

CHAPTER

# 13

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**Status report  
on Part D**

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## Status report on Part D

### Chapter summary

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.

In 2014, Medicare spent \$78 billion for the Part D benefit, accounting for nearly 13 percent of total Medicare outlays. In 2015, about 39 million Medicare beneficiaries were enrolled in Part D: 61 percent were in stand-alone prescription drug plans (PDPs) and the rest were in Medicare Advantage–Prescription Drug plans (MA–PDs). Part D experienced significant growth in 2014 and 2015 program spending, much of which was attributable to new treatments for hepatitis C.

***Medicare beneficiaries' drug coverage in 2015 and benefit offerings for 2016***—In 2015, 70 percent of Medicare beneficiaries were enrolled in Part D plans. Among those 39 million individuals, nearly 12 million received the low-income subsidy (LIS), which provides extra help with premiums and cost sharing. An additional 4 percent received drug coverage through employer-sponsored plans that receive Medicare's retiree drug subsidy. As of 2013, 12 percent of beneficiaries had either no drug coverage or coverage

### In this chapter

- Enrollment and plan choices in 2015 and benefit offerings for 2016
- Market structure and strategies of plan sponsors for controlling growth in premiums
- Drug pricing
- Program spending
- Beneficiaries' access to prescription drugs
- Quality in Part D
- Looking ahead

less generous than Part D. Our previous analysis showed that beneficiaries with no creditable coverage tended to be healthier, on average.

In 2016, plan sponsors are offering 886 PDPs and 1,682 MA-PDs, an 11 percent decrease from 2015 in the number of PDPs offered and a 5 percent increase in MA-PDs. PDP reductions appear to reflect a trend in which sponsors are consolidating their plan offerings into fewer, but more widely differentiated, products. Even with these consolidations, beneficiaries have between 19 and 29 PDPs to choose from, depending on where they live, as well as typically 9 or more Medicare Advantage options. MA-PDs continue to be more likely than PDPs to offer enhanced benefits, but a smaller share is offering gap coverage (beyond what is required by the Patient Protection and Affordable Care Act of 2010) compared with previous years. For 2016, 218 premium-free PDPs are available to enrollees who receive the LIS, a 23 percent decline from 2015. Most regions of the country continue to have at least 3 and as many as 10 PDPs available at no premium to LIS enrollees.

In 2015, about 80 percent of enrollees were in plans with two cost-sharing tiers for generic drugs: a preferred one with lower cost sharing and another generic tier that, in some cases, came with substantially higher cost sharing. In 2015, nearly 90 percent of PDPs used tiered pharmacy networks that included preferred pharmacies offering lower cost sharing. Both of these strategies provide financial incentives for enrollees to use lower cost drugs or providers, potentially reducing program costs. However, because cost sharing for LIS enrollees is set by law, they are less likely to be influenced by plan benefit designs that use cost sharing to encourage the use of lower cost medications and pharmacies. This situation, in turn, may lead to higher growth in spending for Medicare's low-income cost-sharing subsidy compared with cost-sharing amounts paid by non-LIS enrollees.

***Part D program spending and bids***—Between 2007 and 2014, Part D spending on an incurred basis increased from \$46 billion to \$73 billion (an average annual growth rate of about 6.8 percent). (The incurred amount of \$73 billion for 2014 differs from the \$78 billion mentioned earlier because the larger amount includes reconciliation payments between Medicare and plan sponsors for benefits delivered in previous years.) In 2014, Part D program payments increased by nearly 15 percent from the year before, much of that due to spending for new hepatitis C drugs. Also in 2014, Medicare's reinsurance payments to plans surpassed LIS payments to become the single largest component of Part D spending. Reinsurance also remained the fastest growing component, at an average annual rate of 19 percent between 2007 and 2014. Program spending for Part D reflects two underlying trends. First, an unusually large number of patent expirations on widely used brand-name drugs has led to a dramatic shift toward use of generics in Part D.

Generic drugs' share of all Part D prescriptions filled rose from 61 percent in 2007 to 84 percent in 2013. However, between 2012 and 2013, the share of enrollees who incurred spending high enough to reach the catastrophic phase of Part D's benefit grew by nearly 10 percent. Spending for these high-cost individuals grew by 8.4 percent per enrollee, driven primarily by increases in the average price per prescription filled. The pharmaceutical pipeline is shifting toward greater numbers of biologic products and specialty drugs, many of which have high prices and few therapeutic substitutes. The use of high-priced drugs by Part D enrollees will likely grow and put significant upward pressure on Medicare spending for individual reinsurance and the LIS.

***Access to prescription drug coverage***—In general, Part D has improved Medicare beneficiaries' access to prescription drugs, with plans available to all individuals. The amounts enrollees pay in cost sharing can also affect access. Generally, between 2007 and 2013, average out-of-pocket costs remained stable or even decreased somewhat, in part because of the phased closure of Part D's coverage gap. For individuals whose prescription medications are not covered by their plans or are covered but have relatively high cost sharing, a well-functioning exceptions and appeals process is crucial. Plan-level data show low rates of claim rejections and appeals. At the same time, CMS has conducted audits that have found some compliance issues with formulary administration, claims adjudication, and appeals.

***Quality in Part D***—In 2016, the average star rating among Part D plans decreased somewhat for PDPs but increased slightly for MA-PDs. PDP scores changed significantly because of changes to the mix of measures, making it difficult to use star ratings to evaluate changes in quality of services over time. Part D plans are required to implement medication therapy management (MTM) programs to improve quality. Although the Commission supports the goal of improving medication management, we have been concerned with the effectiveness of plans' MTM programs. Beginning in 2017, Medicare will test enhanced MTM programs by providing incentives for stand-alone PDPs to conduct medication reviews and tailor drug benefit designs to encourage adherence to appropriate drug therapies. ■



**TABLE  
13-1**

**Parameters of the defined standard benefit increase over time**

	2006	2015	2016	Average annual growth rate 2006–2016
Deductible	\$250.00	\$320.00	\$360.00	3.7%
Initial coverage limit	2,250.00	2,960.00	3,310.00	3.9
Annual out-of-pocket spending threshold	3,600.00	4,700.00	4,850.00	3.0
Estimated total covered drug spending at annual out-of-pocket threshold	5,100.00	7,061.76*	7,515.22*	4.0
Minimum cost sharing above annual out-of-pocket threshold:				
Copayment for generic/preferred multisource drugs	2.00	2.65	2.95	4.0
Copayment for other prescription drugs	5.00	6.60	7.40	4.0

Note: \*Total covered drug spending at annual out-of-pocket threshold depends on each enrollee’s mix of brand-name and generic drugs filled during the coverage gap. The amounts for 2015 and 2016 are for an individual who is not receiving Part D’s low-income subsidy and has no other supplemental coverage. Part D benefit parameters for 2016 reflect an increase of nearly 12 percent over 2015 due to a more than 6 percent increase in average spending and a revision to prior-year adjustments of over 5 percent (Centers for Medicare & Medicaid Services 2015g).

Source: CMS, Office of the Actuary.

## Background

In 2014, Medicare spent \$78 billion on the Part D program, accounting for nearly 13 percent of Medicare outlays (Boards of Trustees 2015).<sup>1</sup> In 2015, more than 39 million Medicare beneficiaries were enrolled in Part D plans. Each year, the Commission provides a status report on Part D and makes recommendations as necessary. We examine several performance indicators: enrollment patterns, plan benefit offerings, market structure, drug pricing, program costs, beneficiaries’ access to medications, and quality.

## Part D’s approach

Medicare’s payment system for Part D is very 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 amount), formularies, quality of services, and networks of pharmacies.

## The drug benefit

Medicare defines a standard Part D benefit with parameters that change at the same rate as the annual change in beneficiaries’ average drug expenses (Table 13-1).<sup>2</sup> For 2016, the defined standard benefit includes a \$360 deductible and 25 percent coinsurance until the enrollee reaches \$3,310 in total covered drug spending. Enrollees whose spending exceeds that amount face a coverage gap up to a threshold of \$4,850 in out-of-pocket (OOP) spending, excluding cost sharing paid by most sources of supplemental coverage such as employer-sponsored policies. Above the OOP threshold, enrollees pay the greater of either 5 percent coinsurance or \$2.95 to \$7.40 per prescription.

Before 2011, enrollees exceeding the initial coverage limit were responsible for paying the full price of covered drugs (usually without reflecting manufacturers’ rebates) up to the annual OOP threshold. Because of changes made by the Patient Protection and Affordable Care Act of 2010 (PPACA), since 2011, beneficiaries without a low-income subsidy (LIS) face reduced cost sharing for both brand-name and generic drugs filled during the coverage gap

**TABLE  
13-2**

**Nearly three-quarters of Medicare enrollees received drug coverage through Part D, 2015**

	Beneficiaries	
	In millions	Percent of Medicare enrollment
Medicare enrollment	55.8	100%
Part D enrollment		
In Part D plans	39.2	70.3
In plans receiving RDS*	2.2	3.9
Total Part D	41.4	74.2**

Note: RDS (retiree drug subsidy). Part D plan enrollment figures based on enrollment as of April 1, 2015.  
 \*Excludes federal government and military retirees covered by either the Federal Employees Health Benefits Program or the TRICARE for Life program.  
 \*\*The remaining 25.8 percent of beneficiaries not enrolled in Part D receive drug coverage through other sources (such as the Federal Employees Health Benefits Program, TRICARE for Life, and the Department of Veterans Affairs), had no drug coverage, or had coverage less generous than Part D.

Source: MedPAC based on Table IV.B7 and Table V.B4 of the Medicare Board of Trustees' report for 2015 and monthly Part D enrollment data as of April 1, 2015.

(Medicare Payment Advisory Commission 2015b). In 2016, cost sharing for prescriptions filled during the gap phase is 45 percent for brand-name drugs and 58 percent for generic drugs.<sup>3</sup> An individual with no other source of drug coverage is estimated to reach the \$4,850 limit at \$7,515.22 in total drug expenses.

Plan sponsors can and do offer alternative benefit designs. For example, a plan can offer a deductible lower than \$360 or can use tiered copayments rather than coinsurance—provided the alternative benefit meets requirements for actuarial equivalence. Once a plan sponsor offers a plan with basic benefits in a region, it can also offer plans with additional drug coverage, called enhanced plans, that supplement the standard benefit.

Part D includes a LIS that provides assistance with premiums and cost sharing for individuals with low incomes and assets. Individuals who qualify for this subsidy pay no or nominal cost sharing set by statute. In 2016, most individuals receiving the LIS pay up to \$2.95 for generic drugs and up to \$7.40 for brand-name drugs.

**Two avenues of competition in Part D**

Plan sponsors concentrate much of their attention on premium competition to attract enrollees because premiums are seen by most consumers as the most salient feature (particularly by those without the LIS) to compare plan options. Part D plan sponsors submit bids to CMS that represent their revenue requirements (including administrative costs and profit) for delivering the standard benefit to an enrollee of average health. Part D is different from Part C (i.e., Medicare Advantage) in that Medicare's payments do not involve any comparison with an administratively set benchmark amount. Instead, CMS calculates a nationwide enrollment-weighted average among all the bid submissions.

Enrollees pay a base beneficiary premium (\$34.10 in 2016) plus (or minus) any difference between their plan's bid and the nationwide average bid (Medicare Payment Advisory Commission 2015b). If enrollees choose a plan that is costlier than average, they pay a premium that is higher by the difference between the plan's bid and the nationwide average. If they select a plan that has a lower than average bid, their premium is lower by that difference. If enrollees pick a plan that includes supplemental coverage, they 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 sponsors can bid low and keep premiums attractive. At the same time, sponsors must balance this incentive with beneficiaries' desire to have access to medications. A plan with a very limited number of covered drugs might not attract enrollees.

A second avenue of competition involves keeping plan premiums at or below regional LIS benchmarks. Part D's bidding process determines the maximum premium amount Medicare will pay on behalf of LIS enrollees. This amount varies across the country's 34 Part D regions. It is based on an average of premiums for plans (both stand-alone PDPs and MA-PDs) with basic benefits, weighted by each plan's LIS enrollment in the previous year. The formula also ensures that at least one stand-alone PDP 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 turnover in benchmark plans—those that qualify as premium free. 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 PDP. 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 letters about premium-free plan options in the enrollee's region.

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## **Enrollment and plan choices in 2015 and benefit offerings for 2016**

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In 2015, about three-quarters of Medicare beneficiaries were enrolled in Part D or actuarially equivalent employer drug plans for retirees. Enrollment has shifted from retiree drug plans to Part D plans. Only 1 percent of Part D enrollees were in defined standard benefit plans; the rest were in plans that had the same or higher average benefit values but different cost-sharing structures. In 2016, plan sponsors are offering fewer PDPs, but beneficiaries continue to have broad choice among plans. The number of MA-PDs has grown slightly.

### **In 2015, about three-quarters of Medicare beneficiaries were in Part D plans or employer plans that got Medicare's retiree drug subsidy**

In 2015, over 39 million individuals—about 70 percent of nearly 56 million total Medicare beneficiaries—were enrolled in Part D plans (Table 13-2). Additionally, nearly 4 percent of other beneficiaries got drug coverage through employer-sponsored plans that received Medicare's retiree drug subsidy (RDS) for being the primary provider.<sup>4</sup> The remaining nearly 26 percent of Medicare beneficiaries received drug coverage from other sources, had no coverage, or had coverage less generous than Part D.<sup>5</sup>

An estimate from the 2013 Medicare Current Beneficiary Survey (MCBS) suggests that about 12 percent of beneficiaries (a subset of the 26 percent described above) had no "creditable" drug coverage (either no coverage at all or less generous coverage than Part D)—a bit higher than the 10 percent reported by CMS during the first few years of Part D. About half of the 12 percent reported having some drug coverage through public or private insurance. Consistent with previous findings, our analysis

of the 2013 MCBS data suggests that beneficiaries who do not enroll in Part D tend to be healthier (Medicare Payment Advisory Commission 2013).

In recent years, enrollment has shifted noticeably into Part D plans from employer plans that had previously received the RDS (Figure 13-1, p. 376). This shift reflects changes made by PPACA that over time increased the generosity of Part D by eliminating the coverage gap and by altering the tax treatment of drug expenses covered by the RDS. Between 2010 (the year PPACA was enacted) and 2015, the number of beneficiaries whose employers received the RDS fell from 6.8 million to 2.2 million. Over the same period, enrollment in Part D plans that were operated for employers and their retirees (employer group waiver plans, or EGWPs) grew from 2.4 million to 6.6 million.

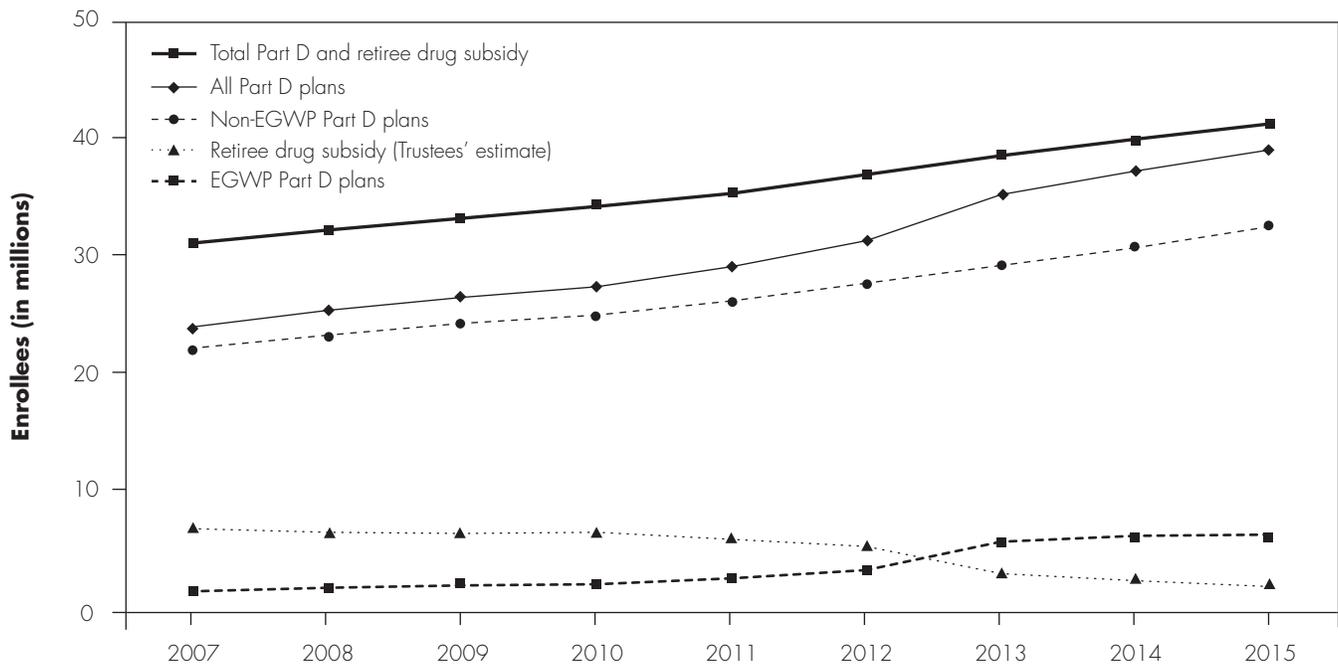
The percentage of Medicare beneficiaries covered under Part D has grown over time, as has the share of enrollees in plans that combine prescription coverage with medical benefits (MA-PDs). Between 2007 and 2015, the share of Medicare beneficiaries enrolled in Part D plans grew from about 54 percent to 70 percent, or an average 6 percent annually (Table 13-3, p. 376). Enrollment in MA-PDs grew more rapidly (10 percent annually) than in PDPs (4 percent annually). In 2015, 39 percent of Part D enrollees were in MA-PDs compared with 30 percent in 2007.

