MA. If these individuals do not choose a Part D plan themselves, CMS autoassigns them randomly to benchmark plans, all of which are PDPs. However, LIS enrollment in MA-PDs (including special needs plans, or SNPs) has grown as some individuals have selected these plans or joined them through the Medicare-Medicaid financial alignment initiative.

Beneficiaries' enrollment decisions in 2017

Most Part D enrollees are in plans that differ from Part D's defined standard benefit; these plans are actuarially equivalent to the standard benefit or are enhanced in some way. Actuarially equivalent plans have the same average benefit value as defined standard plans but a different

benefit structure. For example, a plan may use tiered copayments (e.g., charging \$5 per generic drug and \$50 for a brand-name drug) that can be higher or lower for a given drug compared with the 25 percent coinsurance under the defined standard benefit. Alternatively, a plan may exempt certain types of prescriptions such as preferred generics from the deductible, or use a cost-sharing rate higher than 25 percent rather than having a deductible at all. Once a PDP sponsor offers at least one plan with basic benefits in a region, it can also offer a plan with enhanced benefits by including, for example, lower cost sharing, coverage for drugs filled during the gap (beyond what is required by PPACA), or an expanded drug formulary.

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

In 2017, 59 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copayments (Table 14-4). Another 41 percent of PDP enrollees had enhanced

**TABLE
14-3****Part D plan enrollment trends, 2007-2017**

	2007	2010	2014	2015	2016	2017	Average annual growth rate 2007-2017
Total Part D enrollment (in millions)	24.2	27.6	37.4	39.2	41.0	42.5	6%
Percent of Medicare beneficiaries	54.4%	57.8%	69.2%	70.7%	72.1%	72.5%	N/A
Enrollment by type (in millions)							
PDP	16.9	17.6	23.4	24.0	24.7	25.1	4
MA-PD	7.2	10.0	14.1	15.3	16.3	17.4	9
Percent in MA-PD	30%	36%	38%	39%	40%	41%	N/A

Note: N/A (not applicable), PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). Figures are based on enrollment as of April 1 of each year with the exception of 2007 (enrollment as of July 1, 2007) and 2008 (enrollment as of May 1, 2008).

Source: MedPAC based on Part D enrollment data and Table IV.B7 and Table V.B4 of the Medicare Boards of Trustees' report for 2017.

benefits—the typical enhancement being a lower deductible rather than additional benefits in the coverage gap. No PDP enrollees were in defined standard benefit plans because plan sponsors offered none. MA-PD enrollees were predominantly in enhanced plans with no deductible or a deductible smaller than that used for Part

D's defined standard benefit. In PDPs and MA-PDs, 47 percent of enrollees and 46 percent, respectively, had no deductible in their plan's benefit design.

Under the MA payment system, MA-PDs may use a portion of their MA (Part C) payments to supplement their

**TABLE
14-4****MA-PD enrollees more likely to be in enhanced plans, 2017**

	PDP		MA-PD	
	Number of enrollees (in millions)	Percent	Number of enrollees (in millions)	Percent
Total	20.5	100%	11.9	100%
Type of benefit				
Defined standard	0.0	0	0.1	1
Actuarially equivalent*	12.2	59	1.3	11
Enhanced	8.4	41	10.5	89
Type of deductible				
Zero	9.7	47	5.5	46
Reduced	1.5	7	5.5	46
Defined standard**	9.4	46	1.0	8

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

*Includes actuarially equivalent standard and basic alternative benefits.

**Deductible of \$400 in 2017.

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

**TABLE
14-5**

Changes in average Part D premiums, 2007-2017

	Average monthly premium weighted by enrollment (in dollars)						Average annual growth rate 2010-2017
	2007	2010	2014	2015	2016	2017	
All plans (any coverage)	\$23	\$30	\$29	\$30	\$31	\$32	1.0%
PDPs							
Basic coverage	24	34	30	28	29	31	-1.1
Enhanced coverage	40	50	49	48	53	54	1.2
All types of coverage	27	37	38	37	39	41	1.2
MA-PDs, including SNPs*							
Basic coverage	17	26	25	21	22	26	0.3
Enhanced coverage	9	13	13	16	17	18	4.6
All types of coverage	10	14	16	18	18	19	4.3

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), SNP (special needs plan). The premium amounts do not include monthly adjustment amounts paid by beneficiaries who are subject to income-related premiums or the late enrollment penalty. Figures exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B-only plans. The average premium for any PDP coverage increased, on average, between 2010 and 2017 despite a decrease in the average for basic PDPs because, over time, more beneficiaries enrolled in PDPs with enhanced coverage.
*Reflects the portion of Medicare Advantage plans' total monthly premium attributable to Part D benefits for plans that offer Part D coverage. MA-PD premiums reflect Part C rebate dollars that were used to offset Part D premium costs.

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

Part D drug benefits (such as by lowering deductibles) or to lower Part D premiums.¹¹ Many MA-PDs also use some of their MA rebate dollars to provide additional Part D benefits in the coverage gap. In 2017, 53 percent of MA-PD enrollees (6.3 million beneficiaries) were in plans offering some additional gap coverage (data not shown). By comparison, only 14 percent of PDP enrollees (2.9 million beneficiaries) were in plans that offered benefits in the coverage gap beyond what is required by PPACA. However, 31 percent of PDP enrollees (7.8 million of 25.1 million) received the LIS, which effectively eliminates any coverage gap.

Average enrollee premiums remained flat in 2017

Despite significant growth in catastrophic benefits, average premiums for basic Part D benefits have remained low. (This largely reflects the effects of Medicare's reinsurance subsidy, which has offset benefit spending that would otherwise have increased plan sponsors' bids.) In 2017, monthly beneficiary premiums averaged about \$32 across all plans, and average premiums have remained at or near \$30 per month since 2010 (Table 14-5). However, underlying that average is wide variation, ranging from \$0

for a number of MA-PDs to \$179 for one PDP offering enhanced coverage (data not shown).

On average, premiums were lower for beneficiaries enrolled in MA-PDs compared with those enrolled in PDPs, in part reflecting plan sponsors' use of Part C rebate dollars.¹² Among PDP enrollees, individuals in plans with enhanced coverage paid, on average, \$23 more per month than those in plans with only basic coverage (\$54 vs. \$31, respectively). In contrast, beneficiaries enrolled in MA-PDs, on average, paid lower premiums for enhanced coverage than for basic coverage alone (\$18 vs. \$26, respectively). Between 2010 and 2017, MA-PD premiums grew at a faster average annual rate than PDP premiums—4.3 percent, compared with 1.2 percent (Table 14-5).

Two other factors affect the premium amounts paid by a given enrollee. First, higher income beneficiaries have a lower federal subsidy of their Part D benefits. In 2017, 2.8 million Part D enrollees (7 percent) were subject to the income-related premium (Liu 2017). As with the income-related premium for Part B, the higher Part D premiums apply to individuals with an annual adjusted gross income

**TABLE
14-6**

MA-PDs are more likely to offer enhanced benefits than PDPs, 2018

	PDP		MA-PD	
	Number of plans	Percent	Number of plans	Percent
Total	782	100%	2,003	100%
Type of benefit				
Defined standard	0	0	22	1
Actuarially equivalent*	361	46	101	5
Enhanced	421	54	1,880	94
Type of deductible				
Zero	291	37	908	45
Reduced	88	11	988	49
Defined standard**	403	52	107	5
Some drugs covered in the coverage gap	274	35	703	35

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

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

greater than \$85,000 and to couples with an adjusted gross income greater than \$170,000. A beneficiary whose income exceeds these levels pays an income-related monthly adjustment amount in addition to the Part D premium paid to a plan. In 2018, the adjustment amount ranges from \$13.00 to \$74.80 per month, depending on income.

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

Benefit offerings for 2018

Beneficiaries are encouraged to reexamine plan options each year during an open enrollment period that runs from October 15 until December 7. In addition to changes in

plan availability and premiums, most plans make some changes to their benefit offerings—such as deductible amounts and plan formularies—that can affect access to and OOP costs of medications.

Beneficiaries have a variety of plan options

For 2018, plan sponsors are offering 782 PDPs and 2,003 MA-PDs, about 5 percent and 16 percent, respectively, more plans than in 2017. Beneficiaries continue to have broad choice among plans; options range from 19 PDPs in Alaska to 26 PDPs in the Pennsylvania–West Virginia region, along with MA-PDs in most areas. The number of MA plans available to a beneficiary varies by the county of residence, with an average county having 10 MA plans (20 plans when weighted by Medicare population). A small percentage of beneficiaries have no MA plans available.¹³

MA-PDs are much more likely to offer more generous coverage than PDPs. For example, 94 percent of MA-PDs include enhanced coverage beyond basic benefits, compared with 54 percent of PDPs (Table 14-6). Among plans with basic benefits, the 2018 marketplace includes no PDPs and just 1 percent of MA-PDs (excluding special

**TABLE
14-7**

Change in 2018 premiums for PDPs with high 2017 enrollment

Plan name	2017 enrollment (in millions)	Weighted average monthly premium*		Change in weighted average monthly premium	
		2017 premium	Projected 2018 premium	Dollar	Percent
SilverScript Choice	4.2	\$29.05	\$26.39	-\$2.66	-9%
AARP MedicareRx Preferred	2.8	71.66	83.68	12.02	17
Humana Walmart	2.4	16.81	20.21	3.40	20
Humana Preferred	1.9	27.24	31.33	4.09	15
Aetna Medicare Rx Saver	1.2	31.33	29.68	-1.65	-5
AARP MedicareRx Saver Plus	1.1	37.22	45.26	8.04	22
WellCare Classic	1.1	29.21	30.37	1.16	4
Humana Enhanced	0.9	64.17	75.82	11.65	18
First Health Part D Value Plus	0.8	44.91	56.46	11.55	26
Cigna-HealthSpring Rx Secure	0.5	27.77	35.18	7.41	27
Top 10 PDPs combined	16.7	37.46**	41.58**	4.12**	11
All PDPs	20.4	39.90	43.48	3.58	9

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

*Reflects the average of all PDPs offered under the same plan name in each region of the country, weighted by 2017 enrollment. Note that the projected weighted average premium for 2018 does not reflect any enrollment switching among plans.

**Average weighted by 2017 enrollment.

Source: Cubanski et al. 2017.

needs plans) with the standard benefit design. A larger share of MA-PDs than PDPs charges no deductible (45 percent vs. 37 percent, respectively), and 52 percent of PDPs use the same \$405 deductible as the defined standard benefit. The same share of PDPs and MA-PDs (35 percent) includes some additional coverage in the gap phase. Our analysis of MA plan bids suggests that, on average, MA-PDs allocated about the same share of MA rebate dollars for Part D benefits in 2018 as in 2017 (33 percent, or nearly \$32 per enrollee per month, split about equally between basic and enhanced benefits) (data not shown).

Among the most popular stand-alone PDPs in 2017, many have substantially higher monthly premiums in 2018 (Table 14-7). Premiums for the 10 plans with the highest enrollment rose by a weighted average of \$4 per month (11 percent), ranging from about \$20 per month for the Humana Walmart plan to nearly \$84 per month for AARP

MedicareRx Preferred. Premiums for AARP MedicareRx Preferred, Humana Enhanced, and First Health Part D Value Plus plans rose by about \$12 per month. Premiums for SilverScript Choice and Aetna Medicare Rx Saver plans are lower by an average of nearly \$3 per month and about \$2 per month, respectively.

Although cost-sharing requirements in Part D plans have generally risen over the years, PDPs with the highest enrollment have a mixture of cost-sharing increases and decreases for 2018 (data not shown). The top 10 PDPs (ranked by 2017 enrollment) continue to use a 5-tiered formulary with differential cost sharing between preferred and nonpreferred drugs, as well as a specialty tier for high-cost drugs. Over time, many plan sponsors have moved from charging fixed-dollar copayments to coinsurance for certain tiers. In fact, the top 10 PDPs in 2018 use coinsurance rather than fixed-dollar copayments for medications on nonpreferred drug tiers, charging 35 percent to 50 percent of each prescription's negotiated

price (Cubanski et al. 2017). By charging enrollees a share of the price of their prescriptions rather than a flat copayment, plan sponsors share some of the risk of drug price increases with beneficiaries. Another reason for the move to coinsurance is that some plan sponsors have combined certain brand and generic drugs on the same cost-sharing tier, e.g., for all nonpreferred drugs. When the same tier includes both low- and high-priced drugs, plan sponsors may find it difficult to set a fixed-dollar copayment amount that provides a comparable value of benefit.

Qualifying PDPs

In 2018, PDPs available to LIS enrollees with no premium (“qualifying PDPs”) decreased 6 percent from 2017 levels to 216 plans—the lowest number since Part D began.¹⁴ One region, Florida, has two qualifying PDPs available. However, all other regions have at least 3 PDPs available, while the Arizona region and the Washington, DC–Delaware–Maryland region have 10 such PDPs.

About 1.4 million LIS enrollees (about 1 in 5 LIS enrollees in PDPs) were enrolled in plans during 2017 that have 2018 premiums higher than 2018 regional benchmarks (Cubanski et al. 2017). However, 62 percent of those beneficiaries paid a premium in 2017, meaning they selected a plan rather than accepting Medicare’s random assignment to a benchmark plan.¹⁵ Once an LIS enrollee selects a plan, the enrollee is no longer eligible for reassignment. The remaining 38 percent (more than 0.5 million LIS enrollees) were potentially subject to reassignment. CMS estimated that the agency randomly reassigned 160,000 individuals to new plans (Lyons 2017).

Plan sponsors and their tools for managing benefits and spending

Nearly 300 organizations sponsor Part D plans—both insuring and administering outpatient drug benefits. Plan sponsors carry out marketing, enrollment, customer support, claims processing, coverage determinations, and appeals and grievance processes. Sponsors also either contract with a commercial pharmacy benefit manager (PBM) or perform those functions themselves through an in-house PBM. Sponsors that do not use an in-house PBM must negotiate with their PBM over the amount the PBM retains for its services. By law, the Medicare program is prohibited from becoming involved in negotiations among plan sponsors, drug manufacturers, and pharmacies.

