

CHAPTER

14

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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 (Part D) that describes enrollment levels, plan benefit designs, access to prescription drugs, and the quality of Part D services. The report also analyzes changes in plan bids, premiums, and program costs.

In 2013, Medicare spent almost \$65 billion for the Part D benefit, accounting for more than 12 percent of total Medicare outlays. In 2014, more than 37 million Medicare beneficiaries were enrolled in Part D: About 62 percent were in stand-alone prescription drug plans (PDPs) and the rest were in Medicare Advantage–Prescription Drug plans (MA–PDs). Monthly premiums averaged about \$29 across all plans, but individually, the premium beneficiaries paid varied by their plan, level of income and assets, and whether they were subject to Part D’s late enrollment penalty.

***Medicare beneficiaries’ drug coverage in 2014 and benefit offerings for 2015***—In 2014, about 69 percent of all Medicare beneficiaries were enrolled in Part D plans, and of those, more than 11 million received the low-income subsidy (LIS). An additional 5 percent received drug coverage through employer-sponsored plans that receive Medicare’s retiree drug subsidy, and about 14 percent received coverage that is at least as generous as Part D from other sources. As of 2012, 12 percent of beneficiaries had no drug coverage or

### In this chapter

- Enrollment, plan choices in 2014, and benefit offerings for 2015
- 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

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

In 2015, plan sponsors are offering 1,001 PDPs and 1,608 MA-PDs, a 14 percent decrease in the number of PDPs offered compared with 2014, while the number of MA-PDs remained stable. PDP reductions appear to reflect sponsors consolidating their plan offerings into fewer, more widely differentiated products. Even with these consolidations, beneficiaries have between 24 and 33 PDPs to choose from, depending on where they live, as well as many MA-PDs. 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 2015, 283 premium-free PDPs are available to enrollees who receive the LIS, a 20 percent decline from 2014. Despite this decrease, all regions of the country have at least 4 and as many as 12 PDPs available at no premium to LIS enrollees.

An increasing number of plans use two cost-sharing tiers for generic drugs: a preferred one with lower cost sharing and a nonpreferred one that, in some cases, comes with substantially higher cost sharing. In addition, more plans use tiered pharmacy networks that include preferred pharmacies, for which plans have lower cost-sharing requirements. In 2015, nearly 90 percent of PDPs offer lower cost sharing at preferred pharmacies. Both of these strategies provide financial incentives for enrollees to use lower cost drugs or providers, potentially reducing program costs for basic benefits. However, a risk is that these approaches could increase Medicare's spending for the LIS or affect access to needed medications for some beneficiaries.

***Part D program spending and bids***—Between 2007 and 2013, Part D spending increased from \$46.7 billion to \$64.9 billion (an average annual growth rate of about 6.7 percent). In 2013, LIS payments continued to be the single largest component of Part D spending, while Medicare's reinsurance payments to plans remained the fastest growing component, at an average annual rate of about 16 percent between 2007 and 2013. 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, with generic drugs accounting for 81 percent of all prescriptions filled in 2012 compared with 77 percent and 61 percent in 2011 and 2007, respectively. This increased use of generics is one reason that average drug spending per enrollee decreased between 2011 and 2012 by 1.5 percent. At the same time, however, the pharmaceutical pipeline is shifting toward greater numbers of biologic products and specialty drugs, many of which have few therapeutic substitutes and high prices.

In 2012, the share of enrollees who incurred spending high enough to reach the catastrophic phase of Part D's benefit decreased slightly. However, the share of high-cost enrollees who filled prescriptions for biologic products rose. 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 for the LIS.

***Access to prescription drugs***—Most Part D enrollees appear to have good access to prescription drugs: In 2012, 5 percent reported having trouble obtaining needed medications. While a plan's formulary or utilization management tools can provide measures of beneficiaries' access to prescription drugs, a well-functioning exceptions and appeals process is also crucial. Data show that the number of drug claims that are rejected at the pharmacy counter is relatively low (4 percent), and claims that subsequently go through Part D's exceptions and appeals process is lower still. At the same time, CMS has conducted audits that have found some compliance issues with formulary administration, claims adjudication, and appeals. We are unable to determine whether low rates of claims rejections and appeals are cause for concern. In some cases, claims are rejected for valid reasons, such as ensuring patient safety. Yet a low appeals rate could reflect a lack of transparency in the appeals process or excessive administrative burden on enrollees and prescribers. In some cases, beneficiaries may find alternative medications or ways to obtain needed medicines outside of the exceptions and appeals process, such as by using physician samples.

***Quality in Part D***—The average star rating among Part D plans has increased, particularly among MA-PDs. For 2015, the share of enrollees in high-performing plans (rated 4 stars or more out of the possible 5 stars) is expected to increase to more than 50 percent among PDP enrollees and to about 60 percent among MA-PD enrollees. Newly released data on Part D's medication therapy management programs (MTMPs) show that, in 2012, 3.1 million enrollees (about 11 percent of Part D enrollees) participated in an MTMP. Participation rates varied across plans. Although receiving a comprehensive medication review (CMR) may result in improved quality of care provided under the Part D program, only about 10 percent of MTMP enrollees received a CMR. ■



**TABLE  
14-1**

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

	2006	2014	2015	Average annual percentage change 2006–2015
Deductible	\$250.00	\$310.00	\$320.00	2.8%
Initial coverage limit	2,250.00	2,850.00	2,960.00	3.1
Annual out-of-pocket spending threshold	3,600.00	4,550.00	4,700.00	3.0
Estimated total covered drug spending at annual out-of-pocket threshold	5,100.00	6,690.77*	7,061.76*	3.0
Minimum cost sharing above annual out-of-pocket threshold:				
Copay for generic/preferred multisource drugs	2.00	2.55	2.65	3.2
Copay for other prescription drugs	5.00	6.35	6.60	3.1

Note: \*Total covered drug spending at annual out-of-pocket threshold depends on each enrollee’s mix of brand and generic drugs filled during the coverage gap. The amounts for 2014 and 2015 are for an individual who is not receiving Part D’s low-income subsidy and has no other supplemental coverage.

Source: CMS, Office of the Actuary.

## Background

In 2013, Medicare spent almost \$65 billion on the Part D prescription drug program, accounting for more than 12 percent of total Medicare outlays (Boards of Trustees 2014). In 2014, more than 37 million Medicare beneficiaries were enrolled in Part D. Policy goals for the Part D program are to provide enrollees with good access to needed medications and to do so in a way that is financially sustainable into the future. Each year since 2006, the Commission provides a status report on Part D and makes recommendations as necessary. To monitor the degree to which the program is achieving policy goals, we examine several performance indicators: enrollment patterns, plan benefit offerings for 2015, market structure, drug pricing, program costs, beneficiaries’ access to prescription drugs, and quality of services.

## Part D’s approach

Medicare’s payment system for Part D is very different from its fee-for-service payment systems for Part A and Part B services. For Part D, Medicare pays competing private plans to deliver prescription drug benefits to enrollees. Instead of setting prices administratively, Medicare’s payments to plans are based on bids submitted by plan sponsors. Part D pays for prescription drug benefits whether beneficiaries use traditional Medicare and enroll in stand-alone prescription drug

plans (PDPs) or they enroll in Medicare Advantage plans with drug coverage (Medicare Advantage–Prescription Drug plans (MA–PDs)).

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 their premiums, benefit structure (e.g., deductible amount), formularies, quality of services, and networks of pharmacies. The idea was that competition among plans that bear insurance risk would provide strong incentives for plan sponsors to manage drug use and keep spending in check.

## The drug benefit

Medicare defines a standard Part D benefit structure with parameters that change at the same rate as the annual change in beneficiaries’ average drug expenses (Table 14-1). For 2015, the defined standard benefit includes a \$320 deductible and 25 percent coinsurance until the enrollee reaches \$2,960 in total covered drug spending. Enrollees whose spending exceeds that amount face a coverage gap up to an annual threshold of \$4,700 in out-of-pocket (OOP) spending that excludes cost sharing paid by most sources of supplemental coverage, such as employer-sponsored policies. Above the OOP threshold, enrollees pay the greater of either \$2.65 to \$6.60 per prescription or 5 percent coinsurance.

**TABLE  
14-2****Nearly three-quarters of Medicare enrollees received drug coverage through Part D, 2014**

	Beneficiaries	
	In millions	Percent of Medicare enrollment
Medicare enrollment	54.0	100%
Part D enrollment		
Part D plans	37.4	69.3
Plans receiving RDS*	<u>2.6</u>	<u>4.8</u>
Total Part D	40.0	74.2**

Note: RDS (retiree drug subsidy). Part D plan enrollment figures based on enrollment as of March 1, 2014. Totals may not sum due to rounding.  
 \*Excludes federal government and military retirees covered by either the Federal Employees Health Benefit 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.B8 and Table V.B4 of the 2014 annual report of the Boards of Trustees of the Medicare trust funds and monthly Part D enrollment data as of March 1, 2014.

Before 2011, enrollees exceeding the initial coverage limit were responsible for paying the full discounted 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, non-low-income subsidy beneficiaries face reduced cost sharing for both brand-name and generic drugs filled during the coverage gap (Medicare Payment Advisory Commission 2014b). In 2015, cost sharing for drugs filled during the gap phase is 45 percent for brand-name drugs and 65 percent for generic drugs.<sup>1</sup> An individual with no other source of drug coverage is estimated to reach the \$4,700 limit at \$7,061.76 in total drug expenses.

Plan sponsors can and do offer alternative benefit designs. For example, a plan can offer a deductible lower than \$320, or 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 may also offer plans, called enhanced plans, with additional drug coverage that supplements the standard benefit.

Part D includes a low-income subsidy (LIS) that provides assistance with premiums and cost sharing for individuals with low incomes and assets. Individuals who qualify for this subsidy pay zero or nominal cost sharing set by statute. In 2015, most individuals receiving the LIS pay between \$0 and \$2.65 for generic drugs and between \$0 and \$6.60 for brand-name drugs.

**Two avenues of competition in Part D**

Plan sponsors concentrate much of their attention on premium competition to attract enrollees, since premiums are the most salient feature for consumers (particularly 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 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.

Plan enrollees must pay a base beneficiary premium (\$33.13 in 2015) plus (or minus) any difference between their plan's bid and the nationwide average bid (Medicare Payment Advisory Commission 2014b). If enrollees choose a plan that is costlier than the average, they pay a higher premium—the full 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 plan sponsors the incentive to control their enrollees' drug spending so that they can bid low and keep their premiums attractive. At the same time, sponsors must balance this incentive with beneficiaries' desire to have access to needed medications. A plan with a very limited number of covered drugs might not be attractive to many beneficiaries.

A second avenue of competition involves keeping plan premiums at or below regional benchmarks for the LIS. Part D's bidding process determines the maximum amount that Medicare will pay for premiums on behalf of LIS enrollees. This amount varies across the country's 34 PDP regions. It is based on an average of premiums for plans with basic benefits, weighted by each plan's LIS enrollment in the previous year, and it 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, Medicare conducts an auto-assignment process: It reassigns these enrollees randomly to a new benchmark plan. Instead of accepting the auto-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, plan choices in 2014, and benefit offerings for 2015**

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In 2014, about three-quarters of Medicare beneficiaries were enrolled in Part D or actuarially equivalent employer drug plans for retirees. Enrollment has shifted somewhat from employers’ retiree drug plans to Part D plans. Less than 2 percent of Part D beneficiaries were in defined standard benefit plans; the rest were in plans that allow for higher copays and deductibles compared with the defined benefit. In 2015, plan sponsors are offering fewer, more widely differentiated PDPs, but beneficiaries continue to have broad choice among Part D plans. The number of MA–PDPs remains stable.

### **In 2014, about three-quarters of Medicare beneficiaries were in Part D plans or employer plans that got Medicare’s retiree drug subsidy**

In 2014, 37 million individuals, about 69 percent of 54 million total Medicare beneficiaries, were enrolled in Part D plans (Table 14-2). An additional 5 percent got drug coverage through employer-sponsored plans that received Medicare’s retiree drug subsidy (RDS) for being the primary provider of coverage.<sup>2</sup> The remaining 26 percent of Medicare beneficiaries received drug coverage from other sources (such as the Federal Employees Health Benefits Program, TRICARE for Life, and the Department of Veterans Affairs), had no drug coverage,

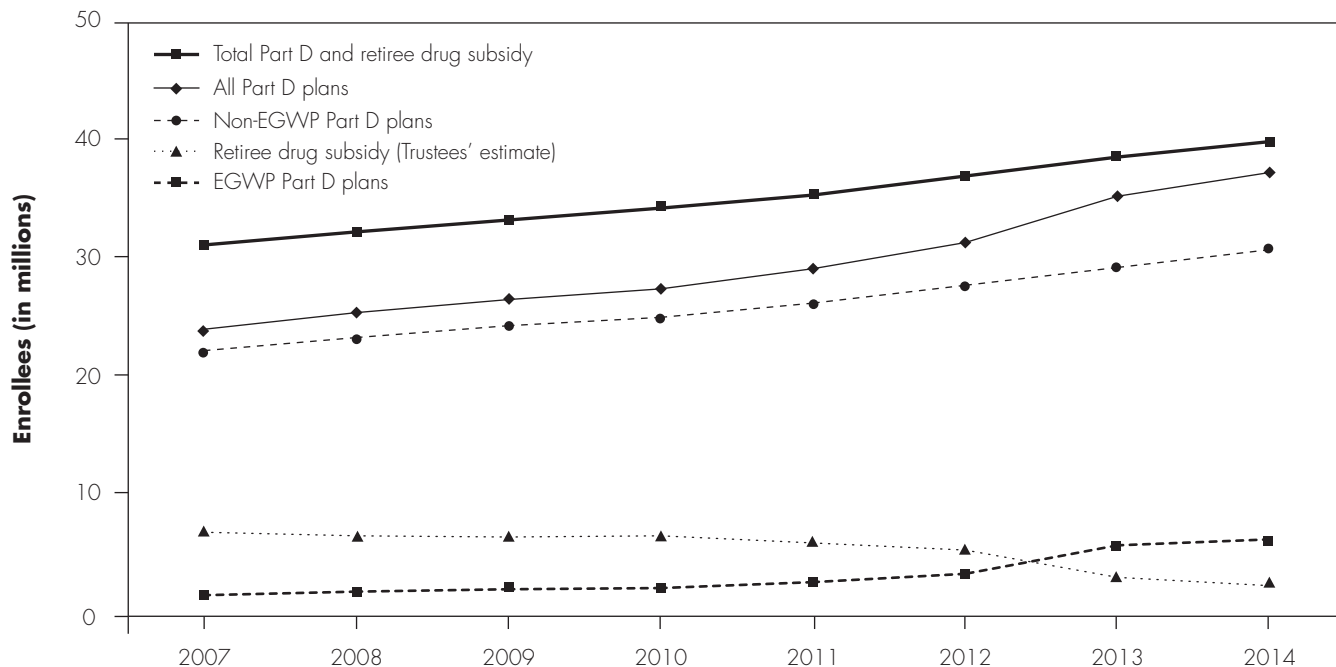
or had coverage less generous than Part D. An estimate from the 2012 Medicare Current Beneficiary Survey suggests that about 12 percent of beneficiaries had no drug coverage or less generous coverage—a bit higher than the 10 percent reported by CMS during the first few years of Part D. Beneficiaries who do not enroll in Part D tend to be healthier and have lower drug spending (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 14-1, p. 354). This shift was probably motivated by changes made by PPACA that increased the generosity of Part D coverage by, over time, eliminating the coverage gap and by altering the tax treatment of drug expenses covered by the RDS. In 2013, about 6 million individuals were in Part D plans operated for employers and their retirees (employer group waiver plans, or EGWPs), with about 2.3 million individuals shifting away from the plans that received the RDS in the previous year.