In 2015, about 12 million beneficiaries (30 percent of Part D plan enrollees) received the LIS (Table 13-3). Of these individuals, more than 7 million were dually eligible for Medicare and Medicaid. Another 4.6 million qualified for the LIS either because they received benefits through the Medicare Savings Programs or the Supplemental Security Income program or because they were eligible after they applied directly to the Social Security Administration (data not shown). Part D enrollees who receive the LIS are more likely to be female, more than twice as likely to be African American, Hispanic, or Asian, and nearly five times more likely to be under age 65 (Medicare Payment Advisory Commission 2015a).

Between 2007 and 2015, enrollment growth for Part D enrollees who received the LIS was slower (3 percent per year) than for non-LIS enrollees (8 percent per year) (Table 13-3). Non-LIS enrollees' faster enrollment growth is partly attributable to the recent growth 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 30 percent.

**FIGURE  
13-1**

**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 monthly Part D enrollment data and Table IV.B7 of the 2015 annual report of the Boards of Trustees of the Medicare trust funds.

**TABLE  
13-3**

**Part D plan enrollment trends, 2007-2015**

	2007	2009	2011	2013	2015	Average annual growth rate 2007-2015
Total Part D enrollment (in millions)	24.2	26.7	29.3	35.4	39.2	6%
Percent of Medicare beneficiaries	54%	57%	60%	67%	70%	
Enrollment by type (in millions)						
PDP	16.9	17.4	18.6	22.5	24.0	4
MA-PD	7.2	9.3	10.7	12.9	15.3	10
Percent in MA-PD	30%	35%	37%	36%	39%	
Enrollment by LIS status (in millions)						
LIS	9.4	9.7	10.5	11.2	11.7	3
Non-LIS	14.8	17.1	18.8	24.2	27.5	8
Percent receiving the LIS	39%	36%	36%	32%	30%	

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy). 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). Components may not sum to stated totals due to rounding.

Source: MedPAC based on monthly Part D enrollment data.

**TABLE  
13-4**

**MA-PD enrollees more likely to be in enhanced plans with reduced or no deductible, 2015**

	PDP		MA-PD	
	Number (in millions)	Percent	Number (in millions)	Percent
Total	19.2	100%	10.6	100%
Type of benefit				
Defined standard	0.0	0	0.1	1
Actuarially equivalent*	10.6	55	2.9	27
Enhanced	8.6	45	7.6	72
Type of deductible				
Zero	9.3	49	6.0	57
Reduced	1.4	7	3.4	32
Defined standard**	8.5	44	1.2	11

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.  
\*\*\$320 in 2015.

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

About 70 percent (8 million) of LIS enrollees were in PDPs; the rest were in MA-PDs (data not shown). Most individuals receiving the LIS are enrolled in traditional Medicare rather than Medicare Advantage. Thus, if these individuals have not chosen a Part D plan themselves, CMS randomly and automatically assigns them to benchmark plans, which are all PDPs. However, LIS enrollment in MA-PDs has grown as some individuals have selected these plans or joined them through the Medicare–Medicaid financial alignment initiative.<sup>6</sup>

**Beneficiaries’ enrollment decisions in 2015**

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, instead of having a deductible, a plan may use a cost-sharing rate higher than 25 percent. 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 that includes non-Part D drugs.

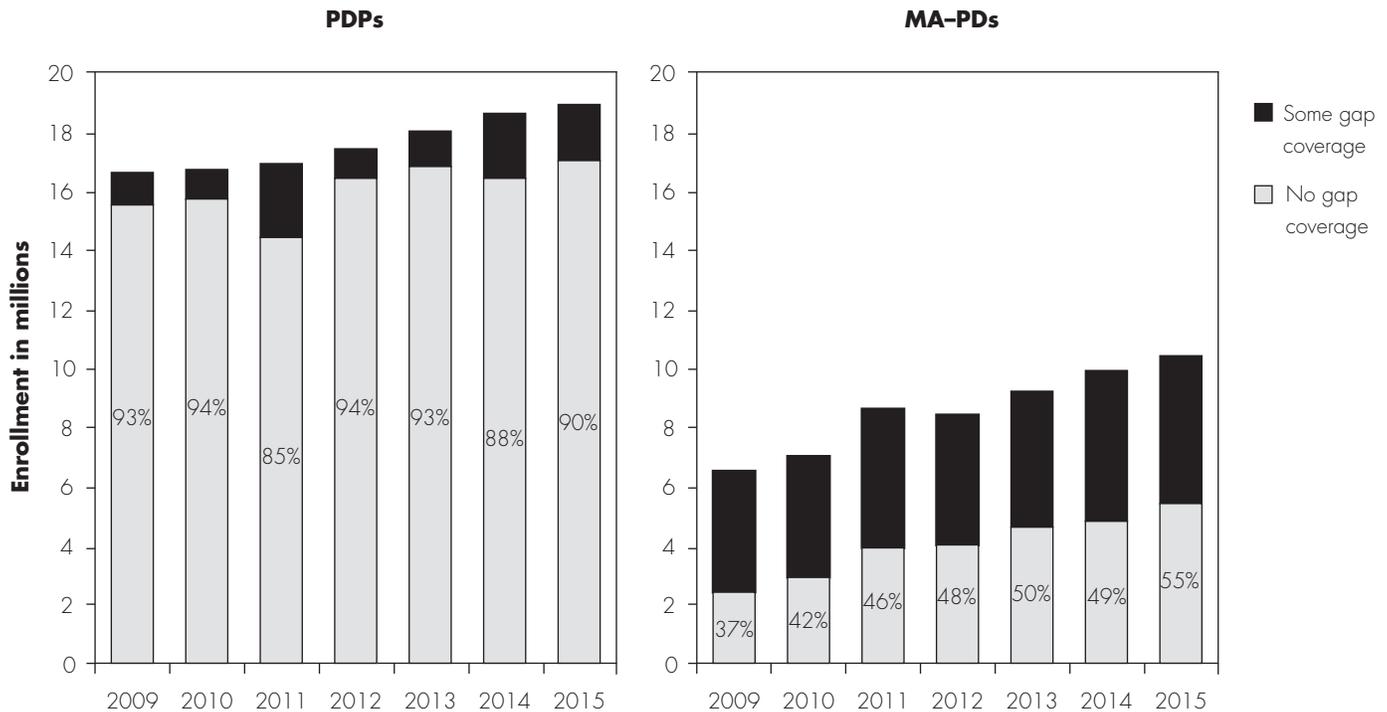
**Enrollment by benefit design**

In 2015, 55 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copayments (Table 13-4). Another 45 percent of PDP enrollees had enhanced benefits—the typical enhancement being a lower deductible rather than benefits in the coverage gap. No PDP enrollees were in defined standard benefit plans. MA-PD enrollees were predominantly in enhanced plans with no deductible or a deductible smaller than the \$360 in Part D’s defined standard benefit. Enrollees in PDPs were more likely to have a deductible in their plans’ benefit design than enrollees in MA-PDs.

Under the Medicare Advantage payment system, MA-PDs may use a portion of their Part C payments to supplement their Part D drug benefits or to lower Part D premiums.<sup>7</sup> Many MA-PDs also use some of their Part C rebate dollars to provide additional Part D benefits in the coverage gap (Figure 13-2, p. 378). In 2015, 45 percent of MA-PD enrollees (nearly 5 million beneficiaries) were in

**FIGURE  
13-2**

**PDP enrollees are less likely to have plans that offer additional benefits in the coverage gap**



Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). Figures exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, demonstrations, and Part B-only plans. Extra coverage in the gap (beyond what is required by the Patient Protection and Affordable Care Act of 2010) is typically restricted to a subset of formulary drugs. In 2015, one-third of PDP enrollees received the low-income subsidy, which effectively eliminates any coverage gap.

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

plans offering some gap coverage. By comparison, only 10 percent of PDP enrollees (about 2 million beneficiaries) were in plans that offered benefits in the coverage gap beyond what is required by PPACA. However, 33 percent of PDP enrollees (8 million of 24 million) received the LIS, which effectively eliminates their coverage gap (data not shown).

**Average enrollee premiums**

On average, Part D premiums have remained flat over the past several years, despite growth in program spending for Part D's catastrophic benefits. In 2015, monthly beneficiary premiums averaged about \$30 across all plans (Table 13-5). Underlying that average is wide variation, ranging from \$0 for a number of MA-PDs to \$172 for a PDP offering enhanced coverage (data not shown).<sup>8</sup> 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 to lower enrollee premiums. Among PDP enrollees, individuals in plans that offered enhanced coverage paid, on average, \$20 more per month than those in plans that offered only basic coverage (\$48 vs. \$28, respectively). In contrast, beneficiaries enrolled in MA-PDs, on average, paid lower premiums for enhanced coverage than for basic coverage alone (\$16 vs. \$21, respectively).

While the overall average Part D premium (including basic and enhanced coverage) has been stable in recent years, averages specific to PDPs and to MA-PDs have shown more fluctuation (Table 13-5). For example, average monthly premiums for enrollees in PDPs that offered enhanced coverage experienced large year-to-year changes between 2011 (\$63) and 2013 (\$49).

**TABLE  
13-5**

**Changes in average Part D premiums, 2007-2015**

	Average monthly premium weighted by enrollment (in dollars)						Average annual growth rate 2007-2015
	2007	2011	2012	2013	2014	2015	
All plans (any coverage)	\$23	\$30	\$30	\$30	\$29	\$30	3.1%
PDPs							
Basic coverage	24	33	33	32	30	28	2.1
Enhanced coverage	40	63	58	49	49	48	2.2
Any coverage	27	38	38	39	38	37	3.9
MA-PDs, including SNPs*							
Basic coverage	17	27	27	29	25	21	2.8
Enhanced coverage	9	13	12	13	13	16	8.3
Any coverage	10	14	14	15	16	18	7.2

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), SNP (special needs plan). Figures exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B-only plans.

\*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.

Two other factors affect the premium amount paid by a given enrollee. First, higher income beneficiaries pay a larger share of their Part D benefits; that is, they have a lower federal subsidy. In 2015, an estimated 2.1 million beneficiaries (about 5 percent of Part D enrollees) were subject to the income-related premium.<sup>9</sup> As with the income-related premium for Part B, the higher Part D premiums apply to individuals with an annual adjusted gross income greater than \$85,000 and to couples with an adjusted gross income greater than \$170,000. A beneficiary whose income exceeds these levels pays an income-related monthly adjustment amount in addition to the Part D premium paid to a plan. In 2015, the adjustment amount ranged from \$12 to \$71 per month, depending on income.

Second, individuals enrolling in Part D outside of 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 went without creditable coverage and is calculated by multiplying 1 percent of the base beneficiary premium times the number of full,

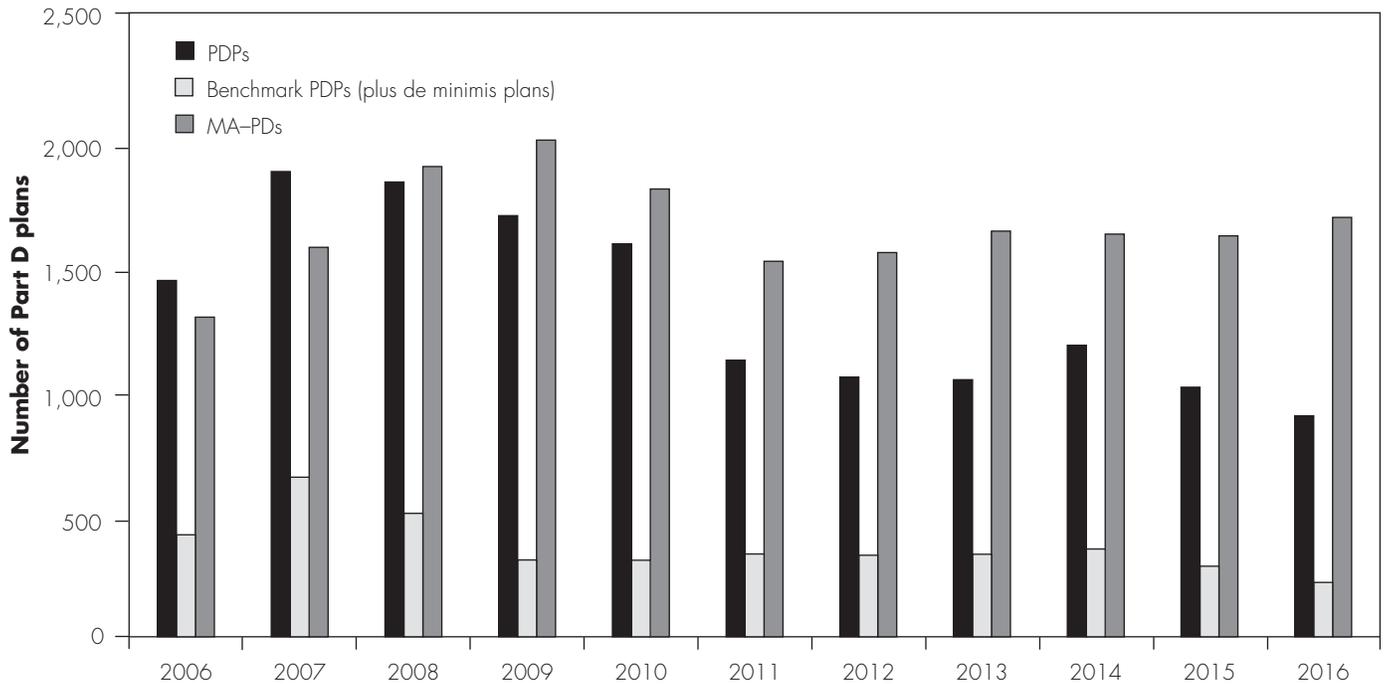
uncovered months an individual was eligible but was not enrolled in a Part D plan and went without other creditable coverage.

**Benefit offerings for 2016**

Beneficiaries are encouraged to reexamine their plan options from time to time. 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 directly affect access to and affordability of medications. We outline notable trends for the 2016 benefit year, including changes in numbers of plans, coverage, premiums, and cost sharing.

**Number of PDPs has declined, but broad choice still available**

For 2016, plan sponsors are offering 11 percent fewer PDPs than in 2015, while the number of MA-PDs increased by 5 percent (Figure 13-3, p. 380). The decline in PDPs is due largely to plan responses to CMS's policy intended to differentiate more clearly between basic and enhanced benefit plans and a policy discouraging plans with low enrollment. In addition, some sponsors may have

**FIGURE  
13-3****A wide variety of plans available in 2016, but fewer benchmark PDPs**

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). "Benchmark PDPs" are plans for which low-income subsidy (LIS) enrollees pay no premium because the plans' premiums are at or below a regional premium threshold. "De minimis plans" are plans that CMS permitted to retain their LIS enrollees because the plan premium was within a certain variance of the regional LIS premium threshold. The figures exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, demonstrations, and Part B-only plans.

Source: CMS landscape and plan report files, 2006–2016.

chosen to reduce their offerings out of concern for rules that were proposed by CMS—but ultimately were not finalized—that would have limited sponsors to offering no more than two PDPs per region (Centers for Medicare & Medicaid Services 2014d).<sup>10</sup>

Even with fewer PDPs, beneficiaries continue to have a wide variety of choice among plans, ranging from 19 PDP options in Alaska to 29 PDPs in the Pennsylvania–West Virginia region, along with MA–PD options in most areas of the country. The number of Medicare Advantage (MA) plans available to a beneficiary varies by the county of residence, with an average county having 9 MA plans to choose from (18 plans when weighted by the Medicare population). A handful of counties have no MA plans available.

In 2016, PDPs available to LIS enrollees with no premium (benchmark plans) declined 23 percent from 2015 levels to 218 plans (Figure 13-3). Most regions of the country

continue to have a number of premium-free PDPs available in 2016, ranging from 3 PDPs in Florida to 10 in Arizona and in the Washington, DC–Delaware–Maryland region. Hawaii has two PDPs that qualify as premium free.

For 2016, an estimated 1.9 million of about 12 million LIS enrollees were affected by the turnover in plans whose premiums no longer fell at or below benchmarks—potentially subject to reassignment to a new benchmark plan by Medicare (Hoadley et al. 2015a). However, over the years, a sizable share of LIS enrollees (by 2010, 43 percent of LIS enrollees in PDPs) had selected plans that differed from their randomly assigned plans and were therefore no longer eligible for reassignment (Hoadley et al. 2015c). In 2015, an estimated 1.2 million LIS enrollees in PDPs (15 percent) remained in a nonbenchmark plan and paid a portion of their premium (Hoadley et al. 2015b). Another 0.4 million LIS enrollees in MA–PDs paid a portion of their premium. CMS estimated that

for 2016, it would need to randomly reassign about 0.5 million LIS enrollees to new benchmark plans (Lyons 2015).

### **Most MA–PDs offer more generous drug coverage than PDPs, but some MA–PDs have less generous coverage compared with last year**

The number of MA–PDs grew by 5 percent between 2015 and 2016, and most MA–PD enrollees continue to have more generous coverage than what is offered typically in PDPs—for example, some enhanced coverage beyond basic Part D benefits. For 2016, the share of MA–PDs offering enhanced benefits increased to 87 percent compared with 81 percent the year before. However, between 2015 and 2016, the share of MA–PDs that charge no deductible dropped from 63 percent to 55 percent. In 2015 and 2016, the percentage of MA–PDs that offer additional coverage in the coverage gap beyond that already called for under PPACA remained steady at 44 percent.

The reasons certain MA–PDs are offering less generous coverage are not fully clear. Our analysis of Part C plan bids suggests that, on average, MA–PDs dedicated about the same percentage of Part C rebate dollars for Part D benefits in 2016 as in 2015 (35 percent, or nearly \$29 per enrollee per month, split fairly evenly between basic and enhanced benefits). One possibility for the less generous coverage is that some plans are using the Part C rebates in other ways rather than reducing deductibles or providing gap coverage. For example, the cost of providing Part D benefits may have risen for MA–PDs, and some plan sponsors chose to scale back coverage to a greater extent than they chose to increase their bids. Another possibility is that MA–PD sponsors do not need to include as much coverage in plan designs because Part D’s benefit is becoming more generous (as the coverage gap phases out) and because MA–PDs are enrolling larger numbers of individuals who receive help with premiums and cost sharing through the LIS.