Concentrated enrollment among plan sponsors

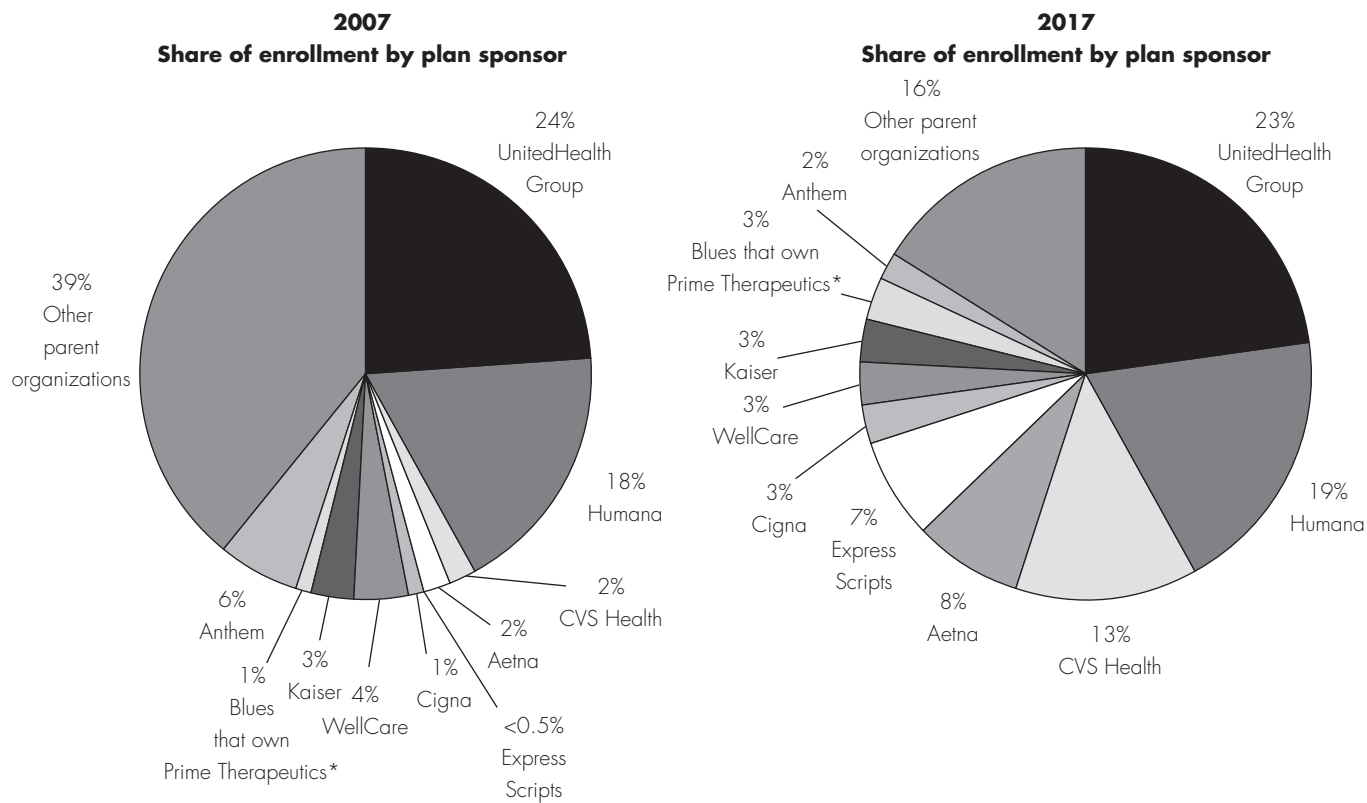
Having large numbers of enrollees and managing their benefits with formularies and tiered cost sharing are the central means by which sponsors and PBMs can exert bargaining leverage with drug manufacturers and pharmacies. Having many enrollees can also lead to economies of scale that lower other costs. Part D enrollment is concentrated among a small number of large organizations. Combined, the two largest plan sponsors, UnitedHealth Group and Humana, have accounted for about 40 percent of the Part D market each year since 2007 (Figure 14-2, p. 412). Over time, other sponsors have expanded their enrollment and market shares. In 2017, the top 9 organizations ranked by enrollment and a group of 14 Blue Cross and Blue Shield companies that collectively own their own PBM (Prime Therapeutics) together accounted for 84 percent of Part D enrollment. By comparison, in 2007, those same organizations had a combined 61 percent of enrollment.

Plan sponsors’ organizational structures differ in the degree to which each company integrates clinical and health plan services, PBM services, and dispensing. Most of the largest sponsors are insurers whose core business function is to offer commercial and MA health plans with combined medical and pharmacy benefits. However, over two-thirds of Medicare beneficiaries remain in the FFS program and thus obtain Part D benefits through stand-alone PDPs (if they choose to enroll). Because PDPs remain an important market opportunity, the insurers serving as MA sponsors also offer PDPs in many or all regions. Other sponsors—Express Scripts and CVS Health—have core business models that focus primarily on pharmacy benefit management and dispensing, and they offer only PDPs.¹⁶ They also serve as PBMs under contract to other Part D sponsors. Further, most top sponsors offer employer group plans, which can take the form of MA–PDs or PDPs.

Enrollment among beneficiaries who receive Part D’s LIS is also concentrated. In 2017, CVS Health had more LIS enrollees than any other sponsor: a total of 2.4 million, or 20 percent of all LIS enrollees. Once a sponsor has a sizable number of LIS enrollees, its bid can influence LIS benchmarks because the benchmarks are calculated as a regional average premium weighted by LIS enrollment. At the same time, should the sponsor miss a regional benchmark by bidding too high, it would stand to lose potentially sizable numbers of LIS enrollees and market share.

**FIGURE
14-2**

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



Note: Market shares are based on Part D enrollment, including both stand-alone prescription drug plans and Medicare Advantage prescription drug plans. Employer group waiver plans are included.

*Prime Therapeutics is a pharmacy benefit manager that, in 2017, was owned by and operated on behalf of the following plans: Blue Cross and Blue Shield (BC/BS) of Alabama, BC/BS of Kansas, BC/BS of Minnesota, BC/BS of Nebraska, BC/BS of North Carolina, BC/BS of North Dakota, BC/BS of Rhode Island, BC/BS of Wyoming, Florida Blue, and Health Care Services Corporation. BC/BS of Alabama, BC/BS of North Carolina, and BC/BS of Rhode Island were not owners in 2007, and their enrollment numbers are included within "Other parent organizations" rather than "Blues that own Prime Therapeutics" for that year.

Source: MedPAC based on enrollment data from CMS.

Tools for managing benefits and spending

Over the first decade of Part D, the use of plan tools and fortuitous timing of patent expirations led to the expanded use of generics. In 2015, about 87 percent of prescriptions filled under Part D were for generics, compared with 61 percent in 2007. Today, generic substitutions may have reached a saturation point, and increasingly plan sponsors are focused on managing use of specialty drugs and biologics for conditions such as cancer, rheumatoid arthritis, and hepatitis C. These treatments are often injectable or infusible biologics, but some are oral tablets or inhalable medicines.¹⁷ Dispensing specialty drugs can

sometimes raise challenging logistical issues, and patients who take them may require closer clinical management. Specialty drugs also have very high prices, some with annual costs of treatment per person in the tens of thousands of dollars or more.

Sponsors use several key tools to manage pharmacy benefits, including formulary design, manufacturer rebates, design of pharmacy networks, and use of specialty pharmacies. However, law and regulations limit how sponsors may manage their Part D populations compared with how the same organizations manage their commercial populations.

Formulary design and management

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

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

Manufacturer rebates

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

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

The share of a drug product's gross price rebated to PBMs and payers can be high when there are close substitutes in the product's drug class. For example, across all payers for Sanofi's insulin product Lantus, the implied rebate—the share of gross drug sales offset by rebates and other discounts—grew from around 10 percent in 2009 to nearly 60 percent by the second quarter of 2016 (*Indianapolis Business Journal* 2016). The extent to which rebates and discounts offset price increases varies across

manufacturers, driven primarily by the mix of products in their portfolios and the competitive pressures they face (Credit Suisse 2015).

Pharmacy networks

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

Part D law and CMS guidance limit plan sponsors in using some 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.¹⁸ However, sponsors can designate a subset of network pharmacies that offer preferred (lower) cost sharing. The strategy of designating certain "preferred cost-sharing pharmacies" has the potential to lower costs for Medicare and enrollees if it encourages enrollees to fill prescriptions at more efficient pharmacies. Differences between cost sharing at preferred pharmacies and other network pharmacies can vary substantially among plans (Medicare Payment Advisory Commission 2016b). Tiered networks as a management tool have been controversial because of past concerns that some enrollees do not have adequate access to preferred pharmacies with lower cost sharing. In addition, if LIS enrollees have less opportunity to use preferred pharmacy networks, the tiered network strategy could lead to higher Medicare spending since 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).

When setting up pharmacy networks, plan sponsors negotiate additional price concessions and incentive payments, which must be reported to CMS as "other direct and indirect remuneration (DIR)," called "pharmacy DIR fees." As with rebates from drug manufacturers, DIR fees are collected after the point of sale. They can include amounts that are a condition for participating as a preferred cost-sharing pharmacy, "true-up" payments related to drug reimbursement rates, and performance fees that are assessed on quality measures (Fein 2016).¹⁹

Pharmacy DIR fees have grown dramatically in recent years, particularly after 2012 (Centers for Medicare & Medicaid Services 2017g). CMS information about the total amount of DIR reported to the agency and the amount attributable to manufacturer rebates suggests that, in 2014, pharmacy DIR fees could have been on the order of \$1 billion (Centers for Medicare & Medicaid Services 2017f, Centers for Medicare & Medicaid Services 2016a).

Specialty pharmacies

Because specialty drugs are now driving growth in overall drug spending, commercial payers typically try to dispense them through a narrower or exclusive network of specialty pharmacies. Specialty pharmacies can help ensure that patients meet specific clinical criteria through their plans' prior authorization process before dispensing the prescription. They can also reduce waste by, for example, initially dispensing a 7- or 14-day supply and observing the patient for side effects, treatment effectiveness, and adherence before providing a 30-day supply.

A variety of ownership types have evolved to dispense specialty drugs. Owners of specialty pharmacies include pharmacy chains, PBMs, health plans, drug wholesalers, hospital systems, and prescriber practices, or the pharmacy can operate as an independent business. Although most manufacturers do not own specialty pharmacies, a number of drug makers pay fees to specialty pharmacies and have contracts that limit which specialty pharmacies may dispense their drug. These relationships can result in specialty pharmacies with financial incentives that align with manufacturers'. Most specialty pharmacies fill prescriptions through home delivery or send deliveries to a convenient location. Specialty pharmacies also play a role in patient education, patient monitoring, and data reporting. For example, they often employ nurses to provide counseling by telephone about side effects and monitor adherence. Before an initial prescription is dispensed, specialty pharmacies address prior authorization requests from the patient's PBM and typically facilitate outreach to patient assistance programs.²⁰

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. Unless dispensing a drug requires "extraordinary specialty handling, provider coordination, or patient education that cannot be met by a network pharmacy," the sponsor cannot

restrict access to a subset of network pharmacies (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. As with general retail pharmacies, Part D plan sponsors negotiate agreements with specialty pharmacies that include DIR fees that are typically collected after the prescription has been filled.²¹

Drug pricing

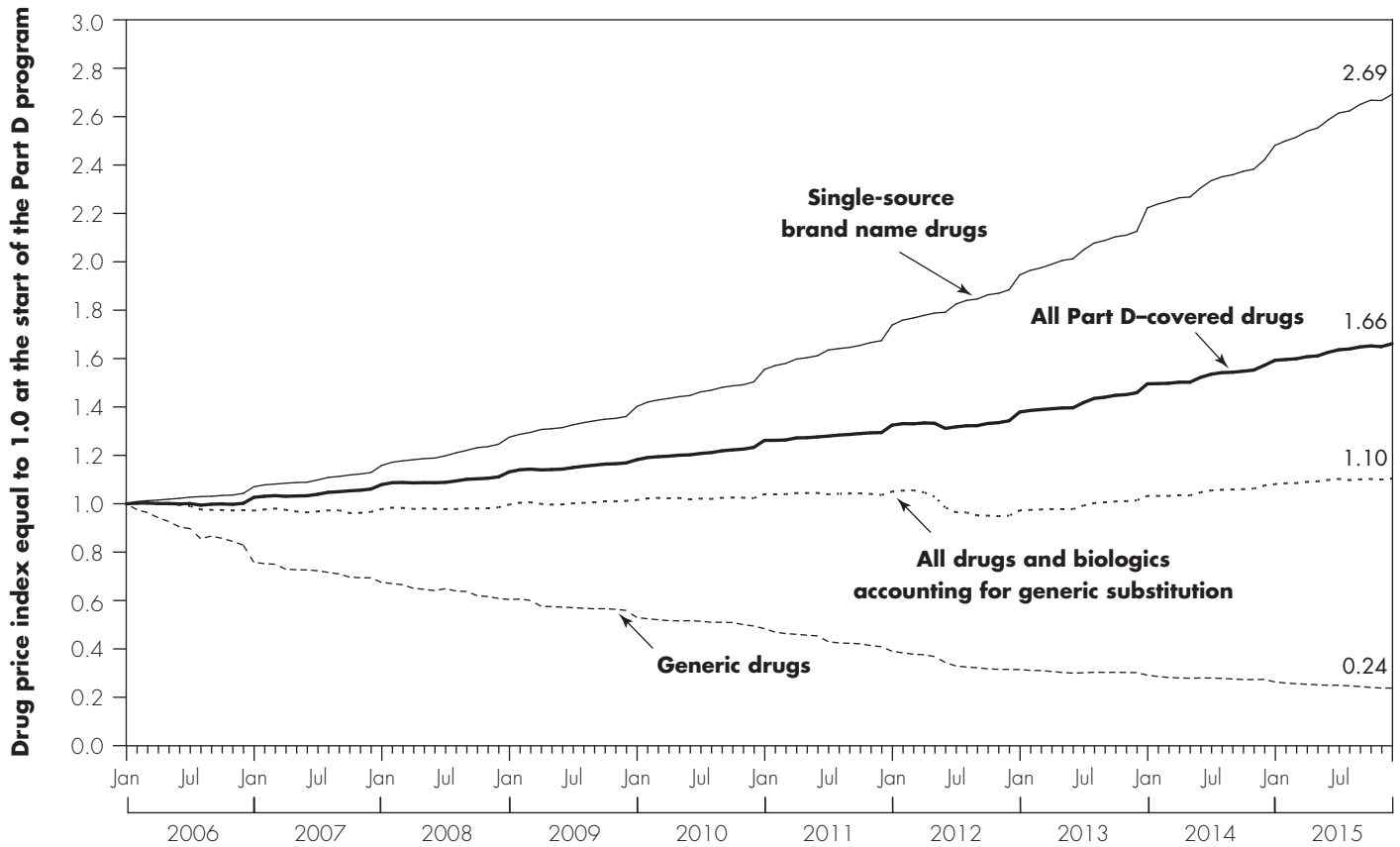
With generics making up nearly 90 percent of all U.S. prescriptions, there is diminishing opportunity for new generic savings (Fein 2017b). At the same time, a pipeline shift toward higher cost medications, combined with changes in the market dynamics of the supply and distribution channels that have increased reliance on price inflation for revenue growth, have put upward pressure on both prices and rebates (Cahn 2017, Fein 2017a, Lopez 2016, Sell 2015). The result has been aggressive growth in prescription prices at the point of sale (POS), which determines gross Part D spending, and a growing divergence between POS prices and prices net of postsale rebates and discounts from manufacturers and pharmacies (net prices).

