

CHAPTER

13

**Status report on Part D,
with focus on beneficiaries
with high drug spending**

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

- 13** The Congress should modify the Part D low-income subsidy copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs when available in selected therapeutic classes. The Congress should direct the Secretary to develop a copay structure, giving special consideration to eliminating the cost sharing for generic drugs. The Congress should also direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

Status report on Part D, with focus on beneficiaries with high drug spending

Chapter summary

Each year the Commission provides a status report on Part D to:

- provide information on beneficiaries' access to prescription drugs—including enrollment figures and benefit and design changes—program costs, and the quality of Part D services.
- analyze changes in plan bids, premiums, benefit designs, and formularies.

In addition, this chapter reports on beneficiaries with high drug spending and the relationship between the high use of drugs and quality of care in Part D. It also includes the Commission's recommendation to revise Part D's low-income cost-sharing subsidy.

Enrollment in Part D—In 2011, more than 70 percent of Medicare beneficiaries were enrolled in Part D plans or in employer plans that receive Medicare's retiree drug subsidy. Other beneficiaries receive their drug coverage through other sources of creditable coverage. Although 2011 data are not available, in 2010, about 10 percent had no drug coverage or coverage less generous than Part D. Among those in Part D plans, 10.6 million low-income individuals (about 36 percent of Part D enrollees) received the low-income subsidy (LIS). Roughly two-thirds of Part D enrollees are in stand-alone prescription drug plans (PDPs); the rest are in Medicare Advantage–Prescription Drug plans (MA–PDs). MA–PD enrollees are much more likely

In this chapter

- Part D enrollees' access to prescription drug benefits in 2011
- Benefit offerings for 2012
- Costs of Part D
- Measuring plan performance in Part D
- Generic substitution and role of the low-income cost-sharing subsidy
- High use of drugs and quality of pharmaceutical care

than those in PDPs to receive basic and supplemental benefits combined in their drug plan. Most enrollees report high satisfaction with the Part D program and with their plans.

Benefit offerings for 2011—The number of plan offerings remained relatively stable from 2011 to 2012. Sponsors are offering about 6 percent fewer stand-alone PDPs and about 2 percent more MA–PDs than in 2011. Beneficiaries will continue to have 25 to 36 PDP options to choose from, along with many MA–PDs. MA–PDs continue to be more likely than PDPs to offer enhanced benefits that include some coverage in the gap.

For 2012, about the same number of premium-free PDPs will be available to enrollees who receive the LIS: 327 plans qualified compared with 332 in 2011. In most regions, LIS enrollees will continue to have many premium-free plans available. In two regions, Florida and Nevada, only a handful of plans qualified despite changes made in the Patient Protection and Affordable Care Act of 2010 to increase the number of qualifying plans.

Part D spending—Between 2006 and 2010, Part D spending increased from about \$43 billion to \$56 billion (average annual growth of about 6 percent), and CMS expects it will have reached \$59 billion in 2011. These expenditures include the direct monthly subsidy plans receive for their Part D enrollees, reinsurance paid for very-high-cost enrollees, premiums and cost sharing for LIS enrollees, and payments to employers that continue to provide drug coverage to their retirees who are Medicare beneficiaries. In 2010, LIS payments continued to be the largest component of Part D spending. Medicare’s reinsurance payments are the fastest growing component of Part D spending, driven primarily by LIS beneficiaries who use many drugs that tend to be expensive brand-name medications.

Between 2007 and 2009, average annual per capita gross spending for Part D–covered drugs grew by 3.6 percent. Growth in per capita spending varied across different groups, with Part D enrollees who do not receive the LIS experiencing significantly lower growth (2.2 percent per year, on average) than LIS enrollees (6.1 percent per year, on average). Although percentage growth in per capita spending among MA–PD enrollees was greater than for PDP enrollees, the average dollar increase was lower for MA–PD enrollees.

Growth in Part D premiums—In 2012, the base beneficiary premium will be \$31.08, which is a slight decrease from \$32.34 in 2011. The base beneficiary premium reflects the basic portion of the benefit (which does not include premiums

for enhanced or supplemental, benefits). The actual premium paid depends on the beneficiary's choice of plans.

Generic substitution and the role of LIS—Switching from brand-name drugs to generic drugs can result in significant cost savings. Plan sponsors have been more successful at encouraging generic drug use among non-LIS enrollees than among LIS enrollees. Multiple factors contribute to the difference in generic use rate across populations, including financial incentives. Plans often use cost-sharing differentials to encourage beneficiaries to use generic drugs. Such tools are not available to manage the drug use of LIS enrollees. By revising the LIS copayment structure, Medicare may be able to reduce program spending without substantially affecting access to needed medications.

The policy we recommend would provide the Secretary with broad authority and flexibility to provide stronger financial incentives to use generic drugs when clinically appropriate. Several safeguards are in place to ensure that access is not negatively affected. First, the policy applies to drug classes where lower cost (or free) generic alternatives are available. Second, the increase in the copay amount we are contemplating for the policy for selected drug classes takes into account the limited incomes of these beneficiaries. Third, most individuals already use or could switch to generics for the classes this policy applies to and are likely to experience reductions in out-of-pocket (OOP) costs for at least some of their medications. This reduction would offset the increase in copays for brand-name drugs in selected classes if beneficiaries or their physicians choose to continue with those brand-name drugs. Fourth, the policy would retain the existing exceptions and appeals process allowing beneficiaries to appeal coverage or cost-sharing amounts. Finally, the true OOP limit under Part D's benefit structure will limit the OOP costs for LIS beneficiaries who need many brand-name medications.

High use of drugs and quality of pharmaceutical care—Beneficiaries with high drug use may have medical problems caused or exacerbated by their heavy use of medications (polypharmacy). They are at increased risk of adverse drug events, drug–drug interactions, and use of inappropriate medications. In addition, research shows that high use of medication is associated with lower adherence to medication therapies.

Part D plans are required to implement medication therapy management programs (MTMPs) to improve the quality of the pharmaceutical care that high-risk beneficiaries receive. Our earlier review of MTMPs revealed wide variations in eligibility criteria, the kinds of interventions provided to enrollees, and the outcomes sponsors measured (Medicare Payment Advisory Commission 2009).

Since 2010, CMS has tightened criteria for MTMPs. The agency has begun an evaluation of the impact of MTMPs on high-risk, chronically ill beneficiaries. We currently do not have sufficient data to determine whether the programs increase the quality of pharmaceutical care to participants but will continue to monitor this program. ■

**TABLE
13-1**

Parameters of the defined standard Part D benefit increase over time

	2006	2011	2012
Deductible	\$250.00	\$310.00	\$320.00
Initial coverage limit	2,250.00	2,840.00	2,930.00
Annual out-of-pocket spending threshold	3,600.00	4,550.00	4,700.00
Total covered drug spending at annual out-of-pocket threshold	5,100.00	6,447.50*	6,657.50*
Maximum amount of cost sharing in the coverage gap	2,850.00	3,607.50	3,727.50
Minimum cost sharing above the annual out-of-pocket threshold:			
Copay for generic/preferred multisource drug prescription	2.00	2.50	2.60
Copay for other prescription drugs	5.00	6.30	6.50

Note: *Total covered drug spending at annual out-of-pocket threshold depends on the mix of brand and generic drugs filled during the coverage gap. The amount for 2012 (\$6,657.50) is for an individual with no other sources of supplemental coverage filling only brand-name drugs during the coverage gap.

Source: CMS, Office of the Actuary.

Each year since 2006, the Commission has provided a status report on Medicare’s Part D program. To monitor the ability of the program—under its competitive approach—to meet Medicare’s goals of maintaining beneficiary access while holding down program spending, we examine several performance indicators: beneficiaries’ access to prescription drugs (including data on enrollment and changes in Part D plan benefit designs and formularies for 2012), program costs, and the quality of services.

In addition, this chapter reports on beneficiaries with high drug spending and the relationship between the high use of drugs and quality of care in Part D. It also includes the Commission’s recommendation to revise Part D’s low-income cost-sharing subsidy.

Background

Medicare’s payment system for Part D is very different from its payment systems for fee-for-service providers. It uses competing private plans to deliver prescription drug benefits; instead of setting prices administratively, Medicare’s payments to Part D plans are based on bids submitted by plan sponsors.

Competitive design

Part D uses two avenues of competition designed to give plan sponsors incentives to offer beneficiaries attractive prescription drug coverage while controlling growth in drug spending. First, private plans must compete for enrollees. Ideally, beneficiaries choose a plan that provides

access to the medications they need at premiums and copayments they are willing to pay, and they reevaluate that decision from time to time.¹ In a second avenue of competition, sponsors may seek to gain market share by annually bidding at a level they hope will fall below regional thresholds to qualify their plans to remain premium-free for most enrollees who receive Part D’s low-income subsidy (LIS).

Only about 6 percent of Part D enrollees switched plans voluntarily in the first few years of the program. (More recent data on switching plans are not available.) This proportion is similar to the share of individuals in the Federal Employees Health Benefits Program who switch plans each year. Experience suggests that beneficiaries do not switch plans in great numbers for several reasons. Many beneficiaries are satisfied with their choice. In other cases, they may want to avoid the difficulties involved in comparing dozens of plan benefits that differ on many dimensions, such as cost-sharing requirements, formularies, utilization management, network of pharmacies, and quality of services. In the future, if beneficiaries are unwilling to switch, even when faced with significant premium increases, sponsors will have less of an incentive to compete on premiums and control drug spending.

Benefit structure

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 13-1). For 2012, the defined standard benefit includes a \$320 deductible and 25 percent coinsurance until the

**TABLE
13-2**

Over 70 percent of Medicare beneficiaries receive drug coverage through Part D plans or RDS, 2011

	Beneficiaries	
	In millions	Percent of Medicare enrollment
Medicare enrollment	48.9	100%
Part D enrollment		
Part D plans	29.3	60
Plans receiving RDS*	6.2	13
Total Part D	35.4	72

Note: RDS (retiree drug subsidy). 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.

Source: MedPAC based on Table III.A3 and Table IV.B8 of the Medicare Board of Trustees' report for 2011.

enrollee reaches \$2,930 in total covered drug spending. Enrollees exceeding that total 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. Enrollees with drug spending exceeding that amount pay the greater of either \$2.60 to \$6.50 per prescription or 5 percent coinsurance.

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), beginning in 2011, beneficiaries face reduced cost sharing for both brand-name and generic drugs in the coverage gap.² In 2012, the cost sharing for drugs filled during the gap phase is 50 percent for brand-name drugs and 86 percent for generic drugs.³ An individual with no other source of drug coverage reaches the \$4,700 limit at \$6,657.50 in total drug expenses (the sum of the enrollee's spending plus spending the Part D plan covers).⁴

Formularies

In Part D, each plan sponsor operates one or more formularies—lists of drugs the plans cover and the terms

under which they cover them—to manage the cost and use of prescription drugs. When designing formularies, sponsors strike a balance between providing enrollees with access to medications and controlling growth in drug spending, which they accomplish by negotiating drug prices and dispensing fees with pharmacies and rebates with pharmaceutical manufacturers and by managing enrollees' utilization. Part D sponsors rely on clinicians—generally physicians and pharmacists who participate on a pharmacy and therapeutics committee—when deciding which drugs to list. Sponsors also select the cost-sharing tier for each listed drug and whether any utilization management tools apply, taking into account clinical and financial factors (such as how tier-placement decisions might affect sponsors' rebates from drug manufacturers). Making all medications readily accessible at preferred (i.e., relatively low) levels of cost sharing can lead to a monthly plan premium that is high relative to a sponsor's competitors, whereas an overly restrictive formulary may keep a plan's premium competitive but may make the plan less attractive to potential enrollees because it covers a limited number of drugs.

Part D enrollees' access to prescription drug benefits in 2011

Implementation of the Part D program in 2006 increased the share of beneficiaries who have significant drug coverage from 75 percent before Part D to about 90 percent. In general, Medicare beneficiaries appear to have good access to prescription drugs. All individuals have access to dozens of Part D plan options, and many continue to receive drug coverage through former employers. Surveys indicate that beneficiaries enrolled in Part D are generally satisfied with the Part D program and with their plan (Department of Health and Human Services 2010, J.D. Power and Associates 2006, Keenan 2007, *Medical News Today* 2009, PRNewswire 2010, Weems 2008).

In 2011, over 70 percent of Medicare beneficiaries were in Part D plans or employer plans receiving retiree drug subsidy

In 2011, about 60 percent of an estimated 48.9 million Medicare beneficiaries were enrolled in Part D plans and about 13 percent had drug coverage through employer-sponsored plans that received Medicare's retiree drug subsidy (RDS) (Table 13-2).⁵ Some beneficiaries receive

their drug coverage through other sources of creditable coverage, including the Department of Veterans Affairs, TRICARE (the Department of Defense’s health benefit for retired military members), and other payers.⁶ In 2010, the most recent year for which data are available, about 10 percent of beneficiaries had no drug coverage or coverage less generous than Part D’s standard benefit. Research indicates that beneficiaries who do not enroll in Part D tend to have lower drug spending, better health, and lower risk scores (Heiss et al. 2006, Riley et al. 2009).