### **Greater differentiation among PDP offerings**

With the reduction in numbers of PDPs, plan sponsors appear to be consolidating offerings into fewer, but more widely differentiated, products. Many sponsors appear to be moving closer toward offering one basic plan and one enhanced plan per region. For 2016, sponsors continue to use alternatives to Part D’s defined standard benefit; the market includes no PDPs with the standard benefit design, which was also true in 2015. In those two years, the percentage of PDPs that charged the defined standard

benefit’s deductible amount (\$360 in 2016) rose from 44 percent to 53 percent, while the percentage of plans that charged no deductible fell from 42 percent to 33 percent. The share of plans that used a deductible less than \$360 remains at 14 percent. A smaller share of PDPs offers additional coverage in the gap: 22 percent in 2016 compared with 26 percent a year earlier. The reduction in the number of PDPs offering gap coverage may, in part, be associated with changes made by PPACA to gradually phase out the coverage gap.<sup>11</sup>

### **Sizable premium increases for several PDPs with the most enrollment**

Although average premiums for Part D remained flat through 2015, monthly premiums for many of the most popular stand-alone PDPs increased (Table 13-6, p. 382). In 2016, average premiums for the eight plans with the highest enrollment ranged from about \$18 per month for Humana Walmart to more than \$66 per month for Humana Enhanced. Among these eight PDPs, only one has a slightly lower premium in 2016. The remaining seven plans have higher premiums for 2016, ranging from about \$1 higher (3 percent) to more than \$13 higher (25 percent).

### **Mixed changes in cost-sharing requirements**

Cost-sharing requirements in Part D plans have generally risen over the years, and some plan sponsors have moved from charging fixed-dollar copayments to coinsurance. By charging enrollees a percentage of the price of their prescriptions rather than a flat copayment, plan sponsors put more of the risk of price increases for those drugs on beneficiaries.

The top eight PDPs (ranked by enrollment) have some noticeable features in common for 2016. All now use a five-tiered formulary structure (CVS Health added a second generic tier to its SilverScript Choice plan), with differential copayments between preferred and other generic medications (Table 13-7, p. 383). All of the top eight PDPs also use a specialty tier for high-cost drugs.

In other ways, the largest PDPs differ in changes to their cost sharing. Two of the top PDPs offered by UnitedHealth under the AARP name moved to charging coinsurance for nonpreferred brand-name drugs rather than copayments. The most popular plan, AARP MedicareRx Preferred, raised copayments for preferred generics from \$2 to \$3 and, for other generics, from \$5 to \$10, but lowered copayments for preferred brands from \$40 to \$35. In creating two generic tiers for 2016, the second most

**TABLE  
13-6**

**Change in premiums for PDPs with the highest 2015 enrollment**

Plan name	Enrollment, 2015 (in millions)	Weighted average monthly premium*		Dollar change	Percentage change
		2015	2016		
AARP MedicareRx Preferred	3.5	\$50.19	\$60.79	\$10.60	21%
SilverScript Choice	3.3	23.13	22.56	-0.57	-2
Humana Preferred	1.7	26.45	28.39	1.94	7
Humana Walmart	1.5	15.67	18.40	2.73	17
AARP MedicareRx Saver Plus	1.4	28.13	35.23	7.10	25
Humana Enhanced	1.1	52.86	66.25	13.39	25
Cigna-HealthSpring Rx Secure	0.9	30.84	36.39	5.55	18
WellCare Classic	0.9	31.05	32.06	1.01	3

Note: PDP (prescription drug plan).

\*These figures reflect the average of all PDPs offered under the same plan name in each region of the country, weighted by 2015 enrollment.

Source: Hoadley et al. 2015a.

popular PDP, SilverScript Choice, lowered copayments for preferred generics to \$3, but raised copayments for other generics to \$13. It also raised copayments for preferred brands from \$35 to \$45 and increased the coinsurance rate for nonpreferred brands slightly, from 45 percent to 46 percent. Humana plans made no changes in cost sharing. Other top PDPs had a mixture of cost-sharing increases and decreases.

### Market structure and strategies of plan sponsors for controlling growth in premiums

Today, numerous organizations participate in Part D as plan sponsors—private entities that act both as insurers and administrators of Medicare prescription drug benefits. The role of plan sponsors is largely the same as in previous years, but the industry’s structure has changed substantially since Part D began.

#### The role of private plan sponsors

Many of the largest sponsors, such as UnitedHealth and Humana, offer both MA–PDs and PDPs. Other sponsors offer just one type of product. For example, integrated delivery system Kaiser Permanente offers only MA–PDs, while CVS Health, a leading pharmacy benefit manager

(PBM) that also operates one of the largest chains of retail drug stores, participates as a Part D sponsor, but offers only PDPs. All sponsors must hold valid insurance licenses in the states in which they operate, and they must carry out basic functions such as administering marketing, enrollment, customer support, claims processing, coverage determinations, and the appeals and grievances process.

Sponsors must also carry out the specialized functions of PBMs, using either corporate-owned organizations or a commercial PBM under contract. These functions include:

- developing and maintaining formularies—lists of drugs the plan covers and the terms under which it covers them;
- negotiating rebates—payments from drug manufacturers for placing their products on a plan’s formulary or preferred cost-sharing tier or for successfully encouraging enrollees to use the manufacturer’s drugs; and
- setting up pharmacy networks and negotiating contracts on prices the sponsor will pay pharmacies for prescriptions filled, dispensing fees, and any discount agreements.

Rebates from pharmaceutical manufacturers and price discounts from pharmacies are key factors affecting the net

**TABLE  
13-7**

**2016 cost-sharing amounts for stand-alone PDPs with highest 2015 enrollment, by tiers**

Stand-alone PDPs with the highest 2015 enrollment	Preferred generics		Other generics		Preferred brands		Nonpreferred brands		Specialty	
	2015	2016	2015	2016	2015	2016	2015	2016	2015	2016
AARP MedicareRx Preferred	\$2	\$3	\$5	\$10	\$40	\$35	\$85	40%	33%	33%
SilverScript Choice*	\$8	\$3	N/A	\$13	\$35	\$45	45%	46%	33%	33%
Humana Preferred Rx Plan	\$1	\$1	\$2	\$2	20%	20%	35%	35%	25%	25%
Humana Walmart Rx Plan	\$1	\$1	\$4	\$4	20%	20%	35%	35%	25%	25%
AARP MedicareRx Saver Plus	\$1	\$1	\$2	\$2	\$20	\$20	\$40	30%	25%	25%
Humana Enhanced	\$3	\$3	\$7	\$7	\$42	\$42	44%	44%	33%	33%
Cigna-HealthSpring Rx Secure	\$1	\$2	\$4	\$6	20%	16%	35%	47%	25%	25%
WellCare Classic	\$0	\$0	\$9	\$10	\$39	\$47	\$89	50%	25%	25%

Note: PDP (prescription drug plan), N/A (not applicable). Enrollment rankings are based on information from October 2015 and exclude employer plans and plans offered in U.S. territories. In cases where plans vary cost-sharing amounts across regions, we report unweighted medians.

\*Indicates just one generic tier in 2015.

Source: NORC/Social & Scientific Systems analysis for MedPAC of formularies submitted to CMS.

prices that plan sponsors pay for enrollees' prescriptions. By law, the Medicare program is prohibited from becoming involved in negotiations among plan sponsors, drug manufacturers, and pharmacies. Sponsors tend to use rebates to offset plans' benefit spending (reducing plan premiums) rather than lower the price of prescriptions at the pharmacy counter.

### Concentrated enrollment

A relatively small number of large insurers offer stand-alone PDPs in each of the 34 Part D regions across the country, and many of those same insurers also offer MA-PDs in selected parts of the country. In 2015, the top 9 insurers (those with 900,000 or more Part D enrollees each) sponsored plans that accounted for 77 percent of total enrollment (Figure 13-4, p. 384). Proposed mergers between some of the largest insurers would concentrate Part D enrollment further. By comparison, in 2007, those insurers (some of which were not among the plan sponsors with the highest market shares at the time) had a combined 60 percent of enrollment.

In 2015, combining stand-alone PDP and MA-PD enrollment, two major companies accounted for nearly 40 percent of the Part D market. UnitedHealth Group, offering plans under the AARP name, had 8.3 million

enrollees in its plans (about 1 in 5 Part D enrollees), and Humana had combined enrollment of 7 million beneficiaries, or 18 percent.

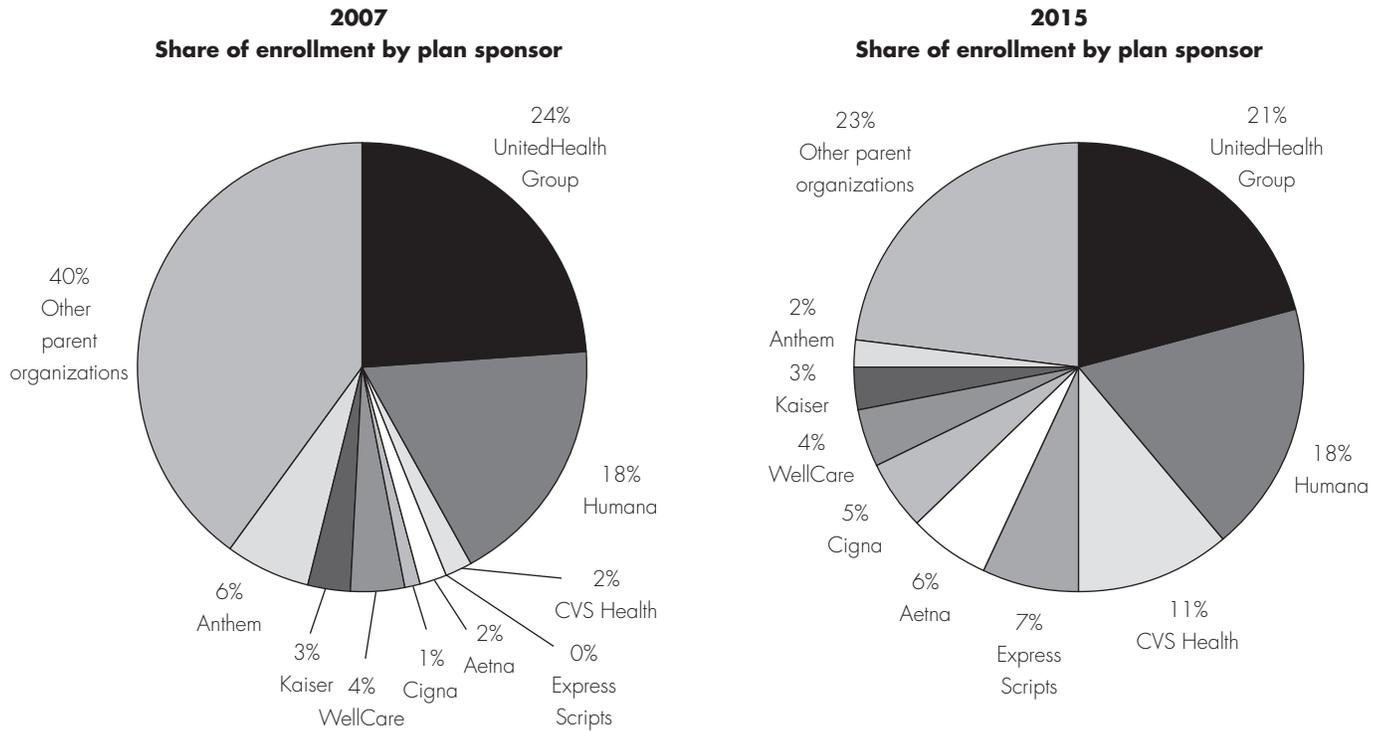
Over time, Aetna has increased its market presence. The insurer had just 2 percent of the Part D market in 2006, but expanded by acquiring Coventry Health Care in 2013. In 2015, Aetna struck a \$37 billion deal to acquire Humana (Bray and Abelson 2015). If the proposed deal moves forward without divestiture of any Medicare plans, the combined entity would account for 24 percent of Part D enrollment.

Other insurers that initially held smaller shares of the Part D market have had a growing presence over time, often through mergers and acquisitions (Hoadley et al. 2014b). The most notable example is CVS Health, which in 2015 had 11 percent of Part D enrollees in its plans. The company itself is a product of the acquisition of the PBM Caremark by CVS in 2007. CVS Health dramatically increased its Part D market share through a series of mergers and acquisitions, including Long's Drug Stores' RxAmerica plans, Universal American's Community CCRx and Pennsylvania Life product lines, and Health Net Orange PDPs.

Similarly, Cigna has increased its market presence, helped by acquiring HealthSpring in 2012 (which had itself

**FIGURE  
13-4**

**Plan sponsors have consolidated their enrollment 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. Note that in 2015, Aetna proposed acquiring Humana. Similarly, in 2015, Anthem proposed acquiring Cigna.

Source: MedPAC based on enrollment data from CMS.

previously acquired Bravo's Part D plans). As a result, Cigna's market share rose from just 1 percent in 2006 to 5 percent by 2015. In 2015, Anthem proposed to buy Cigna for \$54 billion (Herman 2015). If the deal is approved without divestitures, the combined company would account for 7 percent of Part D enrollment.

As the share of enrollment made up by employer groups has grown in Part D, some sponsors have focused on this niche. For example, Express Scripts is perhaps best known as a PBM under contract to commercial health plans and employers. The company participated in Part D as a sponsor in most years of the program, and when it merged with the PBM Medco in 2012, the two companies consolidated their market shares. Since 2010, Express Scripts has significantly ramped up its presence in Part D through EGWP offerings.

**Competition for LIS enrollees**

From a plan sponsor's perspective, LIS enrollees might not be an obvious market niche to pursue. LIS enrollees tend to use more prescription drugs and their cost-sharing requirements are set in law, so plans have less ability to encourage LIS enrollees to use lower cost medicines and pharmacies. Still, there is significant competition among sponsors to bid so that some of their plans have premiums below regional benchmarks. Part D's subsidy payments on behalf of LIS enrollees are risk adjusted to compensate for their higher expected spending. To the extent that LIS enrollees are more likely to reach Part D's OOP threshold, the program pays for most of their higher benefit spending through individual reinsurance. Also, the automatic assignment of LIS enrollees to benchmark plans limits the need for sponsors to spend as much on marketing.

**TABLE  
13-8**

**Distribution of LIS enrollment in Part D plans offered by the largest plan sponsors, 2015**

Plan sponsor	Number of LIS enrollees (in millions)	LIS share of sponsor's total enrollment (in percent)	Sponsor's share of all LIS enrollment (in percent)
CVS Health	2.2	50%	19%
UnitedHealth Group	2.1	26	18
Humana	1.8	26	16
Cigna	1.1	56	9
WellCare	0.8	60	7
Aetna	0.8	36	7
Express Scripts	0.4	14	3
Envision	0.3	86	3
Anthem	0.2	20	2
Kaiser	0.1	11	1
All LIS enrollees	11.7	30	N/A

Note: LIS (low-income subsidy), N/A (not applicable). Enrollment in stand-alone prescription drug plans and Medicare Advantage–Prescription Drug plans is included. Employer groups are included.

Source: MedPAC based on enrollment data from CMS.

For these reasons, many plan sponsors actively pursue the LIS segment of the Part D market. In 2015, CVS Health had more LIS enrollees than any other sponsor: a total of 2.2 million, or 19 percent of LIS enrollees (Table 13-8). About 50 percent of enrollees in CVS Health plans received the LIS. Cigna and WellCare are other companies among the top Part D plan sponsors for which more than half of their enrollees receive the LIS. Envision, a relatively smaller plan sponsor that was purchased by Rite Aid (a pharmacy chain being acquired by competitor Walgreens Boots Alliance) in 2015, accounted for 3 percent of LIS enrollment.

Once a sponsor has a sizable number of LIS enrollees, its bid can influence regional 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.