The aggregate amount of rebate payments in Part D has been growing. Using plan sponsors' assumptions about rebates from their 2016 bids, the Medicare Trustees estimated that Part D DIR—made up predominantly of manufacturers' rebates—amounted to 22 percent of total drug costs (averaged across all drugs, including those for which plans do not receive any rebates) (Boards of Trustees 2017). 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 (Boards of Trustees 2017). This phenomenon is not limited to the Part D program. According to one estimate, in 2016, net prices were 28 percent below total spending based on invoice (list) prices (IQVIA Institute for Human Data Science 2017).²²

The cost of providing the Part D benefit is affected by both POS prices and net prices that reflect rebates and discounts. The former affects patient cost sharing and the rate at which patients reach the catastrophic phase of the benefit, the point after which Medicare pays 80 percent of

**FIGURE
14-3**

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



Note: Chain-weighted Fisher price indexes.

Source: Acumen LLC analysis for MedPAC.

the costs in individual reinsurance. For this reason, from beneficiaries' and Medicare's perspectives, prices paid at the pharmacy are an important indicator of Part D's costs. The latter—net prices—affects premiums and plan profits (see text box on prices, pp. 416–417).

Prices paid at the point of sale

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

In 2015, price increases for brand-name drugs continued to overwhelm the effects of using lower priced generics

Measured by individual national drug codes (NDCs) and excluding manufacturers' rebates, between 2006 and 2015, Part D drug prices rose by an average of 66 percent cumulatively (an index value of 1.66) (Figure 14-3).²³ As measured by a price index that takes the generic substitution into account, Part D prices increased by 10 percent cumulatively.²⁴ The uptick in this price index from 2013 to 2015 is a shift from prior years when increased generic use had kept overall prices stable by offsetting increases in prices of brand-name drugs.

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

The issue of rebates in drug pricing has garnered attention because of its implications for beneficiary cost sharing and for Medicare's program costs. CMS noted that the increase in rebates and the resulting disparity between point-of-sale (POS) prices and net prices lowers costs for plan sponsors while increasing costs to beneficiaries through higher cost sharing and to Medicare through higher reinsurance and low-income cost-sharing subsidies (Centers for Medicare & Medicaid Services 2017g).

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

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

Under the first approach, enrollees who use drugs for which a rebate is negotiated would benefit from the price discount. Under the second approach, the aggregate amount of rebate payments would be used to lower a plan's premium for all enrollees. Enrollees

who must pay cost sharing in the form of coinsurance would pay an amount based on the drug's undiscounted price (i.e., not reflecting rebates). Coinsurance can be especially burdensome for those who require high-priced specialty drugs.

The first approach is not always practical if, for example, the amount of rebate payment is determined retroactively based on performance goals or the magnitude of price increases. In addition, plans and their pharmacy benefit managers overwhelmingly use the second approach because beneficiaries evaluate premiums closely when comparing Part D plans, and premiums are the basis on which plans qualify as premium free to low-income subsidy (LIS) enrollees.

The way in which plan sponsors apply rebates to aggregate benefits affects Medicare program spending in different ways. Using rebates to reduce plan premiums lowers Medicare program spending because (1) Medicare retains a portion of aggregate rebates to offset a share of program payments for individual reinsurance, and (2) the rebates lower the subsidies Medicare pays for a portion of plan premiums for all

(continued next page)

On average, prices of generic drugs are 75 percent to 90 percent lower than the prices of brand-name drugs, and generic prices tend to decline over time (Government Accountability Office 2016). However, in recent years, several analysts have noted that certain generic medications now have high prices or have experienced sharp price increases (Dave et al. 2017, Loftus 2017, Thomas 2016). A number of factors associated with decreased market competition explain price increases for generics, such as drug shortages, disruptions in the supply of drugs, and consolidations among manufacturers of generic drugs (Alpern et al. 2014, Dave et al. 2017). Overall, generic prices decreased at a slower rate between 2012 and 2015 compared with 2006 and 2012. Still, between 2006 and 2015, prices of generic drugs decreased to 24 percent of the average price observed at the beginning of 2006 (Figure 14-3, p. 415).

In comparison, prices of single-source, brand-name drugs (drugs with no generic substitutes, although some may have generic alternatives in the same therapeutic class) grew by a cumulative 169 percent during the same period. Despite accounting for a small share of prescriptions (about 13 percent in 2017), price increases for brand-name drugs overwhelmed the effects of using lower priced generic drugs. The continued strong growth in POS prices suggests that Part D spending will increasingly be affected by high-priced brand-name drugs.

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

Prices have grown rapidly for drugs with few or no generic or biosimilar alternatives. For example, between 2007 and 2015, our price index for insulin (to treat diabetes)

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

enrollees. However, an offsetting effect is that a higher proportion of enrollees reach Part D's out-of-pocket threshold—the point at which Medicare pays for 80 percent of benefits. Additionally, Medicare's subsidy for low-income cost sharing would be higher because it is based on POS prices.

In the Commission's March 2017 report, we highlighted how Part D's unique benefit design, Medicare's reinsurance payments, and plan sponsors' focus on premium competition can affect plan incentives regarding their formulary decisions (Barnhart and Gomberg 2016, Medicare Payment Advisory Commission 2017c). That is, the current Part D construct provides a financial advantage to plan sponsors when they select high-cost, high-rebate drugs over lower cost alternatives. CMS has expressed concerns about this issue, noting that, under Part D's risk corridors, any rebates received above the projected amount contribute primarily to plan profits (Centers for Medicare & Medicaid Services 2017g).

In recent years, plan sponsors have negotiated additional “price-protection” provisions. Under these

agreements, if a drug's list price increases above a specified threshold, the manufacturer rebates any incremental increase above the threshold to the plan sponsor (Kaczmarek 2015, Pharmacy Benefit Management Institute 2017). Sponsors negotiate ceiling prices because manufacturers' midyear price increases may result in benefit costs that are higher than they expected.

While price-protection rebates give more predictability to sponsors, that protection could allow manufacturers to increase their POS prices with less resistance from plan sponsors. In turn, it could contribute to the greater divergence between POS and net prices, potentially worsening the shift in costs toward beneficiaries and the Medicare program that occurs under the current Part D construct. Higher POS prices tend to increase the number of beneficiaries who reach the catastrophic phase of the benefit and thereby increase Medicare's reinsurance payments. Enrollees who pay coinsurance are not protected from price increases. Similarly, to the extent that Medicare pays coinsurance on behalf of LIS enrollees, Part D's low-income cost-sharing subsidy does not benefit from price-protection rebates. ■

grew a cumulative 227 percent (Figure 14-4, p. 418). During the same period, our price index for therapies to treat conditions such as rheumatoid arthritis and multiple sclerosis grew by a cumulative 142 percent and 203 percent, respectively.

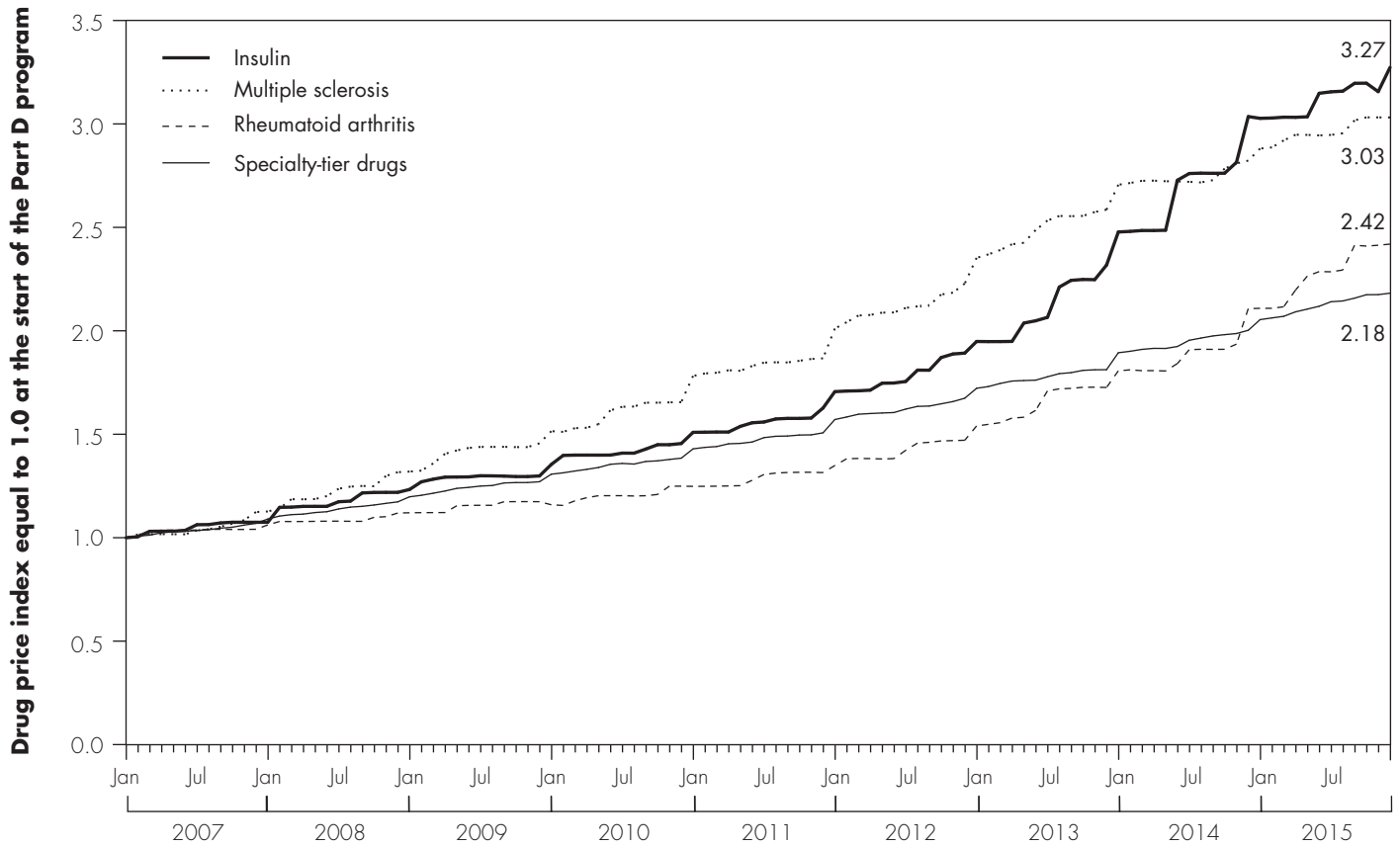
In recent years, a number of biopharmaceutical manufacturers have transformed their research and development (R&D) strategies toward markets for orphan drugs (special status given to drugs under development to treat rare diseases or conditions) and targeted therapies (EvaluatePharma 2017). Food and Drug Administration (FDA) approvals of innovative medicines in the last few years have included an increasing number of biologics and specialty drugs, with new medicines focused on treatments for a range of cancers, viral infections, and autoimmune diseases, among others (Blair and Cox 2016,

Frey 2017).²⁵ Many of these new entrants command higher prices than existing therapies and generally have few or no lower cost alternatives. Although manufacturers must provide clinical trial data to the FDA to demonstrate safety and effectiveness, comparative clinical effectiveness information for the Medicare population is often not available.

This shift in biopharmaceutical R&D is likely behind the aggressive growth in prices of single-source brand-name drugs. For example, between 2011 and 2015, gross Part D spending on specialty-tier drugs (which, by definition, have high prices because of the cost threshold set by CMS) grew by 40 percent per year, on average.²⁶ As a result, specialty-tier drugs now account for over 20 percent of overall gross drug spending in Part D, up from about 6 percent to 7 percent before 2010. Our price index

**FIGURE
14-4**

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



Note: Chain-weighted Fisher price indexes.

Source: Acumen LLC analysis for MedPAC.

for specialty-tier drugs grew by a cumulative 118 percent (index value of 2.18) between 2007 and 2015 (Figure 14-4)—much higher than 62 percent growth across all drugs and biologics covered under Part D during the same period.