As of April 2011, about two-thirds (18.6 million) of Part D enrollees were in stand-alone prescription drug plans (PDPs), while the remaining one-third (10.7 million) were enrolled in Medicare Advantage–Prescription Drug plans (MA–PDs), which offer a combined benefit package of medical services and prescription drugs (Table 13-3).⁷ PDPs are required to be available region wide in 1 of 34 Medicare-designated PDP regions and can serve multiple regions, while MA–PDs can be local, operating on a county-wide basis, or region wide, serving in 1 of 26 MA regions.

Eighty percent of LIS enrollees are enrolled in stand-alone PDPs

In 2011, about 10.5 million individuals, or 36 percent of Part D enrollees, received the LIS. Of these enrollees, 6.4 million were dually eligible to receive Medicare and Medicaid. Another 4.3 million qualified for the LIS either because they received benefits through the Medicare Savings Program or Supplemental Security Income program or because they were determined eligible by the Social Security Administration after applying directly to that agency (Boards of Trustees 2011). Among LIS beneficiaries, 80 percent (8.3 million) were enrolled in PDPs and the rest (2.2 million) were in MA–PDs (Table 13-3). CMS randomly assigns most LIS beneficiaries to PDPs that qualify as premium-free plans unless the beneficiary chooses a plan that is different from the assigned plan. As a result, a much smaller share of LIS beneficiaries are enrolled in MA–PDs.

Distribution of enrollment varies across regions

Part D enrollment varies geographically. In 2009, enrollment ranged between 39 percent and 69 percent of Medicare beneficiaries across the 34 PDP regions (Table 13-4). Part D enrollment tends to be lower in states with large employers that receive Medicare’s RDS—in Michigan and Ohio, for example. In most regions,

**TABLE
13-3**

Part D enrollment by plan type and LIS status, 2011

	Plan type		
	All Part D	PDP	MA-PD
Beneficiaries (in millions)	29.3	18.6	10.7
By LIS status			
LIS	10.5	8.3	2.2
Non-LIS	18.8	10.3	8.5

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

Source: MedPAC based on monthly Part D enrollment data as of April 2011 (<https://www.cms.gov/MCRAdvPartDEnrolData/>).

Medicare beneficiaries received their drug coverage through Part D plans or through drug coverage provided by their former employers that receive the RDS. In region 5 (Delaware–District of Columbia–Maryland), region 7 (Virginia), and region 34 (Alaska), less than 65 percent of beneficiaries were in Part D plans or plans receiving the RDS. In these regions, a higher proportion of Medicare beneficiaries may have received drug coverage from other sources, such as the Federal Employees Health Benefits Program or the Indian Health Service.

Most beneficiaries have access to many PDPs and MA–PDs. In general, MA–PD enrollment is high in regions with higher MA penetration. For example, in 2009, more than 45 percent of Part D enrollees were in MA–PDs in parts of the West (Arizona, California, Colorado, Nevada), in Florida and Hawaii, and in parts of the Northeast (the Pennsylvania–West Virginia region). By comparison, in other parts of the Northeast, Midwest, and several South Central states, less than 20 percent of Part D enrollees are in MA–PDs.

The number of beneficiaries receiving Part D’s LIS also varies considerably by region. In 2009, the share of Part D enrollees receiving the LIS ranged from 27 percent in the upper Midwest and several central western states to 61 percent in Alaska (Table 13-4, p. 346). Participation in Part D’s LIS program is related to many factors, such as underlying rates of poverty and health status in each region, the degree to which a state’s Medicaid program reaches out to enroll eligible individuals, and the criteria

**TABLE
13-4**

Part D enrollment varies widely across regions, 2009

PDP region	State(s)	Percent of Part D enrollment					
		Percent of Medicare enrollment		Plan type		Subsidy status	
		Part D	RDS	PDP	MA-PD	LIS	Non-LIS
1	ME, NH	55%	13%	88%	12%	49%	51%
2	CT, MA, RI, VT	58	18	69	31	42	58
3	NY	59	19	57	43	46	54
4	NJ	53	22	81	19	35	65
5	DE, DC, MD	45	19	85	15	41	59
6	PA, WV	63	13	53	47	33	67
7	VA	52	11	80	20	38	62
8	NC	59	16	75	25	43	57
9	SC	54	16	79	21	45	55
10	GA	60	11	79	21	44	56
11	FL	60	13	54	46	34	66
12	AL, TN	62	12	67	33	47	53
13	MI	54	25	63	37	34	66
14	OH	54	25	65	35	36	64
15	IN, KY	56	18	83	17	41	59
16	WI	54	15	66	34	33	67
17	IL	55	19	87	13	38	62
18	MO	62	12	71	29	35	65
19	AR	61	9	83	17	45	55
20	MS	65	6	90	10	54	46
21	LA	62	13	67	33	49	51
22	TX	57	15	71	29	45	55
23	OK	60	8	80	20	38	62
24	KS	61	7	85	15	29	71
25	IA, MN, MT, NE, ND, SD, WY	66	9	74	26	27	73
26	NM	62	8	63	37	39	61
27	CO	59	13	49	51	29	71
28	AZ	61	12	43	57	31	69
29	NV	56	13	47	53	28	72
30	OR, WA	57	11	60	40	31	69
31	ID, UT	57	11	59	41	28	72
32	CA	69	10	52	48	39	61
33	HI	66	4	48	52	29	71
34	AK	39	25	97	3	61	39

Note: PDP (prescription drug plan), RDS (retiree drug subsidy), MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy). Definition of regions based on PDP regions used in Part D.

Source: MedPAC analysis of Part D enrollment data from CMS.

states use to determine eligibility for their Medicaid programs. For example, states can increase the number of residents eligible for the Medicare Savings Program by not counting certain types of assets or sources of income in their eligibility criteria for Medicaid benefits.

Distribution of enrollment across plan types

Access to prescription drugs can be affected by the type of plan one chooses. 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

**TABLE
13-5****MA-PD enrollees more likely to be in enhanced plans with no deductible, 2011**

	PDP		MA-PD	
	Number (in millions)	Percent	Number (in millions)	Percent
Total	17.0	100%	8.6	100%
Type of benefit				
Defined standard	1.3	8	0.1	1
Actuarially equivalent*	12.6	74	0.6	7
Enhanced	3.0	18	7.9	92
Type of deductible				
Zero	7.3	43	7.8	91
Reduced	2.1	13	0.5	6
Defined standard**	7.6	45	0.2	3

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). The 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 2011.

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

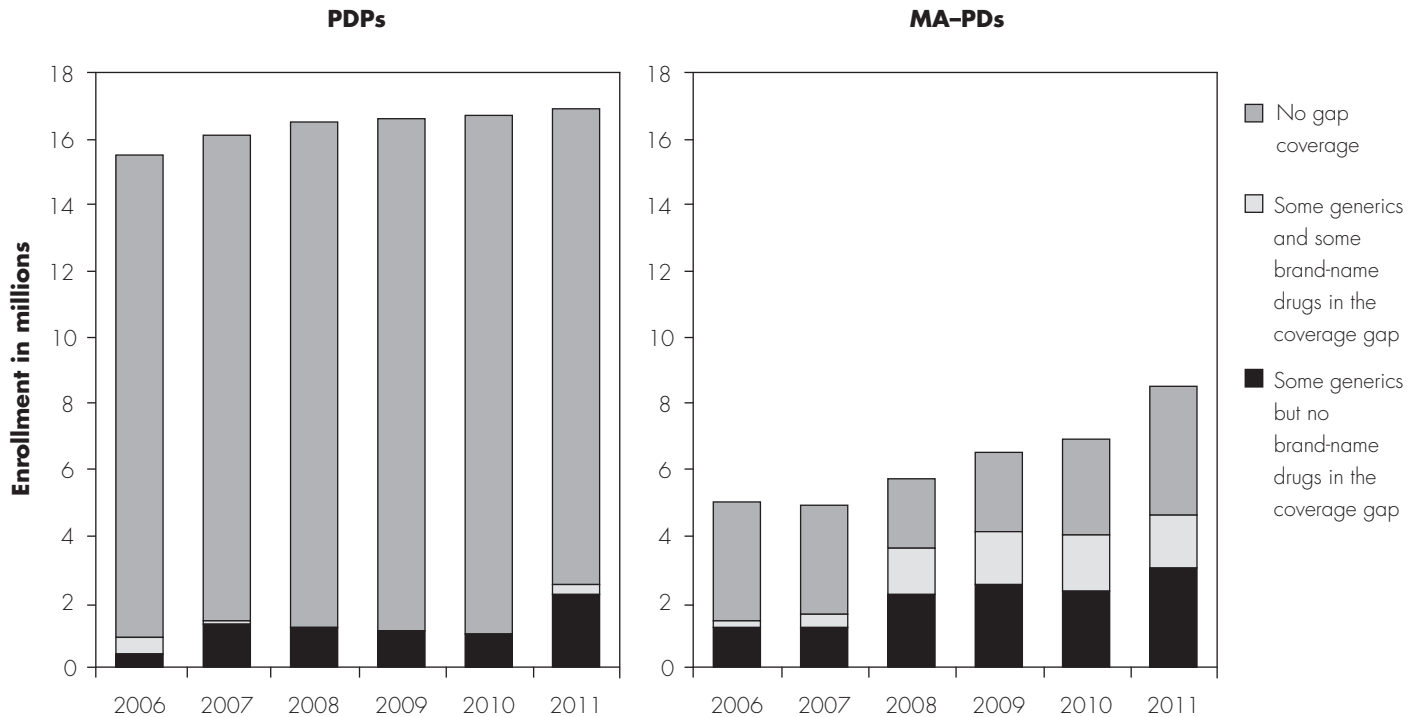
or are enhanced in some way. Actuarially equivalent plans have the same average benefit value as defined standard plans but a different benefit structure (both actuarially equivalent and defined standard plans are referred to as basic benefits).⁸ For example, a plan may use tiered copays (e.g., charging \$7 per generic prescription 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 sponsor offers at least one stand-alone PDP with basic benefits in a PDP region, it may also offer a plan with enhanced benefits—basic and supplemental benefits combined, with a higher average benefit value—by including, for example, lower cost sharing, coverage in the gap, and an expanded drug formulary that includes non-Part D-covered drugs.⁹ Since Medicare does not subsidize supplemental benefits, enrollees must pay the full premium for any additional coverage.

In 2011, 74 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copays. Another 18 percent of PDP enrollees had enhanced benefits—the typical enhancement being a lower deductible rather than benefits in the coverage gap.¹⁰ Eight percent were

in defined standard plans. MA-PD enrollees were predominantly in plans that used copayments, with 99 percent in actuarially equivalent or enhanced plans (Table 13-5).

Enrollees in stand-alone PDPs are more likely to have a deductible in their plans' benefit design than enrollees in MA-PDs. In 2011, slightly more than half of PDP enrollees paid no deductible or a lower deductible than was prescribed in the defined standard benefit; the remaining enrollees were in plans with the standard \$310 deductible. By comparison, 97 percent of MA-PD enrollees had a reduced deductible or no deductible at all (Table 13-5), which reflects the ability of MA-PDs to use MA (Part C) rebate dollars to supplement benefits or lower premiums.¹¹

The ability of MA-PDs to use Part C rebate dollars to enhance their Part D benefits affects the difference between PDPs and MA-PDs in their availability to offer benefits in the coverage gap (Figure 13-1, p. 348). In 2011, 15 percent of PDP enrollees (about 2.5 million beneficiaries) were in plans that offered benefits in the coverage gap, usually for generic drugs rather than brand-name drugs. However, nearly 45 percent of PDP enrollees received Part D's LIS, which effectively eliminated their coverage gap. By comparison, 54

**FIGURE
13-1****PDP enrollees are less likely to have benefits in the coverage gap**

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

Source: MedPAC analysis of CMS landscape and enrollment data.

percent of MA-PD enrollees (about 4.7 million beneficiaries) were in plans offering gap coverage. About two-thirds of these enrollees were in plans that covered generic but not brand-name drugs.

Use of Part D benefits and share of enrollees reaching the coverage gap

Prescription drugs are used widely by Medicare beneficiaries. Based on the Commission's analysis of 2009 prescription drug event (PDE) data taken from Part D claims, 92 percent of Part D enrollees filled at least one prescription during the year. Enrollees filled an average of 4.1 prescriptions per month, with considerably higher average utilization among those who received the LIS (5.0 per month) than among beneficiaries who did not (3.6 per month) (see section on per capita spending and use, p. 357). As mentioned above, most LIS enrollees are in PDPs that are less likely to offer supplemental benefits, such as coverage in the gap. However, the extra help with cost sharing provided by the low-income cost-sharing subsidy limits their OOP spending and effectively eliminates the coverage gap for LIS enrollees.

In 2009, the share of Part D enrollees with spending that was high enough to put them in the coverage gap remained stable at around 30 percent of enrollees (Figure 13-2).¹² In that year, most non-LIS enrollees faced 100 percent of the plan's negotiated cost of the drug for prescriptions filled in the coverage gap, unless they were in a plan that provided some benefits in the gap. LIS enrollees, for whom the gap is eliminated, accounted for more than half of the enrollees with spending high enough to reach the coverage gap (nearly 4.7 million, or about 16 percent of all Part D enrollees). About 2.4 million, or 8 percent of Part D enrollees, had spending high enough to reach Part D's catastrophic coverage phase. Of these 2.4 million individuals, about 2 million (7 percent of Part D enrollees) received the LIS.

Benefit offerings for 2012

Beneficiaries will continue to have many choices of Part D plans in each region. However, each year, a subset of

beneficiaries are affected by the entry and exit of plans resulting from decisions by plan sponsors or CMS not to renew contracts. Changes in business strategies also affect plan benefits that are available in a given region.