### Estimated margins for Part D plans

In 2013, more than 200 parent organizations sponsored Part D plans. To get a sense of the economic returns that make sponsors willing to participate in the program, we examined reconciled, plan-level data from CMS for basic

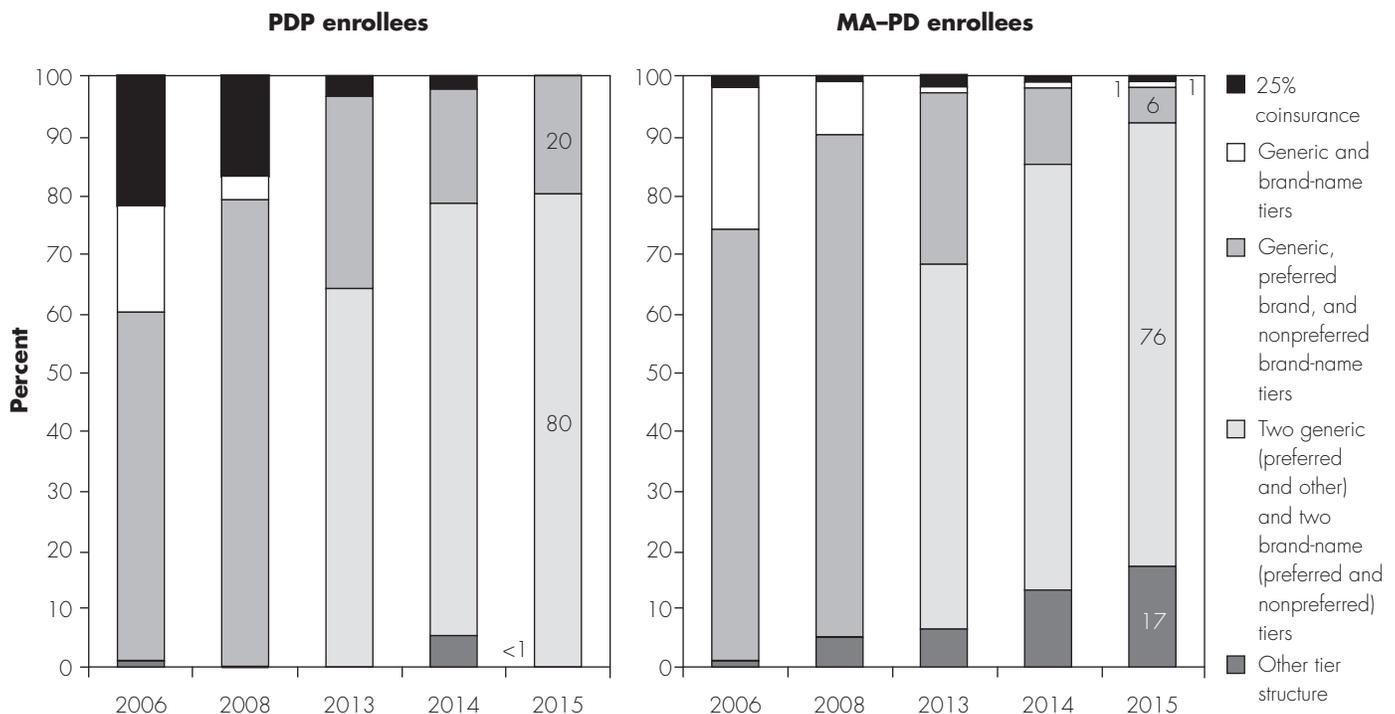
Part D benefits delivered in 2013. These data include gross spending for covered benefits, aggregate discounts and rebates, Medicare's subsidies, enrollee premiums, and risk-corridor payments. The data do not include actual administrative costs, but rather estimates of administrative costs from information submitted by plan sponsors in their Part D bids.<sup>12</sup>

In 2013, revenues for basic benefits delivered by the PDPs and MA–PDs in this analysis—net of rebates from pharmaceutical manufacturers, discounts from pharmacies, and reinsurance payments from Medicare—totaled about \$27 billion. That total comprised \$10.6 billion in enrollee premiums (including premiums paid by Medicare on behalf of low-income enrollees and Part C rebate amounts applied to Part D premiums (see endnote 7) and \$17.4 billion in Medicare's direct subsidy payments, minus \$0.7 billion in risk-corridor payments to Medicare from plan sponsors.<sup>13</sup> After analyzing bid data, we estimate that nonbenefit expenses such as marketing and administrative costs were about 10 percent of revenues.

We used reconciliation data to estimate margins: pre-tax profits (that is, revenues for basic benefits minus basic benefit costs and administrative expenses) as a percentage of revenues, excluding Medicare's reinsurance payments. The calculations also exclude revenues and costs

**FIGURE  
13-5**

**The majority of Part D enrollees are in plans that use a five-tier formulary structure**



Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). In addition to the tiers shown in the figure, all plans use specialty tiers for drugs and biologic products that cost \$600 or more per month. Typically, plans charge enrollees coinsurance of 25% to 33% for specialty-tier products.

Source: NORC/Social & Scientific Systems analysis for MedPAC of formularies submitted to CMS.

associated with enhanced (supplemental) benefits. Because Medicare limits the profits and losses of plan sponsors through Part D’s risk corridors, we took risk-corridor payments into account when estimating revenues.<sup>14</sup> (For more detail about Part D’s risk corridors and reconciliation process, see the Commission’s June 2015 report to the Congress (Medicare Payment Advisory Commission 2015c)). Our analysis showed the following:

- In 2013, the average margin for Part D plans, weighted by revenue and including risk-corridor payments between Medicare and plan sponsors, was 12.4 percent. Excluding risk corridors, the average margin was 2.3 percentage points higher.
- Across categories of plans, PDPs and MA-PDs had similar average margins: 12.6 percent and 12.2 percent, respectively.
- Overall, PDPs that qualified as premium-free for LIS enrollees had an average margin similar to that of

plans with premiums above their regional benchmarks: 12.2 percent compared with 12.9 percent, respectively.

- About 24 percent of PDPs and 16 percent of MA-PDs in this analysis had negative margins for 2013. However, sponsors typically offer more than one plan. When aggregated to the level of parent organization, 13 percent (24 of the 189 plan sponsors we examined) had a combined negative margin. Those sponsors accounted for 4 percent of total revenues and 3 percent of the total enrollee member months.
- In contrast, 87 percent of parent organizations (accounting for 97 percent of total enrollment months) had positive margins in 2013, and many saw strong returns. Fifty-three percent of sponsors had margins of 10 percent or more after risk-corridor payments to Medicare, and they accounted for 75 percent of the total revenues for basic benefits that we examined and 75 percent of total enrollment months.

## Strategies for controlling growth in plan premiums

Plan sponsors decide how many drugs to list on their formulary and whether to apply utilization management, such as requiring prior authorization to fill prescriptions. Sponsors also set differential copayments to encourage enrollees to use preferred medicines or a subset of pharmacies.

In their formulary designs, plan sponsors attempt to strike a balance between providing enrollees with access to medications and controlling growth in drug spending. Part D sponsors rely on clinicians (typically, physicians and pharmacists who serve on pharmacy and therapeutics committees) when deciding which drugs to list, subject to CMS regulations. Sponsors also select the cost-sharing tier for each listed drug (if using a tiered formulary structure) and determine whether to apply utilization management tools.

Sponsors use formularies to structure competition among drug therapies and to shift utilization toward certain products, such as lower cost generics and preferred brand-name drugs. Traditionally, plan sponsors have not received rebates from manufacturers of generic drugs. However, market competition from generics can, over time, lower spending by 80 percent or more, and so promoting the use of generics can play a central part in controlling drug spending (Kesselheim 2014).

### Most enrollees are in plans that use a five-tier formulary structure

Nearly all plans have used cost-sharing tiers for their formularies since the start of Part D, but over time, plans have moved toward more tiers. Most plans now use a five-tier formulary—including preferred generic and other generic tiers, preferred and nonpreferred brand-name drug tiers, and a specialty tier. Plans charge higher copayments for other generics relative to preferred generics to encourage use of less costly medicines. In 2015, 80 percent of PDP enrollees and 76 percent of MA–PD enrollees were in plans with five cost-sharing tiers (Figure 13-5).

### Mixed changes to formularies and continued use of utilization management

Although imperfect measures, the number of drugs listed on a plan’s formulary and utilization management strategies are metrics to gauge the generosity of plans’

coverage.<sup>15</sup> Under contract with the Commission, researchers from Social & Scientific Systems analyzed Part D formulary data for 2016. For this analysis, drugs are defined at the level of chemical entities—a broad grouping that encompasses all of a chemical’s forms, strengths, and package sizes—that combine brand and generic versions of the same specific chemical entity (Medicare Payment Advisory Commission 2008).

The number of drugs in the formulary reference file, which is used as a denominator to calculate the share of all distinct chemical entities listed on plan formularies, increased by about 2 percent between 2015 and 2016. Meanwhile, some of the largest PDPs tightened their formularies between 2015 and 2016, while others kept their formularies nearly the same (Table 13-9, p. 388). For example, two of UnitedHealth Group’s plans, AARP Medicare Rx Preferred plan and AARP MedicareRx Saver Plus, had 5 percentage point and 4 percentage point reductions, respectively, in the share of drugs listed on their formularies. WellCare Classic also tightened its formulary by 4 percentage points. Meanwhile, the formularies of CVS Health’s SilverScript Choice plan and other popular plans offered by Humana kept the breadth of their formularies about the same as in 2015. Cigna-HealthSpring Rx Secure widened its formulary by 2 percentage points.

The application of utilization management tools in Part D—including quantity limits, step therapy, and prior authorization—has grown over the years. Sponsors use 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.

In 2016, the average enrollee in a PDP faces some form of utilization management for 42 percent of drugs listed on a plan’s formulary, up from 38 percent in 2015 (Table 13-9, p. 388). Among the top PDPs, those operated by Humana have the highest share of drugs with utilization management. UnitedHealth Group’s two largest plans (AARP Medicare Rx Preferred and AARP MedicareRx Saver Plus) had the largest increases in the shares of formulary drugs to which utilization management applies: 8 percentage point and 7 percentage point increases, respectively (Table 13-9, p. 388). Other popular PDPs had more modest increases, usually on the order of 1 or 2 percentage points. The most common strategy that plan sponsors use to manage enrollees’ drug use is to apply a

**TABLE  
13-9**

**2016 formularies for stand-alone PDPs with highest 2015 enrollment**

Stand-alone PDPs with the highest 2015 enrollment	Percent of drugs on formulary		Percent of formulary drugs with any utilization management*	
	2015	2016	2015	2016
All PDPs	81%	77%	38%	42%
AARP MedicareRx Preferred	89	84	36	44
SilverScript Choice	74	74	40	40
Humana Preferred Rx Plan	81	81	45	46
Humana Walmart Rx Plan	83	83	45	46
AARP MedicareRx Saver Plus	83	79	36	43
Humana Enhanced	89	89	47	47
Cigna-HealthSpring Rx Secure	77	79	44	45
WellCare Classic	74	70	37	39

Note: PDP (prescription drug plan). Figures reflect the average of all PDPs offered under the same plan name, weighted by 2015 enrollment. Employer plans and U.S. territories are excluded. For 2015, the number of drugs in the formulary reference file, which is used as a denominator to calculate the share of all distinct chemical entities listed on plan formularies, was 1,253; for 2016, the number is 1,316.

\*Utilization management includes prior authorization, quantity limits, and step therapy requirements.

Source: NORC/Social & Scientific Systems analysis for MedPAC of formularies submitted to CMS.

prior authorization requirement. In 2016, about 24 percent of formulary drugs are subject to prior authorization.

**Pharmacy networks**

In addition to their formulary structure, Part D plan sponsors can use pharmacy networks to obtain competitive prices by differentiating among pharmacies in two ways: (1) designating a pharmacy network, and (2) within that network, designating some pharmacies as preferred.

By law, plan sponsors must do business with all pharmacies that are willing to accept the plan sponsors’ terms of contract, and all such pharmacies are considered to be in the plan’s network. However, some pharmacies may 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.

Today, most sponsors use tiered pharmacy networks that encourage enrollees to fill prescriptions at certain pharmacies by offering preferred (lower) cost sharing. Plan sponsors negotiate additional price concessions, incentive payments, or both with that subset of pharmacies. Thus,

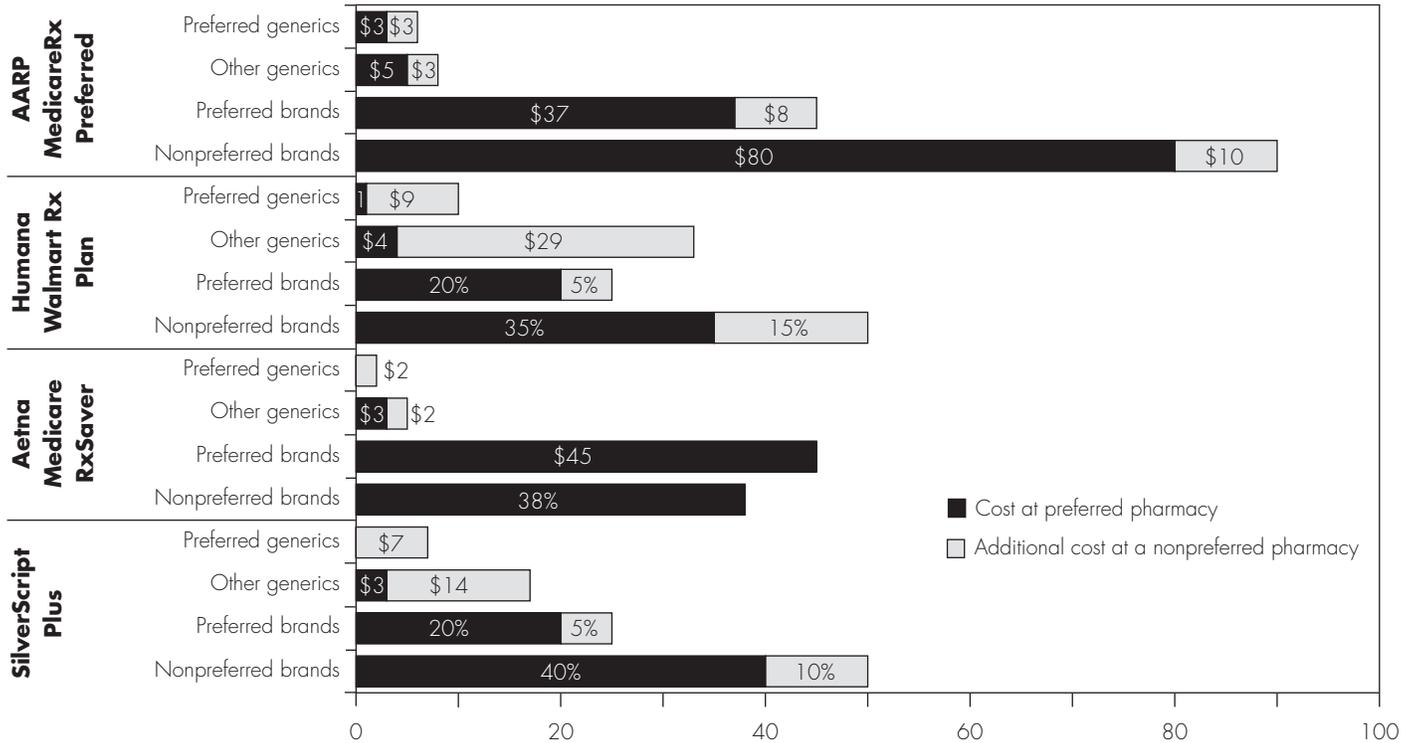
the use of tiered pharmacy networks has the potential to lower costs to the Medicare program and to enrollees.

A Commission-sponsored analysis of pharmacy networks among 2015 Part D plans highlighted two emerging strategies (NORC at the University of Chicago 2015):

- Some PDPs moved toward tighter pharmacy networks than in previous years. For example, 20 percent of PDPs listed 90 percent or fewer pharmacies in their service area(s) as being in their network. Two large national plans—First Health Part D Value Plus and Aetna Medicare Rx Saver—listed, on average, less than 70 percent of pharmacies as in-network. In previous years, the vast majority of plans included over 90 percent of pharmacies in their networks.
- Between 2014 and 2015, the percentage of PDPs designating a subset of pharmacies within their networks as preferred pharmacies increased from 70 percent to 86 percent. As of February 2015, about 81 percent of PDP enrollees were in a plan with a preferred pharmacy network, up from 74 percent in 2014.

**FIGURE 13-6**

**Cost-sharing differentials at preferred versus other pharmacies for selected plans, 2015**



Note: Plans with no cost-sharing amounts shown for preferred generics at preferred pharmacies offer free (preferred) generics. Some plan offerings have slight differences in cost sharing from region to region. The cost sharing displayed in this exhibit is for Region 17.

Source: NORC/Social & Scientific Systems analysis for MedPAC of formularies submitted to CMS.

Beneficiaries' access to a preferred pharmacy varies considerably across plans. In 2015, among the largest plans that used tiered networks, the percentage of pharmacies designated as preferred ranged from 10 percent among Humana plans to about 70 percent for one of the Blue Cross Blue Shield plans.<sup>16</sup> Variation in the share of pharmacies that are designated as preferred also occurs across geographic regions. For example, in AARP Medicare Rx Preferred and AARP Medicare Rx Saver Plus plans for 2015, 18 percent of pharmacies were preferred in the Pennsylvania–West Virginia region, while 74 percent of pharmacies were preferred in the Colorado region.

Plan sponsors typically charge lower cost sharing to encourage enrollees to fill prescriptions through their plans' preferred pharmacy networks. Differences between cost sharing at preferred pharmacies and other network pharmacies can vary substantially among plans, with some

plans providing much stronger incentives to use preferred pharmacies. For example, in Region 17 of the 2015 Aetna Medicare Rx Saver plan, enrollees paid \$2 less for generic prescriptions filled at preferred pharmacies but no difference for brand-name prescriptions. In comparison, the Humana Walmart Rx plan charged \$9 less for preferred generics and \$29 less for other generics at preferred pharmacies (Figure 13-6).

The use of tiered pharmacy networks may allow plan sponsors to better manage Part D spending if it encourages enrollees to use pharmacies with lower costs (Federal Trade Commission 2014, Kaczmarek et al. 2013). However, preferred networks have been controversial because of concern that some enrollees may not have convenient access to preferred pharmacies with lower cost sharing. While the share of pharmacies on plans' preferred lists varies from one plan offering to another,

most preferred networks include less than half of the pharmacies in their networks (Medicare Payment Advisory Commission 2014d, NORC at the University of Chicago 2015).

CMS has noted concern that lower cost sharing offered to beneficiaries at preferred pharmacies could come at the expense of higher Medicare program spending. For example, some plans might encourage beneficiaries to fill prescriptions at pharmacies (including mail-order pharmacies) owned by the same parent organization at prices that are not necessarily lower, or, in some cases, lower cost sharing offered at preferred pharmacies might simply shift more benefit costs to the program. Because of these concerns, CMS conducted a study to examine the implications of the use of preferred pharmacies. The study found that costs at preferred pharmacies were, on average, lower than at other pharmacies (Centers for Medicare & Medicaid Services 2013). However, for a subset of plans, average costs were higher at preferred pharmacies. These findings led CMS to propose a rule that would allow plans to offer lower cost sharing at preferred pharmacies only when the approach does not raise Medicare payments (Centers for Medicare & Medicaid Services 2014d). That rule was not finalized due to comments CMS received from many stakeholders opposing the policy (Centers for Medicare & Medicaid Services 2015d).