Program costs

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

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

Combined, the direct subsidy and expected reinsurance payments aim to cover 74.5 percent of the expected cost of basic benefits. Today, a much larger share of this

overall subsidy takes the form of reinsurance (cost-based reimbursement) rather than the direct subsidy (capitated payments). In addition to reinsurance, Medicare shares risk with plan sponsors by adjusting direct-subsidy payments to reflect the expected costliness of a plan's enrollees and limiting each plan's overall losses or profits through risk corridors if actual benefit spending 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. Part D enrollees also pay any cost sharing required by plan sponsors. Medicare pays plans cost sharing and premiums for their LIS enrollees.

Higher effective subsidy rates increase overall program costs

Data on program spending give a mixed picture of the success of Part D plans at containing costs. In the Commission's June 2015 report to the Congress, we noted regular patterns in Medicare's reconciliation payments with plans (Medicare Payment Advisory Commission 2015). First, many plan sponsors bid too low on the amount of benefit spending they expected above Part D's catastrophic threshold relative to their enrollees' actual catastrophic spending. Second, plan sponsors bid too high on the rest of benefit spending other than catastrophic benefits.

This pattern of bidding provides financial advantage to plan sponsors. By underestimating catastrophic spending, plan premiums are lower than they would have been had they reflected actual costs. Additionally, to the extent that actual costs ultimately are lower than what was estimated in plan bids, the structure of Part D's risk corridors allows plan sponsors to keep most of the difference as profits (Centers for Medicare & Medicaid Services 2017g).

Spending for competitively derived, direct-subsidy payments on which sponsors bear the most insurance risk has grown slowly, while benefit spending on which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, for which Medicare provides 80 percent reinsurance) has grown much faster (Medicare Payment Advisory Commission 2015).

Between 2009 and 2015, the majority of plan sponsors returned a portion of their prospective payments to Medicare through risk corridors.²⁷ Actuaries interviewed by Commission staff suggested that there is significant

uncertainty behind the assumptions they make when projecting drug spending for their bids. At the same time, we suggested that Part D's risk-sharing mechanisms may provide incentives to bid too low on catastrophic spending and too high on spending for the remainder of the Part D benefit. This dynamic and the open-ended nature of retrospective payments for reinsurance have resulted in Medicare subsidy rates for Part D that, in effect, have been higher than 74.5 percent in most years.

Trends in program subsidies and costs

Between 2007 and 2016, program spending (including expenditures for the RDS) rose from \$46.2 billion to \$78.9 billion (Table 14-8, p. 420), or an average 6.1 percent per year. In 2016, Medicare paid \$16.3 billion for direct subsidies, \$34.8 billion for individual reinsurance, \$26.7 billion for the LIS, and \$1.1 billion for the RDS (Boards of Trustees 2017).

In 2016, premiums paid by Part D enrollees (not including the premiums paid by Medicare on behalf of LIS enrollees) totaled \$12.7 billion (Boards of Trustees 2017). That amount has grown by an average of 13.4 percent per year since 2007, reflecting both growth in enrollment, particularly among beneficiaries who do not receive the LIS, and increases in benefit costs.

In addition to monthly premiums, most enrollees are responsible for paying cost sharing as set by plan sponsors or, in the case of LIS enrollees, amounts set in law. (On behalf of LIS enrollees, Part D's low-income cost-sharing subsidy pays for the difference between cost sharing set by plan sponsors and the nominal amounts they pay out of pocket.)

Cost-based reimbursement rather than risk-based payments now accounts for most of Medicare's payments for Part D benefits

Medicare payments for individual reinsurance have grown faster than other components of Part D spending. Between 2007 and 2016, payments for individual reinsurance increased at an annual average of 17.7 percent (Table 14-8, p. 420). This growth accelerated in recent years, expanding at an annual average of over 24 percent between 2010 and 2015 compared with about 12 percent for 2007 through 2010 (data not shown). Reinsurance spending became the largest component of Part D spending in 2014. Growth in spending for reinsurance decelerated to about 5 percent between 2015 and 2016, reflecting slower growth in spending for hepatitis C and diabetes drugs (Hartman et al.

**TABLE
14-8**

Medicare’s reimbursement amounts for Part D

	2007	2010	2012	2013	2014	2015	2016	Average annual growth rate 2007–2016
Reimbursement amount (in billions):								
Direct subsidy*	\$17.6	\$19.6	\$19.7	\$19.6	\$18.5	\$18.1	\$16.3	-0.8%
Reinsurance	<u>8.0</u>	<u>11.2</u>	<u>15.5</u>	<u>19.2</u>	<u>27.2</u>	<u>33.2</u>	<u>34.8</u>	<u>17.7</u>
Subtotal, basic benefits	25.6	30.8	35.2	38.8	45.7	51.3	51.1	8.0
Low-income subsidy	16.7	21.1	22.5	23.2	24.3	25.6	26.7	5.4
Retiree drug subsidy	<u>3.9</u>	<u>3.9</u>	<u>3.0</u>	<u>1.7</u>	<u>1.3</u>	<u>1.2</u>	<u>1.1</u>	<u>-13.1</u>
Total	46.2	55.8	60.7	63.7	71.3	78.1	78.9	6.1
Enrollee premiums	4.1	6.7	7.8	9.3	10.5	11.5	12.7	13.4
Reinsurance as a share of basic benefits	31%	36%	44%	49%	60%	65%	68%	N/A

Note: N/A (not applicable). Numbers above reflect reconciliation. Components may not sum to stated totals due to rounding.
*Net of risk-sharing payments using Part D’s risk corridors.

Source: MedPAC based on Table IV.B10 of the 2017 annual report of the Boards of Trustees of the Medicare trust funds.

2018). However, reinsurance continues to grow as a share of total spending. In 2016, a higher share of Medicare payments were retrospective, cost-based reimbursement rather than prospective, risk-based payments—a result not contemplated in the original design of the program.

Changes in the national average monthly bid amount also reveal higher growth in individual reinsurance. Between 2007 and 2018, plans’ expected total benefit spending per enrollee grew from \$103 per month to \$137 per month, a modest annual growth rate of 2.7 percent (Figure 14-5). However, over that same period, the direct subsidy amount per enrollee fell from about \$50 per month to \$23 per month (nearly 7 percent annually), while expected reinsurance grew from \$26 per month to \$79 per month (nearly 11 percent annually).

A combination of factors has contributed to faster growth in reinsurance. POS prices have grown rapidly for brand-name drugs and new medicines such as hepatitis C therapies (Hartman et al. 2018). Higher prices, accompanied by increasing dollar amounts of postsale rebates and discounts, likely exacerbate the current bidding incentives that keep Part D’s premiums and direct

subsidy low while increasing reinsurance costs. Changes made by PPACA also contributed to reinsurance growth. For example, enrollees may be more likely to use brand-name drugs than generics because of the 50 percent discount that manufacturers provide in the coverage gap. Moreover, for non-LIS enrollees, the coverage-gap discount is counted as though it were their own OOP spending. In addition, PPACA constrained growth in the OOP threshold over the 2014 to 2019 period, effectively reducing the size of the coverage gap.

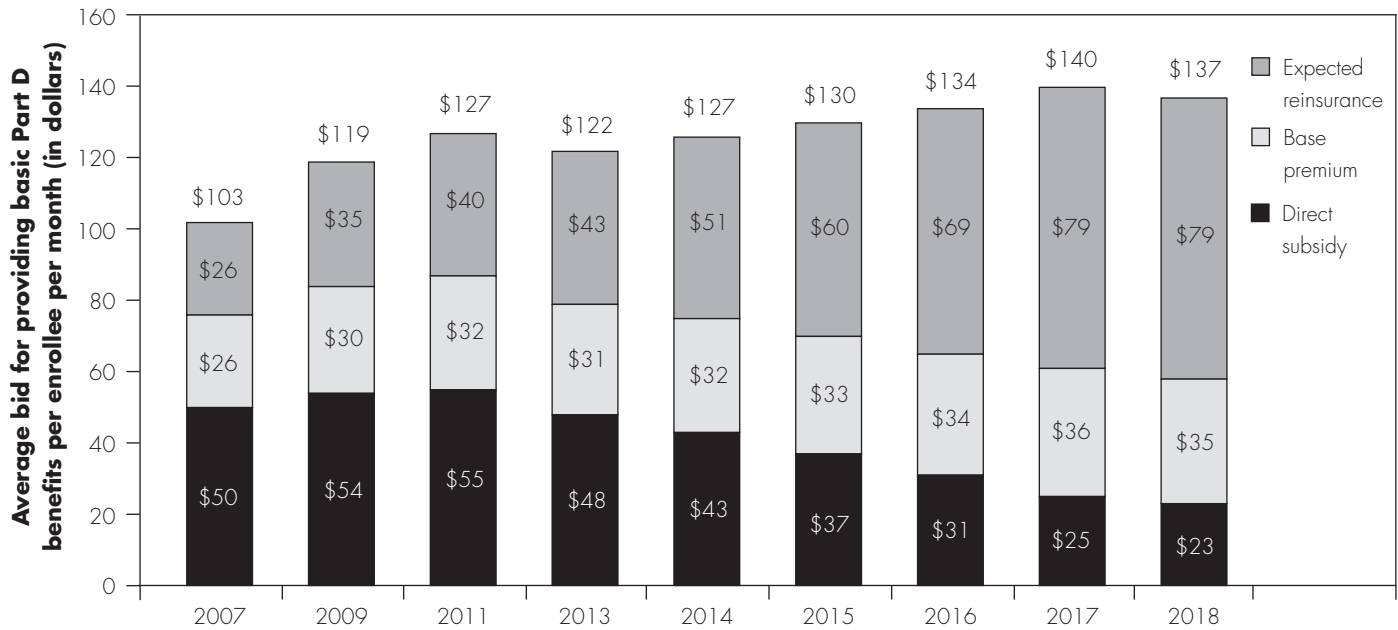
Because of these factors, since 2010, there has been a double-digit increase in the number of non-LIS enrollees who reached the catastrophic phase of the benefit. In turn, larger numbers of high-cost enrollees have led to growth in Medicare’s reinsurance (see text box on the coverage gap, pp. 422–423).

High-cost enrollees drive overall Part D spending growth

Aggregate spending for high-cost enrollees (i.e., not just their catastrophic spending) has grown from about 40 percent of all Part D spending before 2011 to 44 percent in 2011 to 57 percent in 2015. As that share has grown,

**FIGURE
14-5**

National average plan bid for basic Part D benefits



Note: The averages shown are weighted by the previous year's plan enrollment. Amounts do not net out subsequent reconciliation amounts with CMS. Components may not sum to stated totals due to rounding.

Source: MedPAC based on data from CMS.

high-cost enrollees have increasingly affected spending averaged across all Part D enrollees. Between 2010 and 2015, Part D per capita spending grew an annual 4.6 percent (Table 14-10, p. 424). That reflects an annual 10.4 percent increase for high-cost enrollees and an annual 2.1 percent decrease 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 is the single most important factor explaining overall growth in their spending. In turn, that growth reflects not only price inflation but also greater availability of higher priced drugs and biologics and other changes in the mix of medications they were prescribed.

Between 2010 and 2015, the average price per standardized, 30-day prescription for high-cost enrollees grew an annual 10.4 percent, while the number of prescriptions filled per enrollee per month remained flat (Table 14-10, p. 424). This pattern is in stark contrast

to enrollees who did not reach the OOP threshold. The average price of their prescriptions fell by an annual 3.4 percent, while the number of prescriptions they used grew by a modest 1.3 percent per year.

High-cost enrollees tend to use more brand-name drugs. For example, in 2015, the average generic dispensing rate (GDR) among high-cost enrollees was slightly less than 74 percent, or nearly 13 percentage points below the overall Part D average. Some of this GDR difference reflects situations in which brand-name medications are the dominant standard of care within a therapeutic class. Prices of brand-name drugs that do not have generic substitutes are typically much higher and grow more rapidly compared with other drug products. However, many of the drugs used by high-cost enrollees are in drug classes with generic substitutes that are also heavily used by other Part D enrollees. For example, antihypertensive therapy agents for high blood pressure and antihyperlipidemics to treat high cholesterol are both classes of drugs commonly used by all Part D enrollees, including those who reach the OOP threshold. We have

Beneficiaries who reach the coverage gap or catastrophic phase

In 2015, 10.7 million, or 26 percent, of Part D enrollees incurred spending high enough to reach the coverage gap (Figure 14-6). Of those, 3.6 million, or about 9 percent, of Part D enrollees had additional spending high enough to reach the catastrophic phase of the benefit. We refer to individuals who reach the catastrophic phase as high-cost enrollees.