Number of plans remains relatively stable in 2012

In 2012, the total number of stand-alone PDPs has declined slightly (6 percent)—1,041 compared with 1,109 in 2011, while the number of MA-PDs has increased by 2 percent—1,541 compared with 1,506 in 2011 (Figure 13-3).¹³ Although the number of plans offered has fluctuated over the years, there was a significant reduction in the number of PDPs between 2010 and 2011. That reduction was primarily the result of CMS’s policy intended to differentiate more clearly between basic and enhanced benefit plans and a policy discouraging plans with low enrollment. That reduction in the number of plans does not appear to have affected beneficiaries’ access to Part D plans.¹⁴ The number of PDPs available remained relatively stable between 2011 and 2012. In 2012, Medicare beneficiaries continue to have many plans to choose from, ranging from 25 PDP options in Hawaii and Alaska to 36 PDP options in the Pennsylvania–West Virginia region, along with many (sometimes dozens of) MA-PDs. The number of MA-PDs available to a beneficiary varies by the county of residence.

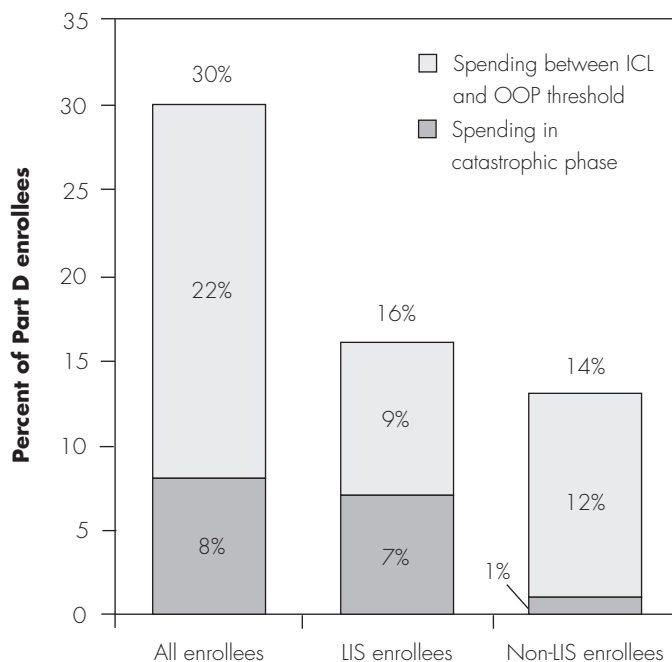
In 2012, 327 PDPs are available to LIS enrollees at no premium, compared with 332 in 2011 (Figure 13-3, p. 350). Most regions continue to have many premium-free plans available. However, in two regions, only a handful of premium-free plans are available (three plans in Florida and two plans in Nevada). As of December 2011, about 2.5 million LIS enrollees were expected to be in plans that do not qualify as premium-free in 2012.¹⁵ CMS estimates that it will have reassigned 700,000 LIS enrollees to different plans because their previous plan’s premium no longer falls below the 2012 threshold.¹⁶ LIS enrollees who selected a plan that differed from their randomly assigned plan have not been reassigned.

Notable changes for 2012 in benefit design

Beneficiaries are encouraged to reexamine their options from time to time. In addition to the annual change in plan availability and premiums charged, most plans make some changes annually to their benefit offerings—such as deductible amounts and plan formularies that can have a direct effect on access to and affordability of medications.

FIGURE 13-2

Part D enrollees with spending in the coverage gap and catastrophic phase, 2009



Note: ICL (Initial coverage limit), LIS (low-income subsidy). For LIS enrollees, the cost-sharing subsidy effectively eliminates the coverage gap. In 2009, Part D enrollees reached the ICL at \$2,700 in gross drug spending. If they had no supplemental coverage, an enrollee reached the annual out-of-pocket (OOP) threshold at \$4,350 of OOP spending. Some non-LIS enrollees who reached the catastrophic phase of the benefit may have had some gap coverage. Sums may not add to totals due to rounding.

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

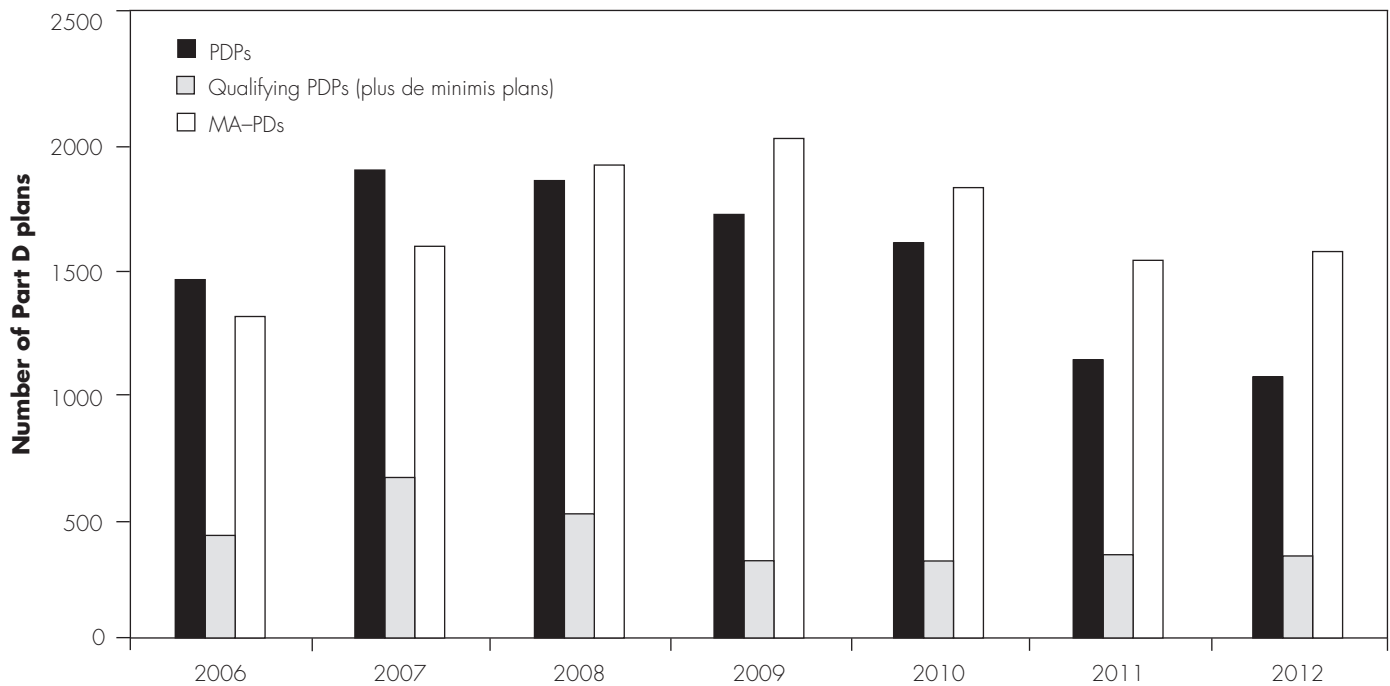
Benefit designs

For the 2012 benefit year, the structure of drug benefits for both stand-alone PDPs and MA-PDs held fairly steady. As in previous years, a smaller share of PDPs have no deductible (47 percent) compared with MA-PDs (89 percent). More than half of PDPs continue to charge a deductible in 2012, with most charging the defined standard amount (\$320) (Table 13-6, p. 350).

In 2012, a smaller percentage of PDPs provide gap coverage than in 2011 (Figure 13-4, p. 351).⁹ In 2011, 33 percent of PDPs included some gap coverage—usually some or all generic drugs but no brand-name medications. For 2012, that share declined to 26 percent. By contrast, the share of MA-PDs with gap coverage held steady at about 50 percent in 2012. The extent of coverage in the gap varies from plan to plan. For example, gap coverage

**FIGURE
13-3**

Part D plans remain stable, but slightly fewer premium-free plans for LIS beneficiaries in 2012



Note: LIS (low-income subsidy), PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). Qualifying PDPs are plans for which 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 from the regional LIS premium threshold.

Source: CMS landscape and plan report files.

**TABLE
13-6**

PDPs are more likely to have a deductible, 2012

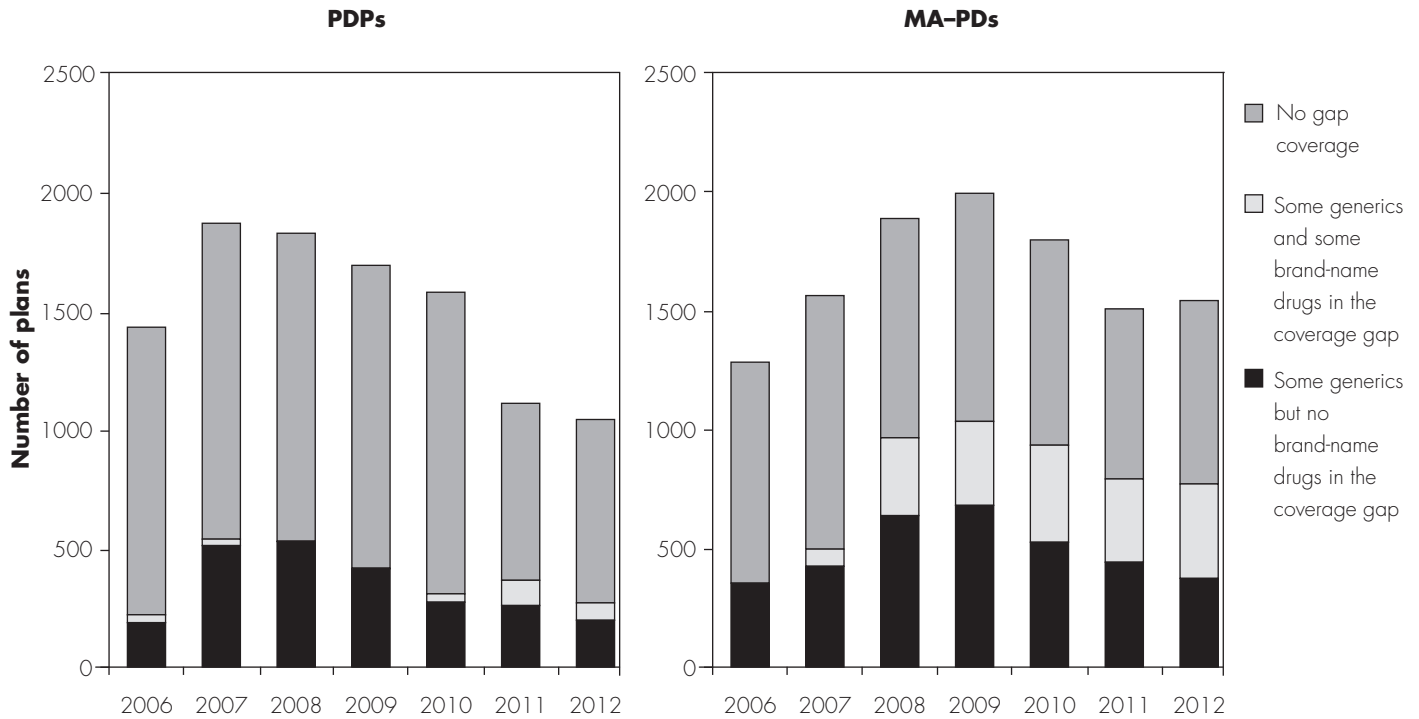
	PDP		MA-PD	
	Number	Percent	Number	Percent
Total	1,041	100%	1,541	100%
Type of benefit				
Defined standard	95	9	37	2
Actuarially equivalent*	446	43	86	6
Enhanced	500	48	1,418	92
Type of deductible				
Zero	488	47	1,372	89
Reduced	108	10	98	6
Defined standard**	445	43	71	5

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-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. Figures are not weighted by enrollment. Totals may not sum due to rounding.

*Includes "actuarially equivalent standard" and "basic alternative" benefits.

**\$310 in 2011.

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

**FIGURE
13-4****MA-PDs are more likely than PDPs to offer benefits in the coverage gap**

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage–Prescription Drug [plan]). Figures are not weighted by enrollment.

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

offered by some plans includes less than 10 percent of generic drugs on the formulary. The share of PDPs that cover brand-name drugs in the coverage gap continues to be small, with only 7 percent covering any brand-name drugs in 2012.

The changes made by PPACA will make supplemental benefits to provide coverage during the gap less important over time, as the gradual phase-out of the coverage gap will be completed by 2020. Beginning in 2011, the manufacturer’s discount for brand-name drugs reduced cost sharing in the coverage gap from 100 percent to 50 percent of the negotiated prices. For generic drugs, beneficiaries paid 93 percent coinsurance. In 2012, beneficiaries are seeing a further reduction (from 93 percent to 86 percent) in their cost sharing for generic drugs filled during the gap.

Plan formularies

Under contract with the Commission, researchers at NORC at the University of Chicago, Georgetown

University, and Social & Scientific Systems analyzed Part D formulary data for 2012. CMS generally requires that plan formularies include at least two drugs in each therapeutic category and class unless only one drug is available. 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 number of drugs that sponsors list on a formulary is one way to measure beneficiaries’ access to prescription drugs under Part D. A plan’s use of utilization management tools—such as its processes for nonformulary exceptions, prior authorization, quantity limits, and step therapy requirements—is another way to measure access.¹⁷ For example, in some cases unlisted drugs are covered through the nonformulary exceptions process, which is relatively easy with some plan sponsors and more burdensome with others.