A further concern is that if LIS enrollees have less opportunity to use preferred pharmacy networks or choose other pharmacies over a preferred one, Medicare will not realize the “savings” that could have resulted had this management strategy been effective (since the LIS covers most or all of these enrollees’ cost sharing).

To participate in Part D, plan sponsors must set up pharmacy networks that meet access requirements.<sup>17</sup> Access standards apply to a plan’s entire network rather than to its preferred network. In 2014, CMS examined access to preferred networks with somewhat surprising results: On average, enrollees living in urban (rather than rural) areas were less likely to have convenient access to preferred pharmacies that offered lower cost sharing (Centers for Medicare & Medicaid Services 2014a).<sup>18</sup> Certain plan sponsors had substantially tighter preferred networks. For the 2016 benefit year, CMS conducted close reviews of “tighter network” plans in areas where potential access appeared low and required plan sponsors to inform enrollees more clearly of their options with respect to preferred cost sharing (Centers for Medicare & Medicaid Services 2015g).

The Commission has expressed support for plan innovations that increase efficiency, and we agree with CMS that the competition created by preferred pharmacy networks should result in lower costs for the program and for Part D enrollees. However, we noted in our comment letter to CMS that a separate pharmacy access standard may be required to ensure that plan enrollees have reasonable access to preferred cost sharing (Medicare Payment Advisory Commission 2014a). In addition, the Commission is concerned that because cost sharing for LIS enrollees is set statutorily, plans may be limited in their ability to encourage individuals with the LIS to use preferred pharmacies.

To examine this issue further, we looked at patterns of pharmacy use for plans offered by the same sponsor in two regions. We found that, in both regions, non-LIS enrollees were twice as likely as LIS enrollees to fill their prescriptions at preferred pharmacies (see online Appendix 13-A, available at <http://www.medpac.gov>, for more detail). Although this finding may not be generalizable, it suggests that plan sponsors may be less successful at encouraging LIS enrollees to fill their prescriptions at a lower cost setting using financial incentives.

In its March 2012 report, the Commission recommended that the Congress give the Secretary authority to provide stronger financial incentives for LIS enrollees to use lower cost generics when available (Medicare Payment Advisory Commission 2012). At the time, a key rationale for the recommendation was that LIS enrollees made up the majority of beneficiaries who reached the catastrophic phase of the Part D benefit. Encouraging LIS enrollees to use lower cost generics could reduce the number of individuals who reach the catastrophic phase of the benefit and thereby reduce the amount Medicare pays to plans in individual reinsurance.

Since 2012, larger numbers of plans have added tiers to their formularies (e.g., put in place two generic tiers) and now most also use tiered pharmacy networks. Given these changes and the potential for other innovations in how plan sponsors manage prescription drug benefits, the Commission may modify the language of its 2012 recommendation in the future.

### **Specialty pharmacies**

Another strategy most commercial health plans have adopted to manage the use of high-cost medicines is to require that enrollees fill prescriptions through a limited network of specialty pharmacies.<sup>19</sup> PBMs and health

plans contend that specialty pharmacies can lead to better patient education and improved adherence. Manufacturers and payers may prefer to use specialty pharmacies to prevent diversion of expensive drugs or the distribution of counterfeits. Specialty pharmacies can reduce waste by, for example, initially dispensing a 7-day or 14-day supply and observing the patient for side effects before providing a 30-day supply. Also, these pharmacies can help prescribers navigate the clinical documentation needed to meet prior authorization requirements. The largest specialty pharmacies are owned by PBMs, and in some cases, they may be able to negotiate lower prices with drug manufacturers.

A variety of business models fall under the term “specialty pharmacy,” and the interests served by some specialty pharmacies may not be aligned with those of payers or patients.<sup>20</sup> For example, Philidor Rx Services, a specialty pharmacy affiliated with Valeant Pharmaceuticals International, “functioned almost as a direct seller for it [Valeant Pharmaceuticals International]” (Nisen 2015). Another specialty pharmacy, Linden Care, is accused of “pushing a single manufacturer’s products” and keeping sales from going to generic drugs “by offering to do paperwork, reimburse patients’ out-of-pocket costs, and fight with insurers for doctors and patients” (Nisen 2015).

Unlike the commercial sector, Medicare guidance prohibits Part D plan sponsors from limiting where beneficiaries fill their prescriptions, so long as the pharmacy selected by the enrollee is in the plan’s network.<sup>21</sup> An exception is if a *manufacturer* of a specialty medication has limited the distribution of its product to certain authorized pharmacies. In this situation, the Part D enrollee would be able to fill that prescription at only one of the designated (specialty) pharmacies.

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## Drug pricing

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Since the start of Part D, plans’ use of differential cost sharing across formulary tiers, combined with the fortuitous timing of an unusually large number of patent expirations on widely used brand-name drugs, has led to a dramatic shift toward the use of generics. Between 2010 and 2013, 30 blockbuster drugs with combined annual sales of about \$100 billion went off patent, and the market for generic drugs expanded rapidly (Galliard Capital Management 2011, Myshko 2012). As a share of total Part D prescriptions, generics rose to about 84 percent in

2013 (the latest year of claims data available), up from 81 percent in 2012. At the same time, the introduction of new generics is slowing and the drug pipeline contains larger numbers of biologic products and specialty drugs. Plan sponsors have had less success at stemming growth in prices of drugs with few or no substitutes in their therapeutic class.

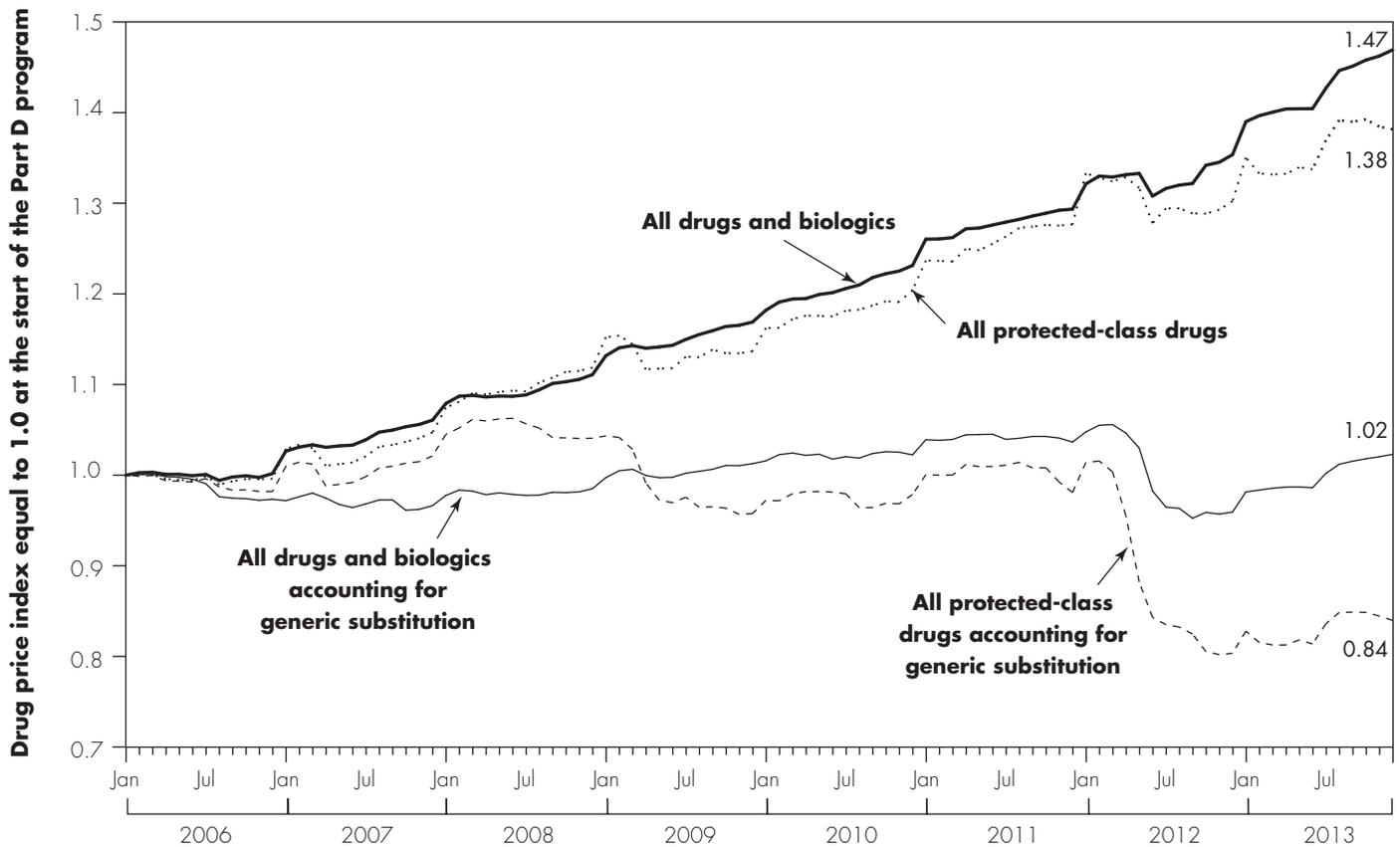
Plan sponsors negotiate substantial rebates on certain brand-name drugs, particularly those that face competition from other brands or generics in the same therapeutic class. Across all types of Part D drugs, the Medicare Trustees estimated that, in 2015, plan sponsors obtained rebates amounting to 16.6 percent of total prescription drug costs, averaged across all prescription drugs (even though plans do not receive any rebates for some drugs) (Boards of Trustees 2015). This estimate is a significant increase from rebates of about 9.6 percent of total prescription drug costs for 2007, 12.9 percent in 2013, and 14.4 percent in 2014. CMS Office of the Actuary attributes the 2015 increase to “the intensified competition in the hepatitis C drug market.”

To track drug prices, the Commission contracted with Acumen LLC to construct a series of volume-weighted price indexes. The indexes do not reflect retrospective rebates or discounts from manufacturers and pharmacies, but rather the prices sponsors and beneficiaries pay to pharmacies at the point of sale (including ingredient costs and dispensing fees).

### **In 2013, price increases more than offset the effects of generic use**

Measured by individual national drug codes (NDCs) and excluding manufacturers’ rebates, between 2006 and 2013, Part D drug prices rose by an average of 47 percent cumulatively (Figure 13-7, p. 392).<sup>22</sup> As measured by a price index that takes the substitution of generics for brand-name drugs into account, Part D prices increased by just 2 percent cumulatively.<sup>23</sup>

Generic substitution has played a key role in constraining growth in Part D’s average price of drug therapy. However, a closer look at the changes in the price index for 2013 reveals cause for concern. First, between December 2012 and December 2013, our index of Part D prices that accounts for generic substitution grew by 6.6 percent—the highest rate observed since the program began. Before 2012, annual growth rates ranged between –2.7 percent and 2.8 percent. In 2012, the Part D price index experienced its largest ever decline (–7.5 percent) as a

**FIGURE  
13-7****Availability of generics, rather than protected status,  
is key to slower price growth under Part D**

Note: Chain-weighted Fisher price indexes.

Source: Acumen LLC analysis for MedPAC.

result of the so-called “patent cliff.” Second, the 2013 increase in the price index occurred even as the share of generic prescriptions rose from 81 percent in 2012 to 84 percent (see text box on the increase in generic use). The changes between 2012 and 2013 suggest a strong uptick in prices of medicines taken by Part D enrollees that more than offset the price-moderating effects of switching to generic medications.

For most therapeutic classes, CMS requires plan formularies to cover at least two drugs, unless only one drug is approved for that class. This policy is intended to protect beneficiaries who need a drug that is the only one available to treat a certain condition and allows competition in classes with multiple products. For six drug classes, CMS requires Part D plans to cover “all

or substantially all” drugs in the class. These classes are antineoplastics, antidepressants, antipsychotics, antiretrovirals, anticonvulsants, and immunosuppressants used by transplant patients.<sup>24</sup> Plans can charge higher cost sharing for drugs in these classes—for example, by placing them on tiers for nonpreferred brands—but plans may have limited ability to influence utilization of these classes of drugs.

As measured by individual NDCs, prices for drugs in the six protected classes showed a trend between 2006 and 2013 similar to that for all Part D drugs, rising by a cumulative 38 percent (Figure 13-7). When protected-class drugs were grouped to take generic substitution into account, their prices fell by a cumulative 16 percent over the eight-year period.

## Generic use has risen, varies across plan types and enrollees

Increased use of generics has played a major role in moderating Part D spending growth. Between 2007 and 2013, the average generic dispensing rate (GDR)—defined as the share of Part D prescriptions dispensed that are generic drugs—increased from 61 percent to 84 percent (Table 13-10). During this period, some of the most popular brand-name drugs lost patent protection, affording more opportunities for generic substitution.

GDRs vary across categories of beneficiaries. For example, Medicare Advantage–Prescription Drug plan (MA–PD) enrollees are more likely to use generics than stand-alone prescription drug plan (PDP) enrollees. Between 2007 and 2013, average GDRs for MA–PD enrollees consistently exceeded those of PDP enrollees by 4 percentage points to 6 percentage points. Low-income subsidy (LIS) enrollees have had a consistently lower GDR than non-LIS enrollees, and that difference has remained stable at about 4 percentage points to 5 percentage points since 2008.<sup>25</sup>

In both PDPs and MA–PDs, LIS enrollees are less likely to use generic drugs than non-LIS enrollees. For example, among PDP enrollees in 2013, the GDR for LIS enrollees was 2 percentage points below that of

non-LIS enrollees. Among MA–PD enrollees in the same year, the GDR for LIS enrollees was 8 percentage points lower.

Multiple factors likely contribute to the higher or lower GDRs among groups of beneficiaries. For example, differences in health status may limit the opportunity for clinically appropriate therapeutic substitutions for some beneficiaries. There can also be differences in prescribing behavior between physicians who are part of a managed care organization and those who are not. Another factor may be the difference in financial incentives faced by LIS and non-LIS enrollees. Because cost sharing for LIS enrollees is set statutorily, that factor may limit how well plan sponsors can manage drug spending for their LIS enrollees.

The Commission’s March 2012 recommendation was intended to encourage LIS enrollees to use generics when they are available (see p. 390 for the discussion of the recommendation). This strategy, in turn, would likely reduce the amount Medicare spends for the LIS. In addition, because about three-fourths of enrollees who reach the catastrophic phase of the benefit receive the LIS, greater use of generics could also reduce the amount Medicare pays in individual reinsurance. ■

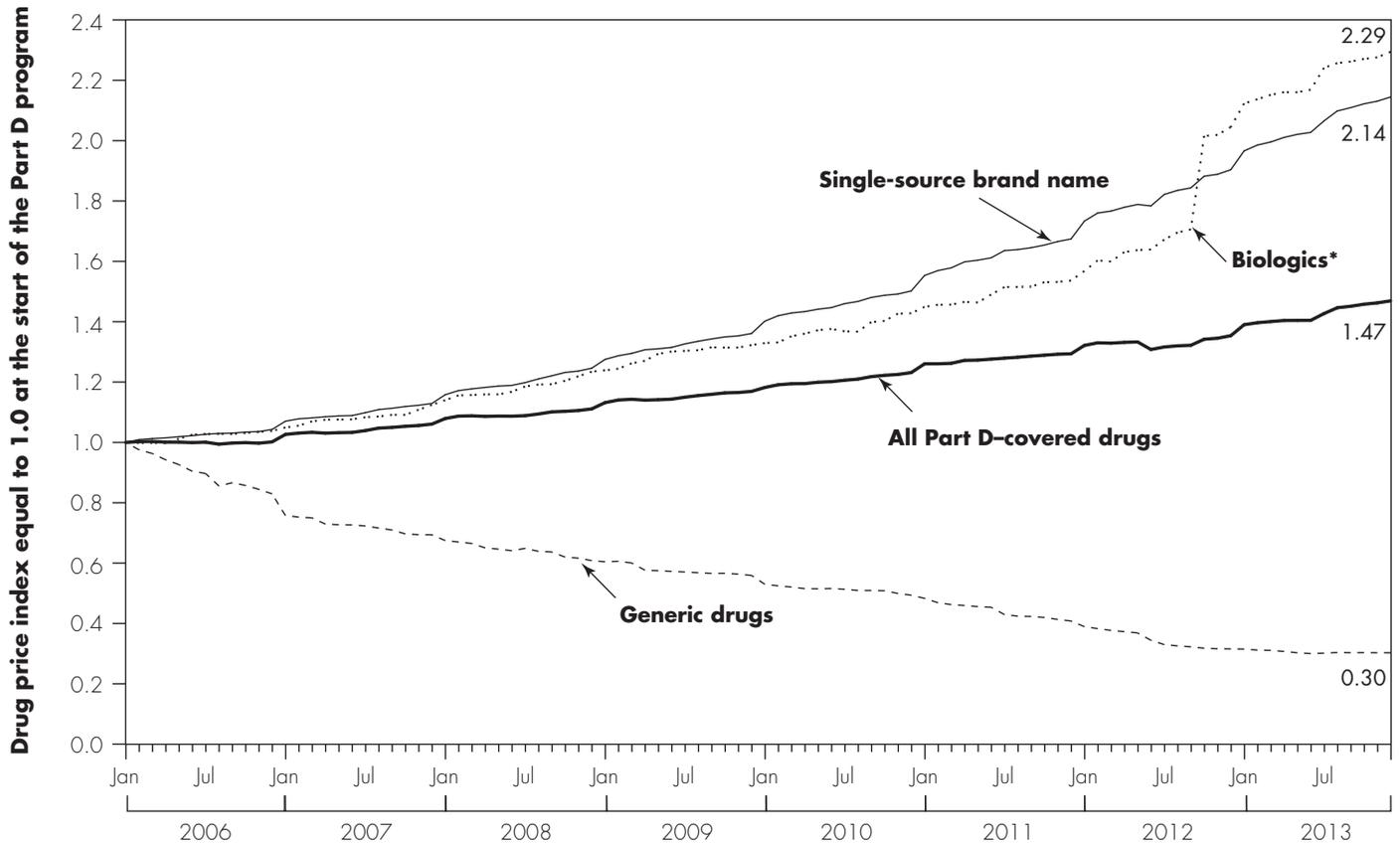
**TABLE  
13-10**

**Generic dispensing rate by plan type and LIS status, 2007–2013**

	2007	2008	2009	2010	2011	2012	2013
All Part D	61%	67%	70%	74%	77%	81%	84%
By plan type							
PDP	60	66	69	72	75	80	82
MA–PD	66	71	74	77	80	84	86
By LIS status							
LIS	60	65	68	71	74	78	81
Non-LIS	62	69	72	76	79	83	85

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Shares are calculated as a percentage of all prescriptions standardized to a 30-day supply. “Generic dispensing rate” is the proportion of Part D prescriptions dispensed that are generic prescriptions.