Most high-cost enrollees received the LIS, but numbers of non-LIS enrollees with high costs grew faster

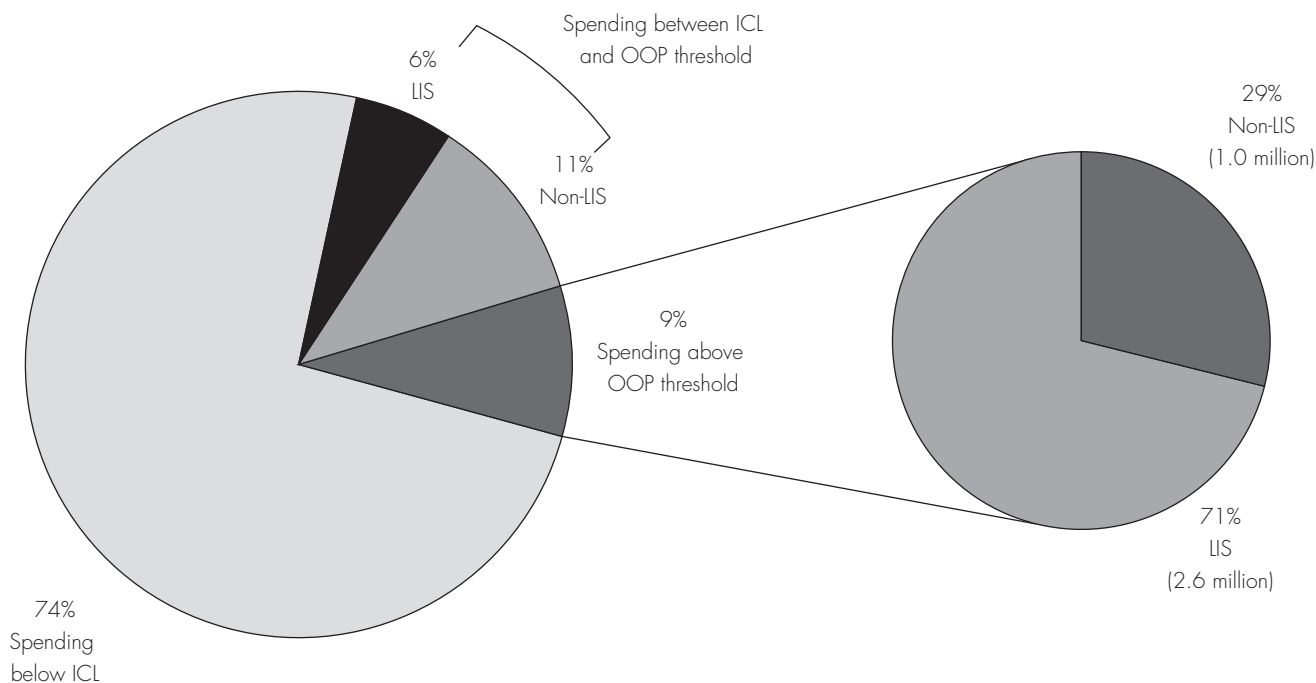
In 2015, more than 2.6 million individuals, or 71 percent of high-cost enrollees, received Part D's low-

income subsidy (LIS) (Figure 14-6). Nearly 20 percent of LIS enrollees are high cost compared with less than 4 percent of non-LIS enrollees (data not shown). Because all LIS enrollees are more likely to be enrolled in stand-alone prescription drug plans (PDPs) than Medicare Advantage–Prescription Drug plans (MA–PDs), 73 percent of high-cost LIS enrollees were in PDPs compared with about 69 percent for non-LIS enrollees with high costs (data not shown). High-cost enrollees were more likely to reside in a long-term care facility and were more likely to be minority, disabled, and under age 65, compared with other enrollees (data not shown).

(continued next page)

FIGURE 14-6

Part D enrollees with spending in the coverage gap and catastrophic phase, 2015



Note: ICL (initial coverage limit), OOP (out-of-pocket), LIS (low-income subsidy). Enrollees with spending between the ICL and the OOP threshold fall within Part D's coverage gap. LIS enrollees do not face a coverage gap because Medicare's low-income cost-sharing subsidy pays for what otherwise would be enrollee cost sharing. In 2015, Part D enrollees reached the ICL at \$2,960 in gross drug spending. With no supplemental coverage, an enrollee reached the threshold at \$4,700 of OOP spending or qualifying drug spending made on behalf of the beneficiary, including the 50 percent discount paid for by pharmaceutical manufacturers for brand-name drugs. Some non-LIS enrollees who reached the catastrophic phase of the benefit may have had some gap coverage.

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

Beneficiaries who reach the coverage gap or catastrophic phase (cont.)

The number of high-cost enrollees has been rising since 2010, growing at an annual rate of 9 percent between 2010 and 2015, compared with 1 percent annually before 2010 (Table 14-9). Gross spending above the catastrophic (i.e., out-of-pocket) threshold also grew more rapidly during that period, rising at an annual 26.6 percent, compared with an annual 12 percent before 2010 (data not shown). Growth in the number of high-cost enrollees between 2010 and 2015 has been more rapid among non-LIS enrollees compared with LIS enrollees—21 percent annually compared with 6 percent annually, respectively.

Prices at the pharmacy affect enrollee cost sharing and the rate at which enrollees reach the catastrophic phase of the benefit. An uptick in prices observed after 2012 was accompanied by an increase in the number of high-cost enrollees, particularly among those who do not receive the LIS. Growth of employer group waiver plans and changes made by the Patient Protection and Affordable Care Act of 2010 have contributed to rapid growth in the number of non-LIS enrollees with high costs.²⁸ ■

**TABLE
14-9**

Part D enrollees reaching the benefit's catastrophic phase, 2007-2015

	2007	2010	2011	2012	2013	2014	2015	Average annual growth rate	
								2007-2010	2010-2015
In millions									
LIS	1.9	2.0	2.1	2.1	2.2	2.5	2.6	1%	6%
Non-LIS	0.4	0.4	0.5	0.5	0.7	0.9	1.0	-2	21
All	2.3	2.4	2.6	2.6	2.9	3.4	3.6	1	9
Percent of all									
Part D enrollees	8.8%	7.9%	8.4%	7.7%	7.6%	8.6%	8.7%	N/A	N/A

Note: LIS (low-income subsidy), N/A (not applicable). Growth rates were calculated using figures before rounding was applied.

Source: Enrollee counts from 2007 are based on published figures from CMS. Enrollee counts from 2010 to 2015 are based on MedPAC analysis of Part D prescription drug event data.

consistently found that high-cost enrollees tend to use more brand-name drugs than other enrollees, even in classes with generic alternatives (Medicare Payment Advisory Commission 2016a). This lower GDR is due, in part, to the fact that most high-cost enrollees receive the LIS. The cost-sharing subsidy, while helping these beneficiaries to afford medications, also minimizes or eliminates the financial incentives plans create to encourage the use of lower cost drugs. One of the Commission's June 2016 recommendations was intended to encourage LIS enrollees to use lower cost alternatives

(including generic drugs and biosimilars) when they are available through moderate changes to financial incentives (see text box on the Commission's 2016 recommendations, pp. 404-405).

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

Among high-cost enrollees, patterns of drug spending vary depending on LIS status. For example, in 2015, drugs in two classes typically associated with specialty-tier drugs (antineoplastics and multiple sclerosis agents) accounted

**TABLE
14-10**

Spending for high-cost enrollees drove overall Part D spending, 2010–2015

	2010	2015	Average annual growth rate, 2010–2015
High-cost enrollees			
Average price per 30-day prescription	\$118	\$193	10.4%
Prescriptions per enrollee per month	<u>9.5</u>	<u>9.5</u>	0.03
Gross drug spending per enrollee per month	\$1,117	\$1,831	10.4
Lower cost enrollees			
Average price per 30-day prescription	\$41	\$34	-3.4%
Prescriptions per enrollee per month	<u>3.7</u>	<u>4.0</u>	1.3
Gross drug spending per enrollee per month	\$151	\$136	-2.1
All Part D enrollees			
Average price per 30-day prescription	\$55	\$65	3.3%
Prescriptions per enrollee per month	<u>4.2</u>	<u>4.5</u>	1.3
Gross drug spending per enrollee per month	\$231	\$290	4.6

Note: Spending includes all payments to pharmacies, including payments by drug plans, Medicare’s low-income subsidy, and beneficiary out of pocket. Changes in the average price per prescription reflect both price inflation and changes in the mix of drugs used. Multiplication of components may not match the figures shown due to rounding.

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

for about 10 percent of high-cost LIS enrollees’ total spending, compared with over 30 percent of spending for the other high-cost enrollees. This pattern is reflected in their higher average spending: In 2015, high-cost enrollees without the LIS had spending of \$272 per prescription and \$27,052 per year compared with \$166 per prescription and \$19,482 per year for high-cost LIS enrollees (Table 14-11).

High-cost LIS enrollees pay much lower cost sharing out of pocket than the other high-cost enrollees. In 2015, average annual OOP spending for high-cost LIS enrollees was \$113, compared with \$2,958 for other high-cost enrollees. One might expect average annual OOP spending for high-cost enrollees without the LIS to be higher than Part D’s OOP threshold in 2015, at \$4,700. However, the average amount is lower primarily because those enrollees were permitted to count the 50 percent discount provided by brand-name manufacturers in the coverage gap as their own OOP spending.

Use of higher cost drugs poses challenges for Part D

The use of higher cost drugs and biologics has grown rapidly. For example, in 2015, drugs with average monthly prices of \$1,000 or more accounted for two-thirds of spending in the catastrophic phase of the benefit, compared with just one-third in 2010 (Office of Inspector General 2017). At the same time, the phase-out of the coverage gap (including the requirement that brand manufacturers provide a 50 percent discount) has reduced the cost sharing of non-LIS enrollees. Average annual OOP spending by high-cost enrollees without the LIS decreased from more than \$4,000 before 2011 to less than \$3,000 in 2011 and subsequent years.

Drugs with very high prices pose a particular challenge for Part D because they tend to be concentrated in treatment classes that are prevalent in the Medicare population. As more expensive therapies become available, larger

**TABLE
14-11**

High-cost enrollees and their prescription use and spending, 2015

High-cost enrollees

	All	LIS status	
		LIS	Non-LIS
Beneficiaries, in millions	3.6	2.6	1.0
Share of total for high-cost enrollees		71%	29%
Total gross spending, in billions of dollars	\$78.9	\$50.8	\$28.2
Share of total for high-cost enrollees		64%	36%
Total numbers of 30-day prescriptions, in millions	408.8	305.5	103.3
Share of total for high-cost enrollees		75%	25%
Gross annual spending per enrollee, in dollars	\$21,642	\$19,482	\$27,052
Average number of prescriptions per enrollee	112	117	99
Average price per prescription, in dollars	\$193	\$166	\$272
Average annual OOP spending per enrollee	\$925	\$113	\$2,958

Note: LIS (low-income subsidy), OOP (out-of-pocket). Components may not sum to totals due to rounding. A beneficiary is classified as "LIS" if that individual received Part D's LIS at some point during the year. Numbers of prescriptions are standardized to a 30-day supply.

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

numbers of beneficiaries will reach the catastrophic phase of the benefit, when Medicare pays for 80 percent of the costs through reinsurance. Coinsurance on high-priced medicines will become increasingly burdensome for enrollees without the LIS as well as for Medicare's low-income subsidy program. At the same time, Medicare's generous reinsurance subsidy and the expanded use of rebates may create incentives for plan sponsors that are not always aligned to encourage the use of lower cost products.

The Commission's 2016 recommendations would help to address the challenges of higher cost treatments. Under the recommendations, Medicare's subsidy of basic Part D benefits would remain unchanged at 74.5 percent, but plan sponsors would receive more of the subsidy through capitated payments and less through open-ended reinsurance. Lowering Medicare's reinsurance from 80 percent to 20 percent of catastrophic spending while providing plan sponsors with greater flexibility to use formulary tools to manage benefits would give plan sponsors stronger incentives to manage the drug spending for high-cost enrollees.

Biosimilars in Medicare Part D

Biologics make up a fast-growing segment of spending and will continue to grow in importance. Some biologics offer beneficiaries important new treatment options. However, many biologics have high prices that raise concerns about their cost burden on patients and the Medicare program. Biosimilars are expected to have lower prices than originator biologics: Enrollees' take-up could introduce price competition and improve patient access (see text box on biologics and biosimilars, p. 426). However, regulatory approval and market entry have been slow. As of December 2017, the FDA had approved just nine biosimilars and had not yet designated any as interchangeable. Among those products, only three have entered the commercial market. The key reasons for delay relate to patent litigation and the fact that some manufacturers of originator biologics use "patent walls," reverse-payment agreements, and contracts that require payers to exclude biosimilars from their formularies as a condition for rebates.²⁹ Other hurdles—including some Part D policies—may also affect take-up. This year,

Biologics and biosimilars

The term *biologics* includes therapies such as insulins and therapeutic proteins that are used to treat diabetes, cancer, rheumatoid arthritis, multiple sclerosis, and other diseases. While most traditional drugs are synthesized chemically, biologics are manufactured through biological processes. Many biologics have more complex molecular structures, and their manufacturing processes can directly affect their structure.

Biosimilars are follow-on products that are highly similar to an originator biologic. Unlike generics, biosimilars are not exact replicas of the originator biologic.³⁰ *Interchangeable* products are a subset of biosimilars that, under federal law, may be substituted for the originator without the intervention of the prescriber. However, 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 for its originator product.

Medicare pays for biologics in both Part B (for provider-administered medicines) and Part D (through outpatient pharmacy benefits). Historically, more of Medicare's spending for noninsulin biologics has been covered under Part B than Part D. However, Part D spending for biologics is growing rapidly, and a number of biologic products in the development pipeline will be self-injectable and covered under Part D.

Some biologics have prices that cost several thousands of dollars or more annually, and Part D plans often place biologic therapies on specialty tiers. For specialty-tier products, enrollees pay coinsurance ranging from 25 percent to 33 percent. Beneficiaries who use drugs or biologics on a specialty tier are likely to incur spending high enough to reach Part D's out-of-pocket threshold, after which Medicare pays 80 percent of costs through individual reinsurance and the enrollee pays 5 percent. Through Part D's low-income subsidy, the program pays for most or all cost sharing on behalf of individuals who are eligible and enrolled. ■

the Commission recommends Part D changes to rectify policies that put biosimilars at a financial disadvantage relative to originator biologics.

Spending on biologics

Part D spending for biologics grew rapidly between 2011 and 2015, from less than \$7 billion (8 percent of all Part D spending) to \$18.7 billion (nearly 14 percent) (Table 14-12). Biologics covered under Part D fall into two broad categories. The first group includes older molecules such as insulin, human growth hormone, and other hormones that have relatively lower prices than the second group. Some of these therapies, such as insulin, are used by large patient populations. The second group includes more complex molecules such as monoclonal antibodies and other therapeutic proteins that tend to have much higher prices and are used by relatively smaller populations.