Overall, between 2007 and 2014, the share of Medicare beneficiaries enrolled in Part D plans grew from about 54 percent to 69 percent, or an average of 6 percent annually (Table 14-3, p. 353). Enrollment in MA–PDPs grew more rapidly (10 percent per year, on average) than in PDPs (5 percent annually). In 2014, 38 percent of Part D enrollees were in MA–PDPs compared with 30 percent in 2007.

In 2014, slightly more than 11 million beneficiaries (30 percent of Part D plan enrollees) received the LIS (Table 14-3, p. 355). Of these individuals, about 7 million were dually eligible for Medicare and Medicaid. Another 4 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. Between 2007 and 2014, the number of Part D enrollees who receive the LIS grew more slowly (3 percent per year) than non-LIS enrollees (8 percent per year). Faster enrollment growth among non-LIS enrollees is partly attributable to the recent growth in EGWPs that shifted beneficiaries into 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; however, spending on behalf of LIS enrollees accounts for about two-thirds of Part D program spending.

More than 70 percent (8.3 million) of LIS enrollees were in PDPs; the rest were in MA–PDPs (data not shown).

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

Note: EGWP (employer group waiver plan).

Source: MedPAC based on monthly Part D enrollment data and Table IV.B8 of the 2014 annual report of the Boards of Trustees of the Medicare trust funds.

Because most LIS enrollees are in traditional Medicare, CMS's process randomly assigns LIS enrollees who have not chosen a plan to benchmark PDPs rather than MA-PDs. However, in recent years, LIS enrollment in MA-PDs has grown because some individuals have selected these plans or joined them through the Medicare-Medicaid financial alignment initiative.

**Beneficiaries' enrollment decisions in 2014**

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 one plan with basic benefits in a region, it may also offer

up to two plans 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.

In 2014, 55 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copayments (Table 14-4). Another 43 percent of PDP enrollees had enhanced benefits—the typical enhancement being a lower deductible rather than benefits in the coverage gap. Just 2 percent of enrollees were in defined standard benefit plans. MA-PD enrollees were predominantly in enhanced plans with no deductible. Enrollees in PDPs were more likely to have a deductible in their plans' benefit design than enrollees in MA-PDs, which reflects the ability of MA-PDs to use a portion of their Part C payments to supplement their Part D drug benefits or to lower Part D premiums.<sup>3</sup>

Many MA-PDs also use some of their Part C rebate dollars to provide additional Part D benefits in the

**TABLE  
14-3****Part D plan enrollment trends, 2007-2014**

	2007	2008	2010	2012	2014	Average annual growth rate 2007-2014
Total Part D enrollment (in millions)	24.2	25.6	27.6	31.5	37.4	6%
Percent of Medicare beneficiaries	54%	56%	58%	60%	69%	
Enrollment by type (in millions)						
PDP	16.9	17.3	17.6	19.8	23.4	5
MA-PD	7.2	8.3	10.0	11.7	14.1	10
Percent in MA-PD	30%	32%	36%	37%	38%	
Enrollment by LIS status (in millions)						
LIS	9.4	9.6	9.9	10.8	11.4	3
Non-LIS	14.8	16.0	17.7	20.7	26.0	8
Percent receiving the LIS	39%	38%	36%	34%	30%	

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

Source: MedPAC based on Table IV.B8 and Table V.B4 of the 2014 annual report of the Boards of Trustees of the Medicare trust funds and monthly Part D enrollment data.

coverage gap (Figure 14-2, p. 356). In 2014, only 12 percent of PDP enrollees (about 2.2 million beneficiaries) were in plans that offered benefits in the coverage gap beyond what is required by PPACA. However, 35 percent of PDP enrollees received the LIS, which effectively

eliminates their coverage gap (data not shown). By comparison, 51 percent of MA-PD enrollees (about 5.1 million beneficiaries) were in plans offering some gap coverage.

**TABLE  
14-4****MA-PD enrollees more likely to be in enhanced plans with no deductible, 2014**

	PDP		MA-PD	
	Number (in millions)	Percent	Number (in millions)	Percent
Total	18.6	100%	9.9	100%
Type of benefit				
Defined standard	0.4	2	0.1	1
Actuarially equivalent*	10.2	55	1.0	10
Enhanced	7.9	43	8.8	89
Type of deductible				
Zero	8.0	43	8.5	86
Reduced	0.7	4	1.1	11
Defined standard**	9.8	53	0.3	3

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

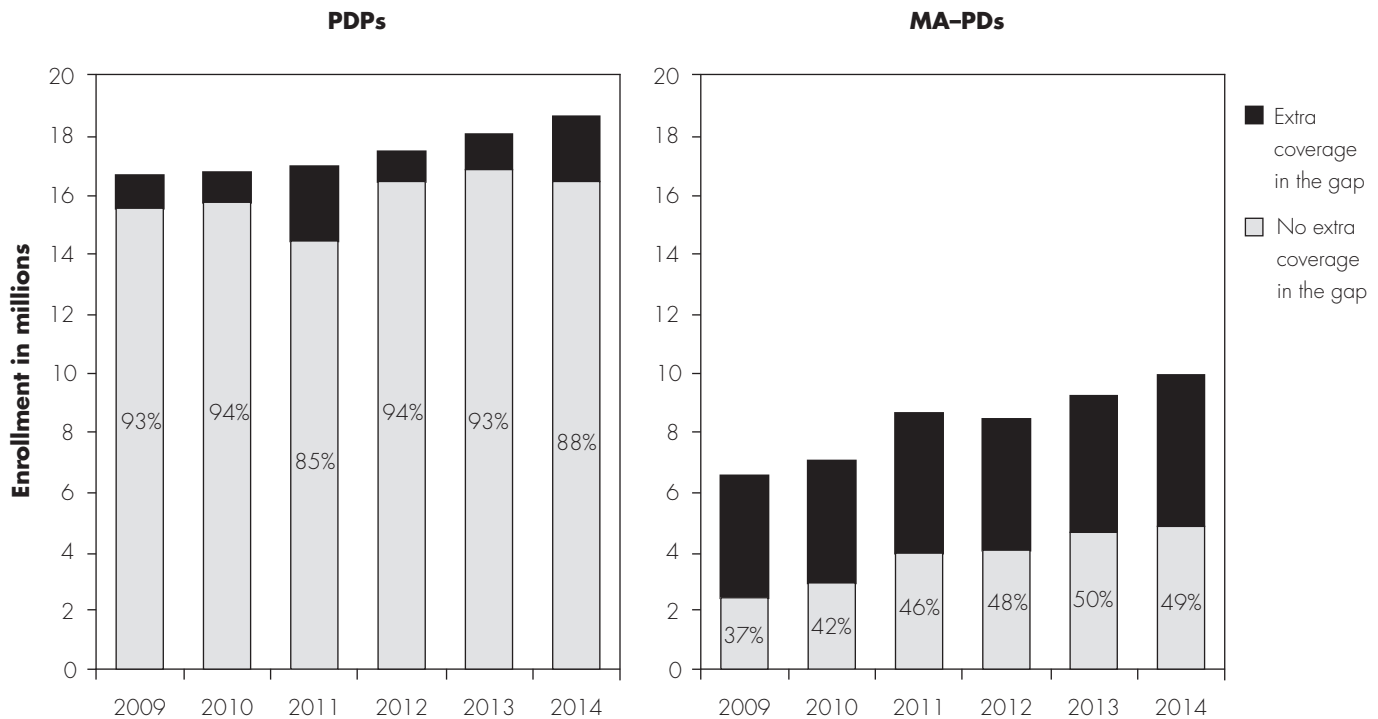
\*Includes actuarially equivalent standard and basic alternative benefits.

\*\*\$310 in 2014.

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

**FIGURE  
14-2**

**PDP enrollees are less likely to have extra 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.

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

**TABLE  
14-5**

**Changes in average Part D premiums, 2007-2014**

	Average monthly premium weighted by enrollment (in dollars)						Average annual growth rate 2007-2014
	2007	2010	2011	2012	2013	2014	
All plans (any coverage)	\$23	\$30	\$30	\$30	\$30	\$29	3.3%
<b>PDPs</b>							
Basic coverage	24	34	33	33	32	30	3.0
Enhanced coverage	40	50	63	58	49	49	2.7
Any coverage	27	37	38	38	39	38	4.7
<b>MA-PDs, including SNPs*</b>							
Basic coverage	17	26	27	27	29	25	5.7
Enhanced coverage	9	13	12	12	13	13	6.5
Any coverage	10	14	14	14	15	16	6.1

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), SNPs (special needs plans). 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 rebate dollars that were used to offset Part D premium costs.

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

In 2014, monthly beneficiary premiums averaged about \$29 across all plans (Table 14-5). However, underlying that average is a wide variation, ranging from \$0 for an MA–PD plan to more than \$170 for a PDP offering enhanced coverage (data not shown).<sup>4</sup> On average, premiums were lower for beneficiaries enrolled in MA–PDs compared with those enrolled in PDPs. Among beneficiaries enrolled in PDPs, individuals in plans that offered enhanced coverage paid, on average, \$19 more per month than those individuals in plans that offered only basic coverage (\$49 vs. \$30). In contrast, beneficiaries enrolled in MA–PDs, on average, paid lower premiums for enhanced coverage than for basic coverage alone (\$13 vs. \$25).

While the average Part D premium (including basic and enhanced coverage) has remained stable over the last few years, average premiums for PDPs and MA–PDs have fluctuated (Table 14-5). For example, average premiums for beneficiaries enrolled in PDPs that offer enhanced coverage experienced large year-to-year fluctuations between 2010 and 2013, ranging from \$49 to \$63.

Two other factors affect the amount of premium paid by a given enrollee. First, higher income beneficiaries pay a larger share of the Part D premium; that is, they have a lower federal subsidy. 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 2014, the adjustment amount ranged from \$12.10 to \$69.30 per month, depending on income. Nearly 1.86 million beneficiaries (about 5 percent of the total Part D enrollment) were subject to the income-related premium in 2014.<sup>5</sup>

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 prescription drug coverage and is calculated by multiplying 1 percent of the base beneficiary premium by the number of full, uncovered months an individual was eligible but was not enrolled in a prescription drug plan and went without other creditable prescription drug coverage.

## Benefit offerings for 2015

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. Here we examine notable changes for the 2015 benefit year.

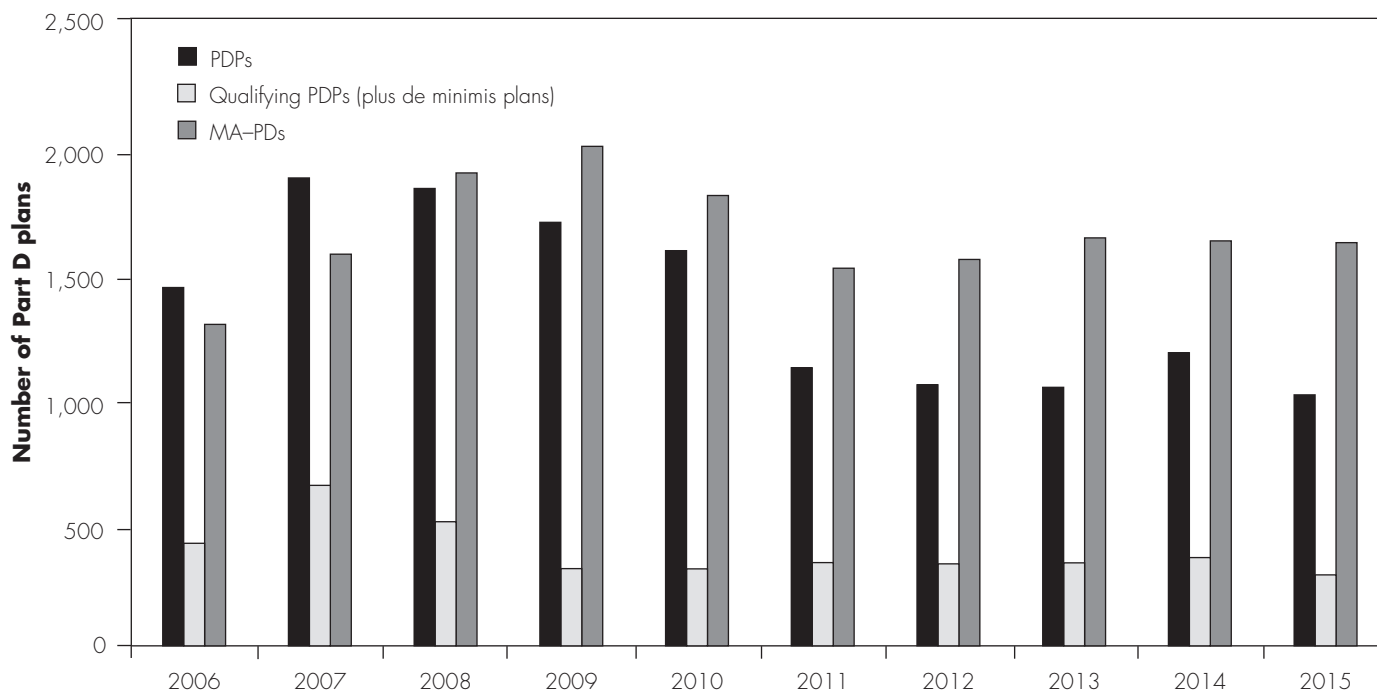
### Number of PDPs has declined, but broad choice still available

For 2015, plan sponsors are offering 14 percent fewer PDPs than in 2014, while the number of MA–PDs remains fairly stable (Figure 14-3, p. 358). The decline in PDPs is due largely to consolidation of plans among sponsors that merged with one another or is in response to CMS's policy intended to differentiate more clearly between basic and enhanced benefit plans and a policy discouraging plans with low enrollment. Most recently, some sponsors may have chosen to reduce their offerings out of concern for rules that were proposed by CMS for 2015—but ultimately were not finalized—that would have limited sponsors to offering no more than two PDPs per region (Centers for Medicare & Medicaid Services 2014f).<sup>6</sup>

Even with fewer PDPs, beneficiaries continue to have a wide variety of choice among plans, ranging from 24 PDP options in Alaska to 33 PDPs in the Illinois region, along with MA–PD options in most areas of the country. The number of MA–PDs available to a beneficiary varies by the county of residence, with a typical county having between 3 and 10 MA–PD plans to choose from. A handful of counties have no MA–PD plans available.