**TABLE
13-7**

Formularies for stand-alone PDPs with highest 2011 enrollment

Stand-alone PDPs with the highest 2011 enrollment	Enrollment, 2011 (in millions)	Percent of drugs on formulary		Percent of formulary drugs with any utilization management*	
		2011	2012	2011	2012
AARP MedicareRx Preferred	4.7	94%	92%	27%	34%
Community CCRx Basic	1.7	76	76	41	46
Humana PDP Enhanced	1.4	94	91	35	41
CVS Caremark Value	1.3	75	75	41	45
First Health Premier	1.0	83	83	36	39
Humana-Walmart	1.0	85	84	33	40
WellCare Classic	0.7	69	70	27	30

Note: PDP (prescription drug plan). Enrollment figures are based on September 2011 and exclude employer plans and territories. The number of drugs on the formulary for 2011 is 1,168; for 2012, the number is 1,180.

*Any utilization management includes the use of prior authorization, quantity limit, and step therapy requirements.

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

For the seven largest PDPs, which accounted for about two-thirds of the enrollment in stand-alone PDPs in 2011, the shares of all distinct chemical entities (drugs) listed on their formularies remained stable or saw modest changes between 2011 and 2012 (Table 13-7). Among the top seven PDPs, three plans—AARP MedicareRx Preferred, Humana PDP Enhanced, and Humana Walmart-Preferred—saw a small decrease in the share of drugs listed in 2012. Although the shares remained stable for the other four plans, the actual number of drugs listed on the formulary increased between 2011 and 2012 for three plans because the number of distinct chemical entities listed on CMS’s formulary reference files also increased between 2011 and 2012.

The use of utilization management tools in Part D—including quantity limits, step therapy, and prior authorization—has grown in the past few years. Sponsors use such tools for drugs that are expensive, potentially risky, or subject to abuse, misuse, and experimental use. They are also often used to encourage the use of lower cost therapies. For 2012, the top seven stand-alone PDPs increased the share of drugs on plan formularies with some type of utilization management. The increase ranged from 3 to 7 percentage points for the seven plans and averaged about 5 percentage points across all PDPs. Among the top seven plans, two plans—Community CCRx Basic and CVS Caremark

Value—continue to have the highest share of drugs with utilization management in 2012.

Costs of Part D

To monitor Part D’s costs, we examine aggregate program spending, trends in plans’ bid amounts and enrollees’ premiums, plans’ cost-sharing requirements, per capita spending, and trends in the prices at the pharmacy counter. Spending for beneficiaries with high drug costs is driving some components of Part D spending to grow more rapidly than others.

Aggregate program costs

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

- Direct subsidy—Medicare makes a monthly payment to plans set as a share of the national average bid for Part D basic benefits, adjusted for the risk of the individual enrollee.
- Reinsurance—Medicare subsidizes 80 percent of drug spending above an enrollee’s annual OOP threshold. Reinsurance reduces risk for Part D sponsors by providing greater federal subsidies for the highest cost enrollees.

**TABLE
13-8**

Medicare’s reimbursement amounts for Part D on an incurred basis

	Calendar year						Average annual percent change 2007–2011
	2006	2007	2008	2009	2010	2011*	
In billions of dollars							
Direct subsidy	\$17.6	\$18.1	\$17.7	\$18.9	\$19.7	\$20.0	2.6%
Reinsurance	6.0	8.0	9.4	10.1	11.3	12.8	12.5
Low-income subsidy	15.1	16.8	18.0	19.6	21.0	22.4	7.5
Retiree drug subsidy	3.8	3.9	3.8	3.8	4.0	4.0	0.7
Total	\$42.5	\$46.7	\$48.9	\$52.4	\$56.1	\$59.2	6.1

Note: The numbers above reflect reconciliation amounts. Most enrollees paid premiums directly to Part D plans and those amounts are not included above. On a cash basis, the Board of Trustees estimates that premiums paid by enrollees totaled \$3.5 billion in 2006, \$4 billion in 2007, \$5 billion in 2008, \$6.1 billion in 2009, \$6.6 billion in 2010, and \$7.2 billion in 2011. Totals may not sum due to rounding.
*Estimated.

Source: MedPAC based on Table IV.B.10 of the Medicare Board of Trustees’ report for 2011.

- LIS—Medicare pays the plan to cover expected cost sharing and premiums for enrollees eligible for the subsidy.

Direct and reinsurance subsidies combined cover 74.5 percent of the cost of basic Part D benefits, on average. In addition to these subsidies, Medicare establishes symmetric risk corridors separately for each plan to limit a plan’s overall losses or profits. Under risk corridors, Medicare limits plans’ potential losses and gains by financing a portion of any higher than expected costs or by recouping a portion of higher than expected profits.

Low-income subsidy continues to be the largest share of Part D costs

Between 2006 and 2010, incurred reimbursements for Part D (including spending for the RDS) grew from \$42.5 billion to \$56.1 billion (Table 13-8). In 2010, the total was made up of \$19.7 billion in direct subsidy payments to plans, \$11.3 billion in payments for individual reinsurance, \$21 billion for the LIS, and \$4 billion in RDS payments. CMS’s Office of the Actuary estimated that Part D spending would be about \$59 billion in 2011 (Boards of Trustees 2011).

In 2010, the LIS continued to be the largest component of Part D spending. Moreover, substantial portions of other categories were spent on behalf of LIS enrollees. Although less than 40 percent of Part D enrollees receive the LIS, these individuals tend to use more medications

than non-LIS enrollees, and so disproportionate shares of spending for the direct subsidy and for individual reinsurance also reflect benefits for LIS enrollees.

Medicare payments for individual reinsurance have grown considerably faster than other components of Part D spending. Multiple factors likely contribute to the growth in reinsurance spending, such as filling more prescriptions and/or using higher priced products that have few, or no, therapeutic substitutes. Our analysis of the drug spending and utilization for Part D enrollees with spending high enough to reach the catastrophic phase of the benefit shows that the growth in reinsurance spending has been driven by the volume of prescriptions filled by these enrollees and by their tendency to use more brand-name medications than enrollees who do not incur high drug spending. Many of the therapies used by beneficiaries who reach the catastrophic phase of the benefit are in therapeutic classes that have generic alternatives that would cost significantly less than their brand-name counterparts (see text box, pp. 354–355). Our analysis of enrollees with high drug spending suggests ways to reduce Medicare spending for reinsurance without substantially affecting access to needed medications.

National average bid

Between 2011 and 2012, national average benefit costs for basic Part D benefits are projected to decrease by 4 percent. During this period, the direct subsidy component

Beneficiaries with high drug spending under Part D

In 2009, about 2.4 million individuals, or about 8 percent of Part D enrollees, incurred spending high enough to reach the catastrophic phase of the benefit (high-cost enrollees). Those enrollees accounted for nearly 40 percent of total spending for drugs covered under Part D. Most were enrolled in stand-alone prescription drug plans. Compared with other Part D enrollees, high-cost enrollees were more likely to receive Part D's low-income subsidy (LIS) and to reside in an institution (Table 13-9). They were also more likely to be disabled beneficiaries under age 65 (data not shown).

In our analysis of Part D prescription drug event data for 2009—the most recent year available—we find that high-cost enrollees fill more prescriptions, on average, and the cost of each prescription tends to be higher compared with non-high-cost enrollees. In 2009, high-

**TABLE
13-9**

Characteristics of Part D enrollees with high drug spending, 2009

	Type of enrollees	
	High cost	Non high cost
Enrollees (in millions)	2.4	26.3
By plan type		
PDP	86%	63%
MA-PD	14	37
By subsidy status		
LIS	83%	34%
Non-LIS	17	66
By institutionalized status		
Institutionalized	14%	4%
Community	86	96

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy). Totals may not sum to 100 percent due to rounding. A beneficiary is classified as LIS if that individual received Part D's LIS at some point during the year. For individuals who switch plan types during the year, classification into plan types is based on a greater number of months of enrollment.

Source: MedPAC analysis of Medicare Part D denominator file and MBD/CMS Medicare Entitlement file.

**TABLE
13-10**

Part D spending and utilization by high-cost and non-high-cost enrollees, 2009

	Type of enrollees	
	High cost	Non high cost
Enrollees (in millions)	2.4	26.3
Aggregate utilization		
Gross drug spending* (in billions)	\$29.2	\$44.6
Prescriptions (in millions)	264	1,074
Average prescriptions per enrollee	111	41
Average spending per prescription	\$110	\$42

Note: Prescriptions standardized to a 30-day supply. Components may not sum to totals due to rounding. We also calculated the drug spending and utilization excluding enrollees residing in institutions. Excluding the institutionalized enrollees did not substantially change the results. *Gross drug spending includes all payments made to pharmacies by Part D plans, enrollees, and other payers for the costs of drugs, dispensing fees, and sales tax.

Source: MedPAC analysis of 2009 Part D prescription drug event data and MBD/CMS Medicare Entitlement file.

cost enrollees filled, on average, 111 prescriptions at \$110 per prescription compared with 41 prescriptions at \$42 per prescription for other Part D enrollees (Table 13-10). That is, they filled, on average, more than nine prescriptions per month compared with about four prescriptions for other enrollees, and the cost of each prescription was more than double that of non-high-cost beneficiaries.

Of the \$29 billion spent on prescription drugs filled by high-cost enrollees, 10 therapeutic classes accounted for slightly more than 60 percent of the total. Eight of the top 10 therapeutic classes coincided with those that are most heavily used by non-high-cost beneficiaries. Although high-cost beneficiaries use many drugs commonly used by non-high-cost enrollees, they tended to use more brand-name drugs than other enrollees.

In 2009, 42 percent of prescriptions filled by high-cost enrollees were for brand-name drugs compared with 26 percent for other enrollees (Table 13-11).

Beneficiaries with high drug spending under Part D (cont.)

Some of the difference likely reflects differences in the health status and the mix of drugs taken by high-cost enrollees, but there were some notable differences within a given therapeutic class. For example, among diabetic therapies, brand-name drugs accounted for 62 percent of the prescriptions filled by high-cost enrollees compared with 33 percent for non-high-cost enrollees. Similarly, among the antihyperlipidemics, used to treat high cholesterol, brand-name drugs accounted for 58 percent of prescriptions filled by high-cost enrollees compared with 36 percent for other enrollees.

Although health status may explain the need for some of the brand-name medications, financial incentives may also affect the choice of brand-name drugs over generic drugs. Most high-cost enrollees receive Part D's low-income cost-sharing subsidy that pays for cost-sharing amounts above the statutorily set copayment. This subsidy may limit how well plan sponsors can manage the drug spending for those individuals. Our findings suggest that a change in the LIS cost-sharing structure has the potential to reduce program spending without substantially affecting access to needed medications. ■

**TABLE
13-11**

Use of brand-name drugs by high-cost and non-high-cost enrollees for selected drug classes, 2009

Percent of prescriptions represented by brand-name drugs, by type of enrollees

	High cost	Non high cost
Diabetic therapy	62%	33%
Asthma/COPD therapy agents	90	91
Analgesics (narcotic)	14	5
Peptic ulcer therapy	44	25
Antihyperlipidemics	58	36
Antihypertensive therapy agents	38	26
Total, all therapeutic classes	42	26

Note: COPD (chronic obstructive pulmonary disease). Shares are calculated as a percent of all prescriptions standardized to a 30-day supply. Therapeutic classification based on the First DataBank Enhanced Therapeutic Classification System 1.0.

Source: MedPAC analysis of 2009 Part D prescription drug event data.

of Part D benefit spending is projected to decrease by 2 percent, while the reinsurance component is expected to decrease by 6 percent (Table 13-12, p. 356). The drop in the expected costs by plan sponsors likely reflects the entry of generic drugs for some of the top-selling brand-name drugs most widely used by Medicare beneficiaries.¹⁸

Growth in per capita benefit cost for Part D has fluctuated over the years. We saw a significant drop between 2006 and 2007 primarily due to many sponsors bidding too high in the first year of the program.¹⁹ The expected benefit costs grew by 9 percent between 2008 and 2009 and by 5 percent between 2009 and 2010. For 2011, the expected costs remained about the same as in 2010, growing by only 1 percent, while actual spending is expected to grow by 5.7 percent (Table 13-8 and Table 13-12). Although year-to-year trends in the national average bid provide information about costs of the drug benefit, those trends are an imperfect measure of spending. Since bids are

projections of sponsors' estimated costs, not actual costs, reconciliation at the end of the year could result in a higher or lower trend in spending for Part D.

Average Part D premiums

In 2012, the base beneficiary premium is \$31.08, a 4 percent decrease from \$32.34 in 2011. Since premiums vary widely across plans, the actual average monthly premium depends on the beneficiary's choice of plans. The base beneficiary premium reflects the basic portion of the benefit (the portion that does not include premiums for enhanced, or supplemental, benefits), and the actual premium paid by individual beneficiaries is higher or lower depending on their selected plan's bid (Medicare Payment Advisory Commission 2011c).