In 2015, insulin was the largest class of biologics in Part D, accounting for \$11.2 billion (nearly 60 percent) of

biologics spending (Table 14-13, p. 428). Between 2011 and 2015, insulin accounted for nearly 90 percent of all prescriptions for biologics, and insulin's share of biologics spending grew from 55 percent to 60 percent (data not shown). Other therapeutic categories that follow insulin in terms of spending include inflammatory diseases (e.g., rheumatoid arthritis, psoriasis, and Crohn's disease) and therapies for multiple sclerosis, which accounted for 19 percent and about 7.5 percent of biologic spending, respectively, in 2015. Between 2011 and 2015, these three classes combined accounted for over 80 percent of biologics spending in any given year and about 88 percent of the spending growth for biologics.

Consistent with the Commission's Part D indexes, rapid increases in prices per prescription have driven spending growth for the three largest classes of biologics. For each of those classes, between 2011 and 2015, the average price per prescription (before rebates) grew by 16 percent to 20 percent annually, explaining half or more of each class's growth in gross spending (Table 14-13, p. 428). In

**TABLE
14-12**

Spending and use of biologics in Part D, 2011–2015

	2011	2012	2013	2014	2015	Growth 2011–2015	
						Cumulative	Average annual rate
Gross spending on biologics (in billions)	\$6.8	\$8.9	\$12.0	\$15.4	\$18.7	\$11.9	29%
As a share of all Part D	8.0%	9.9%	11.6%	12.7%	13.6%		
Number of biologic prescriptions (in millions)	25.3	28.7	32.8	35.0	37.0	11.7	10%
As a share of all Part D	1.7%	1.8%	1.7%	1.7%	1.7%		

Note: Biologic products were identified using an approval pathway for biologics (Biologics License Applications, or BLA) reported by the First DataBank and based on specific national drug codes for products not approved under the BLA. Spending does not reflect any retrospective rebates, discounts, or fees paid by manufacturers and pharmacies to Part D plans. Prescriptions are standardized to a 30-day supply.

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

comparison, prices per prescription for all other biologics combined had an average annual growth of 5 percent over the same period.

Financial disincentives to use biosimilars in Part D

The degree to which biosimilars will temper growth in Part D spending is uncertain. Over the next decade, approval and market entry of more biosimilars may lead to greater price competition. However, multiple factors affect when manufacturers may launch biosimilars and whether prescribers and patients will use those products. Many of those factors are outside of Medicare’s purview, such as product naming conventions, FDA requirements for demonstrating interchangeability, state laws that limit substitution of biosimilars for originator biologics, and competitive tactics among manufacturers. However, Medicare policy also plays a role. We focus on Part D policies that directly affect financial incentives faced by beneficiaries and plan sponsors.

Beneficiary disincentives to use biosimilars

Differential cost sharing across formulary tiers is a fundamental tool used by plan sponsors to encourage enrollees to use lower cost options. However, the 12 million beneficiaries who receive Part D’s LIS either have no cost sharing or they pay nominal amounts. Currently, because biosimilars do not meet CMS’s definition of a

generic or multisource drug, enrollees who receive Part D’s LIS pay the same maximum cost-sharing amount for either a biosimilar or its originator biologic. As a result, even if a plan sponsor were to cover both a biosimilar and its originator product on its formulary and place the biosimilar on a preferred tier with lower cost sharing, LIS enrollees would not have any financial incentive to use the biosimilar. In CMS’s recent proposed rule, the agency would treat biosimilars as generics solely for purposes of determining LIS cost sharing and cost sharing for other enrollees who reach the catastrophic phase (Centers for Medicare & Medicaid Services 2017g).

In its June 2016 report to the Congress, the Commission recommended that the Congress modify Part D’s LIS copayments to encourage the use of generics, preferred multisource drugs, and biosimilars when available in selected therapeutic classes (see text box on the Commission’s 2016 recommendations on pp. 404–405). Increasing the use of biosimilars by LIS beneficiaries could increase price competition among biologic products.

Incentives for beneficiaries without the LIS to use biosimilars can depend on the amount of spending they expect to incur in a given year. If a plan sponsor places a biosimilar on a preferred cost-sharing tier, some beneficiaries may respond to that financial incentive and use the biosimilar rather than the originator product. However, because of how Part D’s coverage-gap discount

**TABLE
14-13**

Increase in prices drove growth in Part D spending for the largest classes of biologics, 2011-2015

	Growth 2011-2015			
	2011	2015	Cumulative	Average annual rate
Insulin				
Average price per prescription	\$165	\$343	\$178	20%
Number of prescriptions, millions	<u>22.7</u>	<u>32.6</u>	9.8	9
Gross spending, billions	\$3.7	\$11.2	\$7.4	31
Therapy for inflammatory diseases				
Average price per prescription	\$1,966	\$3,486	\$1,520	16
Number of prescriptions, millions	<u>0.6</u>	<u>1.0</u>	0.4	14
Gross spending, billions	\$1.2	\$3.6	\$2.4	32
Therapy for multiple sclerosis				
Average price per prescription	\$3,029	\$5,292	\$2,263	16
Number of prescriptions, millions	<u>0.2</u>	<u>0.3</u>	0.03	3
Gross spending, billions	\$0.7	\$1.4	\$0.7	19
All others				
Average price per prescription	\$659	\$801	\$142	5
Number of prescriptions, millions	<u>1.7</u>	<u>3.1</u>	1.4	16
Gross spending, billions	\$1.1	\$2.5	\$1.4	22

Note: Biologic products were identified using an approval pathway for biologics (Biologics License Applications, or BLA) reported by the First DataBank and based on specific national drug codes for products not approved under the BLA. "All others" includes all biologics excluding insulin, therapies for inflammatory diseases, and therapies for multiple sclerosis. Spending does not reflect any retrospective rebates, discounts, or fees paid by manufacturers and pharmacies to Part D plans. Prescriptions are standardized to a 30-day supply. Cumulative growth amounts may be affected by rounding.

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

program is structured, beneficiaries who incur high spending could find that using a biosimilar leads to higher OOP spending than using an originator biologic.

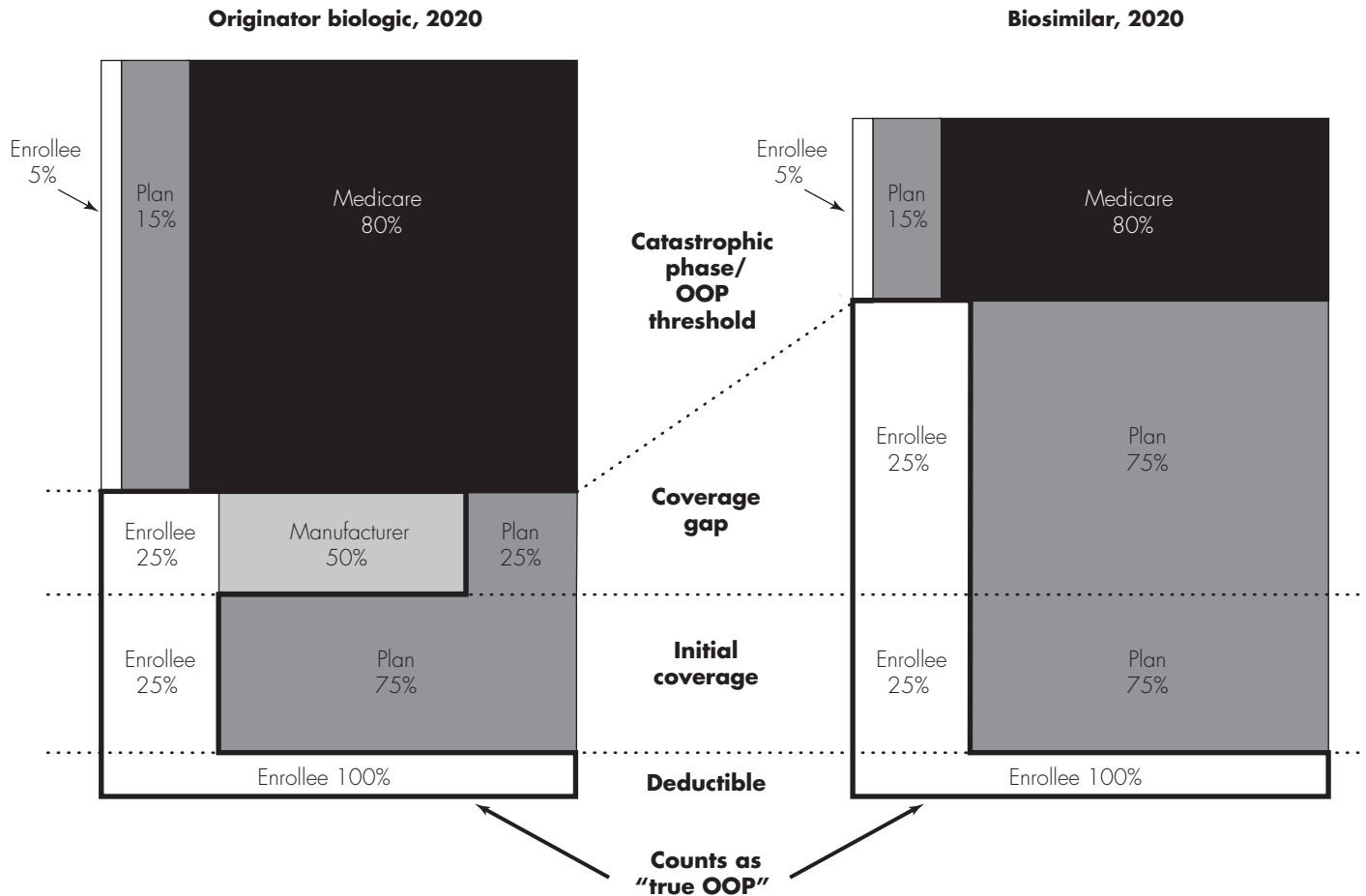
Under Part D's coverage-gap discount, enrollees with spending above the initial coverage limit but less than the OOP threshold receive a 50 percent discount from manufacturers of brand-name drugs and originator biologics. Manufacturers must provide that discount as a condition for having their products covered by Part D. However, current law excludes most biosimilars from this discount.³¹ Before 2020, an enrollee would pay a higher coinsurance rate for the biosimilar product than

for the reference biologic. This unequal treatment distorts beneficiaries' financial incentives and has an effect similar to a copayment coupon: By replacing their cost-sharing liability, the beneficiary has greater incentive to use brand-name drugs even when lower cost options are available (Maggs and Kesselheim 2014).

The coverage gap is scheduled to be phased out by 2020. Even so, Medicare will continue to track the range of spending at which the coverage gap would otherwise apply, and brand manufacturers will continue to provide the 50 percent discount. In 2020 and thereafter, the Part D benefit will cover 25 percent of covered brand-name drug

FIGURE 14-7

Counting manufacturers' 50 percent discount on an originator biologic as if it were enrollee's OOP spending disadvantages biosimilars



Note: OOP (out-of-pocket). "True OOP" refers to Part D spending counted toward the enrollee's OOP threshold. Under current law, the 50 percent discount provided by manufacturers of brand-name drugs and originator biologics in Part D's coverage gap are counted as though they were the enrollee's OOP spending. Biosimilar manufacturers are currently excluded from the coverage-gap discount.

Source: MedPAC.

spending in what is now the coverage gap, the enrollee will pay 25 percent cost sharing, and brand manufacturers will continue to provide a 50 percent discount on price (Figure 14-7). Beginning in 2020, the enrollee would also pay 25 percent cost sharing for the biosimilar.

Even after 2020, a separate provision could lead to higher OOP spending if the beneficiary used a biosimilar. Generally, only cost sharing paid by the enrollee counts toward the OOP threshold—known as Part D's "true OOP" provision. Currently, however, the 50 percent discount is added to the enrollee's own spending for

purposes of determining whether the enrollee has reached the OOP threshold. As a result, patients who take an originator biologic would be likely to reach the OOP threshold more quickly (i.e., with lower OOP spending) than if they took the biosimilar. (For this reason, in Figure 14-7, the catastrophic phase of the originator product begins at a lower level of spending than for the biosimilar.)

In turn, this treatment of the discount affects Medicare's spending for reinsurance. Once enrollees reach the OOP threshold, they pay 5 percent coinsurance, the plan pays 15 percent, and Medicare pays for 80 percent through

individual reinsurance. The number of enrollees without the LIS who reached Part D's catastrophic phase has grown more rapidly since 2010, the year the coverage-gap discount provisions became law. Because of distortions the discount policy creates in relative prices, in 2016, the Commission recommended that the Congress change Part D law to exclude manufacturer discounts in the coverage gap for calculating enrollees' true OOP spending (see text box on the Commission's 2016 recommendations, pp. 404–405).

Disincentives for plans to place biosimilars on their formulary

Generally, sponsors want to encourage their enrollees to use lower cost products to keep plan premiums low, and many analysts anticipate that biosimilars will have lower prices than their originator biologics. However, for enrollees without the LIS, 50 percent of coverage-gap spending for an originator biologic would be financed with the manufacturer's discount. As a result, the plan would be responsible for proportionately less spending. In 2020, the plan would pay for 25 percent of coverage-gap spending for the originator biologic, compared with 75 percent for the biosimilar (Figure 14-7, p. 429).³² Moreover, because an enrollee would reach the OOP threshold at a lower level of spending for the originator product, Medicare reinsurance would further reduce what the plan must cover from 25 percent to 15 percent. As a result, plan sponsors may find it financially advantageous to include originator biologics on their formularies rather than the lower priced biosimilars.