In 2015, the number of qualifying PDPs available to LIS enrollees with no premium declined 20 percent, from 352 in 2014 to 283 (Figure 14-3, p. 358).<sup>7</sup> Although this decrease is sizable, all regions of the country continue to have a number of premium-free PDPs available, ranging from 4 plans in Florida and Nevada to 12 in Arizona, the Alabama–Tennessee region, and the Idaho–Utah region.

For 2015, about 1.8 million LIS enrollees were affected by the turnover in plans whose premiums no longer fell at or below benchmarks for 2015—potentially subject to reassignment to a benchmark plan by the Medicare program (Hoadley et al. 2014a). However, a sizable share of LIS enrollees (more than 40 percent of total LIS enrollment in recent years) selected a plan that differed from their randomly assigned plan (Hoadley et al. 2014b, Hoadley et al. forthcoming). CMS estimated that for 2015,

**FIGURE  
14-3****A wide variety of plans available in 2015, but fewer benchmark PDPs**

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). "Qualifying PDPs" refers to 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.

it would need to randomly reassign about 300,000 LIS enrollees to new benchmark plans (e-mail communication from CMS staff, December 10, 2014).

**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 remains fairly stable, and most MA-PD enrollees continue to have more generous coverage than what is typically offered in PDPs—for example, no deductible or some enhanced coverage beyond basic Part D benefits. At the same time, certain MA-PDs are offering less generous coverage than was available in 2014. For example, for 2015, the share of MA-PDs offering enhanced benefits declined to 81 percent compared with 88 percent the year before. From 2014 to 2015, the share of MA-PDs that charge no deductible dropped from 82 percent to 63 percent. Similarly during that time, the share of MA-PDs that

offer no additional coverage in the coverage gap beyond that already called for under PPACA increased from 50 percent of MA-PDs to 56 percent. Note, though, that the increase in the generosity of Part D's basic benefit may be replacing some of the supplemental benefits provided in previous years during the gap phase of the benefit.

The reasons certain MA-PDs are offering less generous coverage are not fully clear. Our analysis of the plan bids suggests that, on average, most MA-PDs continue to allocate about the same amount of Part C rebate dollars for Part D benefits in 2015 as in 2014 (\$26 per enrollee per month, split fairly evenly between basic and enhanced benefits). One possibility is that new plan entrants into the MA-PD market are less generous on average. Another reason may be that the cost of providing Part D benefits rose for MA-PDs, and some plan sponsors chose to scale back the generosity of coverage to a greater extent than they chose to increase their bids. A piece of evidence supporting this hypothesis is that, as a part of their bids,

**TABLE  
14-6**

**Change in premiums for PDPs with the highest 2014 enrollment**

Plan name	Enrollment, 2014 (in millions)	Weighted average monthly premium*		Dollar change	Percentage change
		2014	2015		
AARP MedicareRx Preferred	3.6	\$43.43	\$50.15	\$5.72	15%
SilverScript Choice	2.5	29.47	23.16	-6.33	-21
Humana Preferred	1.7	22.75	26.40	3.65	16
Humana Enhanced	1.3	47.57	52.81	5.24	11
AARP MedicareRx Saver Plus	1.2	23.08	28.00	4.92	21
WellCare Classic	1.1	20.64	31.46	10.82	52
Humana Walmart	0.8	12.60	15.67	3.07	24
CIGNA-HealthSpring Rx Secure	0.8	30.75	31.78	1.03	3
Aetna Medicare Rx Saver	0.5	32.03	24.46	-7.57	-24
First Health Value Plus	0.5	44.50	38.81	-5.69	-13

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 2014 enrollment.

Source: Hoadley, J., J. Cubanski, E. Hargrave, et al. 2014. *Medicare Part D: A first look at plan offerings in 2015*. Washington, DC: Kaiser Family Foundation. October.

MA-PD plan sponsors projected a large increase in LIS enrollees for 2015—about twice as large as the increase in LIS members projected by PDP sponsors. Even though plan sponsors are supposed to bid on the costs of providing drug benefits to an enrollee of average health, perhaps they anticipated higher costs because of more LIS enrollees.

**Greater differentiation among PDP offerings**

With the reduction in the number of PDPs, plan sponsors appear to be consolidating offerings into fewer of the more widely differentiated products. Many sponsors appear to be moving closer toward offering one basic plan and one enhanced plan per region. MA-PDs continue to be more likely to include supplemental coverage in their drug benefits. Nevertheless, the share of PDPs with enhanced coverage rose in 2015—55 percent compared with 50 percent in 2014.

For 2015, sponsors continue to use alternatives to Part D’s defined standard benefit—the market includes no PDPs with that benefit design, down from 3 percent of PDPs in 2014. In those two years, the share of PDPs that charge the defined standard benefit’s deductible amount (\$320 in 2015) also fell, from 49 percent to 44 percent, as did the share of plans that charged no deductible (47 percent compared with 42 percent). Instead, a greater share used a deductible less than \$320.

For 2015, a larger share of PDPs offers additional coverage in the gap—26 percent compared with 21 percent a year earlier. This increase occurred even as the basic Part D benefit became slightly more generous under changes made by PPACA to gradually phase out the coverage gap.<sup>8</sup>

**Premiums increased for several PDPs with the highest enrollment**

For 2015, monthly premiums for several of the most popular stand-alone PDPs increased, some by substantial percentages. A few popular plans saw premiums decline.

Average premiums for the 10 plans with the highest enrollment ranged from about \$16 per month for Humana Walmart to nearly \$53 per month for Humana Enhanced. Among these 10 PDPs, 3 have premiums that are lower in 2015, ranging from about \$6 to \$8 less per month (Table 14-6). The remaining seven plans saw premiums increase between 2014 and 2015, ranging from about \$1 higher (3 percent) to nearly \$11 higher (52 percent).

**Mixed changes in cost-sharing requirements**

Cost-sharing requirements in Part D plans have generally been rising over the years. In 2015, changes in cost sharing for the top 10 PDPs across the nation in number

**TABLE  
14-7**

**2015 cost-sharing amounts for stand-alone PDPs with highest 2014 enrollment**

Stand-alone PDPs with the highest 2014 enrollment	Preferred generics		Nonpreferred generics		Preferred brands		Nonpreferred brands		Specialty	
	2014	2015	2014	2015	2014	2015	2014	2015	2014	2015
AARP MedicareRx Preferred	\$3	\$2	\$6	\$5	\$40	\$40	\$85	\$85	33%	33%
SilverScript Choice*	\$2	\$8	N/A	N/A	20%	\$35	35%	45%	25%	33%
Humana Preferred Rx Plan	\$1	\$1	\$2	\$2	20%	20%	35%	35%	25%	25%
Humana Enhanced	\$2	\$3	\$5	\$7	\$42	\$42	\$92	44%	33%	33%
AARP MedicareRx Saver Plus	\$1	\$1	\$2	\$2	\$20	\$20	\$35	\$40	25%	25%
WellCare Classic	\$0	\$0	\$15	\$9	\$40	\$39	\$94	\$89	33%	25%
Humana Walmart	\$1	\$1	\$4	\$4	20%	20%	39%	35%	25%	25%
Cigna-HealthSpring Rx Secure	\$0	\$1	\$3	\$4	\$30	20%	\$65	35%	25%	25%
Aetna Medicare Rx Saver*	\$2	\$0	N/A	\$3	\$43	\$45	\$95	37%	25%	25%
First Health Value Plus	\$3	\$0	\$11	\$3	\$37	\$35	\$88	50%	33%	25%

Note: PDP (prescription drug plan), N/A (not applicable). Enrollment figures are for November 2014 and exclude employer plans and plans offered in U.S. territories. In cases where plans vary cost-sharing amounts across regions, we report unweighted median cost-sharing amounts.

\*Indicates just one generic tier in 2014 (Aetna Medicare Rx Saver) or in both 2014 and 2015 (SilverScript Choice).

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

of enrollees vary from plan to plan. All but one of the 10 PDPs now use a 5-tiered formulary structure, with differential copays between preferred and nonpreferred generic medications (Table 14-7).

Top PDPs offered by UnitedHealth and Humana generally had few changes in cost sharing (Table 14-7). From 2014 to 2015, SilverScript Choice, a basic plan offered by CVS Health that has premiums below regional benchmarks in 32 out of 34 regions, increased generic copays from \$2 to \$8, moved to flat \$35 copays for preferred brand-name drugs, and increased coinsurance rates for nonpreferred brands as well as for therapies on its specialty tier. One of the top plans, WellCare Classic, decreased all cost-sharing requirements for 2015. Other top PDPs had a mixture of cost-sharing increases and decreases.

Several of the top 10 PDPs moved toward using coinsurance for some formulary tiers rather than copayments. For example, Humana Enhanced charges 44 percent coinsurance for nonpreferred brand-name drugs in 2015 rather than a \$92 copayment. Similarly, Cigna-HealthSpring Rx Secure now charges 20 percent and 35 percent coinsurance on preferred and nonpreferred brand-name drugs, respectively, rather than fixed dollar amounts as it did in 2014. First Health Value Plus and Aetna Medicare Rx Saver had similar changes. By charging enrollees a percentage of the cost of their prescriptions

rather than a flat copayment, plan sponsors share some of the risk of price increases for those drugs with beneficiaries.

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

Today, more than 250 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.

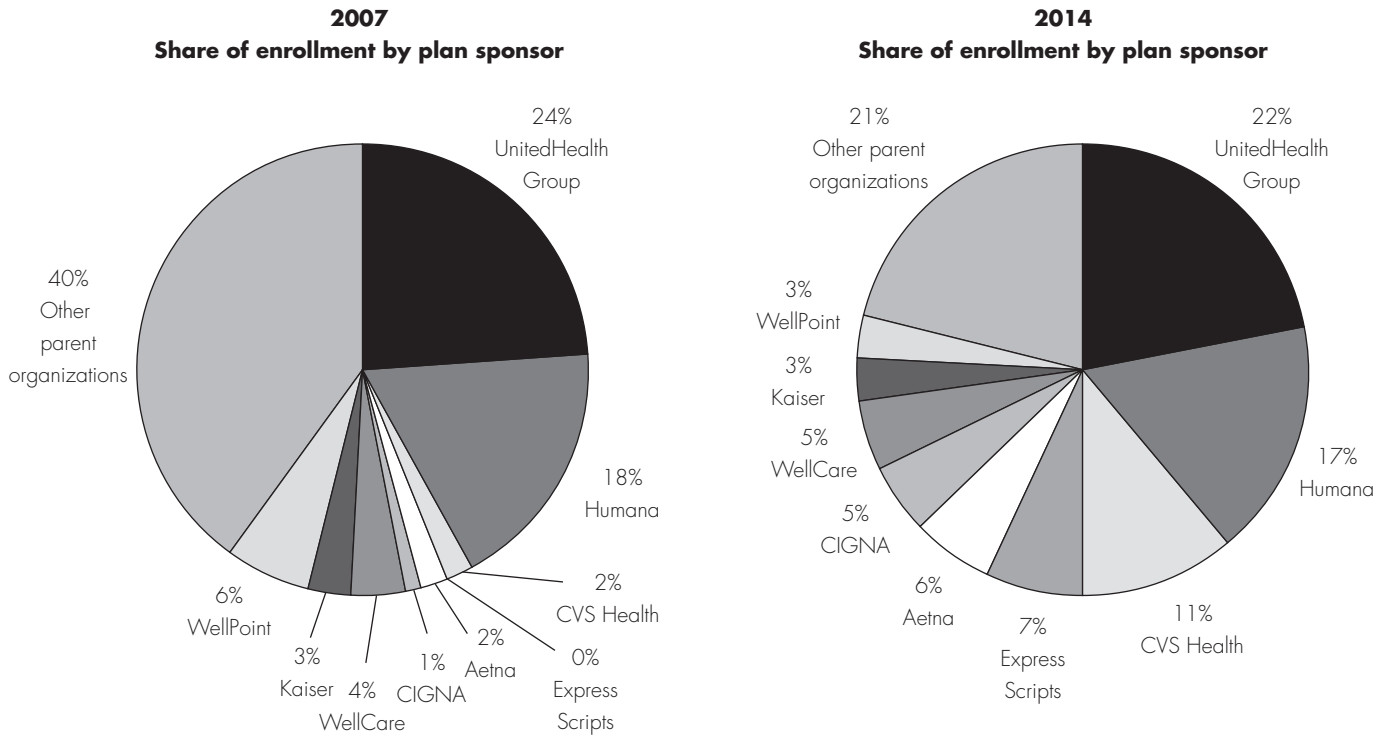
### The role of private plan sponsors

Many of the largest plan 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 marketing, enrollment,



**FIGURE  
14-4**

**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 groups are included.

Source: MedPAC based on enrollment data from CMS.

customer support, claims processing, making coverage determinations, and responding to appeals and grievances.

Sponsors must also carry out the specialized functions of PBMs, using either corporate-owned organizations or a commercial PBM under contract. Those 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
- negotiating contracts, including discount agreements, with pharmacies and pharmacy networks on the price the sponsor will pay the pharmacy for prescriptions filled and dispensing fees.