In the past, the Commission has calculated the expected average Part D premiums as well as the expected increase or decrease in premiums for the coming year using the

**TABLE
13-12**

National average bid and components of average prospective monthly payments per enrollee for basic coverage

	2006 ^a	2007 ^b	2008 ^c	2009 ^d	2010 ^d	2011 ^d	2012 ^d
Amounts in dollars							
National average monthly bid							
Base beneficiary premium	\$32.20	\$27.35	\$27.93	\$30.36	\$31.94	\$32.34	\$31.08
Monthly payment to sponsors	60.10	53.08	52.59	53.97	56.39	54.71	53.42
Subtotal	92.30	80.43	80.52	84.33	88.33	87.05	84.50
Expected individual reinsurance	<u>33.98</u>	<u>26.82</u>	<u>29.01</u>	<u>34.73</u>	<u>36.92</u>	<u>39.77</u>	<u>37.38</u>
Total average benefit cost	126.28	107.25	109.53	119.06	125.25	126.82	121.88
Annual percent change							
National average monthly bid							
Base beneficiary premium	N/A	-15%	2%	9%	5%	1%	-4%
Monthly payment to sponsors	N/A	-12	-1	3	4	-3	-2
Subtotal	N/A	-13	0	5	5	-1	-3
Expected individual reinsurance	N/A	-21	8	20	6	8	-6
Total average benefit cost	N/A	-15	2	9	5	1	-4

Note: These amounts reflect averages based on bids to provide basic Part D benefits; they do not net out subsequent reconciliation amounts with CMS. They were calculated from bids by plans to provide the defined standard benefit or actuarially equivalent basic benefits, as well as the portion of enhanced Part D coverage attributable to basic benefits. Enrollees in plans with enhanced coverage must pay the full price of benefits that supplement basic coverage. The combination of monthly payments to plans and expected payments for individual reinsurance make up 74.5 percent of total average monthly benefit costs.

a. Since Part D began in 2006, Medicare law directed CMS to weight the bids of stand-alone drug plans equally (with an aggregate weight representing enrollment in traditional Medicare) and weight bids from Medicare Advantage (MA) drug plans by their prior-year MA enrollment.

b. CMS used its general demonstration authority to calculate these values using 20 percent enrollment weighting and 80 percent weighting as in the 2006 approach.

c. CMS used its general demonstration authority to calculate these values using 60 percent enrollment weighting and 40 percent weighting as in the 2006 approach.

d. Bids are fully weighted by prior-year enrollment as called for by law.

Source: MedPAC based on CMS releases of Part D national average monthly bid amounts and base beneficiary premiums for 2006 through 2012, as well as other data provided by CMS.

current year enrollment. We have not calculated the expected average premiums for 2012, as they would be sensitive to the assumptions we make about beneficiary switching. During the first few years of the program, a relatively small share (around 6 percent) of enrollees switched plans in any given year. However, that figure has not been updated for several years.

As a result of changes made in PPACA, the premium subsidy for higher income beneficiaries is lower than the statutorily defined subsidy of 74.5 percent. Similar to the income-related premium for Part B, the reduced subsidy applies to individuals with an annual adjusted gross income greater than \$85,000 and to couples with an adjusted gross income greater than \$170,000. In 2011, about 885,000 beneficiaries were subject to the reduced premium subsidy.²⁰

Plans' cost-sharing requirements

Cost-sharing requirements have generally been rising over the past few years. In 2012, cost-sharing requirements for the top seven stand-alone PDPs based on enrollment in 2011 saw some modest changes that tended to increase the difference in cost-sharing amounts between tiers (Table 13-13). For example, of the top seven plans, three plans (AARP MedicareRx Preferred, Community CCRx Basic, and Humana PDP Enhanced) lowered cost sharing for preferred brand-name drugs, and two plans (AARP MedicareRx Preferred and WellCare Classic) increased cost sharing for nonpreferred brand-name drugs, widening the difference in cost-sharing amounts between preferred and nonpreferred brand tiers. Two plans, First Health Premier and Humana Walmart-Preferred, lowered cost-sharing amounts for generic drugs (the reduction was for preferred generic drugs for Humana Walmart-Preferred).

**TABLE
13-13**

Cost-sharing amounts for stand-alone PDPs with highest 2011 enrollment

Stand-alone PDPs with the highest 2011 enrollment	Enrollment, 2011 (in millions)	Generic		Preferred brand		Nonpreferred brand		Specialty	
		2011	2012	2011	2012	2011	2012	2011	2012
AARP MedicareRx Preferred*	4.7	\$7	\$4/\$8	\$45	\$41	\$79	\$95	33%	33%
Community CCRx Basic	1.7	2	2	31%	25%	60%	46%	25	25
Humana PDP Enhanced	1.4	7	7	\$39	\$38	\$73	\$73	33	33
CVS Caremark Value	1.3	5	6	\$39.75	\$45	\$95	\$95	25	25
First Health Premier	1.0	8	5	17%	20%	36%	36%	29	26
Humana Walmart-Preferred*	1.0	2/5	1/5	20%	20%	35%	35%	N/A	N/A
WellCare Classic	0.7	0	0	\$42	\$41	\$92	\$95	25	25

Note: PDP (prescription drug plan), N/A (not applicable). Enrollment figures are based on September 2011 and exclude employer plans and territories. In cases where plans vary cost-sharing amounts across regions, we report unweighted median cost-sharing amounts.

*Indicates plans with two tiers, preferred and nonpreferred, for generic drugs in 2011 and/or 2012.

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

CVS Caremark Value increased its cost sharing for generic drugs to \$6 from \$5 in 2011, but since the plan also increased the cost sharing for preferred brand-name drugs by about \$5, the difference in cost-sharing amounts between generic and preferred brand-name tiers is wider than in 2011.

For 2012, coinsurance for drugs on a specialty tier remains flat for most of the top seven plans. One exception is First Health Premier, which reduced the coinsurance for drugs on the specialty tier to 26 percent from 29 percent in 2011. Humana Walmart-Preferred, a plan that entered the market in 2011, does not have a specialty tier.

From an enrollee’s perspective, cost-sharing requirements for specialty-tier drugs can be high until the enrollee reaches Part D’s catastrophic spending limit. In addition, under CMS’s regulations, enrollees may not appeal specialty-tier cost sharing as they can for other drugs, such as those on tiers for nonpreferred brands. Because drugs on specialty tiers are often used to treat serious chronic illnesses, such as rheumatoid arthritis and multiple sclerosis, patients who need these drugs can face relatively high cost sharing for medications on top of significant OOP costs for their medical care. From a sponsor’s perspective, high-cost drugs may be used more widely than the evidence of their effectiveness supports, and higher coinsurance may temper their use. Some sponsors may use a specialty tier if most of their competitors also use one to limit the risk of attracting enrollees who take very expensive drugs.

Per capita spending and use

Under the Part D program, payments to plans are based on the average of the bids plan sponsors submit to CMS each year. The bids are intended to reflect the expected costs for a Medicare beneficiary of average health; CMS adjusts payments to plans based on the actual health status of the plans’ enrollees.

Between 2007 and 2009, the average per capita spending for Part D–covered drugs for MA–PD enrollees has been consistently lower than for stand-alone PDP enrollees by about \$90 per member per month. The average per capita spending for LIS enrollees has been about double that of non-LIS enrollees, with the difference between the two groups growing over time (Table 13-14, p. 358).

Growth in average per capita spending between 2007 and 2009 shows that spending for non-LIS enrollees remained relatively stable (2.2 percent) compared with LIS enrollees (6.1 percent). Some of the difference in per capita spending growth between LIS and non-LIS enrollees is due to higher growth in the average number of prescriptions filled by LIS enrollees (4.3 percent compared with 3.3 percent for non-LIS enrollees). Although the growth in per capita drug spending among MA–PD enrollees was greater than for stand-alone PDP enrollees (5.8 percent compared with 4.3 percent), the average growth was lower for MA–PD enrollees in terms of the dollar increase (\$9 compared with \$11).

**TABLE
13-14**

Average per capita spending and use per month for Part D-covered drugs, 2007-2009

Part D spending and utilization per enrollee

	Average spending			Average annual change, 2007-2009		Average prescription use			Average annual percent change, 2007-2009
	2007	2008	2009	In dollars	In percent	2007	2008	2009	
All Part D	\$212	\$221	\$228	\$8	3.6%	3.9	4.1	4.1	2.8%
By plan type									
PDP	239	250	260	11	4.3	4.1	4.3	4.4	2.8
MA-PD	151	162	169	9	5.8	3.4	3.6	3.7	4.1
By LIS status									
LIS	301	324	339	19	6.1	4.6	4.9	5.0	4.3
Non-LIS	156	159	163	3	2.2	3.4	3.6	3.6	3.3

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy). Part D prescription drug event (PDE) records are classified into plan types based on the contract identification on each record. For purposes of classifying the 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. Gross drug spending includes all payments to pharmacies, including payments by drug plans, Medicare's LIS, and beneficiary out-of-pocket. Prescriptions standardized to a 30-day supply.

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

Part D drug prices

Most plan sponsors do not negotiate drug prices directly with pharmaceutical manufacturers. Instead, sponsors engage in two separate negotiations:

- The first involves pharmacies or a network of pharmacies over the prices the plan will pay the pharmacy for drug ingredient costs and dispensing fees.
- The second involves the terms under which manufacturers pay retrospective rebates.

Plan sponsors tend to use rebate revenues to offset plans' benefit spending (reducing plan premiums) rather than lowering the price of prescriptions at the pharmacy counter. As a result, drug prices measured in this section are not affected by the outcomes of the second negotiations.

Part D plan sponsors have had mixed success at influencing drug prices. They have been quite successful at encouraging enrollees to use generic alternatives when available (Congressional Budget Office 2010, Office of Inspector General 2007). Plan sponsors regularly use cost-sharing differentials to encourage enrollees to use generic drugs and negotiate rebates from manufacturers for brand-name drugs that have therapeutic alternatives.

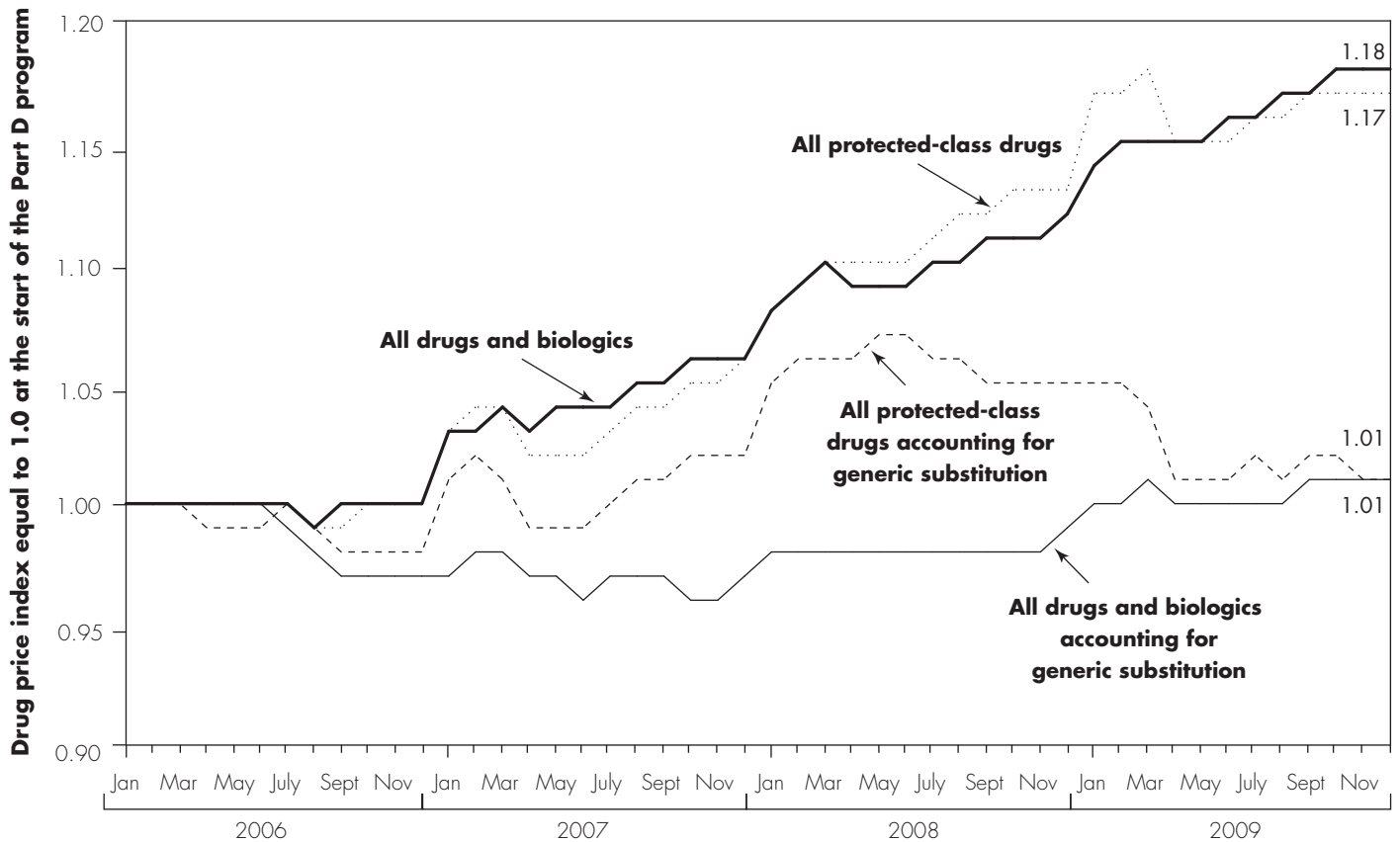
But sponsors have had less success negotiating rebates for unique drug and biologic products.