RECOMMENDATION 14

Changes in policy are needed to correct the disincentives for using biosimilars that exist under current law and to help promote greater price competition among biologic products. For this reason, the Commission's recommendation would require Part D's coverage-gap discount to apply to biosimilars in the same manner that it now applies to originator biologics. The policy fits within the construct of the Commission's 2016 recommendations to improve Part D because it would also exclude biosimilar manufacturers' discounts in the coverage gap from counting as enrollees' true OOP spending. (Online Appendix 14-A, available at <http://www.medpac.gov>, provides a numeric example of the effects of the Commission's recommendation.) Specifically, the Commission makes the following recommendation:

The Congress should change Part D's coverage-gap discount program to:

- **require manufacturers of biosimilar products to pay the coverage-gap discount by including biosimilars in the definition of "applicable drugs" and**
- **exclude biosimilar manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending.**

(Subsequent to the Commission's vote on this recommendation, the Bipartisan Budget Act of 2018 directed biosimilar manufacturers to, beginning in 2019, provide a discount on their products in the coverage gap. However, unlike the Commission's recommendation, the discount amount would continue to count as though it were the enrollees' own OOP spending. The text that follows reflects current law prior to this change.)

RATIONALE 14

Under current law, manufacturers of brand-name drugs and originator biologics must provide a 50 percent discount to "applicable enrollees" (i.e., beneficiaries who do not receive the LIS) while they are in the coverage-gap phase of the benefit. However, by law, biosimilars are excluded from this coverage-gap discount. This unequal treatment of biosimilars and originator biologics distorts financial incentives, favoring originator products by making them appear less expensive to plan sponsors and beneficiaries. The recommendation would apply the coverage-gap discount equally to remove this distortion in price signals and promote price competition between originator products and biosimilars.

The second part of the recommendation would treat biosimilar manufacturers' new coverage-gap discount in a way that is consistent with the Commission's 2016 recommendations. The earlier recommendations call for discontinuing the policy of crediting brand-name manufacturers' discounts toward an enrollees' OOP spending threshold, as if the enrollee paid that amount out of pocket. By counting the discount amount toward the threshold, current policy both lowers the relative price of brand-name drugs and originator biologics and quickens the pace at which an enrollee reaches the OOP threshold (the point at which Medicare begins paying for 80 percent of benefits through reinsurance). Instead, the 2016 recommendation would discontinue that practice, thereby placing OOP spending for brand-name and generic drugs on more equal footing. Similarly, this recommendation

would treat OOP spending in the coverage gap for originator biologics and biosimilars equivalently.

The Commission makes this recommendation in conjunction with its standing Part D recommendations from 2016, which include eliminating enrollee cost sharing above the OOP threshold. In other words, this recommendation serves as an amendment to the package of changes discussed in 2016 rather than a recommendation that stands on its own. In general, the policy change to no longer count manufacturer discounts toward the OOP threshold would increase cost sharing for enrollees who use brand-name drugs, originator biologics, or biosimilars and have spending high enough to reach the coverage gap. To address the issue of a higher cost-sharing burden, the Commission's 2016 recommendations would provide real insurance protection to enrollees against catastrophic OOP spending. To the extent that the adoption of the Commission's set of recommendations results in net program savings, the Congress could consider enhancing protections for non-LIS enrollees facing high cost-sharing burdens.

IMPLICATIONS 14

Spending

- Because the Commission considers this recommendation an addition to its standing 2016 recommendations for Part D, we asked the Congressional Budget Office (CBO) to provide one combined estimate inclusive of the new biosimilar component. In 2016, CBO estimated that the Commission's overall package of recommendations (described in the text box on pp. 404–405) would lead to one-year program savings of more than \$2 billion relative to baseline spending and more than \$10 billion in savings over five years. CBO now estimates that the combined savings—including the newer recommendation—would remain at more than \$2 billion in one year and more than \$10 billion over five years. Few biosimilars that would be covered under Part D are as yet available on the market, so additional near-term savings are unlikely to be large. Over the longer term, however, program savings could be significant if the recommendation led to price competition between biosimilars and originator biologics.

Beneficiaries and providers

- Because the recommendation would apply the coverage-gap discount equally to biosimilars and originator biologics, plan sponsors would be more

likely to place biosimilars (which we expect to have lower prices than originators) on their formularies. At the same time, excluding coverage-gap discounts from enrollees' true OOP spending would tend to increase plan sponsors' liability for benefit spending. With fewer enrollees reaching the OOP threshold, plan sponsors would receive a larger proportion of Medicare's 74.5 percent subsidy through direct-subsidy payments and less through reinsurance payments.

Manufacturers of brand-name drugs and biologics would pay more in coverage-gap discounts under the recommendation. Biosimilar manufacturers, which are not now eligible to participate in the coverage-gap discount program, would begin providing discounts. The recommendation could also spark greater price competition between manufacturers of originator biologics and biosimilars.

Relative to current-law spending, the recommendation would have offsetting effects. On the one hand, to the extent that plan sponsors place lower priced biosimilars on their formularies and those biosimilar manufacturers provide a coverage-gap discount, beneficiaries who take those medicines may see reduced cost sharing per prescription. However, because the recommendation would exclude manufacturer discounts from true OOP spending, enrollees would remain in the coverage gap longer. In other words, they would reach the OOP threshold at a higher level of total drug spending. However, the Commission's 2016 recommendations would eliminate cost sharing above the OOP threshold, thereby providing greater protection for beneficiaries with the highest drug spending.

Beneficiaries' access to prescription drugs

A key 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 one of the most important tools used by plan sponsors to strike this balance.

Greater flexibility to use management tools could help ensure that prescribed medicines are safe and appropriate for the patient, potentially reducing overuse and misuse. However, for some beneficiaries, those same tools could potentially limit access to needed medications. To ensure beneficiary access, CMS reviews and approves each plan's formulary to check that it provides access to a wide range of therapeutic classes used by the Medicare population. Part D law also requires sponsors to have a transition process to ensure that new enrollees, as well as current members whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.³³ Medicare also requires plan sponsors to establish coverage determination and appeals processes.

Part D's exceptions and appeals process

Online Appendix 14-B, available at <http://www.medpac.gov>, provides an overview and detail about Part D's exceptions and appeals process. The process begins when an enrollee's prescription is rejected at the pharmacy because the drug is not listed on the plan's formulary or because of a plan's utilization management requirements. The pharmacy is required to provide the enrollee with written information on how to obtain a detailed written notice from the enrollee's plan about why the benefit was denied and the right to appeal. The enrollee must contact the plan for the basis of the denial of benefits and initiate a request for a coverage determination with supporting justification from the prescriber.

Part D requires quicker adjudication time frames than for Medicare Advantage medical benefits because "the majority of Part D coverage requests involve prescription drugs an enrollee has not yet received, which increases the risk of adverse clinical outcomes if access to the drug is delayed" (Centers for Medicare & Medicaid Services 2016b, Centers for Medicare & Medicaid Services 2016c). Plan sponsors must make a decision about exceptions and coverage determination within 72 hours of a request or within 24 hours for expedited requests. If the plan contacts the prescriber but is not able to obtain the supporting information needed to make a coverage determination within the allotted time, the plan must issue a denial and then process any subsequent information it receives as a redetermination. If the enrollee is dissatisfied with the outcomes of those steps, he or she may appeal the decision

to an independent review entity (IRE) and potentially to higher levels of appeal.

Part D plan sponsors report to CMS some data on pharmacy claims that are rejected at the point of sale, as well as outcomes of coverage determinations and redeterminations.³⁴ In 2015, only about 4 percent of prescriptions were rejected at the pharmacy for reported reasons—most commonly because the drug was not on the plan's formulary, followed by plan requirements for prior authorization, quantity limits, or step therapy (see online Appendix 14-B, available at <http://www.medpac.gov>). In that same year, only about 9 percent of reported rejections proceeded to a plan coverage determination, and, further, 9 percent of these determinations were subsequently appealed or sent on automatically for plan redeterminations. Although outcomes vary considerably among plans, in 2015, 64 percent and 70 percent of determination and redetermination decisions, respectively, were fully favorable to the enrollee. Rates per 1,000 enrollees at which individuals sought coverage determinations and redeterminations have both increased in recent years. This trend may indicate that enrollees and prescribers are more aware of or willing to make use of the appeals process or that their prescriptions are increasingly subject to utilization management requirements.

CMS also reports on the decisions in the IRE step of the appeals process and uses these data for one measure in Part D plans' star ratings. In 2015, only about 5 percent of redeterminations were appealed or automatically forwarded to an IRE. CMS has noted considerable gaps in data reporting for IRE appeals for the majority of plans. However, when data were reported and validated, the IRE agreed with the plans' redetermination decisions most of the time.

CMS continues to find that a significant share of audited plans has difficulties in the areas of Part D transition fills, coverage determinations, appeals, and grievances. For example, a common shortfall is that many plans provide enrollees with too little information about the rationale for a coverage denial or do not demonstrate that they have reached out to prescribers for additional information to make a coverage decision (Centers for Medicare & Medicaid Services 2016d). At the start of benefit year 2016, CMS applied intermediate sanctions against several Part D plan sponsors for failure to comply with regulations in multiple areas, including Part D formulary and benefit administration and Part D coverage determinations, appeals, and grievances (Centers for Medicare & Medicaid

Services 2017i). The sanctions imposed immediate suspension of marketing to and enrollment of Medicare beneficiaries, and they remained in effect until corrective actions were taken.

At the same time, exceptions and appeals that routinely overturn plans' coverage decisions could undermine plans' efforts to manage drug spending. A plan sponsor's representative described for us the sponsor's experience in which the plan's decisions denying coverage of drugs because they were not on the plan's formulary were routinely overturned at the IRE level of appeal. The plan sponsor was generally not successful in appealing IRE decisions, which were typically denied on the grounds that supporting statements provided by prescribers proved the medical necessity for the drug—even when those statements were extremely general such as, “this is the right drug for the patient.” Because a Part D plan's star rating includes how often its coverage decisions are overturned by the IRE, such cases can have a chilling effect on a plan's willingness to use formulary tools—including on-formulary or off-formulary status—to manage the use of expensive medications. That reluctance to use formulary tools, in turn, can affect the rebate negotiations with pharmaceutical manufacturers.

Several beneficiaries who participated in the Commission's focus groups described learning that a drug prescribed by their provider was not covered by insurance or was much more expensive than they expected (Summer et al. 2017). If a prescription drug was too expensive or not covered, beneficiaries generally seemed familiar with the process of working with their pharmacy and their physician to either get a new prescription or go through the necessary prior authorization, step therapy, or appeal process. This familiarity is a notable change from several years ago, when beneficiaries in our focus groups were less aware of available options to resolve this type of problem and would sometimes report that they walked away from the pharmacy without a prescription.

A more efficient approach would be to resolve any issues at the point of prescribing rather than at the pharmacy counter through real-time formulary checks, e-prescribing, and electronic prior authorization (ePA). Such tools could reduce the need for coverage determinations and appeals and increase the likelihood that beneficiaries receive an appropriate medicine at the pharmacy. Automated processes could also lower the administrative burden and lead to a more uniform approach for beneficiaries,

prescribers, and plans (American Medical Association 2015). Part D plan sponsors are required to support electronic prescribing, but e-prescribing and electronic prior authorization are optional for physicians and pharmacies.³⁵ While beneficiary advocates are generally supportive of such steps, some contend that they would not be sufficient to address persistent challenges (Medicare Rights Center 2016). Perhaps the most essential requirement for adoption of ePA is clinician acceptance and use, which can require paying fees and embracing practice pattern change.

Quality in Part D

CMS collects quality and performance data to monitor sponsors' operations. A subset of data is used to rate plans in a 5-star system, from which CMS determines MA quality bonus payments (quality bonus payments do not apply to stand-alone PDPs). Quality data are also made available to the public to help beneficiaries evaluate their plan options during Part D's annual open enrollment. CMS also requires plan sponsors to carry out medication therapy management (MTM) programs to improve the quality of the pharmaceutical care for high-risk beneficiaries. Although the Commission supports CMS's goal of improving medication management, we have ongoing concerns about the effectiveness of plans' MTM programs. In 2017, CMS began a new enhanced MTM model. We plan to examine the effectiveness of the new MTM program once additional information becomes available.

Measuring plan performance

CMS collects Part D plan quality and performance data from several sources—the Consumer Assessment of Healthcare Providers and Systems[®] (CAHPS[®]) survey, agency monitoring of plans, data furnished by plan sponsors, and claims information (Centers for Medicare & Medicaid Services 2017e). Selected performance measures are available on the Plan Finder at www.medicare.gov to help beneficiaries evaluate their plan options during Part D's annual open enrollment. The lowest rated plans are flagged to caution beneficiaries about choosing those plans. The highest rated plans can enroll beneficiaries outside the annual open enrollment period. In addition, for MA-PDs, Part D performance data affect the MA program's overall plan ratings to determine the amount of bonus payment.

For 2018, 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 2017b). Intermediate outcome measures (three metrics, e.g., adherence to selected class of medications) each receive a weight of 3, while the eight 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 (e.g., accuracy of drug prices posted on the Plan Finder) receive a weight of 1. Finally, drug plan quality improvement, a measure reflecting changes in drug plans' performance from one year to the next, is assigned the highest weight (5). Most MA-PDs are rated on up to 34 measures that assess the quality of medical services provided under the MA program, in addition to the 14 measures used to assess the quality of prescription drug (Part D) services provided. CMS aggregates individual scores for each measure (14 for PDPs and 48 for MA-PDs) on the Plan Finder in a 5-star system; 5 stars reflects excellent performance, and 1 star reflects poor performance.

Among PDPs, the average star rating for 2018 (weighted by 2017 enrollment) increased to 3.62 from 3.55 a year earlier (Centers for Medicare & Medicaid Services 2017b). About 47 percent of PDP enrollees (based on the 2017 enrollment) are in contracts with 4 or more stars. Among MA-PDs offered for 2018, the average star rating (for Part D metrics) remained stable at about 4. (See Chapter 13 for a discussion of star ratings for MA plans and MA-PDs.) Seventy-three percent of MA-PD enrollees are in contracts with 4 or more stars.

Star ratings could 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 focus groups mentioned using the Medicare star ratings as a source of information to choose a health plan (Summer et al. 2017). 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, all 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, the medication adherence of current members may not be an important factor when choosing among plan options. Additionally, plans may not be in the best position to assess whether the prescribed medications were clinically appropriate. At the same time, measuring plans on member adherence to medications could encourage plans to structure benefits in a way to provide better access. In the future, we plan to look into the characteristics of quality measures that reflect plan performance in a way that is meaningful for beneficiaries when they compare their plan options.