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

**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 2014, the top 9 insurers (those with 1 million or more Part D enrollees each) sponsored plans that accounted for nearly 80 percent of total enrollment (Figure 14-4). 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.

**TABLE  
14-8**

**Distribution of LIS enrollment in Part D plans offered by the largest plan sponsors, 2014**

Plan sponsor	Number of LIS enrollees (in millions)	LIS percent of sponsor's total enrollment (in percent)	Sponsor's share of all LIS enrollment (in percent)
CVS Health	2.3	55%	20%
UnitedHealth Group	2.0	25	18
Humana	1.7	28	15
CIGNA	1.2	72	11
WellCare	0.9	52	8
Aetna	0.7	31	6
Express Scripts	0.4	15	3
WellPoint	0.2	21	2
Kaiser	0.1	11	1
All LIS enrollees	11.4	31	N/A

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

Source: MedPAC based on enrollment data from CMS.

In 2014, just two major companies accounted for nearly 40 percent of the Part D market. UnitedHealth Group offers plans under the AARP name, and in 2014, the insurer had more than 6 million enrollees in its plans (about 1 in 5 Part D enrollees). Humana has also been a large part of this market, with combined enrollment of 17 percent in 2014. After winning a large portion of enrollment at the start of Part D in 2006 through low premiums, Humana lost a significant portion of its market share in 2009 and 2010. However, in 2011, Humana began a cobranding strategy with Walmart to create a network of preferred pharmacies through the retailer that allowed the insurer to offer a low-premium, low-copay plan and regain market share.

Other insurers that initially held smaller shares of the Part D market have had growing influence over time, often through mergers and acquisitions (Hoadley et al. 2014b). The most notable example is CVS Health, which in 2014 had 11 percent of all Part D enrollees in its plans. The company itself is a product of the acquisition of the PBM Caremark by CVS in 2007. CVS Caremark (now 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, Aetna and CIGNA have increased their market presence

through mergers and acquisitions: CIGNA acquired HealthSpring in 2012 (which had itself previously acquired Bravo's Part D plans), while Aetna acquired Coventry Health Care in 2013.

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 offerings of EGWPs.

### 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, auto-assignment of LIS enrollees to benchmark plans limits the need for sponsors to spend as much on marketing.

For these reasons, many plan sponsors actively pursue the LIS segment of the Part D market. In 2014, CVS Health had more LIS enrollees than any other sponsor: a total of 2.3 million, or 20 percent of all LIS enrollees (Table 14-8). About 55 percent of enrollees in CVS Health plans receive the LIS. CIGNA and WellCare are other companies among the top nine Part D plan sponsors for which more than half of their enrollees receive the LIS.

Once a sponsor has a sizable number of LIS enrollees, their 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.

### **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 copays to encourage enrollees to use preferred medicines or a subset of pharmacies.

When designing formularies, 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 any utilization management tools such as prior authorization.

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. In general, plan sponsors do not receive rebates from manufacturers of generic drugs. However, market competition from generics can, over time, lower prices by 80 percent or more, so promoting the use of generics can play a central part in controlling drug

spending (Kesselheim 2014). 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 estimate that in 2014, plan sponsors obtained rebates averaging 13.5 percent of total prescription drug costs, across all types of prescription drugs, whether the plans received rebates for them or not (Boards of Trustees 2014). The CMS Office of the Actuary reports that “many brand-name prescription drugs carry substantial rebates, often as much as 20–30 percent.” Sponsors tend to use rebates to offset plans' benefit spending (reducing plan premiums) rather than to lower the price of prescriptions at the pharmacy counter.

### **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 (Hoadley et al. 2014b). Most plans now use a five-tier formulary—including preferred and nonpreferred generic tiers, preferred and nonpreferred brand-name drug tiers, and a specialty tier. The innovation in this formulary structure involves higher copays for nonpreferred generics relative to preferred, to encourage use of less costly generics. In 2014, 73 percent of PDP enrollees and 72 percent of MA–PD enrollees were in plans with five cost-sharing tiers (Figure 14-5, p. 364).

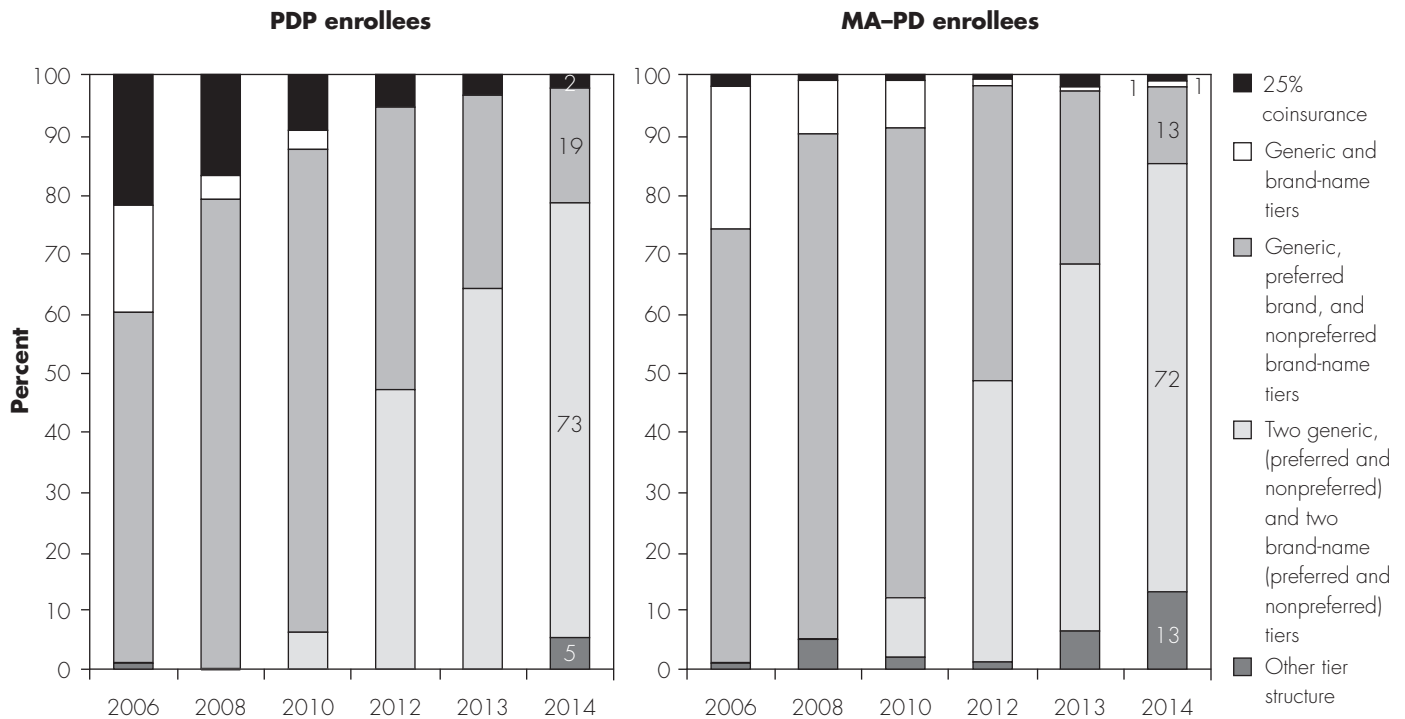
### **Mixed changes to formularies and continued use of utilization management**

Although imperfect, the share of drugs listed on a plan's formulary and the use of utilization management are measures to gauge the generosity of the plan's coverage.<sup>9</sup> Under contract with the Commission, researchers from NORC at the University of Chicago and from Social & Scientific Systems analyzed Part D formulary data for 2015. 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-name and generic versions of specific chemicals (Medicare Payment Advisory Commission 2008).

The use 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. Such

**FIGURE 14-5**

**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]).

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

**TABLE 14-9**

**2015 formularies for stand-alone PDPs with highest 2014 enrollment**

Stand-alone PDPs with the highest 2014 enrollment	Percent of drugs on formulary		Percent of formulary drugs with any utilization management*	
	2014	2015	2014	2015
AARP MedicareRx Preferred	92%	89%	23%	36%
SilverScript Choice	N/A	74	N/A	40
Humana Preferred Rx Plan	80	81	48	45
Humana Enhanced	89	89	50	47
AARP MedicareRx Saver Plus	83	83	25	36
WellCare Classic	73	74	38	37
Humana Walmart	82	83	49	45
Cigna-HealthSpring Rx Secure	85	77	38	44
Aetna Medicare Rx Saver	79	73	32	38
First Health Value Plus	78	80	41	38

Note: PDP (prescription drug plan), N/A (not available). Enrollment excludes employer plans and plans in U.S. territories. The number of drugs on the formulary for 2014 is 1,233; for 2015, the number is 1,253.

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

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

tools are also often used to encourage the use of lower cost therapies. In 2015, the average enrollee in a PDP faces some form of utilization management for about 38 percent of drugs listed on a plan's formulary; the comparable share for the average MA-PD enrollee is 39 percent.

Some of the 10 largest nationwide PDPs, which accounted for 86 percent of PDP enrollment in 2014, saw their formularies tighten between 2014 and 2015, while others broadened their formularies (Table 14-9).<sup>10</sup> For example, UnitedHealth's AARP Medicare Rx Preferred plan had a modest reduction (3 percentage points) in the number of drugs listed on their formularies. Cigna-HealthSpring Rx Secure and Aetna Medicare Rx Saver tightened their formularies by 6 percentage points to 8 percentage points. Meanwhile the formularies of Humana Preferred Rx Plan, WellCare Classic, Humana Walmart, and First Health Value Plus widened modestly.

The use of utilization management increased for 4 of the 10 largest PDPs and decreased for 5 (Table 14-9). Many plans require some type of utilization management on more than one-third of drugs listed on their formularies. The most common strategy that plan sponsors use to manage enrollees' drug use is to apply a prior authorization requirement. In 2015, about 23 percent of formulary drugs are subject to prior authorization. Among the top 10 PDPs, those operated by Humana have the highest share of drugs with utilization management.

### **Tiered pharmacy networks**

In addition to cost-sharing tiers for specific drugs, many sponsors have moved toward building tiered pharmacy networks that encourage enrollees to fill prescriptions at certain pharmacies by offering preferred (lower) cost sharing.<sup>11</sup> In 2014, about 70 percent of PDPs had a preferred network and about 74 percent of PDP enrollees were in a plan that used a tiered pharmacy network (NORC at the University of Chicago 2014).

By law, Part D plan sponsors must do business with all pharmacies that are willing to accept the plan sponsors' terms of its contract, and all such pharmacies are considered to be in the plan's network. However, sponsors may have arrangements with a subset of network pharmacies that offer enrollees preferred cost sharing. Sponsors negotiate additional price concessions, incentive payments, or both with that subset of pharmacies. In some cases, such arrangements are based on pharmacies achieving performance goals for generic dispensing. The use of tiered pharmacy networks has the potential to lower costs to the

Medicare program and to enrollees, but the practice has been controversial (see text box, pp. 366–367).

The Commission has expressed support for plan innovations that can 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 also note 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). A further concern is that because cost sharing for individuals with the LIS is set statutorily, LIS enrollees do not respond to differential copays, so the approach of using tiered pharmacy networks could increase Medicare's spending for low-income cost sharing.

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## **Drug pricing**

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The 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 81 percent in 2012 (the latest year of claims data available), up from 77 percent just one year earlier. 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.

To track drug prices, the Commission contracted with researchers at 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).

### **Enrollees' use of generics led to lower Part D drug prices in 2012**

Measured by individual national drug codes (NDCs) and excluding manufacturers' rebates, Part D drug prices

## Use of tiered pharmacy networks

Between 2010 and 2014, the share of prescription drug plans (PDPs) that used tiered pharmacy networks grew from 11 percent to 70 percent (Table 14-10). In 2014, the 767 PDPs with tiered pharmacy networks accounted for 74 percent of PDP enrollment, an increase from 53 percent in 2013 and 13 percent in 2012.

The share of pharmacies on plans' preferred lists can vary dramatically from one plan to another (Figure 14-6). In 2014, among the largest plans that used tiered pharmacy networks, this share ranged from 10 percent for plans operated by Humana to about 50 percent for some of the Blue plans.<sup>12</sup> The share of pharmacies that are preferred can vary from one region to another within a single plan (or plans that share the same pharmacy networks). For example, in AARP's three plans, 19 percent of pharmacies were preferred in Region 6 (Pennsylvania–West Virginia region), while 74 percent of pharmacies were preferred in Region 27 (Colorado).

Cost sharing for beneficiaries is lower at preferred pharmacies than at nonpreferred pharmacies, with varying degrees of cost-sharing differentials across

plans. Some plans have much stronger incentives than others for their enrollees to use preferred pharmacies. For example, in the 2014 Aetna/CVS Pharmacy Plan, there was a \$3 difference for generics and no difference for brands. By contrast, in the Cigna Medicare Rx Secure plan, cost sharing was \$10 more for preferred generics and brands if an enrollee used a nonpreferred pharmacy, and more than \$20 more for nonpreferred generics and brands (NORC at the University of Chicago 2014).

In January 2014, CMS proposed that cost sharing reductions at preferred pharmacies be permissible only if the reductions did not increase Medicare's payments to plans (Centers for Medicare & Medicaid Services 2014f). CMS's proposal, which was not included in the final rule, was based on research that found higher unit costs among some preferred pharmacies that offered lower cost sharing relative to nonpreferred pharmacies. In September 2014, CMS requested feedback on draft subregulatory guidance that would have required plan sponsors to report all price concessions and incentive payments that could reasonably be approximated at the point of sale (Centers for Medicare & Medicaid Services 2014d). The agency later said that it would

*(continued next page)*

**TABLE  
14-10**

**Growth in the number of stand-alone PDPs with tiered pharmacy networks, 2010–2014**

	PDPs by use of tiered pharmacy networks									
	2010		2011		2012		2013		2014*	
	Count	Percent	Count	Percent	Count	Percent	Count	Percent	Count	Percent
No tiers for pharmacy network	1,396	89%	952	86%	890	86%	557	54%	334	30%
Tiered pharmacy networks	179	11	157	14	151	14	474	46	767	70
Total	1,575	100	1,109	100	1,041	100	1,031	100	1,101	100

Note: PDP (prescription drug plan).