To track drug prices, the Commission contracted with researchers at Acumen, LLC, to construct a series of volume-weighted price indexes (Figure 13-5). The indexes do not reflect retrospective rebates from manufacturers but do reflect the prices sponsors and beneficiaries paid to pharmacies at the point of sale (including ingredient costs and dispensing fees). Measured by individual national drug codes (NDCs), Part D drug prices rose by an average of 18 percent cumulatively between January 2006 and December 2009.²¹ At the same time, Part D sponsors have had success encouraging enrollees to switch from brand-name drugs to generic substitutes, particularly during the program's first two years. As measured by a price index that takes this substitution into account, Part D prices grew cumulatively by 1 percent between January 2006 and December 2009.²²

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 therapeutically equivalent, unless only one drug is approved for that class. This policy protects beneficiaries who need a drug that is the only one available to treat a certain condition and allows competition in classes with multiple products. For six

**FIGURE
13-5**

**Availability of generics, rather than protected status,
key to slower price growth under Part D**



Note: Chain-weighted Fisher price indexes.

Source: Acumen, LLC, analysis for MedPAC.

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. Although plans can still charge higher cost sharing for them—for example, by placing them on tiers for nonpreferred brands—plans may have limited ability to influence utilization for these classes of drugs.

As measured by individual NDCs, prices for drugs in the six classes showed a trend similar to that for all Part D drugs, rising by a cumulative 17 percent over the four-year period (Figure 13-5). This growth is influenced heavily by two classes of drugs: antidepressant medications, which account for about half of the volume in the six classes and had many generics on the market during this period, and anticonvulsants, which account for more than a quarter

of the volume and also had generic alternatives available during the same period.

Our price index for the individual NDCs of antidepressant and anticonvulsant drugs fell by nearly 4 percent and 10 percent, respectively, during the four-year period (data not shown). Other classes are made up almost entirely of brand-name drugs, and prices for these products grew rapidly, ranging from a little more than 20 percent for antiretrovirals to 46 percent for antineoplastics.

When protected-class drugs were grouped to take generic substitution into account, their prices grew by a cumulative 1 percent over the four-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 are available. However, it is possible that the drugs’ protected status may keep plan

sponsors from negotiating rebates from manufacturers in classes in which one brand-name drug can be a therapeutic substitute for another brand-name drug. We lack rebate information to test this hypothesis.

Measuring plan performance in Part D

CMS collects quality and performance data for Part D plans to monitor sponsors' operations and help beneficiaries choose among plans. CMS relies on several sources for these data—the Consumer Assessment of Healthcare Providers and Systems survey, agency monitoring of plans, data furnished by sponsors, and claims information (Centers for Medicare & Medicaid Services 2011d).

For 2012, 17 metrics are grouped into four domains:

- drug plan customer service (five measures);
- member complaints, problems getting services, and choosing to leave the plan (three measures);
- member experience with the drug plan (three measures); and
- drug pricing and patient safety (six measures).

Compared with previous years, the 2012 plan rating puts more emphasis on patient safety and appropriate medication use. For example, in 2012, CMS added three measures of medication adherence to the drug pricing and patient safety domain. These measures use Part D's PDE data to assess how frequently plan enrollees adhere to the recommended medication therapy for oral antidiabetics, antihypertensives, and antihyperlipidemics (statins). Finally, CMS has dropped some nonclinical measures, including two that were related to call center operations.

For MA–PDs, the star ratings on Medicare's web-based Plan Finder are based on 53 measures, including 36 measures that assess the quality of medical services provided in addition to the 17 measures used for stand-alone PDPs to assess the quality of prescription drug services provided.

CMS aggregates individual scores for each of the measures (17 for PDPs and 53 for MA–PDs) on the Plan Finder under a 5-star system; 5 stars means excellent performance and 1 star reflects poor performance. CMS presents star ratings that combine individual scores in each

domain as well as a summary rating that represents overall performance. For 2012 ratings, clinical measures are weighted three times as much as process measures (such as enrollment timeliness), and enrollee experience (such as access to medications) is weighted one and a half times as much as the process measures. In previous years, all measures were weighted equally.

In 2012, ratings for stand-alone PDP sponsors range from 2 stars to 5 stars, while ratings for MA–PD sponsors range from 1.5 stars to 5.0 stars. Weighted by enrollment, the average star rating among PDP sponsors is 2.96 compared with 3.49 for 2011, and the average among MA–PD sponsors is 3.44 compared with 3.18 for 2011 (Centers for Medicare & Medicaid Services 2011b). However, given the number of changes CMS made for 2012 measures and how they are weighted, plan ratings for 2012 are not directly comparable to ratings for 2011 and earlier years.

Generally, LIS enrollees do not tend to be in plans run by sponsors with star ratings that differ systematically from plans that enroll more non-LIS beneficiaries (Medicare Payment Advisory Commission 2011d). Based on the Commission's calculation using enrollment as of April 2011, the ratings for PDP sponsors ranged from 2 stars to 5 stars for both LIS and non-LIS enrollees, with an enrollment-weighted average of about 3 stars for both groups of enrollees. Similarly, the ratings for MA–PD sponsors ranged from 1.5 stars to 5 stars for both LIS and non-LIS enrollees, with an enrollment-weighted average of about 3.4 stars for non-LIS enrollees and 3.2 stars for LIS enrollees.

Generic substitution and role of the low-income cost-sharing subsidy

Generic substitution can result in significant reductions in spending. The Commission's set of volume-weighted indexes shows that, when taking into account generic substitution, prices for Part D drugs grew cumulatively by just 1 percent between January 2006 and December 2009.²³ However, measured by individual NDCs, Part D drug prices rose by an average of 18 percent cumulatively over the same period. This finding suggests that, overall, generic substitution has played a key role in keeping down prices for Part D drugs. The Congressional Budget Office (CBO) estimates that, in 2007, dispensing generic drugs rather than their brand-name counterparts reduced total prescription drug costs for Part D by about \$33 billion

(Congressional Budget Office 2010). Even so, for the same year, the CBO estimates that Part D could have saved an additional \$900 million if all prescriptions for multiple-source brand-name drugs had instead been filled with their generic counterparts and an additional \$4 billion if generics had been dispensed as therapeutic substitutes for brand-name drugs in seven drug classes.²⁴

For many therapeutic classes, plan sponsors use differences in cost-sharing amounts along with other utilization management tools to encourage generic substitution (a switch from a brand-name drug to the chemically equivalent generic drug) and therapeutic substitution (a switch from a brand-name drug to the generic form of a different drug within the same therapeutic class).²⁵ Plan sponsors have been more successful at encouraging generic drug use among non-LIS enrollees than among LIS enrollees. The Commission estimates that, in 2009, non-LIS enrollees had an overall average generic dispensing rate (GDR) of 72 percent compared with 68 percent for LIS enrollees (Medicare Payment Advisory Commission 2011a). Although this difference does not seem large, greater differences in GDRs are apparent for some of the most widely used categories of drugs. For example, in the therapeutic class of antihyperlipidemics (cholesterol-lowering drugs), non-LIS enrollees had a GDR of 63 percent compared with 56 percent for LIS enrollees. Among prescriptions filled for diabetic therapies, non-LIS enrollees had a GDR of 67 percent while LIS enrollees had a 53 percent GDR. Among peptic ulcer therapies, non-LIS enrollees achieved a GDR of 76 percent compared with 66 percent for LIS enrollees.

Multiple factors can contribute to 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. Since LIS beneficiaries are more likely to be disabled and tend to have a greater disease burden than non-LIS enrollees, some of the difference in GDRs likely results from differences in medication needs between the two groups. Prescriber behavior and pharmacy incentives can also affect beneficiaries' use of generics when available. Wide variations in generic use rate seen across states may be due, at least in part, to regional differences in physician prescribing behavior and state regulations about dispensing generic drugs (see text box, p. 363). At the same time, since one of the key tools used by plan sponsors to manage drug spending—using cost-sharing differentials between drugs on different tiers to encourage enrollees to use lower cost drugs—is not available to

manage the drug spending of LIS enrollees, sponsors have limited ability to manage spending for this population.

Under Part D, cost sharing for LIS enrollees is set by law rather than by each plan. Most LIS enrollees (more than 80 percent) pay nominal copays.²⁶ Smaller numbers of other LIS enrollees pay 15 percent coinsurance.²⁷ Although copays for LIS enrollees are structured to encourage the use of lower cost generics when they are available, the financial incentives are much weaker than those non-LIS enrollees typically face. For example, in 2011, dual-eligible beneficiaries with incomes at or below 100 percent of poverty paid \$1.10 for generic drugs and preferred multiple-source drugs and \$3.30 for all other brand-name drugs. Corresponding amounts for dual-eligible beneficiaries with incomes above 100 percent of poverty were \$2.50 and \$6.30 for generic drugs and brand-name drugs, respectively. By comparison, median copays for non-LIS enrollees were \$7 for a generic drug, \$42 for a preferred brand-name drug, and about \$80 for a nonpreferred brand-name drug. Non-LIS enrollees typically paid 25 percent to 30 percent of the negotiated price of a drug on a plan's specialty tier (Medicare Payment Advisory Commission 2011b).

Cost differentials that make generic prescriptions relatively more attractive can have a strong impact on generic use. However, a policy based on financial incentives must be carefully constructed, particularly for the LIS population, to ensure access to needed medications. For example, policymakers may want to reduce or eliminate copays for generic drugs and increase copays for brand-name drugs in therapeutic classes where generic substitutes are available. An example of a policy that would change the copay amounts to encourage the use of generic drugs is shown in Table 13-15 (p. 362). The policy would eliminate the cost sharing for generic drugs and increase the brand copay from \$3.30 to \$6 when generic substitutes are available in the same drug class. For brand-name drugs that do not have generic substitutes, policymakers would want to keep the cost-sharing amounts at the current level, as shown in the example below, so that beneficiaries will continue to have the same level of access to needed medications.

Reducing or eliminating copays for generic drugs would improve access for LIS enrollees. Many individuals who switch from brand-name drugs to generic drugs will likely see their OOP costs reduced, and individuals currently using generic drugs also would see their OOP costs go down (see text box, p. 364). Lower cost sharing could also improve their adherence to the medication therapies.

**TABLE
13-15**

Example of a change to LIS cost-sharing structure to encourage the use of generic drugs

	Drug class:	
	With generic substitute(s)	With no generic substitutes
Current LIS cost-sharing		
Generic drug	\$1.10	\$1.10
Brand-name drug on preferred tier	\$3.30	\$3.30
Brand-name drug on nonpreferred tier	\$3.30	\$3.30
Alternative LIS cost-sharing		
Generic drug	\$0	Same as under current law
Brand-name drug on preferred tier	\$6	
Brand-name drug on nonpreferred tier	≥\$6	

Note: LIS (low-income subsidy). Copay amounts are for 2011 and apply to noninstitutionalized LIS beneficiaries with incomes at or below 100 percent of poverty.

Beneficiary education will play an important role in encouraging clinically appropriate generic substitutions. For example, CMS may want to coordinate with plan sponsors to increase awareness of the availability of free or lower cost medications and provide accurate information about generic drugs to dispel any misperceptions or concerns that beneficiaries may have. Plan sponsors can further encourage the use of generic drugs through the use of utilization management tools and through prescriber education. In the future, CMS may want to rate plan performance, in part, based on generic dispensing rates for selected drug classes where generic substitutes are available.

During the next several years, patents for many top-selling brand-name products will expire, and many are likely to become available in generic forms.²⁸ This change provides a significant opportunity to reduce Part D's growth in spending, particularly for the faster growing reinsurance and LIS program components, through increased generic substitutions. A policy that encourages more use of generic drugs by LIS enrollees will lower the cost-sharing subsidy Medicare pays on behalf of LIS enrollees. In addition,

since more than 80 percent of beneficiaries whose spending reaches the catastrophic phase of the benefit receive the LIS, such a policy has the potential to also reduce Medicare's payments for individual reinsurance.

A policy that uses financial incentives to make generic drugs relatively more attractive raises some concerns, as it could negatively affect access to brand-name medications that are in classes with generic substitutes. To address this concern, such a policy should have appropriate protections in place to ensure beneficiaries' access to medications they need.

To achieve the policy goal of encouraging generic and therapeutic substitutions in classes where such substitutions are clinically appropriate (e.g., antihyperlipidemics used to lower high cholesterol), the Secretary should be given a broad authority and flexibility to determine appropriate therapeutic classifications for implementing the policy. This authority would allow the Secretary to define a drug class broadly or narrowly, depending on the clinical appropriateness of the therapeutic substitution.

There will be classes where therapeutic substitutions are not clinically appropriate (e.g., HIV/AIDS and cancer drugs). The Secretary would have the authority to exclude those classes from the policy even if there are generic substitutes in the same class. For brand-name drugs in those excluded classes, the copay amounts would remain the same as under current law.

Second, current exceptions and the appeals process should remain in effect when clinical reasons prevent enrollees from substituting with a lower cost medication in the same therapeutic class. The Commission would strongly encourage the Secretary to closely monitor the program for any unintended effects, particularly as it relates to beneficiaries' access to needed medications. The Secretary should take advantage of her access to various administrative data to evaluate changes in beneficiaries' access and the effectiveness of exceptions and the appeals process.

