CHAPTER 5

Status report on Part D

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Chapter summary

Part D of Medicare provides an outpatient prescription drug benefit through the use of competing private plans. To observe program performance, we examined several indicators of beneficiary access and program spending, discussed below.

Enrollment in Part D—All but about 4.5 million of 45 million Medicare beneficiaries have Part D drug coverage or its equivalent. In early 2009, about 59 percent of beneficiaries were enrolled in Part D plans, 31 percent had other sources of creditable coverage, and 10 percent had no drug coverage or coverage less generous than Part D. Among those in Part D plans, nearly 10 million low-income individuals (21 percent of all Medicare beneficiaries) received extra help with premiums and cost sharing through 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).

Benefit offerings for 2010—Sponsors are offering about 7 percent fewer PDPs than in 2009. About 10 percent fewer MA–PDs are available, reflecting a decline in the number of private fee-for-service plans and local health maintenance organizations. Beneficiaries will continue to have a choice of 41 to 55 PDP options, along with many MA–PDs. For 2010, sponsors are

In this chapter

tightening benefit designs for PDPs with respect to deductibles and gap coverage while keeping largely the same benefit structure for MA–PDs.

Growth in Part D premiums—At the time of publication, Part D enrollees in 2010 are paying, on average, about $30.50 per month, up less than $2 (6 percent) from 2009. In 2010, the average PDP enrollee pays about $37.70 per month, about $2.60 more (7 percent) than in 2009. For the average MA enrollee, the portion of MA premiums attributable to drug benefits declined by about $0.60 (4 percent) to $14 per month.

Plans available at no premium to LIS enrollees—CMS sets a maximum amount in each region that Medicare will pay for extra help with premiums through the LIS. If a basic-benefit plan's premium falls below that threshold, LIS enrollees in that plan pay no premium. In 2010, about the same number of PDPs met this criterion as in 2009 (307), and each region has at least 4 such PDPs. CMS needed to reassign an estimated 1.06 million LIS enrollees to plans offered by a different sponsor because their previous plan's premium no longer fell below the 2010 LIS threshold—roughly the same number as in 2009.

Part D spending—In 2008 and 2009, Part D spending totaled $49 billion and an estimated $53 billion, respectively. In 2008, payments for premiums and cost-sharing assistance under the LIS were the largest component of Part D spending. In 2008 and 2009, Medicare's reinsurance payments for the highest spending enrollees were the fastest growing component of Part D, partly because of the difficulty of negotiating rebates for high-cost drugs and biologics that have few competing therapies.

Measuring quality in Part D—CMS publishes 19 performance metrics aggregated into a 5-star rating system through the Medicare Prescription Drug Plan Finder at www.medicare.gov. Two metrics address patient safety, and the rest focus on customer service and enrollee satisfaction. For 2010, CMS has set more requirements addressing how sponsors operate, monitor, and report on their plans' medication therapy management programs. ■

TABLE 5–1 **Parameters of the defined standard benefit increase over time**

	2006	2007	2008	2009	2010
Deductible	$250.00	$265.00	$275.00	$295.00	$310.00
Initial coverage limit	2,250.00	2,400.00	2,510.00	2,700.00	2,830.00
Annual out-of-pocket spending threshold	3,600.00	3,850.00	4,050.00	4,350.00	4,550.00
Total covered drug spending at annual out-of-pocket threshold	5,100.00	5,451.25	5,726.25	6,153.75	6,440.00
Maximum amount of cost sharing in the coverage gap	2,850.00	3,051.25	3,216.25	3,453.75	3,610.00
Minimum cost sharing above annual out-of-pocket threshold:					
Copay for generic/preferred multisource drug prescription	2.00	2.15	2.25	2.40	2.50
Copay for other prescription drugs	5.00	5.35	5.60	6.00	6.30

Source: CMS, Office of the Actuary.

Each year since 2006, the Commission has provided a status report on Medicare's Part D prescription drug program. To monitor the ability of the program—under its competitive approach—to meet the Medicare goals of maintaining beneficiary access while holding down program spending, we examine several performance indicators: beneficiaries' access to prescription drugs, including among other things data on enrollment and changes in Part D plan benefit designs and formularies for 2010; program costs; and the quality of services.

Background

Medicare's payment system for Part D, which uses competing private plans to deliver drug benefits, is very different from its fee-for-service (FFS) payment systems. Instead of prices set administratively, as in FFS, Part D payments are based on bids submitted by plan sponsors.

Part D uses two avenues of competition designed to give plan sponsors an incentive to offer beneficiaries attractive prescription 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 copays they are willing to pay, and they reevaluate that decision from time to time. In a second avenue of competition, sponsors may seek to gain market share by annually bidding below thresholds to qualify their plans to remain premium-free for most enrollees who receive Part D's low-income subsidy (LIS).