\*Excludes the 68 plans sponsored by SmartD Rx because of CMS sanctions in 2014.

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

## Use of tiered pharmacy networks (cont.)

not use this guidance for contract year 2016 based on stakeholder feedback. While pharmacies have generally been supportive of proposals for more transparency in contracts signed by preferred pharmacies and plans, CMS has faced strong opposition from pharmacy benefit managers. They contend that Medicare is interfering in negotiations between pharmacies and plans, which is prohibited by law.

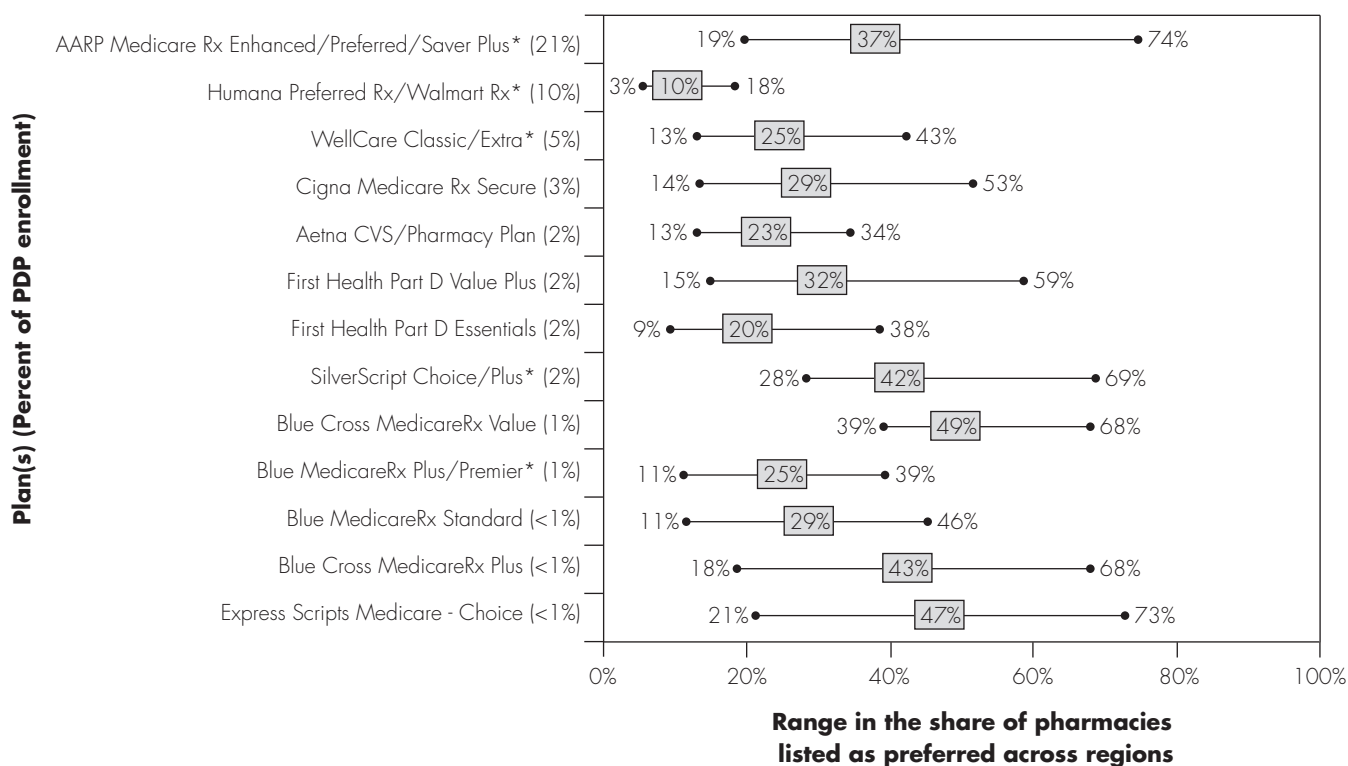
In the same proposed rule, and again in the 2015 Call Letter, CMS also raised concerns about and announced that it would examine beneficiaries' access to preferred pharmacy networks. The study found that, on average, beneficiaries residing in urban areas were less likely

to have convenient access to preferred pharmacies that offered lower cost sharing (Centers for Medicare & Medicaid Services 2014b).<sup>13</sup>

The Commission believes that the use of tiered pharmacy networks can be beneficial for the program and its enrollees if the price concessions that plan sponsors obtain are reflected in prices at the pharmacies or are used to lower premiums. In our comment letter to CMS, we suggested making several programmatic changes to ensure that the use of tiered pharmacy networks does not increase Medicare costs or harm beneficiaries (Medicare Payment Advisory Commission 2014a). ■

**FIGURE 14-6**

**Share of pharmacies listed as preferred for selected plans, 2014**



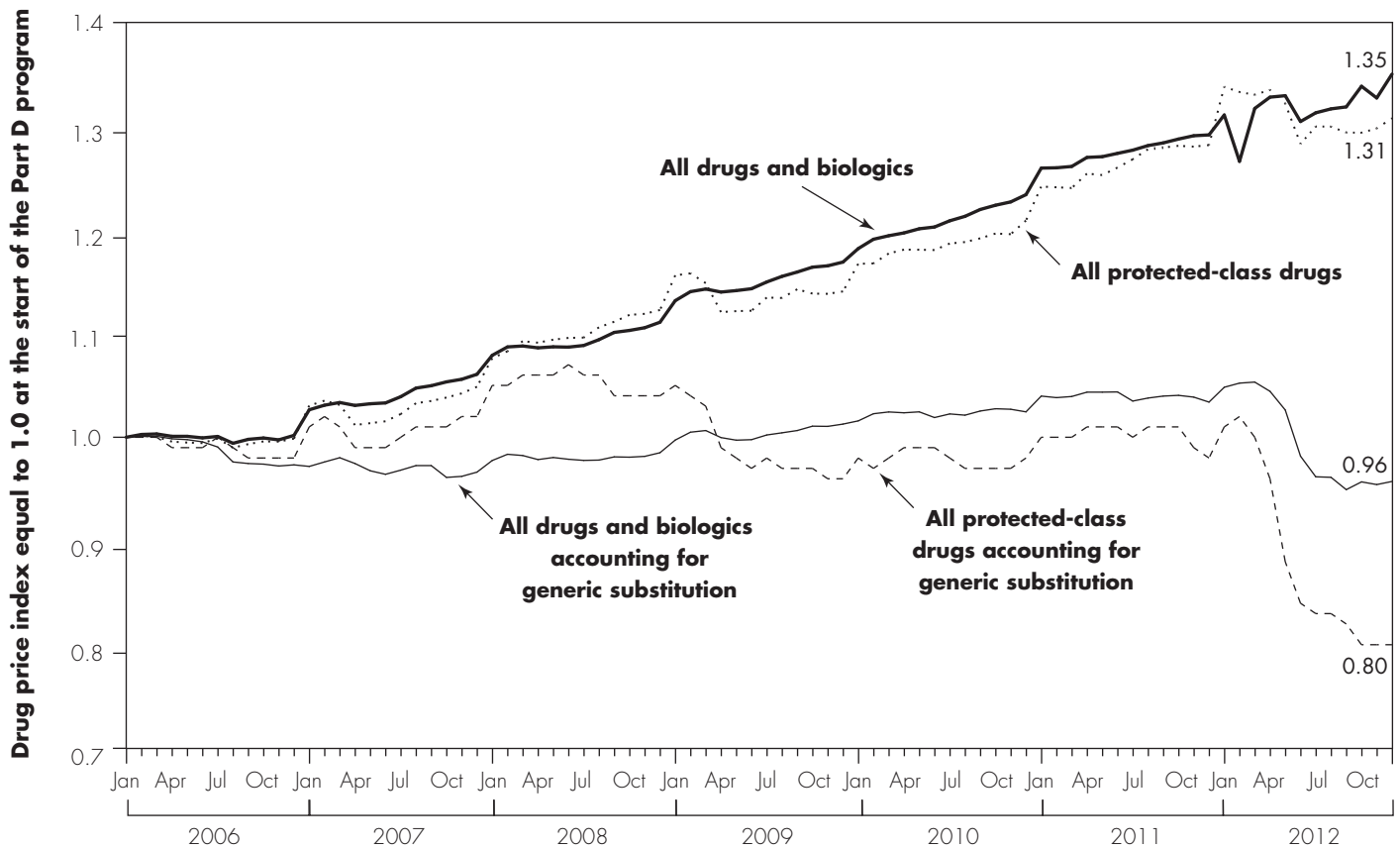
Note: PDP (prescription drug plan). Figures show the minimum and maximum share of pharmacies listed as preferred across regions served by a plan. The average share of pharmacies listed as preferred (shown in the box) is not weighted by enrollment. A plan's share of PDP enrollees is based on enrollment as of February 2014.

\*Plans operated by the same sponsor and use the same pharmacy network.

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

**FIGURE  
14-7**

**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.

rose between 2006 and 2012 by an average of 35 percent (Figure 14-7).<sup>14</sup> As measured by a price index that takes the substitution of generics for brand-name drugs into account, Part D prices decreased cumulatively by 4 percent.<sup>15</sup>

For most drug classes, CMS requires plan formularies to cover at least two drugs in every therapeutic class and key drug type that are not therapeutic substitutes, 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 it 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. Those classes are antineoplastics, antidepressants, antipsychotics,

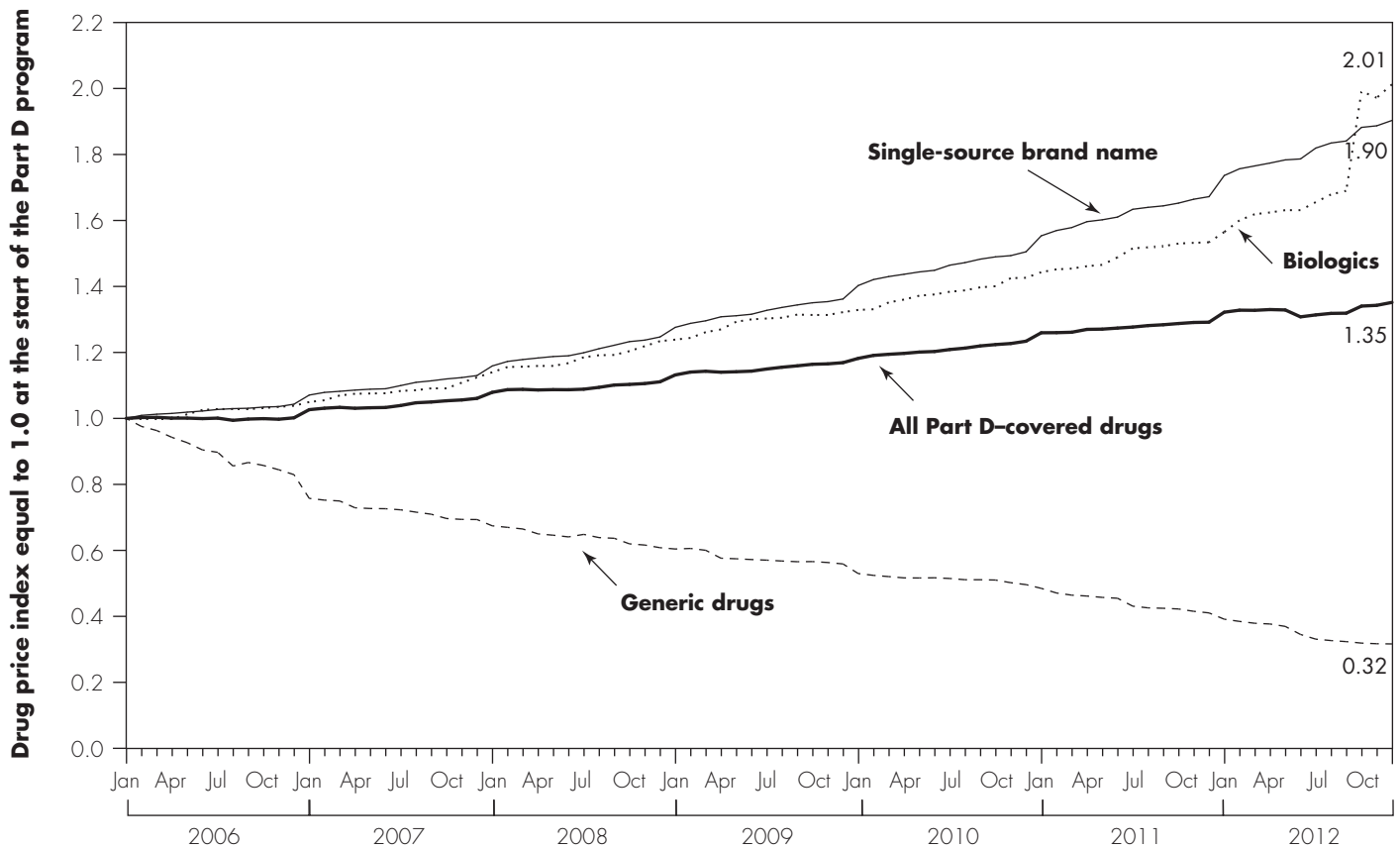
antiretrovirals, anticonvulsants, and immunosuppressants used by transplant patients.<sup>16</sup> Plans can charge higher cost sharing for drugs in these classes—for example, by placing them on tiers for nonpreferred brands—but plans may have limited ability to influence utilization of these classes of drugs.

As measured by individual NDCs, prices for drugs in the six protected classes showed a trend between 2006 and 2012 similar to that for all Part D drugs, rising by a cumulative 31 percent (Figure 14-7). This growth was influenced heavily by two classes of drugs: antidepressant and anticonvulsant medications, which accounted for much of the volume of prescriptions in the six classes, and of which there were many generics on the market during this period. Our price indexes for the individual NDCs of antidepressant and anticonvulsant drugs fell by



**FIGURE  
14-8**

**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.

Source: Acumen LLC analysis for MedPAC.

4 percent and 20 percent, respectively, during the seven-year period (data not shown). Growth in the price index for immunosuppressants slowed in recent years due to generic entries in 2009. Other classes are made up almost entirely of brand-name drugs, and the prices of these products grew rapidly, ranging from 40 percent for antiretrovirals to more than 90 percent for antineoplastics.