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

**FIGURE  
13-8****Decline in generic prices and sustained aggressive price growth under Part D for single-source brand-name drugs and biologics**

Note: Chain-weighted Fisher price indexes.

\*The shift in biologics price index in October of 2012 is due in part to a change in how prescription quantities were reported for Avonex, a product used to treat multiple sclerosis.

Source: Acumen LLC analysis for MedPAC.

These trends are influenced heavily by three classes of drugs: antidepressants, antipsychotics, and anticonvulsant medications, which accounted for over 90 percent of the volume of prescriptions in the six classes. With the exception of antiretroviral drugs, many drugs in the six classes now have generic versions available. In 2013, between 80 percent and 90 percent of prescriptions dispensed for protected-class drugs other than antiretrovirals were generic. This trend has translated into a modest growth in prices even when measured at individual NDCs: Between 2006 and 2013, average prices grew by 3 percent for antidepressants and decreased by 5 percent for anticonvulsants. Recent entry of generics has also slowed growth in price indexes for immunosuppressants and antipsychotics.

In the case of anticancer drugs, however, growth in prices for very expensive brand-name medications has likely driven overall growth in the category. Our price index for antineoplastics (measured at individual NDCs) grew by more than 90 percent between 2006 and 2013. This level of growth far exceeds the price index growth observed for other protected-class drugs, even antiretrovirals, which consists almost entirely of brand-name drugs.<sup>26</sup> The growth in our price index for antineoplastics is especially striking given that generic drugs accounted for 90 percent of the prescriptions dispensed for that class in 2013.

Overall, when a drug has protected status, plan sponsors have had success at moving enrollees toward generics when available. However, the extent to which increases

in the use of generics help to keep prices stable varies by drug class. In addition, the drugs' protected status may limit the amount of rebates plan sponsors are able to obtain from manufacturers for drugs in these classes. We lack rebate information to test this hypothesis.

### Prices of brand-name drugs and biologics have grown aggressively

Patterns of price growth across classes of drugs suggest that prices for drugs with few or no generic substitutes have grown rapidly. Our index of prices for drugs with no generic substitutes (single-source, brand-name drugs) grew between 2006 and 2013 by a cumulative 114 percent (Figure 13-8). By comparison, our price index for generic drugs decreased to just 30 percent of the average index value observed at the beginning of 2006.

Among biologic products covered by Part D, few (if any) today have follow-on products on the market that compete with them through price. Our price index for biologic products grew between 2006 and 2013 by a cumulative 129 percent—even higher than that observed for single-source brand-name drugs (Figure 13-8). However, the rapid increase in our biologics index for 2012 bears further examination.<sup>27</sup>

Several analysts have noted that certain generic medications now have high prices or have experienced sharp price increases (Alpern et al. 2014, Fein 2014, Kesselheim 2014). Overall, the Commission's generic price index decreased at a slower rate (about -4 percent between December 2012 and December 2013) compared with double-digit declines in nearly every year between 2006 and 2012. Because of growing reliance on generics, the price increases have drawn the attention of policymakers (Rosenthal 2014). The high price of some generics may be one motivation for Part D plan sponsors to move toward a five-tier formulary structure, with two generic tiers. A number of factors explain price increases for generics, including drug shortages, disruptions in the supply of drugs, and consolidations among manufacturers of generic drugs (Alpern et al. 2014). Factors associated with decreased market competition can lead to high and rising prices.

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### Program spending

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Evidence on program spending gives a mixed picture about the success of Part D plans at containing costs. Consistent with what the Commission observed in its

June 2015 report to the Congress, spending for the competitively derived direct-subsidy payments on which sponsors bear the most insurance risk has continued to grow 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 2015c).

### Program subsidies and costs

Medicare pays plan sponsors three major subsidies on behalf of each enrollee in their plans:

- **Direct subsidy**—Medicare pays plans a monthly amount set as a share of the national average bid for Part D basic benefits, adjusted for the risk of the individual enrollee.
- **Reinsurance**—Medicare reimburses plans for 80 percent of drug spending above an enrollee's annual OOP threshold.
- **LIS**—Medicare pays plans to cover expected cost sharing and premiums for enrollees eligible for the low-income subsidy.

Combined, the direct subsidy and reinsurance cover 74.5 percent of basic benefits, on average. Beneficiary premiums cover the remainder.

Between 2007 and 2014, program spending (including the retiree drug subsidy (RDS)) rose from \$46.2 billion to \$73.3 billion (Table 13-11, p. 396). In 2014, Medicare paid \$19.6 billion for direct subsidies, \$27.8 billion for individual reinsurance, \$24.3 billion for the LIS, and \$1.6 billion for the RDS (Boards of Trustees 2015). Payments to plans for the three subsidies combined with RDS payments grew by an average of 6.8 percent per year.

In 2014, for the first time since the program began, payments for individual reinsurance exceeded payments for the LIS to become the largest component of Part D spending. Medicare payments for individual reinsurance have grown faster than other components of Part D spending, increasing between 2007 and 2014 at an annual average of 19.5 percent (Table 13-11). This growth appears to have accelerated in recent years, in part due to the gradual phase out of the coverage gap that began in 2011. Since 2010, there has been a double-digit increase in the number of non-LIS enrollees who reach

**TABLE  
13-11**

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

	Calendar year						Average annual growth rate 2007–2014
	2007	2009	2011	2012	2013	2014	
Reimbursement amount (in billions):							
Direct subsidy*	\$17.6	\$18.2	\$19.2	\$19.7	\$19.6	\$19.6	1.5%
Reinsurance	8.0	10.1	13.7	15.5	19.2	27.8	19.5
Low-income subsidy	16.7	19.6	22.2	22.5	23.2	24.3	5.5
Retiree drug subsidy	3.9	3.9	3.6	3.0	1.8	1.6	-12.0
Total	46.2	51.8	58.7	60.7	63.8	73.3	6.8

Note: Numbers above reflect reconciliation. Most enrollees paid premiums directly to plans, and those amounts are not included. On a cash basis, the Boards of Trustees estimate that premiums paid by enrollees were \$4.1 billion in 2007, \$5.0 billion in 2008, \$6.1 billion in 2009, \$6.7 billion in 2010, \$7.3 billion in 2011, \$7.8 billion in 2012, \$9.3 billion in 2013, and \$10.5 billion in 2014. 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 2015 annual report of the Boards of Trustees of the Medicare trust funds.

the catastrophic phase of the benefit, which, in turn, triggers Medicare’s individual reinsurance (see text box on beneficiaries who reach the coverage gap or OOP threshold, pp. 398–399, and Table 13-12, p. 399). Between 2010 and 2014, payments for individual reinsurance grew by about 26 percent per year compared with 12 percent for 2007 through 2010 (data not shown).

Changes in the national average bid also reveal higher growth in individual reinsurance. Between 2007 and 2016, expected total benefit spending per member per month has grown at a modest rate of 3 percent annually, from \$103 to \$134 (Figure 13-9). During that period, the monthly amount that plans expect to receive through the direct subsidy has fallen 5.4 percent annually, from about \$50 to \$31. Over the same period, the amount per member per month that sponsors expect to receive in reinsurance has grown 11.3 percent annually, from \$26 to about \$69.

In the Commission’s June 2015 report to the Congress, we observed regular patterns in Medicare’s reconciliation payments with plans (Medicare Payment Advisory Commission 2015c). First, many plan sponsors have 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 have bid too high on the rest of benefit spending other than catastrophic benefits. Between 2009 and 2013, about three-fourths of parent organizations returned a portion of their prospective payments to Medicare through

risk corridors. 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 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. When plan sponsors underbid on the amount of individual reinsurance they will ultimately receive, Medicare pays an overall Part D subsidy higher than the 74.5 percent specified in law. We estimate this higher subsidy has occurred in each year between 2007 and 2014.

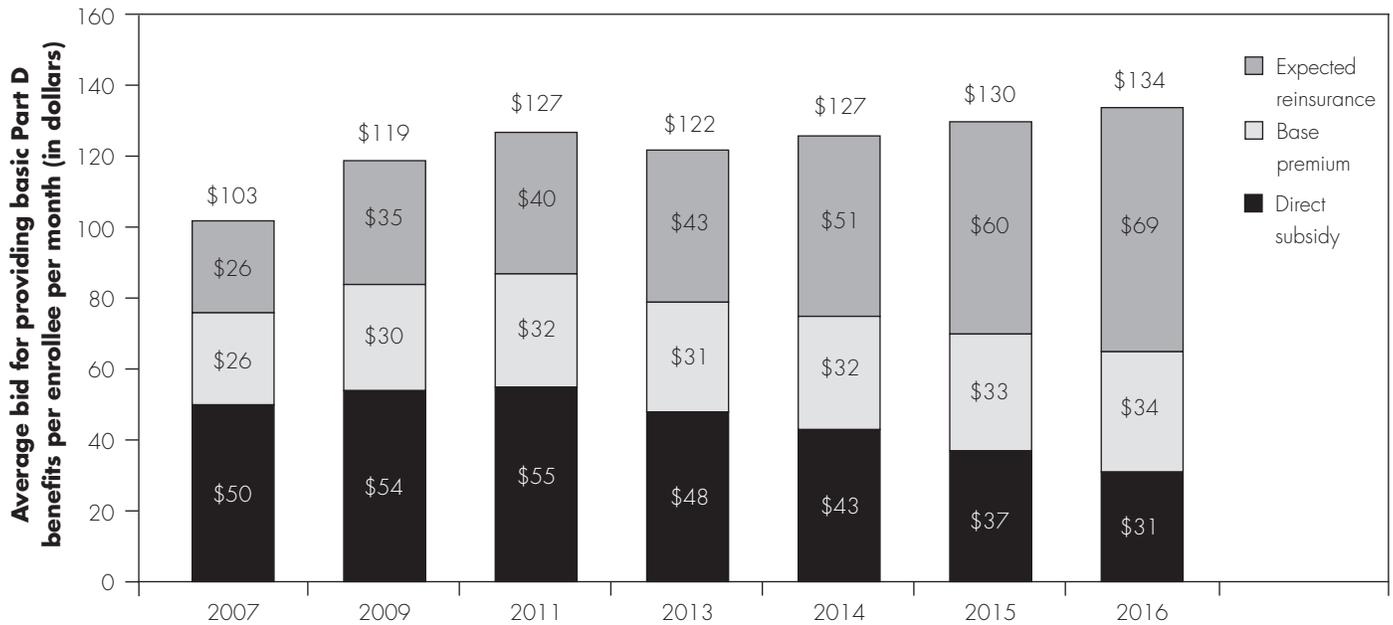
For benefits delivered in 2014, 81 percent of plan sponsors received additional individual reinsurance payments from Medicare at reconciliation, much of which was likely due to higher than anticipated spending on new hepatitis C therapies. Ultimately, however, 62 percent of Part D plan sponsors made risk-corridor payments to Medicare for 2014 benefits. In the aggregate, those payments totaled less than \$100 million, much lower than risk-corridor payments from plan sponsors to Medicare in previous years.

**A growing share of program spending is for high-cost enrollees**

The share of spending accounted for by high-cost enrollees—those who reach the catastrophic phase of the benefit—has grown in recent years, from about 40 percent of the gross spending before 2011 to 44 percent in 2011,

**FIGURE  
13-9**

**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 analysis based on data from CMS.

and to about 47 percent in 2013. This growth has occurred, even as these high-cost enrollees' share of Part D enrollees has decreased (see text box, pp. 398–399).

**Increase in prices per prescription drove growth in spending for high-cost enrollees**

Between 2007 and 2013, per capita spending for all Part D enrollees grew an annual 2.2 percent, compared with an annual 8.4 percent for high-cost enrollees (Table 13-13, p. 400). On average, growth for all Part D enrollees was driven by an increase in the number of prescriptions filled, which grew by an average annual 2.2 percent, while the average price for each prescription remained nearly flat (an annual growth rate of less than 0.1 percent).

By comparison, the pattern is very different for high-cost enrollees. Between 2007 and 2013, prices per prescription for high-cost enrollees grew an annual 6.9 percent, while the number of prescriptions filled per enrollee per month grew an annual 1.4 percent (Table 13-13, p. 400). That is, the growth in prices explains much of the spending growth (8.4 percent) for high-cost enrollees during this period.

The higher growth in prices of drugs taken by high-cost enrollees can be explained by their tendency to use more brand-name drugs. For example, in 2013, the average generic dispensing rate (GDR) among high-cost enrollees was slightly over 70 percent, or about 13 percentage points below the overall Part D average. This lower GDR is due, in part, to the fact that most of the high-cost enrollees are individuals who receive the LIS. The cost-sharing subsidy, while helping these beneficiaries to afford medications, also minimizes or eliminates the financial incentives plans employ to encourage the use of lower cost drugs. At the same time, for certain classes of drugs, generic substitution is not available. Prices of many drugs (e.g., specialty drugs) that do not have generic substitutes are typically much higher and grow more rapidly compared with other drug products.<sup>28</sup>

**Use of higher cost drugs poses challenges for Part D**

Drugs with very high prices pose a particular challenge for Part D. As more expensive therapies become available, larger numbers of beneficiaries will reach the catastrophic

## Beneficiaries who reach the coverage gap or out-of-pocket threshold

In 2013, a quarter of Part D enrollees incurred spending high enough to reach the coverage gap (Figure 13-10). Of those, about 2.9 million, or about 8 percent of all Part D enrollees, had spending high enough to reach the catastrophic phase of the benefit, up from 2.6 million in 2012.<sup>29</sup> We refer to individuals who reach the catastrophic phase as high-cost enrollees.

### Most high-cost enrollees received the LIS in 2013

In 2013, slightly over 2.1 million, or three-quarters of high-cost enrollees, received Part D's low-income

subsidy (LIS). Because LIS enrollees are more likely to be enrolled in prescription drug plans (PDPs), a larger share of high-cost enrollees was in PDPs compared with other enrollees (78 percent compared with 63 percent, respectively). High-cost enrollees were also more likely to reside in an institution, be disabled beneficiaries under age 65, and be non-White compared with other enrollees (data not shown).

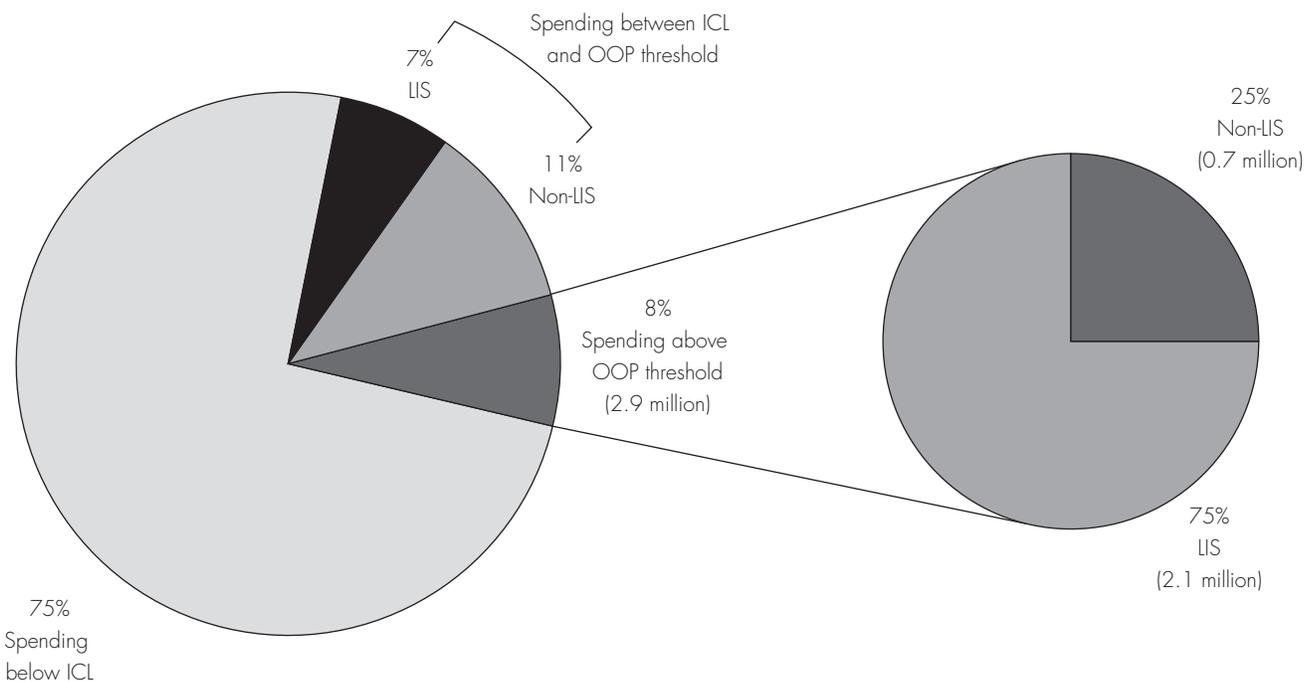
### High-cost enrollees without the LIS increased faster than those with the LIS

Even though non-LIS enrollees made up just 25 percent of high-cost enrollees in 2013, their proportion has been rising. Between 2010 and 2013, the number of

*(continued next page)*

**FIGURE 13-10**

**Part D enrollees with spending in the coverage gap and catastrophic phase, 2013**



Note: ICL (initial coverage limit), LIS (low-income subsidy), OOP (out-of-pocket). Enrollees with spending in between the ICL and the OOP threshold fall within Part D's coverage gap. LIS enrollees do not face a coverage gap. In 2013, Part D enrollees reached the ICL at \$2,970 in gross drug spending. With no supplemental coverage, an enrollee reached the threshold at \$4,750 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. Components may not sum to stated totals due to rounding.