The Commission also plans to use Part D's PDE data and any other publicly available data on access under Part D (such as measures used for Part D plan rating) to monitor the effects of such a policy. In addition, we hope to obtain data on the exceptions and appeals process used by Part D plans to evaluate the effectiveness of these processes in ensuring beneficiaries' access to medications they need.

States' mandatory generic substitution laws and generic drug use by enrollees receiving the low-income subsidy

States have implemented a variety of policies with regard to generic substitution. As of 2007, about a quarter of the states had laws mandating that pharmacists dispense the generic version of a drug, unless specifically directed by the prescriber to dispense the brand version of the drug (Epilepsy.com 2012, Shrank et al. 2010). The other three-quarters allow pharmacists to substitute a generic version of the drug when the prescriber does not specify that the brand version be dispensed. States with mandatory generic substitution laws generally do not require the pharmacist to obtain patient consent, while most of the states that allow (but do not mandate) pharmacists to substitute with a generic version require them to obtain patient consent.

All states (including those with mandatory generic substitution laws) have policies that allow doctors (or other prescribers) to specify that the pharmacist dispense the brand-name drug. The ease of indicating that the prescription should not be substituted with a generic version varies across states. Thirty-seven states require that the doctor handwrite “brand medically necessary,” “dispense as written,” or something equivalent on the prescription form. Seven states require the doctor to sign on the “dispense as written” line, as opposed to the “product selection permitted” line on the prescription form. Eight states require the doctor to check or write her initials in the “dispense

as written” box on the form (American Academy of Neurology 2008).

In our analysis of 2009 Part D prescription drug event data, we did not find a systematic relationship between generic dispensing rates (GDRs) for Part D enrollees receiving the low-income subsidy (LIS) and the characteristics of the states' generic substitution policy. For example, GDRs among LIS enrollees residing in states that require mandatory generic substitution ranged from 61 percent to 72 percent, with an average GDR of about 67.5 percent, while the GDR for LIS enrollees residing in states that do not require mandatory generic substitution ranged from 64 percent to 74 percent, with an average GDR of about 68.5 percent.

Many states have added requirements that prescribers must meet to have the brand version of a drug dispensed for their Medicaid populations. For example, in Arkansas and Georgia, prescribers must submit a form explaining the medical basis for using the brand version of the drug; in Connecticut, they must indicate the basis for medical necessity on the prescription form. Other states have simpler requirements, such as signing on an extra line, or checking an extra box. Although these requirements do not directly affect Medicare beneficiaries, such policies could affect prescriber behavior and pharmacy incentives in a given state, contributing to the difference in GDRs across states. ■

RECOMMENDATION 13

The Congress should modify the Part D low-income subsidy copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs when available in selected therapeutic classes. The Congress should direct the Secretary to develop a copay structure, giving special consideration to eliminating the cost sharing for generic drugs. The Congress should also direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.

RATIONALE 13

Many Part D plan sponsors use cost differentials that make generics or lower cost drugs relatively more attractive to manage drug spending. However, since cost sharing for LIS enrollees is set by law rather than by each plan, sponsors have limited ability to manage drug spending for this population. Although copays for LIS enrollees are structured to encourage the use of lower cost generics when they are available, the financial incentives are much weaker than those non-LIS enrollees typically face. The policy would give the Secretary the authority to provide stronger financial incentives to use lower cost generics

An illustrative example of how beneficiary out-of-pocket costs may change under an alternative cost-sharing structure

The change in the beneficiary out-of-pocket (OOP) costs that would result from lowering the copay for generics while raising the copay for brand-name drugs in selected classes is likely to vary from individual to individual. For a low-income subsidy (LIS) enrollee who currently takes generic drugs and no brand-name drugs, the policy would result in a reduction in his or her OOP costs. For an individual on both generic and brand-name medications, the net change in his or her OOP costs would depend on multiple factors:

- the mix of generic and brand-name medications;
- the plan's cost-sharing requirements (although they do not apply directly to LIS beneficiaries) that determine when the individual enters the catastrophic phase of the benefit, beyond which there is no cost sharing for LIS beneficiaries;
- the extent to which the individual switches to generic medications in response to the change in copay amounts under the policy; and
- the extent to which brand-name drugs are in classes where generic drugs are available and substitution is clinically appropriate.

For example, an LIS enrollee (with an income at or below 100 percent of the poverty level) who fills 10 prescriptions for brand-name drugs every month spends \$33 (\$3.30 multiplied by 10 prescriptions) per month until he or she reaches the catastrophic phase of the benefit.²⁹ Under a policy that eliminates copays for generics and increases copays for brand-name drugs from \$3.30 to \$6 when generic substitutes are available (see Table 13-15), if 5 of the 10 prescriptions are in classes with generic substitutes, this enrollee could reduce his or her monthly OOP from \$33 to \$16.50 (\$0 multiplied by 5 prescriptions plus \$3.30 multiplied by 5 prescriptions) by switching to generics for all 5 medications. Even if the individual switches to generics for only three medications, the reduction in OOP costs would more than offset the increase in the copays for the two brand-name drugs that have a \$6 copay. On the other hand, if he or she continues to take the brand-name medications in classes with generic substitutes, the monthly OOP costs would increase to \$46.50 (\$6 multiplied by 5 prescriptions plus \$3.30 multiplied by 5 prescriptions). However, an individual taking many expensive medications is likely to reach the catastrophic phase of the benefit at some point during the year, which limits how much an LIS enrollee spends OOP in a given year. ■

when they are available, while taking into account the limited income of this population.

IMPLICATIONS 13

Spending

- This recommendation would decrease federal program spending relative to current law.

Beneficiary and provider

- A lower generic copay would reduce OOP costs for beneficiaries on generic medications and beneficiaries who switch from brand-name medications to generic medications. This change could increase beneficiaries' access to medications and improve adherence to medication therapies.
- Some plan sponsors may experience a decrease in

the costs of providing the benefit if their LIS enrollees switch from brand-name drugs to generic drugs. This switch would tend to decrease premiums for all beneficiaries and reduce subsidy payments Medicare makes to Part D plans.

- Some pharmacies may experience an increase in profits from dispensing more generic medications.

High use of drugs and quality of pharmaceutical care

Although adoption of a policy that encourages the use of generic drugs will reduce costs for the program and for LIS enrollees if these individuals switch to generic drugs, it does not address the quality of pharmaceutical care.

Medication problems can arise from underuse, overuse, or inappropriate use of prescription drugs. Various problems are associated with high use of prescription drugs. However, the success of plans' medication therapy management programs (MTMPs), designed to improve pharmaceutical quality of care for high drug users, has been difficult to determine.

Problems associated with high use of prescription drugs

Beneficiaries with high use of prescription drugs may have medical problems caused or exacerbated by their heavy use of medications. They are at risk for adverse drug events (ADEs), harmful drug interactions, and use of inappropriate medications. When a patient is prescribed multiple drugs, generally five to seven, clinicians warn of polypharmacy. This condition occurs when a patient is prescribed more drugs than are clinically warranted (often by multiple prescribers) or when all the prescribed medications are appropriate but the total is too many for the patient to ingest and manage safely (Haque 2009). The elderly, who are most likely to have multiple chronic conditions, are at high risk for polypharmacy.

ADEs, harmful drug interactions, and use of inappropriate medications are responsible for many medical encounters. Using the National Ambulatory Medical Care Survey and the National Hospital and Ambulatory Care Survey (2005–2007), Sarkar and colleagues (2011) found 4.3 million outpatient visits related to ADEs, with the elderly having the highest age-specific rate. The most consistent risk factor for ADEs is the number of drugs being taken, and the risk increases exponentially as the number of drugs increases (Chrischilles et al. 2009, Laird 2001, Lorincz et al. 2011). In one study, researchers found that the mean number of ADEs increased by 10 percent for each additional medication taken (Gandhi et al. 2003).

Many of these adverse events are similar to problems frequently experienced by the elderly, like falling, confusion, urinary retention, and general failure to thrive (Gray and Gardner 2009). As a result, an ADE may be mistaken for a new medical condition and treated with additional medications, leading to a prescribing cascade and potentially additional ADEs.

In addition to the large number of drugs prescribed for people with high use, many in this group take drugs considered inappropriate for the elderly. Researchers have developed lists of medications that are most likely to produce adverse consequences in elderly patients

(Beers 1997, Beers et al. 1991, Fick et al. 2003, Gill et al. 2007, Hamilton et al. 2011), the most well-known of which is the Beers list. Studies show conflicting results on the extent to which listed medications lead to adverse events. For example, Budnitz and colleagues (2007) found more emergency department visits associated with use of warfarin, insulin, and digoxin than with medications found on the Beers list. In contrast, Berdot and colleagues (2009) found that use of long-acting benzodiazepines and other psychotropic drugs—medications on the Beers list—is associated with a significant risk of falling in elderly patients. One study found a positive relationship between regions with high rates of potentially inappropriate prescribing and higher nondrug medical spending (Zhang et al. 2010).

Although studies use different criteria to determine drugs inappropriate for the elderly, they show a significant relationship between the number of drugs a person is taking and the likelihood the person is taking medications classified in the study as inappropriate (Berdot et al. 2009, Chrischilles et al. 2009, Steinman et al. 2006). Without diminishing the importance of safeguarding against the use of inappropriate medications, Laroche and colleagues (2007) concluded that reducing the number of drugs taken by the elderly is the most important step that can be taken to decrease ADEs.

Polypharmacy is also the strongest predictor of nonadherence to drug regimens (Laird 2001). Nonadherence can be intentional as patients try to balance increased costs, side effects, and the inconvenience of taking multiple medications at different times of day. Patients may not discuss these issues with their physicians. In a recent study, Mansur and colleagues (2009) documented a direct relationship between the number of medications, inappropriate prescriptions, and nonadherence in patients discharged from hospitals.

Medication therapy management programs

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires PDPs and MA-PDs to implement MTMPs to improve the quality of pharmaceutical care for high-risk beneficiaries. Legislators intended MTMPs to improve medication use and reduce adverse events for beneficiaries taking multiple medications.

In our 2009 review of MTMPs, we examined research evaluating the programs in general and available data under Part D (Medicare Payment Advisory Commission

2009). We also conducted interviews with CMS, pharmacists, health plan sponsors, pharmacies, trade associations, and companies that provide medication therapy management services under contract to sponsors. We found that MTMPs differed on the number and type of chronic conditions and prescriptions a beneficiary must have to be eligible, the kinds of interventions provided to enrollees, and the outcomes sponsors measure. We did not have sufficient data to determine whether the programs increased the quality of pharmaceutical care to participants.

Since 2010, CMS has tightened criteria for MTMPs (Centers for Medicare & Medicaid Services 2011a), although plans still have considerable flexibility in determining eligibility criteria. New requirements include:

- Plan sponsors must enroll targeted beneficiaries using an opt-out method of enrollment.
- All programs must conduct an interactive comprehensive medication review at least annually with written summaries. They must perform quarterly medication reviews with follow-up interventions, if necessary.
- Sponsors must offer interventions to prescribers to resolve drug therapy problems.

CMS reports that as of 2010, 2.6 million of 3 million eligible enrollees participated in MTMPs (Centers for Medicare & Medicaid Services 2011a, Centers for Medicare & Medicaid Services 2011c). The agency awarded a two-year contract in 2011 to evaluate the impact of MTMPs on high-risk, chronically ill enrollees. However, CMS has not provided any data on the outcomes achieved by these programs. The goals of the study are to:

- evaluate the extent to which MTMPs target populations with medication therapy issues.
- evaluate the impact of MTMPs on key clinical outcomes, drug adherence, and Medicare costs.
- gather information on pharmacists' perspectives on MTMP implementation and impacts.
- evaluate how best practices can inform CMS operational guidelines (Centers for Medicare & Medicaid Services 2011c).