When protected-class drugs were grouped to take generic substitution into account, their prices fell by a cumulative 20 percent over the seven-year period. Thus, despite the drugs' protected status, plan sponsors appeared to have had success at moving enrollees toward generics for these drugs when generic substitutes were available. However, 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**

The patterns of price growth across different classes of drugs suggest that prices for drugs with few or no generic substitutes have grown rapidly. When we measured the price growth for drugs with no generic substitutes (single-source brand-name drugs), the growth in prices from 2006 to 2012 was much higher (90 percent) compared with the growth for all Part D-covered drugs (35 percent) (Figure 14-8). Similarly, our price index for biologic products, few (if any) of which have follow-on products available, more than doubled over the same period, while prices of generic

drugs decreased to about 32 percent of the average prices observed at the beginning of 2006.

In the years beyond 2012 (for which Part D claims data are not yet available), 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). The high price of some generics may be one motivation for Part D plan sponsors to move toward a five-tier formulary structure, placing higher cost generics on a nonpreferred generic tier.

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 that are associated with decreased market competition can lead to high and rising prices. Because of growing reliance on generics among Part D enrollees, other populations, and payers, the price increases have drawn the attention of policymakers (Rosenthal 2014).

Similarly, price growth for brand-name and specialty drugs was strong in 2013 (Hartman et al. 2015). By one estimate, retail prices for 227 brand-name drugs that are widely used by older Americans rose by nearly 13 percent in 2013, or about 8 times the rate of general inflation (Schondelmeyer 2014).

### **Use of higher cost drugs poses a big challenge for the future**

Drugs with very high prices pose a future challenge for Part D. As more and more expensive therapies become available, larger numbers of beneficiaries may reach the phase of benefit spending in which Medicare bears most of the insurance risk and pays for 80 percent of benefit spending through individual reinsurance. It is not clear to what degree Part D plan sponsors will be able to negotiate prices with drug manufacturers for these therapies.

Specialty drugs are, by definition, high-cost drugs.<sup>17</sup> Most biologics (large-molecule drugs) are a subset of specialty drugs. Historically, most specialty drugs have been injectables or infusables, but the category now also includes a broader variety of oral and inhaled treatments. One example is the new oral therapy Sovaldi—with an average wholesale price of about \$1,000 per pill or \$84,000 per regimen—and Harvoni, a combination drug that includes Sovaldi, as a treatment for a potentially large population of patients with hepatitis C (Silverman 2014). Because of differences in how they are administered and handled,

spending for specialty therapies spans across both medical and prescription drug benefits.

Among 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 around 30 percent and may reach 50 percent of total spending by 2018 (Roberts 2013). Few specialty drugs have generics or biosimilars, and many of the treatments have limited therapeutic substitutes. For this reason, prices for specialty drugs tend to be high, and PBMs and insurers may have less ability to exert downward pressure on price.

The efforts of a few PBMs and Part D plan sponsors to push back on the price of new drugs may be instructive. At the end of 2014, the Food and Drug Administration (FDA) gave its approval to pharmaceutical manufacturer AbbVie to begin marketing Viekira Pak, a treatment for the most common form of hepatitis C, genotype 1. Express Scripts announced in December 2014 that in 2015, it would no longer cover Gilead's products (Sovaldi and Harvoni) or Johnson & Johnson's product (Olysio) for enrollees initiating treatment for hepatitis C, except under limited circumstances (Murphy 2014). Instead, the company will include Viekira Pak as the preferred treatment for hepatitis C patients with genotype 1. AbbVie announced that the list price of a standard course of therapy of Viekira Pak would be \$83,300, but the company reportedly will provide Express Scripts with sizable discounts (described by one investment analyst as on the order of 40 percent) in return for listing the drug on its formulary (Loftus 2014). In January 2015, CVS Health announced that it had reached an agreement with Gilead for discounts on Sovaldi and Harvoni in return for preferred formulary status (Walker 2015).

Because Part D beneficiaries fill so many prescriptions for traditional medicines, enrollees' use of high-cost drugs has thus far made up a limited share of total drug spending. Milliman estimates that in 2011, fewer than 2 percent of non-LIS enrollees and fewer than 5 percent of LIS enrollees filled a specialty-tier prescription (Pyenson et al. 2013). They estimate that in 2012, specialty-tier drugs made up 11 percent of gross per member per month Part D spending for aged, nondual beneficiaries. A previous Commission analysis of enrollees who reached the catastrophic phase of the benefit shows that most of their spending was driven by the volume of traditional prescriptions filled as well as a tendency to use brand-name medications (Medicare Payment Advisory Commission 2013). Many prescriptions

filled by high-cost enrollees were in therapeutic classes that had generic alternatives, rather than products with few therapeutic substitutes. The Commission found that in 2010 and 2011, fewer than 10 percent of enrollees with high drug spending used biologics, and biologics accounted for 6 percent to 7 percent of spending for these beneficiaries.

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. However, some plans may use management tools such as prior authorization to restrain use somewhat. The benefits and costs of broader use of specialty-tier therapies vary substantially from drug to drug.

For the future, the high and increasing cost of specialty drugs poses a big challenge in Part D. Major PBMs and insurers uniformly project that growth in price and use of specialty drugs will continue to drive trends in spending. In the drug pipeline, fewer blockbuster drugs are going generic, and more than half of the FDA's approvals of new drugs in 2013 were for specialty drugs (CatamaranRx 2014). Specialty spending tends to be concentrated in treatments for rheumatoid arthritis and inflammatory diseases, multiple sclerosis, and cancer (Express Scripts 2014)—conditions more prevalent in the Medicare population.

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 will also rise.

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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. Predictably, spending for the competitively derived direct-subsidy payments on which sponsors bear the most

insurance risk has grown slowly, while benefit spending on which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, where Medicare provides 80 percent reinsurance) has grown much faster.

## 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 subsidy.

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

Between 2007 and 2013, program spending (including the retiree drug subsidy (RDS)) rose from \$46.7 billion to \$64.9 billion (Table 14-11, p. 372). In 2013, direct subsidy payments made up \$20.3 billion, while Medicare paid \$19.5 billion for individual reinsurance, \$23.3 billion for the LIS, and \$1.9 billion in RDSs (Boards of Trustees 2014). Payments to plans for the three subsidies (excluding the RDS) grew by 6.7 percent per year on average.

In 2013, LIS payments continued to be the largest component of Part D spending. Moreover, substantial portions of other categories were spent on behalf of LIS enrollees. Because these individuals tend to use more medications than other Part D enrollees, disproportionate shares of spending for the direct subsidy and individual reinsurance also reflect benefits for LIS enrollees.

Medicare payments for individual reinsurance have grown faster than other components of Part D spending, increasing at an annual average of 16 percent between 2007 and 2013 (Table 14-11, p. 372). This growth has accelerated in recent years, due, in part, to the gradual phase out of the coverage gap that began in 2011. Between 2010 and 2013, payments for individual reinsurance grew

**TABLE  
14-11**

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

	Calendar year						Average annual growth rate 2007-2013
	2007	2009	2010	2011	2012	2013	
Reimbursement amount (in billions):							
Direct subsidy	\$18.1	\$18.9	\$19.7	\$20.1	\$20.8	\$20.3	1.9%
Reinsurance	8.0	10.1	11.2	13.7	15.5	19.5	15.9
Low-income subsidy	16.7	19.6	21.0	22.2	22.5	23.3	5.7
Retiree drug subsidy	3.9	3.9	3.9	3.6	3.2	1.9	-11.4
Total	46.7	52.4	55.8	59.6	62.0	64.9	5.6

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 estimates that premiums paid by enrollees were \$4.1 billion in 2007, \$5 billion in 2008, \$6.1 billion in 2009, \$6.7 billion in 2010, \$7.3 billion in 2011, \$7.8 billion in 2012, and \$9.3 billion in 2013. Totals may not sum due to rounding.

Source: MedPAC based on Table IV.B9 of the 2014 annual report of the Boards of Trustees of the Medicare trust funds.

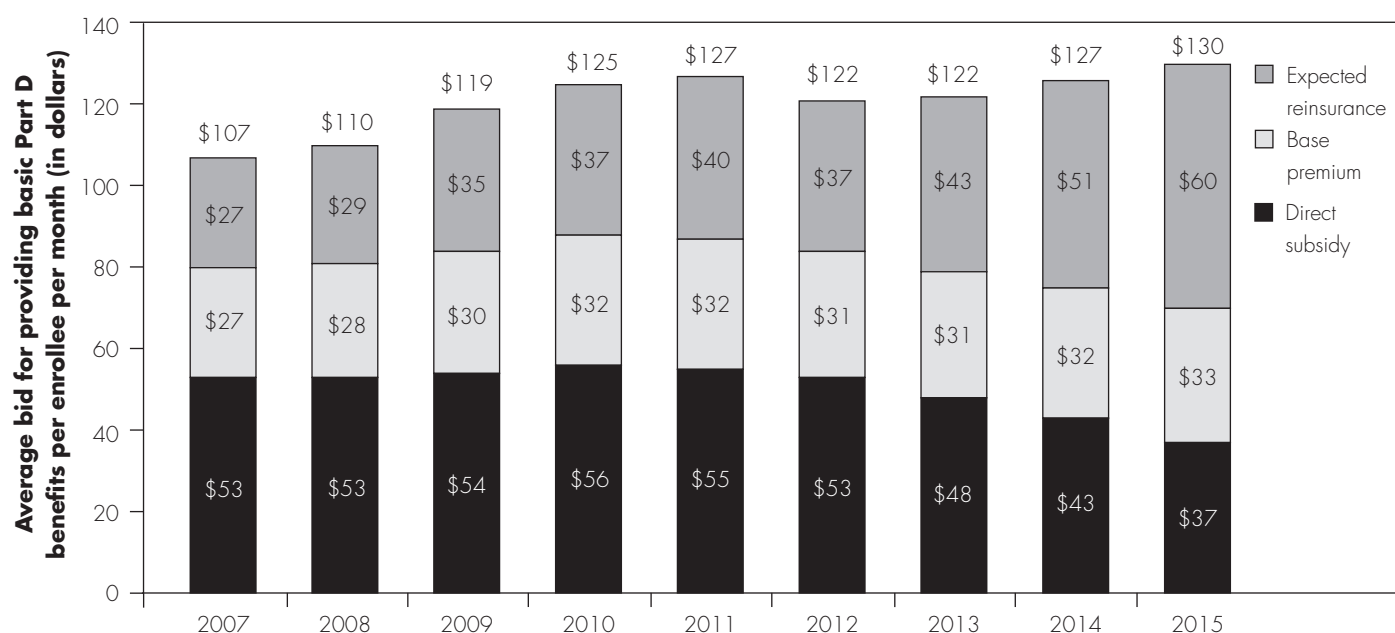
by about 20 percent per year compared with 12 percent for 2007 through 2010 (data not shown).

Changes in the national average bid also reflect higher growth in individual reinsurance. Between 2007 and 2015, expected total benefit spending per member per month has grown at a modest rate of 2.4 percent annually, from \$107

to \$130 (Figure 14-9). During that period, the monthly amount that plans expect to receive through the direct subsidy has fallen 4.4 percent annually, from about \$53 to \$37. Over the same period, the amount per member that sponsors expect to receive in reinsurance has grown 10.5 percent annually, from \$27 to about \$60.

**FIGURE  
14-9**

**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.

Source: MedPAC based on data from CMS.

**TABLE  
14-12**

**Average per capita spending per month for Part D-covered drugs, 2007-2012**

	Average Part D spending per enrollee per month					
	2007	2008	2009	2010	2011	2012
<b>Average spending</b>						
All Part D	\$212	\$221	\$228	\$231	\$239	\$235
By LIS status						
LIS	301	324	339	348	364	362
Non-LIS	156	159	163	163	167	167
<b>Annual percentage change</b>						
All Part D	4.7%	4.2%	3.0%	1.5%	3.2%	-1.5%
By LIS status						
LIS	8.0	7.7	4.5	2.6	4.6	-0.4
Non-LIS	5.8	2.0	2.3	0.0	2.8	-0.3

Note: LIS (low-income subsidy). For purposes of classifying the Part D prescription drug event (PDE) records by LIS status, monthly LIS eligibility information in Part D's denominator file was used. Estimates are sensitive to the method used to classify PDE records to each plan type and LIS status. Spending includes all payments to pharmacies, including payments by drug plans, Medicare's LIS, and beneficiary out of pocket.

Source: MedPAC analysis of Medicare Part D PDE data and denominator file from CMS.

**Enrollment growth among non-LIS enrollees and higher generic use kept per capita spending stable**

Between 2011 and 2012, the most recent years for which we have data, average per capita (gross) spending for Part D-covered drugs decreased (-1.5 percent) for the first time since the program began (Table 14-12).<sup>18</sup> Before 2012, per capita spending grew at an annual average of 3 percent. Per capita spending decreased for both LIS and non-LIS enrollees by 0.4 percent and 0.3 percent, respectively, while the number of prescriptions filled continued to grow for both categories of enrollees. Because the number of prescriptions rose, much of the decrease in spending was likely due to increased use of lower cost drugs. Another factor behind the decrease was faster growth in the number of non-LIS enrollees, who tend to have lower drug spending than LIS enrollees.

The use of generic medications has increased over time. Between 2007 and 2012, the overall average generic dispensing rate (GDR) increased from 61 percent to 81 percent (Table 14-13, p. 374). During this period, some of the most popular brand-name drugs lost patent protection, affording more opportunities for generic substitution. GDRs vary across groups of beneficiaries. For example,

MA-PD enrollees are more likely to use generics than PDP enrollees. From 2007 to 2012, average GDRs for MA-PD enrollees consistently exceeded those of PDP enrollees by 4 percentage points to 6 percentage points. LIS enrollees have had a consistently lower GDR than non-LIS enrollees, and that difference grew from 2007 to 2012 from 2 percentage points to 5 percentage points.

LIS enrollees in both PDPs and MA-PDs are less likely to use generic drugs than non-LIS enrollees in their respective plan types. For example, in 2012, the GDR for LIS enrollees was 3 percentage points below that of non-LIS enrollees in PDPs, and 5 percentage points below that of non-LIS enrollees in MA-PDs. For some of the most commonly used classes of drugs, use of generic drugs by LIS enrollees was from 5 percentage points to 13 percentage points below that of non-LIS enrollees for both plan types (data not shown).