Medication therapy management programs

Part D plans are required to implement MTM programs to improve the quality of pharmaceutical care for beneficiaries who are at risk for adverse drug events, including adverse drug interactions. These programs are intended 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 annual drug spending that exceeds the annual cost threshold for MTM (\$3,967 for 2018). 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).

Plan sponsors are required to enroll, with opt-out provisions, all eligible enrollees in their MTM programs. At a minimum, MTM programs must offer a comprehensive medication review (CMR) at least annually and a targeted medication review (TMR) at least quarterly for ongoing monitoring and follow-up of any medication-related issues.³⁶ CMS has changed the criteria for plans' MTM programs over time to broaden eligibility. Currently, 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 2017h).

While there continues to be variation across MTM program characteristics and eligibility criteria, trends in eligibility and participation have moved upward (Centers

for Medicare & Medicaid Services 2017a). For example, in 2015, nearly 13 percent of Part D enrollees were eligible for MTM services, up from 12.4 percent in 2013 (Centers for Medicare & Medicaid Services 2017d). The share of MTM program enrollees receiving a CMR increased from about 13 percent (about 2 percent of Part D enrollees) in 2013 to over 25 percent (about 3 percent of Part D enrollees) in 2015.

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

At the same time, we continue to be concerned that sponsors of stand-alone PDPs do not have financial incentives to engage in MTM or other activities that, for example, increase adherence to appropriate medications. CMS's analysis of the MTM data consistently finds PDPs to be lagging behind MA-PDs in terms of the rate CMRs are provided to MTM enrollees. Further, the effectiveness

of the current MTM services in improving the quality of overall patient care is unclear and may, according to CMS, "fall short of their potential to improve quality and reduce unnecessary medical expenditures" (Centers for Medicare & Medicaid Services 2015b, Marrufo et al. 2013).

In 2015, CMS announced its intent to implement an enhanced MTM model to test whether payment incentives and greater regulatory flexibility in designing MTM programs will "achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions" (Center for Medicare & Medicaid Innovation 2015). Six Part D sponsors operating PDPs in five regions of the country are participating in the enhanced MTM model over a five-year period that began on January 1, 2017 (Medicare Payment Advisory Commission 2017c). Regulatory flexibility combined with financial incentives provided under the model have the potential to address some of the Commission's concerns regarding coordination with a beneficiary's care team and plans' incentive to offer MTM programs (Medicare Payment Advisory Commission 2014). We will continue to monitor how well the current MTM program is working and report on the new enhanced MTM model as more information becomes available. ■

Endnotes

- 1 The prescription drug coverage that beneficiaries had before 2006 may not have been as generous as the Part D benefit. Since 2006, 88 percent of beneficiaries have had drug coverage that is as generous as Part D's basic benefit.
- 2 Table II.B.1 of the Medicare Trustees' 2017 report lists Part D expenditures for 2016 as \$99.5 billion (Boards of Trustees 2017). That larger amount includes reconciliation payments made during 2016 between Medicare and plan sponsors for benefits delivered in previous years.
- 3 In 2018, the Part D benefit provides gap coverage of 15 percent for brand-name drugs, in addition to a 50 percent discount provided by drug manufacturers, reducing cost sharing in the gap to about 35 percent (Centers for Medicare & Medicaid Services 2017c). Cost sharing for brand-name drugs depends on the dispensing fee charged since the 15 percent covered by Part D applies to both the ingredient cost and the dispensing fee, while the 50 percent manufacturer discount applies only to ingredient costs.
- 4 Beneficiaries' level of drug spending at the OOP threshold depends on the mix of brand-name and generic prescriptions they fill in the coverage gap. CMS estimates that for a non-LIS enrollee with an average mix of drugs and no supplemental coverage, the amount would be \$8,417.60.
- 5 Even though enrollees will no longer see a coverage gap as of 2020, Medicare will continue to track the range of spending at which the coverage gap would otherwise apply, and manufacturers will continue to provide a discount.
- 6 The goal of CMS's meaningful difference policy is to help beneficiaries distinguish among plan options more clearly. To be considered meaningfully different for 2018, a beneficiary's expected OOP costs between basic and enhanced plans must differ by at least \$20 per month. If a sponsor is offering two enhanced PDPs in the same service area, the second plan must have a higher value than the first, with an OOP difference of at least \$37 per month. Some plan sponsors have criticized the meaningful difference policy as one that restricts choice because it prevents sponsors from offering additional plan options. CMS has proposed removing meaningful-difference requirements in 2019 when plan sponsors offer two enhanced plans. However, the requirement would remain in place to distinguish between basic and enhanced plans (Centers for Medicare & Medicaid Services 2017g).
- 7 CMS's de minimus policy (codified under Section 3303(a) of PPACA) allows plan sponsors to voluntarily waive the portion of the monthly adjusted basic beneficiary premium that is above the low-income subsidy benchmark for a subsidy-eligible individual, up to a de minimus amount. The de minimus amount for 2018 is \$2.
- 8 If an employer agrees to provide primary drug coverage to retirees with an average benefit value equal to or greater than Part D (called "creditable coverage"), Medicare provides a tax-free subsidy to the employer for 28 percent of each eligible retiree's drug costs that fall within a specified range of spending. Under PPACA, employers still receive the RDS tax free, but as of 2013, they can no longer deduct drug expenses for which they receive the subsidy as a cost of doing business. However, they can still deduct prescription drug expenses not covered by the subsidy.
- 9 Other sources of creditable coverage include the Federal Employees' Health Benefits Program, TRICARE for Life, and the Department of Veterans Affairs.
- 10 EGWPs are Part D plans sponsored by employers that contract directly with CMS or with an insurer or a pharmacy benefit manager to administer a drug benefit on the employer's behalf. EGWPs differ from employer plans that receive the RDS in that they are considered Part D plans; that is, Medicare Part D is the primary payer rather than the employer. However, unlike other Part D plans, EGWPs are offered only to Medicare-eligible retirees of a particular employer (i.e., the requirement that anyone be allowed to enroll in such a plan is waived).
- 11 Under the MA payment system, a portion of the difference between the plan's benchmark payment and its bid for providing Part A and Part B services is referred to as *MA rebate dollars*. The rebate dollars can be used to supplement benefits or lower premiums for services provided under MA or Part D.
- 12 MA-PD premiums reflect Medicare Advantage plans' total monthly premium attributable to Part D benefits for plans that offer Part D coverage. The premiums are net of Part C rebate dollars that were used to offset Part D premium costs.
- 13 Most MA plans are MA-PDs, offering combined medical and outpatient drug benefits. However, a small share of MA plans (including Medicare Medical Savings Account plans) do not offer prescription drug coverage.
- 14 That number includes 14 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.

- 15 About half of LIS enrollees who paid a premium in 2017 were in enhanced plans (Cubanski et al. 2017).
- 16 CVS Health has announced that it plans to purchase Aetna, pending a federal antitrust review (Small 2017).
- 17 Some specialty drugs fall under a health plan's *medical* benefit—typically because they are administered by a provider. For example, a patient undergoing chemotherapy might receive regular infusions in a physician's office or hospital outpatient department while monitored by a provider. In Medicare, that type of drug would be reimbursed under Part B because it would be related to clinical services. Other specialty drugs that can be self-administered are usually reimbursed under outpatient pharmacy benefits, and in Medicare, those drugs generally fall under Part D. There are some exceptions, however. For example, as some older chemotherapy drugs became available in oral form, the Congress decided to cover under Part B oral chemotherapy and antiemetic drugs that are exact replacements for covered infusible drugs.
- 18 Some pharmacies choose not to contract with certain plans because they do not like the terms and conditions the plans offer. Plan sponsors are not obligated to cover prescriptions at an out-of-network pharmacy, except under certain circumstances.
- 19 Critics contend that the way in which plan sponsors and their PBMs calculate pharmacy DIR fees is not transparent and that plan sponsors ignore or understate DIR fees when preparing Part D bids, leading to enrollee premiums that are too high (National Community Pharmacists Association 2016). PBMs and sponsors that support the use of pharmacy DIR fees counter that they are a means to encourage greater use of generics and reduce enrollees' premiums and OOP spending (Holtz-Eakin 2014). To the extent that beneficiaries select plans with tiered networks and use preferred pharmacies that are more efficient, the approach may also lower Medicare spending (Kaczmarek et al. 2013).
- 20 Part D enrollees may 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 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).
- 21 The growing dollar amounts of those fees, their retrospective nature, and the criteria plan sponsors use for setting performance-based fees have led to criticism from independent specialty pharmacies (Seeking Alpha 2016).
- 22 IQVIA Institute (formerly IMS) defines invoice prices as the amounts paid to distributors by their pharmacy or hospital customers, which is different from gross spending reflected in Part D's prescription drug event data (total payments to pharmacies before accounting for any rebates or discounts pharmacies retain). Net prices measure the amount received by pharmaceutical manufacturers and therefore reflect rebates, off-invoice discounts, and other price concessions made by manufacturers to distributors, health plans, and intermediaries.
- 23 An individual NDC uniquely identifies the drug's labeler, drug, dosage form, strength, and package size.
- 24 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 the median price more closely reflects the degree to which market share has moved between the two.
- 25 Although there is no consistent definition of specialty drugs, they tend to be characterized as high cost and are used to treat a rare condition, require special handling, use a limited distribution network, or require ongoing clinical assessment. Most biologics are a subset of specialty drugs (*American Journal of Managed Care* 2013).
- 26 These figures are based on the Acumen analysis for the Commission of Part D prescription drug event data. Most plans use specialty tiers for drugs and biologic products. Beginning in 2007, CMS began setting a cost threshold per month (\$670 in 2017) for drugs that may be placed on a specialty tier. A specialty-tier drug is different from a specialty drug in that it is identified based on its placement on a plan's specialty tier and varies across plans. Typically, plans charge enrollees coinsurance of 25 percent to 33 percent for drugs placed on specialty tiers.
- 27 For benefits delivered in 2014 and 2015, the majority of the plan sponsors received additional individual reinsurance payments from Medicare at reconciliation, much of which was because of higher than anticipated spending on new hepatitis C therapies and continued growth in costs of specialty drugs (Boards of Trustees 2016). Even with that unexpectedly higher spending, most plan sponsors made risk-corridor payments to Medicare.
- 28 The Patient Protection and Affordable Care Act of 2010 changed the tax treatment of Medicare's retiree drug subsidy

and made the Part D benefit more generous by gradually closing the coverage gap. To close the gap, the law called for (1) a 50 percent manufacturer discount on brand-name drugs filled during the coverage gap; (2) a gradual reduction in cost sharing during the coverage-gap phase; and (3) slower increases to Part D's OOP threshold over the 2014 to 2019 period. These changes likely motivated many employers that had previously provided primary drug coverage to former workers to set up Part D employer group waiver plans for their retirees.

- 29 For example, biosimilars to Humira—AbbVie's treatment for rheumatoid arthritis and other autoimmune diseases—have been among the most widely anticipated. The FDA approved two biosimilars to Humira (Amjevita and Cyltezo), but as of January 2017, neither had entered the market. Even though AbbVie's main patent on the composition of Humira expired in 2016, the company holds more than 70 newer patents covering formulations and uses as well as manufacturing processes (Pollack 2016). In September 2017, AbbVie signed a settlement agreement with Amgen, maker of Amjevita, to delay the biosimilar's U.S. launch until 2023 (Sagonowsky 2017). When reverse payments are used to delay market entry of a generic, manufacturers must report the settlement agreement to the Federal Trade Commission and may be subject to antitrust litigation. However, no such reporting requirements exist for settlement agreements between manufacturers of originator biologics and biosimilars licensed under the Biologics Price Competition and Innovation Act (Richardson 2013).
- 30 Originator biologics can also experience differences in their molecular structures—for example, batch to batch variation when the manufacturer makes changes to its production line.
- 31 Specifically, the law excludes products licensed under Section 351(k) of the Public Health Services Act, which is the main abbreviated approval pathway for biosimilars.
- 32 For most LIS enrollees, Part D's low-income cost-sharing subsidy fills in the coverage gap. For this reason, LIS enrollees do not receive coverage-gap discounts. In 2020,

when the coverage gap is fully phased out, plans will pay 75 percent for all drugs and biologics filled by LIS enrollees in the coverage gap. By comparison, for the other Part D enrollees, plans will be responsible for paying only 25 percent of the price of brand-name prescriptions in the coverage-gap phase, but 75 percent for biosimilars and generics.

- 33 The transition fill is a temporary one-time supply provided within the first 90 days of coverage in a new plan or the new contract year for existing enrollees. Each year since 2012, CMS has conducted a transition monitoring program analysis to evaluate whether plan sponsors are following Part D transition requirements. In 2016, 6 percent of Part D contracts exceeded CMS's thresholds of noncompliance (Centers for Medicare & Medicaid Services 2016e).
- 34 Sponsors are not required to report all rejections, but must report rejections associated with nonformulary claims, prior authorizations, step therapy, quantity limits, and certain high-cost edits. The plan-reported and IRE data are incomplete and should be interpreted with caution. Not all Part D plan data must be reported, and some that are reported do not pass data validation requirements. See online Appendix 14-B, available at <http://www.medpac.gov>, for more detail.
- 35 The exception is New York, which mandates electronic prescribing.
- 36 CMRs must include an interactive person-to-person or telehealth consultation performed by a pharmacist or other qualified provider and a written summary of the review that includes a medication list and action plan, if any, provided to beneficiaries in CMS's standardized format. A TMR is distinct from a CMR because it is focused on specific medication-related problems, actual or potential. A TMR can be conducted person to person or be system generated, and interventions can be delivered by mail or faxed to the beneficiary or the prescriber, as appropriate (Centers for Medicare & Medicaid Services 2014a).

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