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

## Beneficiaries who reach the coverage gap or out-of-pocket threshold (cont.)

non-LIS enrollees who reached the catastrophic phase of the benefit increased noticeably, with a more than 27 percent increase between 2010 and 2011 and a nearly 33 percent increase between 2012 and 2013 (Table 13-12). Much of this increase is likely a result of changes made by the Patient Protection and Affordable Care Act of 2010 (PPACA). Specifically, PPACA called for a 50 percent manufacturer discount on brand-name

drugs in the coverage gap and allowed that discount to count toward the out-of-pocket spending threshold. However, the increase also reflects higher enrollment growth among non-LIS enrollees between 2007 and 2013—over 8 percent per year compared with less than 3 percent per year among LIS enrollees (data not shown). ■

**TABLE  
13-12**

**Part D enrollees reaching the benefit's out-of-pocket threshold, 2007-2013**

	2007	2008	2009	2010	2011	2012	2013
<b>In millions</b>							
LIS	1.9	2.0	2.0	2.0	2.1	2.1	2.1
Non-LIS	<u>0.4</u>	<u>0.4</u>	<u>0.4</u>	<u>0.4</u>	<u>0.5</u>	<u>0.5</u>	<u>0.7</u>
All	2.3	2.4	2.4	2.4	2.6	2.6	2.9
<b>Annual percentage change</b>							
LIS		4.6%	-0.5%	-0.1%	9.0%	-3.4%	4.0%
Non-LIS		4.9	-6.2	-3.9	27.6	6.8	32.7
All		4.6	-1.6	-0.8	12.1	-1.4	9.9

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

Source: Data from 2007 and 2008 are based on published figures from CMS. Data from 2009 to 2013 are based on MedPAC analysis of Part D prescription drug event data.

phase of the benefit, when Medicare pays for 80 percent of the costs through individual reinsurance. We are already beginning to observe this trend with biologic products. Between 2009 and 2013, the share of high-cost enrollees who filled at least one prescription for a biologic product grew from 8 percent to 12 percent. During the same period, the share of spending accounted for by biologic products grew from 6 percent to 10 percent. According to data released by CMS, spending for new hepatitis C therapies has led to a large spike in Part D spending in 2014 (see text box, pp. 402-403).

Part D enrollees' use of high-cost drugs has thus far made up a limited share of total drug spending (see Medicare Payment Advisory Commission (2015d) for a more detailed discussion). One likely reason for the limited use

of high-cost drugs in Part D so far is that nearly all plans have specialty tiers, which typically carry 25 percent to 33 percent cost sharing. High cost-sharing amounts may discourage some non-LIS enrollees from initiating or completing high-cost treatment. In addition, under Part D rules, enrollees may not appeal cost-sharing amounts for specialty-tier drugs. A similar strategy would not be effective for enrollees whose cost sharing is paid by the LIS.

For the future, the high and increasing cost of specialty drugs poses a big challenge in Part D because these drugs are concentrated in drug classes that treat conditions such as rheumatoid arthritis and inflammatory diseases, multiple sclerosis, cancer, and HIV, which are more prevalent among the Medicare population (Express Scripts 2014). Major PBMs and insurers uniformly

**TABLE  
13-13**

**Increase in prices drove growth in per capita spending for high-cost enrollees, 2007-2013**

	2007	2013	Average annual growth rate, 2007-2013
<b>All Part D enrollees</b>			
Average price per 30-day prescription	\$54	\$54	<0.1%
Prescriptions per enrollee per month	<u>3.9</u>	<u>4.5</u>	2.2
Gross drug spending per enrollee per month	\$212	\$242	2.2
<b>High-cost enrollees</b>			
Average price per 30-day prescription	\$97	\$145	6.9%
Prescriptions per enrollee per month	<u>8.9</u>	<u>9.7</u>	1.4
Gross drug spending per enrollee per month	\$868	\$1,410	8.4

Note: Spending includes all payments to pharmacies, including payments by drug plans, Medicare's low-income subsidy, and beneficiary out of pocket.

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

project that growth in price and use of specialty drugs will continue to drive trends in spending.<sup>30</sup> In the drug pipeline, fewer blockbuster drugs are losing patent protection, and more than half of the FDA's approvals of new drugs in 2013 were for specialty drugs (CatamaranRx 2014). Because many of these therapies have limited therapeutic substitutes, prices for specialty drugs tend to be high, affording PBMs and insurers less ability to exert downward pressure on price.

As the use of specialty drugs increases, Part D enrollees and the Medicare program will face increasingly higher costs. Plans will likely continue to require 25 percent to 33 percent coinsurance on high-priced medicines. If larger numbers of beneficiaries begin to use specialty drugs just as the coverage gap is growing smaller, the number who reach Part D's OOP threshold could rise significantly. In turn, Medicare spending for individual reinsurance and low-income cost sharing also will rise.

**Beneficiaries' access to prescription drugs**

Implementation of the Part D program in 2006 increased the share of beneficiaries with drug coverage from 75 percent to nearly 90 percent.<sup>31</sup> In general, Part D has

improved Medicare beneficiaries' access to prescription drugs, with plans available to all individuals. Surveys indicate that beneficiaries enrolled in Part D continue to be generally satisfied with the Part D program and their plans (Healthcare Leadership Council 2015a, Healthcare Leadership Council 2015b, KRC Research 2013).

**Enrollee cost sharing**

Cost-sharing requirements have generally been rising over the years. This trend is primarily the result of a provision in the law that requires a constant generosity of the Part D's benefit over time, which means that an increase in average total drug expenses requires a commensurate increase, on average, in benefit parameters.

To measure how the beneficiary's share of the drug costs has changed over time, we contracted with researchers at Acumen LLC to calculate the average cost-sharing amounts for different intervals of spending. Table 13-14 shows cost-sharing amounts for beneficiaries with annual total drug spending that falls within different phases of the benefit (e.g., below the 2013 defined-standard benefit's deductible of \$324).<sup>32</sup> Cost-sharing amounts shown are for a hypothetical enrollee with average spending in each spending range based on actual spending in 2013. For an LIS enrollee, we also show the combination of Medicare's low-income cost-sharing subsidy and the LIS beneficiary's OOP spending.

**TABLE  
13-14**

**Examples of cost sharing paid by Part D enrollees in 2007 and 2013**

Gross drug spending per beneficiary	Percent of enrollees in 2013	Percent of spending in 2013	Beneficiary OOP*						Medicare's low-income cost-sharing subsidy combined with LIS enrollee OOP		
			Non-LIS			LIS			2007	2013	Change 2007-2013
			2007	2013	Change 2007-2013	2007	2013	Change 2007-2013			
\$0	7%	0%	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
\$1-\$324	20	1	83	93	10	12	19	7	97	124	27
\$325-\$2,969	47	22	460	440	-20	62	68	6	527	573	46
\$2,970-\$6,954.51	17	27	1,988	1,480	-509	160	130	-29	2,419	2,429	10
\$6,954.52-\$9,999	4	11	3,863	2,932	-931	173	148	-25	4,651	4,805	154
≥\$10,000	5	39	4,357	4,388	31	88	113	25	5,043	5,619	576

Note: OOP (out-of-pocket), LIS (low-income subsidy). The dollar amounts for 2007 are adjusted by the consumer price index for all urban consumers into 2013 dollars. \*Beneficiary OOP includes all payments made by or for a beneficiary (excluding low-income cost sharing) that would be treated as OOP for the purpose of determining when he or she has reached the catastrophic phase of the benefit. Average spending per beneficiary was \$146 for enrollees with spending between \$1 and \$324, \$1,276 for enrollees with spending between \$325 and \$2,969, \$4,426 for enrollees with spending between \$2,970 and \$6,954.41, \$8,272 for enrollees with spending between \$6,954.52 and \$9,999, and \$22,073 for enrollees with spending at or greater than \$10,000.

Source: MedPAC based on Acumen LLC analysis for MedPAC.

In general, the amounts Part D enrollees paid OOP remained relatively stable or decreased between 2007 and 2013. Cost-sharing amounts for non-LIS enrollees generally decreased, with larger decreases for those who had spending high enough to reach the coverage gap or catastrophic phase of the benefit (ranges \$2,970–\$6,954.51 and \$6,954.52–\$9,999, respectively). The decrease is primarily due to the closing of the coverage gap (i.e., an increase in generosity of the Part D benefit) that began in 2011. For LIS enrollees, changes in the amounts paid out of pocket were relatively small (less than 1 percent) with the exception of those in the lowest spending category (\$1–\$324), which grew by \$7 (from \$12 to \$19).<sup>33</sup>

In contrast, Medicare's low-income cost-sharing subsidy combined with the OOP amount paid by LIS enrollees grew across all spending ranges. This amount depends on many factors—such as the disease burden of enrollees, whether the enrollee is in a plan with a deductible, the tier placement of the enrollee's drugs, whether the enrollee chose brand-name drugs or generics, and whether the enrollee filled his or her prescriptions at a preferred pharmacy. Comparing the average amounts of LIS cost sharing to averages for non-LIS enrollees is complicated because the relative generosity of the Part D benefit has differed over time for these two groups. While LIS

enrollees generally have never faced a coverage gap, since 2011, the coverage gap for non-LIS enrollees has become smaller (i.e., coverage has become more generous). Still, the average combined low-income cost-sharing subsidies and LIS OOP amounts grew more than did average non-LIS cost sharing (Table 13-14). Some of this growth is likely due to the fact that LIS OOP amounts, set by law, make LIS enrollees less likely to be influenced by their plans' benefit designs, which use cost sharing to encourage the use of lower cost medications and pharmacies. In turn, this effect may lead to higher growth in spending for Medicare's low-income cost-sharing subsidy in the Part D program compared with cost-sharing amounts paid by non-LIS enrollees.

### Exceptions and appeals process

The number of drugs listed on a formulary or the use of utilization management tools—prior authorization, quantity limits, and step therapy requirements—can provide a measure of beneficiaries' access to prescription drugs. However, for individuals whose prescription medications are not covered by their plans or are covered but have relatively high cost sharing, a well-functioning exceptions and appeals process is crucial to ensuring access to needed medications.

## Part D spending for new hepatitis C medicines

**H**epatitis C is a blood-borne virus that causes inflammation of the liver.<sup>34</sup> The hepatitis C virus (HCV) can remain asymptomatic for years, even decades, but can also lead to cirrhosis, liver failure, and higher risk of liver cancer. An estimated 3 million people in the United States have HCV, many without realizing it, and the virus is disproportionately concentrated among baby boomers (Centers for Disease Control and Prevention 2015). As of January 2015, about 363,000 Medicare beneficiaries (1.7 percent of the fee-for-service population) had been diagnosed with HCV (Segal 2015). Prevalence rates for low-income subsidy (LIS) enrollees in Part D are six times higher than for non-LIS enrollees: 3.7 percent versus 0.6 percent, respectively.

Olysio, Sovaldi, Harvoni, and Viekira Pak are examples of new oral therapies that offer significant promise for patients with HCV; they substantially reduce or eliminate viral load, may halt progression of disease, and are much more tolerable than older treatments. However, prices for the new drugs are very high: Sovaldi was first offered in December 2013 at \$84,000 per treatment regime, or \$1,000 per pill. More recently, the FDA approved other HCV therapies, and Gilead (Sovaldi's manufacturer) began offering rebates that

lowered the price by about 40 percent (Loftus 2014). Initial data show that new HCV drugs can substantially increase the number of patients achieving a sustained virologic response compared with previous therapies. However, a 2014 comparative clinical and cost-effectiveness analysis of Olysio and Sovaldi found that, even though newer agents may prevent more liver events such as cancer or transplantation, over a 20-year period, those fewer events would offset only three-quarters of the incremental cost of the new drugs. If a large number of patients were treated, "the clinical advantages of newer treatment regimens would come with a substantial potential impact on health care budgets" (Loftus 2014, Tice et al. 2014).

The use of new hepatitis C therapies has had a very significant impact on Part D spending. Medicare Trustees estimate that in 2014, Part D program payments increased by nearly 15 percent, and they attribute the size of the increase to the use of new hepatitis C drugs (Boards of Trustees 2015). As of January 2015, about 57,000 Medicare fee-for-service beneficiaries (only 16 percent of those identified as having HCV) had filled at least 1 prescription for an HCV drug (Segal 2015). Nevertheless in 2014, gross Part D spending for new HCV drugs before

*(continued next page)*

Part D's exceptions and appeals process is complex, involving multiple levels (Medicare Payment Advisory Commission 2014d). It begins either when an enrollee's prescription is denied at the pharmacy because of a plan's utilization management or cost-sharing requirements or because the drug is not listed on the plan's formulary. To initiate a request for an appeal, the enrollee, prescribing physician, or authorized representative must ask the plan for a redetermination.

In 2013, we examined Part D's appeals data that pertained to the second of five levels of the appeals process, for which plans' adverse coverage determinations were reviewed by an independent review entity. However, the data did not provide information sufficient for us to assess the effectiveness of the exceptions and appeals process in ensuring access to needed medications (Medicare

Payment Advisory Commission 2014d). Subsequently, CMS released data on the exceptions and appeals process at the plan level. Our analysis of that data showed low rates of claims rejections and appeals (Medicare Payment Advisory Commission 2015d). We were unable to determine whether those findings were cause for concern because claims can be rejected for valid reasons, such as exceeding the quantity limits based on FDA labeling. In other cases, beneficiaries may work with their physicians to find alternative medications or obtain samples. A low appeals rate could be cause for concern if it reflects a lack of transparency in the process or excessive administrative burden imposed on enrollees and prescribers that discourages them from submitting an appeal.

At the same time, CMS audits continue to find that plans have difficulties in the areas of Part D coverage

## Part D spending for new hepatitis C medicines (cont.)

rebates was \$4.8 billion, and as of June 30, 2015, the comparable figure had reached \$4.6 billion (Committee on Finance 2015). Part D plan sponsors did not fully anticipate the spending effects of new HCV drugs when they submitted their plan bids for 2014, and in 2015, Medicare paid plans an additional \$11 billion in 2014 reconciliation payments.<sup>35</sup> Since all Part D enrollees with HCV must have reached the out-of-pocket threshold and many likely had assistance with cost sharing through the LIS, the Medicare program paid for the vast majority of new HCV spending.

Several factors account for why the higher spending in 2014 was not anticipated accurately. Physicians who treat HCV knew that more tolerable medicines would soon become available, and some of these physicians “warehoused” patients (delayed treatment) in anticipation of newer therapies (Committee on Finance 2015). A further reason is that once the FDA approved the first two breakthrough therapies, Part D plans were obligated to cover them; plans had little negotiating leverage over the drugs’ prices until the introduction of additional HCV therapies. The only prior authorization Part D plans could require was to clinically document that the enrollee had one of the HCV indications listed on the drug’s label. By comparison, 33 state Medicaid programs used tighter utilization management—covering

new HCV treatment only for patients with more advanced liver disease (Ward and Mermin 2015).

New HCV drugs pose difficult challenges for public payers, including Medicare. One challenge is the issue of opportunity costs: steep increases in spending for HCV drugs leave fewer resources available for other important uses. A competing issue is whether public programs may restrict care when effective treatments are available. In a November 2015 notice to state Medicaid programs, CMS cautioned that the programs should not deny access to clinically appropriate HCV treatments (Centers for Medicare & Medicaid Services 2015e). At the same time, CMS encouraged manufacturers of HCV drugs to disclose how they might use value-based pricing agreements. A further challenge is that new HCV infections have risen significantly in the United States, fueled by the use of injected drugs (Ward and Mermin 2015). Some public health analysts contend that broader treatment with new HCV drugs may reduce the rate of new infections (Van Nuys et al. 2015), while others voice concern that without measures to reduce illicit drug use, some treated HCV patients may become reinfected and the virus could potentially become drug resistant (Wilkerson 2015). ■

determinations, appeals, and grievances (Centers for Medicare & Medicaid Services 2015a). In beneficiary focus groups convened for the Commission during 2015, we continued to find limited experience with the exceptions and appeals process (Hargrave et al. 2015). Some of the beneficiaries we spoke with were aware of the appeals process, but many chose not to appeal the plans’ (negative) coverage determinations. Many reported working with their physicians to find alternative medications instead of appealing plans’ coverage decisions. In our focus groups, many providers reported that it was time consuming and frustrating to speak with insurance companies on behalf of a patient for a particular prescription.

### Quality in Part D

CMS collects quality and performance data to monitor sponsors’ operations. A subset of these data is used to rate plans on a 5-star system, which is used to determine MA quality bonus payments and is made available to the public to help beneficiaries evaluate their plan options during Part D’s annual open enrollment. CMS also requires Part D plans to implement 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 been concerned with the effectiveness of plans’ MTM programs. In September 2015, CMS announced that it would test a new 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 Health Providers and Systems<sup>®</sup> survey, agency monitoring of plans, data furnished by plan sponsors, and claims information (Centers for Medicare & Medicaid Services 2015f). Selected performance measures are available on the Plan Finder at [www.medicare.gov](http://www.medicare.gov) to help beneficiaries evaluate their plan options during Part D’s annual open enrollment. 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 2016, Part D plan ratings are based on up to 15 metrics that measure plan performance on intermediate outcomes, patient experience, access, and process. Four measures of intermediate outcomes receive twice as much weight as the seven metrics that reflect patient experience and access. Two new measures have been added for 2016: MTM completion rate for comprehensive medication reviews and beneficiary access and plan performance problems, a measure reflecting any CMS sanctions, civil monetary penalties, or compliance actions (Centers for Medicare & Medicaid Services 2015f). These new measures receive relatively less weight, as do other process measures. 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 32 measures that assess the quality of medical services provided under Part C (i.e., the MA program), in addition to the 15 measures used to assess the quality of prescription drug (Part D) services provided. CMS aggregates individual scores for each measure (15 measures for PDPs and 47 measures for MA–PDs) on the Plan Finder under a 5-star system; 5 stars reflect excellent performance, and 1 star reflects poor performance.