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 the prescribing behavior of physicians who are part of a managed care organization and those who are not. Another

**TABLE  
14-13**

**Generic dispensing rate by plan type and LIS status, 2007-2012**

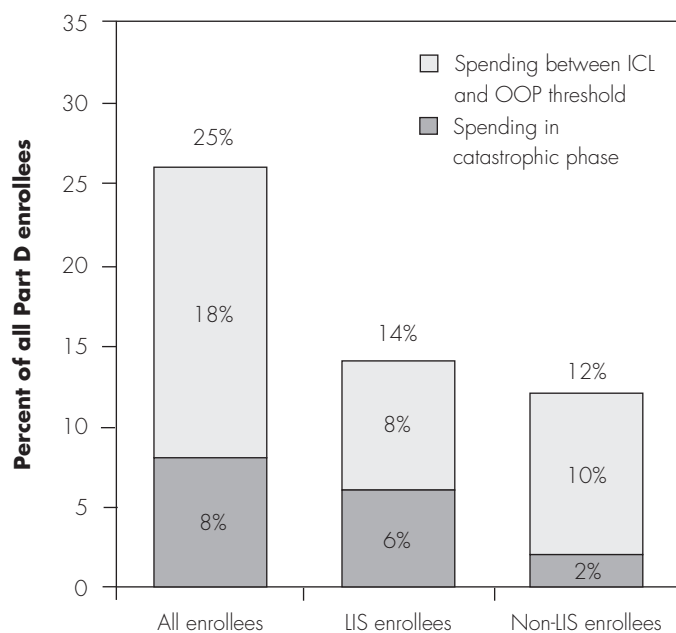
	2007	2008	2009	2010	2011	2012
All Part D	61%	67%	70%	74%	77%	81%
By plan type						
PDP	60	66	69	72	75	80
MA-PD	66	71	74	77	80	84
By LIS status						
LIS	60	65	68	71	74	78
Non-LIS	62	69	72	76	79	83

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). Shares are calculated as a percent of all prescriptions standardized to a 30-day supply. "Generic dispensing rate" is defined as the proportion of generic prescriptions dispensed. Part D drug event records are classified as PDP or MA-PD records based on the contract identification on each record.

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

**FIGURE  
14-10**

**Part D enrollees with spending in the coverage gap and catastrophic phase, 2012**



Note: ICL (initial coverage limit), OOP (out of pocket), LIS (low-income subsidy). LIS enrollees do not face a coverage gap. In 2012, Part D enrollees reached the ICL at \$2,930 in gross drug spending. With no supplemental coverage, an enrollee reached the threshold at \$4,700 of OOP spending or qualifying drug spending made on behalf of the beneficiary, including the 50 percent discount paid for by pharmaceutical manufacturers for brand-name drugs. Some non-LIS enrollees who reached the catastrophic phase of the benefit may have had some gap coverage. Figures may not sum to totals due to rounding.

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

factor may be the difference in the financial incentives faced by LIS and non-LIS enrollees. Because the LIS limits the cost-sharing liability to the statutorily set copayment amounts, it may limit how well plan sponsors can manage drug spending for their LIS enrollees.

In our March 2012 report, we recommended that the Congress give the Secretary the authority to provide stronger financial incentives to use lower cost generics when they are available (Medicare Payment Advisory Commission 2012). The policy has the potential to reduce the amount Medicare spends on the two largest components of the program's spending—payments for the LIS and the individual reinsurance. Because about 80 percent of beneficiaries who reach the catastrophic phase of their benefit are those who receive the LIS, encouraging the use of lower cost generics could have a significant effect on reducing the number of individuals who reach the catastrophic phase of the benefit and reducing the amount Medicare pays in individual reinsurance.

### **Increase in generic use reduced the number of high-cost enrollees**

In 2012, a smaller share of Part D enrollees incurred spending high enough to reach the coverage gap (25 percent compared with 28 percent in 2011) (Figure 14-10). LIS enrollees accounted for more than half of those who reached the coverage gap (4.7 million, or about 14 percent of Part D enrollees). Just more than 2.6 million, or 7.7 percent of enrollees, had spending high enough to

**TABLE  
14-14****Part D enrollees reaching the benefit's catastrophic cap, 2007-2012**

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

Note: LIS (low-income subsidy). Growth rates calculated using figures before rounding was applied.

Source: Data from 2007 and 2008 are based on published figures from CMS. Data from 2009 to 2012 are based on MedPAC analysis of Part D prescription drug event data.

reach the OOP phase of the benefit (high-cost enrollees), a reduction from 8.4 percent in 2011. About 2 million of the high-cost enrollees (about 6 percent of Part D enrollees) received the LIS.

Although about 80 percent of high-cost enrollees were individuals who received the LIS, there was a noticeable increase in the number of non-LIS enrollees who reached the OOP phase of the benefit in 2011—from about 400,000 in 2010 to slightly more than 500,000 in 2011, or an increase of more than 27 percent (Table 14-14). Much of this increase is likely a result of changes made by PPACA.<sup>19</sup> 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 OOP spending threshold.

The number of high-cost enrollees decreased by 1.4 percent between 2011 and 2012, likely reflecting greater use of generic medications in 2012 (Table 14-14). The number of high-cost enrollees who received the LIS decreased by about 73,000 (3.4 percent), while the number of high-cost enrollees who did not receive the LIS increased by 34,000 (6.8 percent). Much of the increase in the number of non-LIS enrollees who incurred high costs likely reflects the higher overall enrollment growth among the non-LIS enrollees (10 percent between 2011 and 2012, data not shown).

### Growth in spending and use for high-cost enrollees

Between 2009 and 2012, total drug spending by high-cost enrollees grew by 37 percent cumulatively (Table 14-15, p. 376). About two-thirds of that increase can be explained by the higher drug prices, as measured by the 23 percent increase in the average price paid per prescription during this period. The remainder is attributable to growth in the number of prescriptions filled (11 percent), which is mostly due to the increase in the number of high-cost enrollees (10 percent).

The average price of prescriptions filled by Part D enrollees remained stable from 2009 to 2011, and it decreased by more than 2 percent in 2012. Increases in the use of generic drugs likely offset some of the increases in prices of brand-name drugs during this period. By comparison during this period, average spending per prescription filled among high-cost enrollees grew by 23 percent (about 7 percent annually between 2009 and 2011, and 8 percent between 2011 and 2012).

High-cost enrollees tend to use more brand-name drugs compared with other Part D enrollees. For example, in 2012, the average GDR among high-cost enrollees was slightly less than 68 percent, or about 13 percentage points below the overall Part D average of 81 percent. While the higher growth in prices of drugs taken by high-cost

**TABLE  
14-15****Part D spending and utilization by high-cost enrollees, 2009-2012**

	2009-2012					
	2009	2010	2011	2012	Change	Percent change
Enrollees (in millions)	2.4	2.4	2.6	2.6	0.2	10%
Aggregate utilization						
Gross spending (in billions)	\$29.2	\$31.2	\$37.1	\$39.9	\$10.7	37
Prescriptions (in millions)	264.3	264.3	294.0	293.0	28.7	11
Average prescriptions per enrollee	111	112	111	113	1	1
Average spending per prescription	\$110	\$118	\$126	\$136	\$26	23

Note: "Change" and "percent change" columns were calculated using figures before rounding was applied.

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

enrollees can be explained by their tendency to use more brand-name drugs, for certain classes of drugs, generic substitution is not available. An increasing number of drugs covered under the Part D program falls in the biologics category, for which prices have grown more rapidly compared with other drug products.

### Growth in spending for biologics among high-cost enrollees

From 2009 to 2012, the share of high-cost enrollees who filled at least one prescription for a biologic product grew from 8 percent to 11 percent (Table 14-16). High-cost enrollees who did not receive the LIS were more likely to use biologics compared with those who received the LIS, with about 15 percent of non-LIS enrollees filling at least one prescription for biologics in 2012 compared with 10 percent of LIS enrollees (data not shown).

Gross spending on biologics by high-cost enrollees grew from \$1.9 billion to \$3.5 billion, or by more than 90 percent, from 2009 to 2012 (Table 14-16). The faster growth in spending for biologics (32 percent growth in the volume of prescriptions and 45 percent growth in prices) increased biologics' share of total spending on drugs by high-cost enrollees from about 6 percent to about 9 percent (data not shown).

The number of prescriptions for biologic products grew more slowly from 2009 to 2012 (32 percent) than the number of high-cost enrollees using biologics (58 percent)

(Table 14-16). While biologic prescriptions per user declined during this period, average price per prescription for biologics grew by 12 percent to 14 percent per year, resulting in a net increase in spending for biologics per user of more than 20 percent by 2012 compared with 2009.

### 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 about 90 percent.<sup>20</sup> In general, Part D has improved Medicare beneficiaries' access to prescription drugs, with plans available to all individuals.

### Most Part D enrollees report good access to prescription drugs

Most Part D enrollees appear to have good access to prescription drugs. Overall, in 2012, about 80 percent were satisfied with the drugs listed on plan formularies, and more than 90 percent reported having good access to pharmacies (Table 14-17). While only 7 percent reported having had prescriptions for medications they did not obtain during the year, that share was somewhat higher among LIS enrollees (9 percent) compared with non-LIS enrollees (6 percent). Among the 7 percent of all enrollees, cost was the main reason for not obtaining



**TABLE  
14-16**

**Growth in spending and utilization for biologics by high-cost enrollees, 2009-2012**

	2009	2010	2011	2012	Percent change 2009-2012
Number of high-cost enrollees using biologics (in thousands)	188.3	183.3	255.4	298.3	58%
As percent of all high-cost enrollees	8%	8%	10%	11%	
Gross spending on biologics (in billions of dollars)	\$1.9	\$2.1	\$2.7	\$3.5	91
Annual percent change	N/A	14%	26%	33%	
Prescriptions for biologics (in millions)	1.11	1.12	1.26	1.47	32
Annual percent change	N/A	1%	12%	16%	
Gross spending per prescription	\$1,672	\$1,885	\$2,120	\$2,419	45
Annual percent change	N/A	13%	12%	14%	

Note: N/A (not available).

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

medications, accounting for nearly 40 percent, followed by nonformulary status of the medication(s). Combined, cost and the nonformulary status of the medication(s) resulted in about 5 percent of the beneficiaries not obtaining at least one medication during the year. The remaining 2 percent reported that they chose not to obtain medications because they were concerned about reactions to the medications, the medication was not necessary, or they did not think the medication would help.

**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.

**TABLE  
14-17**

**Part D enrollees’ access to prescription drugs, 2012**

	All Part D	Plan type		LIS status	
		PDP	MA-PD	LIS	Non-LIS
Percent:					
Satisfied with plan list of drugs covered*	80%	78%	83%	81%	80%
Satisfied with the ease of finding pharmacy that accepts drug plan*	92	91	92	90	92
With medication(s) not obtained	7	8	7	9	6
With medication(s) not obtained due to cost or nonformulary status	5	5	4	6	4

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy).

\*A small share refused to respond, indicated that they did not know the answer to the question, or had no experience related to the question. For the question about the plan list of drugs, that share was 6 percent. For the question about the ease of finding a pharmacy that accepts the drug plan, the share was about 4 percent.

Source: MedPAC analysis of 2012 Medicare Current Beneficiary Survey Access to Care file.

Part D's exceptions and appeals process is complex, involving multiple levels (Medicare Payment Advisory Commission 2014c). It begins when an enrollee does not receive his or her prescription at a 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 reported on the effectiveness of the exceptions and appeals process based on data that were available at the time. Although there are multiple levels of appeals, the data we had access to pertained only to the second level of the appeals process, where the plans' adverse coverage determinations were reviewed by an independent review entity. The data were insufficient to make a comprehensive assessment of the plans' administration or effectiveness of the process in ensuring access to needed medications (Medicare Payment Advisory Commission 2014c).

Subsequently, CMS released data on the exceptions and appeals process at the plan level for 2012.<sup>21</sup> On average, the number of pharmacy claims that were rejected because of formulary restrictions (e.g., the requested drug was not on the plan's formulary, or it required a prior authorization) was small—about 4 percent of claims processed by Part D plans in 2012. When claims were rejected, beneficiaries did not request an appeal in about 94 percent of the cases. For the cases that did reach the first level of appeal (request for a redetermination from the plan), decisions were favorable to beneficiaries in about two-thirds of the cases.

At the same time, CMS audits for benefit years 2012 and 2013 found that plans had difficulties in the areas of Part D coverage determinations, appeals, and grievances (Centers for Medicare & Medicaid Services 2014a, Centers for Medicare & Medicaid Services 2013b). In beneficiary focus groups convened for the Commission during 2014, we continued to find limited awareness and experience with the exceptions and appeals process (Hargrave et al. forthcoming). Among the few who had experience working with their providers to appeal an adverse coverage determination, most found the process to be burdensome. Many reported working with their physicians to find alternative medications instead of appealing plans' coverage decisions.

We are unable to determine whether low rates of claims rejections and appeals are cause for concern. Claims

can be rejected for valid reasons, such as exceeding the quantity limits based on FDA labeling; in the case of certain controlled substances, quantity limits may be applied for patient safety reasons. In other cases, beneficiaries may work with their physicians to find alternative medications or obtain needed medications outside of the exceptions and appeals process, for example, using samples obtained from their physicians. Beneficiaries often avoid this process altogether by switching to a plan—which LIS enrollees can do monthly—whose formulary has their medications. Nevertheless, a low appeals rate could be cause for concern if it reflects a lack of transparency in the appeals process or excessive administrative burden imposed on enrollees and prescribers that discourages them from submitting an appeal.

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## Quality in Part D

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CMS collects quality and performance data for Part D plans to monitor sponsors' operations and uses a subset of these data to rate plans on a 5-star system. In 2014, CMS for the first time released plan-level information on medication therapy management programs (MTMPs).