CMS is also considering adding a patient safety measure related to MTMPs for the 2013 Plan Finder. We will continue to monitor this program going forward. ■

Endnotes

- 1 Beginning in 2012, Medicare beneficiaries enrolled in PDPs or MA-PDs are allowed to switch to a plan that has the highest rating (5 stars) based on CMS's quality and performance rating system for Part D plans at any point during the year.
- 2 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 generics beginning in 2011, (3) phasing down cost sharing for brand-name drugs beginning in 2013, and (4) reducing the OOP threshold on true OOP spending over the 2014 to 2019 period.
- 3 As a result of the changes made by PPACA, pharmaceutical manufacturers of brand-name drugs must provide a 50 percent discount for drugs filled while beneficiaries are in the coverage gap. Beneficiaries are responsible for the remaining 50 percent of the cost of the drugs. Since the manufacturer discount applies only to the ingredient costs, the effective cost sharing for brand-name drugs filled during the coverage gap will be slightly higher than 50 percent once dispensing fees and sales taxes are factored in.
- 4 The amount of total covered drug spending at which a beneficiary meets the annual OOP threshold depends on the mix of brand-name and generic drugs an individual fills during the coverage gap. The 2012 amount of total drug expenses at the annual OOP threshold of \$6,657.50 is for an individual with no other sources of supplemental coverage filling only brand-name drugs during the coverage gap.
- 5 If an employer agrees to provide primary drug coverage to its retirees with an average benefit value that is equal to or greater than Part D (called creditable coverage), Medicare provides the employer with a tax-free subsidy for 28 percent of each eligible individual's drug costs that fall within a specified range of spending. Under PPACA, employers would still receive the RDS on a tax-free basis, but, beginning in 2013 they will no longer be able to deduct prescription drug expenses for which they receive the subsidy as a cost of doing business.
- 6 Creditable coverage refers to prescription drug benefits through sources such as a former employer that are at least as generous as the standard Part D benefit.
- 7 Enrollment figures based on CMS's Monthly Summary Report as of April 2011 (<https://www.cms.gov/MCRAAdvPartDEnrolData/MCESR/list.asp#TopOfPage>, accessed October 17, 2011).
- 8 Medicare allows insurers to offer two types of plans that have the same average benefit value as the defined standard benefit. The first type, which CMS calls actuarially equivalent, uses the same deductible as the defined standard benefit but has different cost sharing during the plan's initial coverage phase. The second type, called basic alternative, allows insurers to use a lower deductible than the defined standard benefit, different cost sharing, and a modified initial coverage limit. Because they have the same average benefit value as the defined standard benefit, in this chapter we refer to both types as actuarially equivalent benefits.
- 9 As a result of the changes made by PPACA, Part D's basic benefit includes some coverage in the gap. Enhanced benefit plans that include coverage in the gap must provide coverage in the gap beyond what is required by PPACA.
- 10 Sponsors can enhance benefits in other ways as well—for example, covering drugs not allowed under basic Part D benefits, such as weight-loss medications and over-the-counter products. In the first few years of the Part D program, a handful of PDP sponsors offered insurance products that covered some brand-name and generic drugs in the coverage gap. However, those plans attracted beneficiaries with relatively high drug spending and the plans experienced financial losses. In the following years, nearly all affected sponsors withdrew those products from the market.
- 11 Under the Part C payment system, which is used to pay MA plans, 75 percent 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.
- 12 Commission analysis based on 2009 PDE data. Estimates are derived by comparing an individual's gross drug spending with the level of spending at which the beneficiary enters the coverage gap under the defined standard benefit. In the past, our estimates of the number of beneficiaries who had spending high enough to enter the coverage gap have been comparable to those published by CMS.
- 13 In previous years, we have treated different segments of an MA-PD as separate plans for the purpose of reporting the number of plans available. Beginning this year, we no longer distinguish between different segments of a plan. With the previous methodology, the increase in the number of MA-PDs would have been 4 percent (compared with 2 percent using the new method of counting)—1,633 compared with 1,566 in 2011.

- 14 CMS is allowing sponsors to offer only one basic plan and up to two enhanced plans in any given region, with a requirement that the plans have “meaningful differences”—defined as a difference of at least \$22 per month in a beneficiary’s expected monthly OOP cost for a common market basket of drugs between basic and enhanced plans. If a sponsor is offering two enhanced plans in the same service area, the second enhanced plan must have a higher value than the first and include coverage of at least some brand-name drugs in the coverage gap. Beginning with the 2012 plan year, CMS is also requiring a “meaningful difference”—defined as a difference of at least \$16 in a beneficiary’s expected monthly OOP cost between the two enhanced plan offerings.
- 15 This estimate is based on the Commission’s analysis of CMS enrollment and crosswalk data files.
- 16 Email correspondence with CMS on November 16, 2011.
- 17 Prior authorization refers to requirements for preapproval from a plan before coverage. Quantity limits refer to a plan limiting the number of doses of a particular drug covered in a given time period. Under step therapy, plans require the enrollee to try specified drugs before moving to other drugs.
- 18 For example, Lipitor, a popular drug used to treat high cholesterol with annual sales of about \$6 billion is expected to face competition from a generic market entry later this year. Many more medications are expected to face generic competition in the next few years. For example, Lexapro (for treatment of depression and anxiety), Seroquel (for treatment of schizophrenia and bipolar disorder), and Plavix (used to prevent blood clots) will likely face competition from generic drugs beginning in 2012.
- 19 For 2006, the first year of the program, plan sponsors had no claims experience on which to base their bids and many sponsors bid too high. Payment reconciliation resulted in a net payment of \$4.3 billion from the sponsors to Medicare as part of the payment reconciliation.
- 20 Based on CMS’s estimate as of October 2011.
- 21 An individual NDC uniquely identifies the drug’s labeler, drug, dosage form, strength, and package size. Because each specific drug often is available in different dosages, strengths, and package sizes, the same drug typically has many different NDCs.
- 22 For this index, Acumen grouped NDCs that are pharmaceutically identical, aggregating prices across trade drug 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.
- 23 Acumen, LLC, analysis for the Commission (2011). The indexes reflect the prices plan sponsors and beneficiaries paid to pharmacies at the point of sale and do not reflect retrospective rebates from manufacturers.
- 24 CBO’s estimated savings from therapeutic substitution analyzed the effects of switching an enrollee from a single-source brand-name drug to the generic form of a different drug that is in the same therapeutic class. The seven classes selected for the analysis totaled about \$10 billion out of \$60 billion in payments to plans and pharmacies in 2007.
- 25 Therapeutic substitution also includes a switch from a brand-name drug on a nonpreferred tier to another brand-name drug on a preferred tier within the same therapeutic class.
- 26 Dual-eligible beneficiaries in institutions do not pay cost sharing.
- 27 A small number of LIS enrollees receive a partial subsidy that pays for a portion of their premiums and provides extra help with their cost sharing. These beneficiaries account for less than 5 percent of LIS enrollees. In 2012, they have a \$65 deductible, a 15 percent coinsurance up to the OOP threshold, and maximum copayments of \$2.60 for generic and preferred multiple-source drugs and \$6.50 for all other brand-name drugs above the OOP threshold.
- 28 Between 2011 and 2013, brand-name products that account for more than \$47 billion in annual U.S. drug sales will lose patent protection. A disproportionate drop in cost will be seen in 2012 due to nearly \$24.5 billion in brand-name agents losing patent protection (Express Script 2010 drug trend report).
- 29 The term “true out-of-pocket,” or TrOOP, refers to a feature of Part D that allows only certain types of spending to count toward the catastrophic threshold. In addition to a beneficiary’s own OOP spending, spending made on behalf of the beneficiary by family members, official charities, qualifying state pharmaceutical assistance programs, or Part D’s LIS count toward the OOP threshold. Once an LIS enrollee reaches the catastrophic phase of the benefit, the LIS covers all cost sharing required by the plan.

References

- American Academy of Neurology. 2008. *A guide to state "dispense as written" laws*. Guide developed by Abbott Laboratories, Inc. and provided to AAN. Saint Paul, MN: AAN. <http://www.aan.com/globals/axon/assets/4698.pdf>.
- Beers, M. H. 1997. Explicit criteria for determining potentially inappropriate medication use by the elderly. An update. *Archives of Internal Medicine* 157, no. 14 (July 28): 1531–1536.
- Beers, M. H., J. G. Ouslander, I. Rollinger, et al. 1991. Explicit criteria for determining inappropriate medication use in nursing home residents. UCLA Division of Geriatric Medicine. *Archives of Internal Medicine* 151, no. 9 (September): 1825–1832.
- Berdot, S., M. Bertrand, J. F. Dartigues, et al. 2009. Inappropriate medication use and risk of falls—A prospective study in a large community-dwelling elderly cohort. *BMC Geriatrics* 9: 30.
- Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2011. *2011 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds*. Washington, DC: Boards of Trustees.
- Budnitz, D. S., N. Shehab, S. R. Kegler, et al. 2007. Medication use leading to emergency department visits for adverse drug events in older adults. *Annals of Internal Medicine* 147, no. 11 (December 4): 755–765.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011a. 2011 Medicare Part D medication therapy management (MTM) programs. Fact sheet. June 30.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011b. *2012 Part C and D plan ratings*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011c. E-mail communication with staff, September 14.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011d. *Medicare health & drug plan quality and performance ratings 2012 Part C & Part D technical notes*. Baltimore, MD: CMS.
- Chrischilles, E. A., R. VanGilder, K. Wright, et al. 2009. Inappropriate medication use as a risk factor for self-reported adverse drug effects in older adults. *Journal of the American Geriatrics Society* 57, no. 6 (Jun): 1000–1006.
- Congressional Budget Office. 2010. *Effects of using generic drugs on Medicare's prescription drug spending*. Washington, DC: CBO.
- Department of Health and Human Services. 2010. Prescription drug cost relief to more than 750,000 Medicare beneficiaries. News release. August 10. <http://www.hhs.gov/news/press/2010pres/08/20100810a.html>.
- Epilepsy.com. 2012. State laws or statutes governing generic substitution by pharmacists. http://professionals.epilepsy.com/page/statutes_by_pharmacists.html.
- Fick, D. M., J. W. Cooper, W. E. Wade, et al. 2003. Updating the Beers criteria for potentially inappropriate medication use in older adults. Results of a US consensus panel of experts. *Archives of Internal Medicine* 163, no. 22 (December 8): 2716–2724.
- Gandhi, T. K., S. N. Weingart, J. Borus, et al. 2003. Adverse drug events in ambulatory care. *New England Journal of Medicine* 348, no. 16 (Apr 17): 1556–1564.
- Gill, S. S., S. E. Bronskill, S. L. Normand, et al. 2007. Antipsychotic drug use and mortality in older adults with dementia. *Annals of Internal Medicine* 146, no. 11 (June 5): 775–786.
- Gray, C. L., and C. Gardner. 2009. Adverse drug events in the elderly: An ongoing problem. *Journal of Managed Care Pharmacy* 15, no. 7 (September): 568–571.
- Hamilton, H., P. Gallagher, C. Ryan, et al. 2011. Potentially inappropriate medications defined by STOPP criteria and the risk of adverse drug events in older hospitalized patients. *Archives of Internal Medicine* 171, no. 11 (June 13): 1013–1019.
- Haque, R. 2009. ARMOR: A tool to evaluate polypharmacy in elderly persons. *Annals of Long Term Care* (June): 26–30.
- Heiss, F., D. McFadden, and J. Winter. 2006. Who failed to enroll in Medicare Part D, and why? Early results. *Health Affairs* 25, no. 5 (September–October): w344–354.
- J.D. Power and Associates. 2006. Three-fourths of beneficiaries enrolled in Medicare Part D are satisfied with their drug plan. Press release. <http://businesscenter.jdpower.com/news/pressrelease.aspx?ID=2006200>.
- Keenan, T. A. 2007. *Prescription drugs and Medicare Part D: A report on access, satisfaction, and cost*. Washington, DC: AARP.
- Laird, R., University of Kansas Medical Center, Center on Aging. 2001. Polypharmacy in the elderly. Presentation.

- Laroche, M. L., J. P. Charmes, Y. Nouaille, et al. 2007. Is inappropriate medication use a major cause of adverse drug reactions in the elderly? *British Journal of Clinical Pharmacology* 63, no. 2 (February): 177–186.
- Lorincz, C. Y., E. Drazen, P. E. Sokol, et al. 2011. *Research in ambulatory patient safety 2000–2010: A 10-year review*. Chicago, IL: American Medical Association.
- Mansur, N., A. Weiss, and Y. Beloosesky. 2009. Is there an association between inappropriate prescription drug use and adherence in discharged elderly patients? *Annals of Pharmacotherapy* 43, no. 2 (February): 177–184.
- Medical News Today*. 2009. Medicare Part D continues to earn strong marks from America’s seniors. <http://www.medicalnewstoday.com/releases/170820.php>.
- Medicare Payment Advisory Commission. 2008. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2011a. *A data book: Healthcare spending and the Medicare program*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2011b. *Medicare Part D formularies, 2006–2011: Update to chartbook*. A study conducted by staff from NORC at the University of Chicago, Georgetown University, and Social & Scientific Systems, Inc., for MedPAC. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2011c. *Payment basics: Part D payment system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2011d. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Office of Inspector General, Department of Health and Human Services. 2007. *Generic drug utilization in the Medicare Part D program*. No. OEI–05–07–00130. Washington, DC: OIG.
- PRNewswire. 2010. Medicare Part D continues to earn strong marks from America’s seniors. <http://www.prnewswire.com/news-releases/medicare-part-d-continues-to-earn-strong-marks-from-americas-seniors-69867642.html>.
- Riley, G. F., J. M. Levy, and M. A. Montgomery. 2009. Adverse selection in the Medicare prescription drug program. *Health Affairs* 28, no. 6 (November–December): 1826–1837.
- Sarkar, U., A. López, J. H. Maselli, et al. 2011. Adverse drug events in U.S. adult ambulatory medical care. *Health Services Research*: 10.1111/j.1475-6773.2011.01269.
- Shrank, W. H., N. K. Choudhry, J. Agnew-Blais, et al. 2010. State generic substitution laws can lower drug outlays under Medicaid. *Health Affairs* 29, no. 7 (July): 1383–1390.
- Steinman, M. A., C. S. Landefeld, G. E. Rosenthal, et al. 2006. Polypharmacy and prescribing quality in older people. *Journal of the American Geriatrics Society* 54, no. 10 (October): 1516–1523.
- Weems, K. 2008. The Medicare drug benefit: Are private insurers getting good discounts for the taxpayer? Statement by Kerry Weems, Acting Administrator, Centers for Medicare & Medicaid Services, before the Committee on Oversight and Government Reform, House of Representatives. 110th Congress, 2nd sess. July 24.
- Zhang, Y., K. Baicker, and J. P. Newhouse. 2010. Geographic variation in the quality of prescribing. *New England Journal of Medicine* 363, no. 21 (November 18): 1985–1988.