The average star rating (weighted by 2015 enrollment) for 2016 is 3.40, down from 3.75 in 2015. CMS noted changes in the PDP scores because of the discontinuation of one measure and the introduction of three new measures (Centers for Medicare & Medicaid Services 2015b). For

MA–PDs, the average is 4.03, up from 3.92 in 2015 (see Chapter 12 for a discussion of stars ratings for MA plans and MA–PDs.). In general, changes in the composition of the measures CMS uses to rate plans over the years makes it difficult to use the star rating system to measure changes in quality of services provided by plans across years.

## Medication therapy management programs

Part D plans are required to implement MTM programs to improve the quality of the pharmaceutical care for high-risk beneficiaries. These programs are intended to improve medication use and reduce adverse drug events for beneficiaries who have multiple chronic conditions, take multiple medications, and are likely to have annual drug spending that exceeds the annual cost threshold (\$3,507 for 2016). 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).

CMS has been tightening criteria for MTM programs since 2010 and has used multiple guidances to specify MTM requirements. For example, under CMS MTM criteria, plan sponsors cannot require beneficiaries to have more than three chronic conditions or use more than eight medications to be eligible for their MTM programs. Plan sponsors are required to offer all MTM-program-eligible enrollees a comprehensive medication review (CMR) at least annually and a targeted medication review (TMR) at least quarterly for ongoing monitoring and follow-up of any medication-related issues.<sup>36</sup>

Although the Commission supports CMS’s goal of improving medication management, we have been concerned with the effectiveness of Part D’s MTM programs. As CMS has noted in the past, plans are unable to contact many eligible beneficiaries, and many beneficiaries refuse the service. MTM program data released by CMS showed that, in 2010 and 2012, only 10 percent of MTM participants (about 1 percent of Part D enrollees) completed a CMR (Marrufo et al. 2013, Medicare Payment Advisory Commission 2015d). In addition, physicians may be reluctant to accept recommendations from drug plans with which they have no direct relationship. Evidence suggests that the effectiveness of the MTM services currently offered by Part D plans “fall[s] short of their potential to improve quality and reduce unnecessary medical expenditures” (Centers for Medicare & Medicaid Services 2015h, Marrufo et al. 2013).

In September of 2015, CMS announced that it would test whether providing payment incentives and greater regulatory flexibility in designing the MTM programs would “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). The regulatory flexibility combined with the financial incentives provided under the model test have the potential to address some of the Commission’s concerns regarding coordination with a beneficiary’s care team and a plan’s incentive to offer MTM programs (Medicare Payment Advisory Commission 2014a) (see text box, p. 406). We plan to continue to monitor how well the current MTM program is working and report on the new enhanced MTM model as more information becomes available.

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## Looking ahead

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Medicare does not set drug prices administratively for Part D; prices are determined through negotiations between private plan sponsors, pharmacies, and pharmaceutical manufacturers. The law that created Part D included a clause that explicitly prohibits the Secretary from “interfer[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors.”<sup>37</sup> The law also prohibits the Secretary from requiring a particular formulary or instituting a price structure for reimbursement. This reliance on market-based prices was premised on the notion that competition among Part D plans that bear insurance risk would provide a strong incentive for plan sponsors to manage drug use and keep spending in check. Plan sponsors and their PBMs carry out this responsibility by developing and maintaining formularies, using differential cost sharing to encourage enrollees to use lower cost options, and negotiating rebates and discounts from manufacturers and pharmacies. However, for medicines with limited therapeutic substitutes or for which coverage is required, plan sponsors have less bargaining leverage to exert downward pressure on price.

This chapter describes the growing effects of high-cost enrollees (those who reach Part D’s OOP threshold) on program spending. In 2013, about three-fourths of high-cost enrollees received the LIS, and past research by the Commission has shown consistently that plan sponsors are less successful at encouraging LIS enrollees to use

generics. Encouraging LIS enrollees to use lower cost generics could reduce the number of individuals who reach the catastrophic phase of the benefit and thereby reduce the amount Medicare pays to plans in individual reinsurance. Meanwhile, the numbers of non-LIS enrollees who reach Part D’s OOP threshold are growing faster than those with the LIS. Phased closure of the coverage gap combined with the pipeline shift toward drugs with very high prices have contributed to this trend and pose a particular challenge because Medicare pays for 80 percent of catastrophic costs through individual reinsurance.

Going forward, the Commission will continue to evaluate policy options that could improve the efficiency of Part D within the context of the program’s market-based approach. For example, plan sponsors could be asked to shoulder more insurance risk for their Part D enrollees while, at the same time, plans could be allowed greater flexibility around formulary tools. Such steps could be designed to increase plans’ incentives and ability to manage benefit spending. Policy changes would need to be accompanied by well-functioning appeals and grievance procedures to ensure that enrollees maintain good access to appropriate medications.

It would also be important to consider medication use within the context of broader Medicare spending. For example, we may want to consider Medicare policies that encourage the use of medications that improve health outcomes and reduce the use of other health care services. Our previous research on this topic highlighted the difficulty of measuring the effects of medication use (adherence) on the use of other health care services among Medicare beneficiaries (Medicare Payment Advisory Commission 2014c). A related issue is that harmful effects can result from polypharmacy (use of multiple medications), especially among Medicare beneficiaries, who tend to have multiple chronic conditions (Medicare Payment Advisory Commission 2015c).<sup>38</sup> Thus, in contemplating policy interventions to encourage appropriate medication use, we need a better understanding of how the effects of medication use vary by condition and by population. We plan to revisit these issues in the future. ■

## Part D Enhanced Medication Therapy Management Model test

CMS plans to implement the new program called the Part D Enhanced Medication Therapy Management Model in selected prescription drug plan (PDP) regions through the Center for Medicare and Medicaid Innovation with a proposed five-year performance period, from 2017 through 2021.<sup>39</sup> Part D's program requirements related to uniformity of benefits and cost sharing will be waived for participating PDPs, which would provide them with the ability to offer medication therapy management (MTM) interventions tailored to an individual's needs, including cost-sharing assistance to financially needy beneficiaries (Centers for Medicare & Medicaid Services 2015h).

CMS's stated goal is for the participating PDPs to explore different communication strategies to improve beneficiary, pharmacist, and medical provider coordination and engagement. To aid that effort, CMS can provide participating PDPs with their enrollees' Part A and Part B claims data and information on beneficiaries' participation in integrated care models, such as accountable care organizations.

Because stand-alone PDPs may not necessarily benefit financially from providing MTM services that could improve enrollees' health outcomes and lower costs for the Medicare program, the model test also includes financial incentives for participating PDPs:

- a plan-specific prospective payment for MTM services that is outside the annual Part D bid and would not therefore affect plan premiums, and
- a performance-based payment in the form of an increased beneficiary premium subsidy (in a future year) for plans that successfully achieve a 2 percent reduction in expected beneficiary fee-for-service expenditures (net of model prospective payments).

PDPs participating in the enhanced MTM model will be required to collect and submit MTM-related encounter data for both monitoring and evaluation purposes. The MTM encounter data will also be used to construct certain quality metrics that reflect clinical significance and outcomes (Center for Medicare & Medicaid Innovation 2015). ■

## Endnotes

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- 1 This amount includes reconciliation payments made during 2014 between Medicare and plan sponsors for benefits delivered in previous years.
- 2 Part D benefit parameters for 2016 reflect an increase of nearly 12 percent over 2015 due to a more than 6 percent increase in average spending and a revision to prior-year adjustments of over 5 percent (Centers for Medicare & Medicaid Services 2015g).
- 3 In 2016, the Part D benefit provides gap coverage of 5 percent for brand-name drugs, in addition to a 50 percent discount provided by drug manufacturers, reducing cost sharing in the gap to about 45 percent. Cost sharing for brand-name drugs filled depends on the dispensing fee charged since the 5 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 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.
- 5 Other sources of coverage include the Federal Employees' Health Benefits Program, TRICARE for Life, and the Department of Veterans Affairs.
- 6 CMS is conducting demonstration projects in which certain beneficiaries who are eligible for both Medicare and Medicaid receive all of their care through a single health plan, known as a Medicare–Medicaid Plan (MMP). The number of beneficiaries enrolled in MMPs rose from 17,000 in 2014 to about 320,000 in 2015. They are included in the MA–PD category.
- 7 Under the Part C 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 Part C rebate dollars. The rebate dollars can be used to supplement benefits or lower premiums for services provided under Part C or Part D.
- 8 MA–PD premiums reflect Medicare Advantage plans' total monthly premium attributable to Part D benefits for plans that offer Part D coverage and are net of rebate dollars that were used to offset Part D premium costs.
- 9 These figures are based on CMS's estimate as of December 2015. Cubanski and Neuman (2015) provide a similar estimate.
- 10 CMS allows sponsors to offer multiple plans in a given service area only when the plans are substantially different from one another. To be considered "substantially different" for 2016, a beneficiary's expected monthly OOP costs between basic and enhanced PDPs must differ by at least \$18 per month. If a sponsor is offering two enhanced PDPs in the same service area, the second enhanced plan must have a higher value than the first, with a difference of at least \$30 in a beneficiary's expected monthly OOP costs between the two enhanced plan offerings.
- 11 Information on the extent of coverage plans provide in the gap phase is not available for 2015 or 2016. However, in the past, plans often provided limited coverage in the gap. For example, in 2014, about one-fourth of PDPs with some additional coverage in the gap included fewer than 10 percent of formulary drugs in that coverage (Hoadley et al. 2014a).
- 12 Plan sponsors do not submit Part D bids for EGWP plans, and so we do not have bid information about their administrative costs. For that reason, we excluded EGWP plans from this analysis. We also excluded the Program of All-Inclusive Care for the Elderly and low-income new enrollment transition plans, which allow individuals who are eligible for the LIS but not yet enrolled in a Part D prescription drug plan to obtain immediate prescription drug coverage.
- 13 For 2013, plan sponsors were able to negotiate rebates and discounts that reduced total gross benefit spending by about 13 percent. The net benefit spending is calculated by allocating those rebates and discounts in proportion to the gross spending amounts incurred across different phases of the benefit.
- 14 In 2014 and thereafter, Part D contracts are subject to "medical loss ratio" requirements that they spend at least 85 percent of revenues on benefit costs. Because the data analyzed here are from 2013, those requirements did not apply.
- 15 The measure needs to be used with caution because it can be misleading in some circumstances. For example, some plan sponsors list relatively few drugs on their formulary but have an exceptions process that permits good access to other medications. Alternatively, other sponsors list most drugs on their formulary but require prior authorization for relatively larger numbers of drugs.

- 16 The average share of pharmacies is not weighted by enrollment.
- 17 The minimum standard for pharmacy network access, based on the TRICARE standard, is as follows: urban areas—at least 90 percent of Medicare beneficiaries in the sponsor’s service area reside within 2 miles of a network retail pharmacy; suburban areas—at least 90 percent of Medicare beneficiaries in the sponsor’s service area reside within 5 miles of a network retail pharmacy; rural areas—at least 70 percent of Medicare beneficiaries in the sponsor’s service area reside within 15 miles of a network retail pharmacy.
- 18 Beneficiaries had access to preferred pharmacies in 46 percent of plans in urban areas, 87 percent in suburban areas, and 95 percent in rural areas.
- 19 Sixty-six percent of commercial health plans mandate that self-administered specialty drugs be dispensed by a specialty pharmacy, and about three-quarters of health plans require beneficiaries to use designated specialty pharmacy providers (Fein 2015).
- 20 Specialty pharmacies can be operated by PBMs, retail drugstore chains, health plans, pharmaceutical wholesalers, physician practices, and hospital systems (Fein 2015).
- 21 CMS regulations state that Part D plans may not restrict access to certain Part D drugs to “specialty” pharmacies within their Part D network in such a manner that contravenes the convenient access protections of §1860D–4(b)(1)(C) of the Social Security Act and 42 CFR §423.120(a).
- 22 An individual NDC uniquely identifies the drug’s labeler, drug, dosage form, strength, and package size. Typically, the same drug has many different NDCs.
- 23 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.
- 24 In a proposed rule published January 6, 2014, CMS suggested removing three classes—antidepressants, antipsychotics, and immunosuppressants for transplant rejection—from protected status. In a comment letter, the Commission was supportive of CMS’s approach in applying objective criteria to determine drug categories or classes of clinical concern while balancing the goals of beneficiary access and welfare with Part D plans’ tools to manage the drug benefit and appropriately constrain costs. The Commission also shared CMS’s concerns about antipsychotics and supported CMS’s move to proceed slowly (Medicare Payment Advisory Commission 2014a). However, CMS did not include the proposed action in its final rule.
- 25 Differences in GDRs vary by therapeutic classes. In 2012, for some of the most commonly used classes of drugs, the average GDR for LIS enrollees was from 5 percentage points to 13 percentage points lower than that of non-LIS enrollees. We observed this finding in both PDPs and MA–PDs.
- 26 The price index for antiretrovirals grew by 46 percent between 2006 and 2013.
- 27 In 2012, our price index for biologic products rose steeply by about 30 percent, a rate much higher than was observed in previous years. The increase was due in part to a change in how prescription quantities were reported for Avonex, a self-injectable biologic used to treat multiple sclerosis. Spending for Avonex accounted for a relatively high share of total expenditures for the market basket of biologic products used to calculate the price index. We are exploring this issue further.
- 28 The industry does not have one consistent definition of specialty drugs, but these drugs tend to be characterized as high cost (e.g., the Medicare threshold described by the Centers for Medicare & Medicaid Services (2015c) of \$600 or more per month) 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. See <http://www.ajmc.com/payer-perspectives/0213/The-Growing-Cost-of-Specialty-PharmacyIs-it-Sustainable>.
- 29 The share of Part D enrollees who reach the catastrophic phase of the benefit decreased between 2007 and 2013 (from 8.8 percent to 7.6 percent), due to the influx of relatively younger and healthier cohorts of enrollees associated with the retirement of baby boomers and employer group waiver plans (EGWPs). Much of the growth in EGWPs is likely attributable to the changes made by the Patient Protection and Affordable Care Act of 2010 (PPACA) that increased the generosity of Part D coverage. (See <http://www.medpac.gov/documents/payment-basics/part-d-payment-system-15.pdf?sfvrsn=0> for more detail on changes made by PPACA to phase out the coverage gap, and see endnote 4 in this chapter for changes to the tax treatment of the retiree drug subsidy.)
- 30 Among pharmacy benefit managers (PBMs), growth in price and use of specialty drugs has been driving the overall trend in spending. Across their entire non-Medicare and Medicare books of business, PBMs’ spending on specialty drugs has reached about 30 percent in 2012 and may reach 50 percent of total spending by 2018 (Roberts 2013).
- 31 The prescription drug coverage that beneficiaries had before 2006 may or may not have been as generous as the Part D benefit. Since implementation of Part D, nearly 90 percent of beneficiaries have drug coverage that is as generous as Part D’s basic benefit.

- 32 We first estimated the share of drug costs that were paid by beneficiaries (OOP share) by annual spending levels in \$100 increments for both 2007 and 2013. We then calculated the average spending by benefit phase, using 2013 data on drug spending, and multiplied those amounts by the OOP shares that would have applied in 2007 and 2013 to obtain the hypothetical cost-sharing amounts that would have applied for a beneficiary with average spending in each spending range (benefit phase) in 2007 and 2013.
- 33 The maximum OOP amounts for LIS enrollees are set by law, with the majority paying nominal copays that are indexed to the consumer price index for all urban consumers. Because the law requires the copays to be indexed in this manner, the OOP amounts would not be expected to follow the patterns observed for average total program spending or the cost-sharing amounts set by plan sponsors.
- 34 Today, the most common way people become infected with hepatitis C is by sharing needles or equipment to inject drugs, but the virus can also be transmitted through contact with infected blood (e.g., needle sticks in health care settings or, before 1992, blood transfusions) or less commonly through sexual contact.
- 35 The \$11.1 billion was for all drugs provided through Part D, not just HCV drugs. The amount was made up of \$2.2 billion in additional low-income cost-sharing subsidies and \$8.9 billion in additional individual reinsurance subsidies for enrollees who reached Part D's out-of-pocket limit, but net of \$0.1 billion in risk-corridor payments from plans to Medicare (data provided to Commission staff by CMS as of October 29, 2015). Two billion dollars of the \$8.9 billion in additional reinsurance payments were to EGWPs, which receive all of their reinsurance subsidies as a lump sum at reconciliation rather than through prospective payments during the benefit year.
- 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 person-to-person or system generated, and interventions can be delivered by mail or faxed to the beneficiary or the prescriber, as appropriate (Centers for Medicare & Medicaid Services 2014b).
- 37 Section 1860D-11 [42 U.S.C. 1395w-111].
- 38 There is no consensus on what constitutes polypharmacy. Some researchers identify polypharmacy in terms of the number of drugs taken concurrently by a patient. Most commonly, researchers describe polypharmacy as a situation in which a patient takes five to seven drugs concurrently.
- 39 A Request for Application for the model test was released in early November 2015 to sponsors of basic stand-alone PDPs in the following five regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona) (<https://innovation.cms.gov/initiatives/enhancedmtm/>).

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