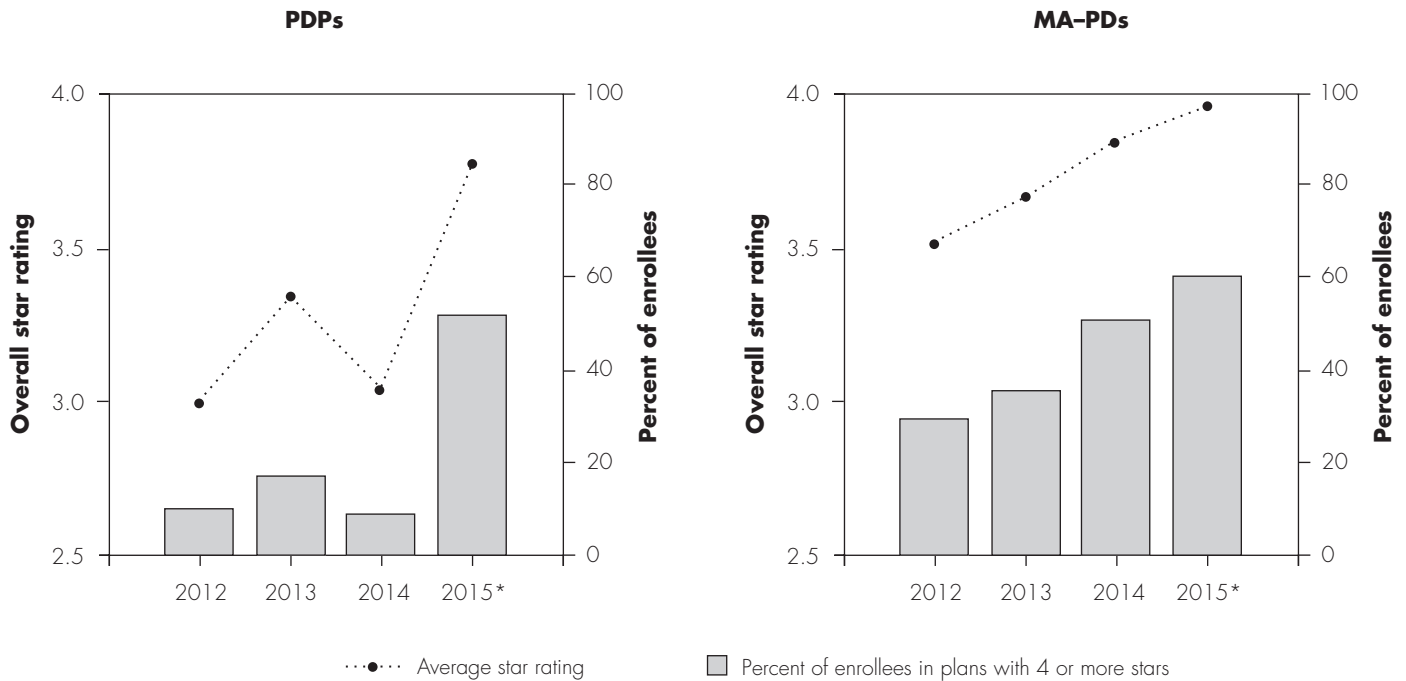
### Measuring plan performance

CMS collects quality and performance data for plan sponsors 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 2014e). CMS makes selected performance measures 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 Medicare Advantage (MA) program's overall plan ratings used to determine the amount of bonus payment.

For 2015, Part D plan ratings are based on up to 13 metrics that measure plan performance on intermediate outcomes, patient experience, access, and process (Centers for Medicare & Medicaid Services 2014e). Intermediate outcomes measures (5 metrics) receive a weight of 3, while measures related to patient experience and access receive a weight of 1.5.<sup>22</sup> In 2015, CMS increased the

**FIGURE 14-11**

**MA-PDs have more consistent increases in overall star rating and the share of enrollees in high-performing plans**



Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). Figures exclude contracts that are too new to be measured, contracts that do not have enough data available for reporting, and contracts terminating at the end of the calendar year.  
\*Estimated using 2014 enrollment.

Source: MedPAC based on CMS’s fact sheet on 2015 star ratings.

weight assigned to drug plan quality improvement, a measure reflecting changes in drug plans’ performance from one year to the next, to 5 (from 3 in 2014 and 1 in 2013). Most MA-PDs are rated on up to 44 measures that assess the quality of medical services provided under Part C (i.e., the MA program), in addition to the 13 measures used to assess the quality of prescription drug (Part D) services provided. CMS aggregates individual scores for each measure (13 for PDPs and 44 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 2014 enrollment) for 2015 is 3.92 for MA-PDs and 3.75 for PDPs. For 2015, the share of enrollees in plans rated 4 stars or more (high-performing plans) is expected to increase to more than 50 percent among PDP enrollees and to about 60 percent among MA-PD enrollees (assuming no change in the distribution of enrollees across plans in 2015) (Figure 14-11).

Between 2012 and 2014, the share of enrollees in high-performing plans increased steadily for MA-PDs, while a steady increase was not the case with enrollees in PDPs. For example, in 2014, the overall rating among PDPs as well as the share of PDP enrollees in high-performing plans declined. The lower average star rating among PDPs reflected reductions in the ratings for the two contracts (the SmartD Rx PDPs and the SilverScript PDPs) that were placed under CMS enrollment sanctions during the annual open enrollment for the 2014 benefit year. If this enrollment penalty had not been applied, the average rating for PDPs would have been 3.23 for 2014 rather than 3.04 (Centers for Medicare & Medicaid Services 2013a).

In general, changes in the composition of the measures CMS uses to rate plans over the years make it difficult to use star ratings to measure the changes in quality of services provided by plans across years. For example, more emphasis has been placed on intermediate outcome measures in recent years—such as the use of medications

**TABLE  
14-18**

**Use of medication therapy management programs by plan type, 2012**

	All	PDP	MA-PD
Number of medication therapy management enrollees (in millions)	3.1	1.9	1.3
Medication therapy management participation rate			
Overall	11%	10%	11%
Under age 65	11	10	13
Percent of enrollees in long-term care	4%	7%	2%
Percent of enrollees who received medication therapy management service(s)			
Comprehensive medication review	10%	6%	15%
Targeted medication review	97	98	96
Percent of enrollees who had any prescriber intervention(s)			
Received a comprehensive medication review	52%	55%	51%
Did not receive a comprehensive medication review	31	33	28
Received comprehensive medication review and/or targeted medication review	34	34	32
Percent of enrollees who had any therapy change(s)			
Received a comprehensive medication review	33%	29%	35%
Did not receive a comprehensive medication review	13	14	13
Received comprehensive medication review and/or targeted medication review	16	15	17

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). Figures exclude plans that do not meet the minimum data requirement and plans with invalid data.

Source: MedPAC based on the 2012 public use file for medication therapy management from CMS.

with a high risk of serious side effects and the share of enrollees obtaining medications recommended to treat selected conditions—and less emphasis on process measures such as price accuracy on Medicare’s Plan Finder.

### Medication therapy management programs

Part D plans are required to implement MTMPs 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 (\$3,138 for 2015). Our earlier review of the MTMPs 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 MTMPs since 2010 and has used guidance from multiple programs to specify MTMP requirements. For example, under CMS MTMP

criteria, plan sponsors cannot require beneficiaries to have more than three chronic conditions or use more than eight medications to be eligible for their MTMP. Plan sponsors are required to offer all MTMP-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>23</sup>

Until recently, little information was available to assess the effectiveness of the MTMPs under Part D. In 2014, CMS released plan-level data on MTMPs for the 2012 benefit year. Data values for some plans were suppressed because of the small number of observations or other data issues identified by CMS. The plans that were included in our analysis represented 29.6 million enrollees, or about 88 percent of Part D enrollees in 2012.

In 2012, 3.1 million, or about 11 percent of Part D enrollees, participated in an MTMP (Table 14-18). Program participation varied widely across plan sponsors. On average, beneficiaries in MA-PDs were slightly

more likely than those in PDPs to enroll in an MTMP (11 percent vs. 10 percent). Participation rates likely varied by beneficiary characteristics, potentially reflecting differences in eligibility criteria and outreach efforts used by plan sponsors. For example, among individuals under age 65 (disabled), those in MA–PDPs were more likely to enroll in MTMPs compared with those in PDPs (13 percent vs. 10 percent). Individuals residing in long-term care (LTC) institutions were more likely to participate in an MTMP, with a participation rate of about 21 percent (data not shown).

Although CMR was offered to virtually all MTMP enrollees, only 10 percent of them (about 1 percent of all Part D enrollees) received a CMR in 2012, a rate comparable with that observed in the 2010 benefit year (Table 14-18) (Marrufo et al. 2013). MTMP enrollees in MA–PDPs were more than twice as likely as those in PDPs to receive a CMR (15 percent vs. 6 percent). Nearly all enrollees received at least one TMR during the year.

Receiving a CMR can result in more prescriber interventions or therapy changes. For example, in 2012, plan sponsors reached out to prescribers in more than 50 percent of the cases for which a CMR was conducted compared with about 30 percent of the cases for which no CMR was completed (Table 14-18). Changes in therapies were also more likely among cases for which a CMR was completed (33 percent) compared with cases for which no CMR was completed (13 percent), with a higher rate of therapy changes among individuals enrolled in MA–PDPs compared with those enrolled in PDPs (35 percent vs. 29 percent).

However, a few caveats are needed in interpreting the findings from the 2012 MTMP data. First, despite the observed association between a CMR completion and MTMP interventions, the data do not allow us to determine whether the higher number of interventions observed among individuals who received a CMR was due to having had a CMR. For example, individuals who accept the offer of a CMR may be more likely to have medication-related issues that need to be addressed. In that case, the observed differences in MTMP interventions would be attributable to the selection of individuals rather than to CMR performance. In other words, a lower rate of MTMP interventions among individuals who did not receive a CMR may or may not indicate a problem.

Although the data showed higher participation in MTMPs by individuals in LTC facilities, less than 1 percent of LIS enrollees received a CMR. Because beneficiaries in LTC facilities are more likely to take multiple medications and may be at a higher risk for polypharmacy, periodic review of their medications is particularly important to their health. In the future, we hope to examine how well Part D's MTMP program is working in LTC settings, particularly given the difference in beneficiary characteristics (e.g., higher prevalence of cognitive issues), potentially different goals (e.g., reducing potentially harmful medications rather than increasing adherence), and the facility environment (e.g., nursing facilities are required by Medicare to conduct a monthly medication review of their residents by a consultant pharmacist). ■

## Endnotes

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- 1 In 2015, the Part D benefit provides gap coverage of 5 percent for brand-name drugs in addition to a 50 percent discount provided by pharmaceutical manufacturers, reducing the cost sharing during the coverage gap to about 45 percent. The cost-sharing amount for brand-name drugs filled during the coverage gap depends on the amount of the dispensing fee charged, since the 5 percent covered by the Part D benefit applies to both the ingredient cost and the dispensing fee, while the 50 percent manufacturer discount applies only to the ingredient cost.
- 2 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 beginning in 2013, they can no longer deduct drug expenses for which they receive the subsidy as a cost of doing business (but they can still deduct prescription drug expenses not covered by the subsidy).
- 3 Under the Part C payment system, which is used to pay MA plans, 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.
- 4 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 Part C rebate dollars that were used to offset Part D premium costs.
- 5 These figures are based on CMS's estimate as of December 2014.
- 6 CMS allows a sponsor to offer multiple plans in any given service area only if those offerings are substantially different from one another. To be considered "substantially different" for 2015, PDPs must have a difference of at least \$20 per month in a beneficiary's expected monthly OOP costs between basic and enhanced plans. 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 \$25 in a beneficiary's expected monthly OOP costs between the two enhanced plan offerings.
- 7 Another 20 PDPs (Express Script's SmartD Rx Saver plans and Avalon Insurance Company's SecureRx plans) have premiums below their regional benchmarks, but are subject to CMS marketing and enrollment sanctions. LIS enrollees who were in those 20 plans in 2014 may remain in them for 2015 without paying any of the premium. However, sanctioned PDPs may not receive new LIS enrollees through auto-assignment even when their monthly premium is below the regional benchmark.
- 8 Information on the extent of the coverage provided during the gap is not available for 2015. 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).
- 9 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. Alternately, other sponsors might list most drugs on their formulary but require prior authorization for relatively larger numbers of drugs.
- 10 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 2014 and 2015.
- 11 CMS has moved away from referring to pharmacies within a plan's network as preferred and nonpreferred pharmacies, depending on the cost sharing amounts that are applicable to medications filled at the pharmacy. Instead, CMS refers to them as pharmacies that offer preferred (lower) or standard cost sharing.
- 12 The average share of pharmacies is not weighted by enrollment.
- 13 *Convenient access* was defined as 90 percent of urban beneficiaries having access to pharmacies within 2 miles of their residence, 90 percent of suburban beneficiaries having access within 5 miles of their residence, and 70 percent of rural beneficiaries having access within 15 miles of their residence.
- 14 An individual NDC uniquely identifies the drug's labeler, drug, dosage form, strength, and package size. Because each drug is often available in different dosages, strengths, and package sizes, the same drug typically has many different NDCs.

- 15 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.
- 16 In a proposed rule published January 6, 2014, CMS proposed to remove three classes—antidepressants, antipsychotics, and immunosuppressants for transplant rejection—from the protected status. 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. We also shared CMS’s concerns about antipsychotics and supported CMS’s move to proceed slowly. However, the agency did not include the measure in its final rule.
- 17 The industry does not have one consistent definition of specialty drugs, but they tend to be characterized as high cost (e.g., the Medicare call letter threshold 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. See <http://www.ajmc.com/payer-perspectives/0213/The-Growing-Cost-of-Specialty-PharmacyIs-it-Sustainable>.
- 18 The reduction in per capita spending net of rebates is slightly larger than the 1.5 percent reported since the rebates as a share of drug spending increased between 2011 and 2012 (from 11.5 percent to 11.7 percent) (Boards of Trustees 2014).
- 19 PPACA eliminates the coverage gap by (1) requiring pharmaceutical manufacturers to offer a 50 percent discount on brand-name drugs filled during the coverage gap, (2) gradually phasing down cost sharing for generic drugs beginning in 2011, (3) phasing down cost sharing for brand-name drugs beginning in 2013, and (4) reducing the OOP threshold on true out-of-pocket spending over the 2014 to 2019 period.
- 20 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, 90 percent of beneficiaries have drug coverage that is as generous as Part D’s basic benefit.
- 21 After excluding plans with missing or invalid data values, our sample included 769 PDPs and 1,992 MA–PDs, representing nearly 26 million beneficiaries, or about 82 percent of total Part D enrollees, based on enrollment as of April 2012. For the 88 plans that were missing the count of total claims processed in 2012 but had valid records for other data elements used in our analysis, we used Part D claims data for 2012 to assign the total number of claims for each plan.
- 22 CMS assigns a weight of 1 to process measures and measures that are newly introduced in that year.
- 23 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 actual or potential medication-related problems. A TMR can be person to person or system generated, and interventions may be delivered by mail or faxed to the beneficiary and/or the prescriber, as appropriate (Centers for Medicare & Medicaid Services 2014c).

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