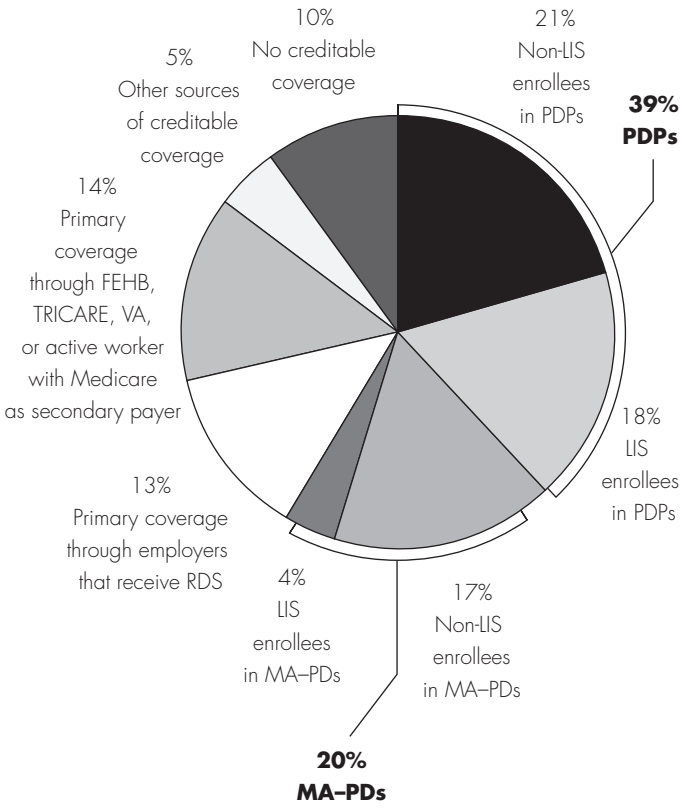
Medicare defines a standard Part D benefit structure with parameters that change at the same rate as the annual change in beneficiaries' average drug expenses (Table 5-1). (Within limits, plan sponsors can offer alternative benefit designs that have different benefit parameters.) For 2010, the defined standard benefit includes a $310 deductible and 25 percent coinsurance until the enrollee reaches $2,830 in total covered drug spending. Enrollees exceeding that total face a coverage gap, under which the enrollee is responsible for the full discounted price of covered drugs (usually without including manufacturers' rebates) up to an annual threshold of $4,550 in out-of-pocket spending that excludes cost sharing paid by most sources of supplemental coverage, such as employer-sponsored policies. An individual with no other source of drug coverage reaches this limit at $6,440 in total drug spending (the combination of the enrollee's spending plus spending the Part D plan covers). Enrollees with drug spending exceeding that amount pay the greater of either $2.50 to $6.30 per prescription or 5 percent coinsurance.

Part D enrollees' access to prescription drug benefits

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 employers. A potential concern is whether enrollees who do not receive the LIS and have many prescriptions stay on their drug regimens once they reach Part D's coverage gap.

FIGURE 5–1

In 2009, 90 percent of Medicare beneficiaries were enrolled in Part D plans or had other sources of creditable drug coverage



Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), RDS (retiree drug subsidy), FEHB (Federal Employees Health Benefits program), VA (Department of Veterans Affairs). TRICARE is the health program for military retirees and their dependents. Creditable coverage means drug benefits that are of equal or greater value to the basic Part D benefit. Sums may not add to totals due to rounding.

Source: CMS Management Information Integrated Repository data as of February 2009.

In 2009, 90 percent of Medicare beneficiaries had drug coverage, 59 percent were in Part D plans

In 2009, all but 10 percent of Medicare beneficiaries had drug coverage at least as generous as Part D's defined standard benefit—called creditable coverage (Figure 5-1). In February 2009, nearly 27 million of 45 million Medicare beneficiaries (59 percent of all beneficiaries, or 65 percent of those with creditable drug coverage) were enrolled in Part D plans.[1] Thirty-one percent of beneficiaries had other sources of creditable coverage, such as employer-sponsored plans that receive Medicare's retiree drug subsidy (RDS), the Department of Veterans Affairs, TRICARE (the Department of Defense's health benefit for retired military members), and other payers.[2] An estimated 4.5 million Medicare beneficiaries (10 percent) had no drug coverage or coverage less generous than Part D's benefit. Research indicates that beneficiaries who do not enroll in Part D tend to have lower drug spending, better health, lower risk scores, and lower income (Heiss et al. 2006, Riley et al. 2009).

In 2009, about 9.7 million individuals (21 percent of all Medicare beneficiaries, or 36 percent of Part D enrollees) received the LIS. Of them, 6.3 million were dually eligible to receive Medicare and Medicaid. Another 3.3 million qualified for extra help either because they receive benefits through the Medicare Savings Program or Supplemental Security Income Program, or because they were determined eligible by the Social Security Administration (SSA) after applying directly to that agency. Among LIS beneficiaries, about 8 million (18 percent of all Medicare beneficiaries) are enrolled in stand-alone prescription drug plans (PDPs) and 1.7 million (4 percent) are in Medicare Advantage–Prescription Drug plans (MA–PDs). At the end of 2009, approximately 0.4 million Part D enrollees lost their "deemed status" for the LIS because they no longer qualified for Medicaid, no longer belonged to a Medicare Savings Program, or no longer received Supplemental Security Income. This means that, to receive the LIS in 2010, they had to apply to the SSA and be found eligible (Centers for Medicare & Medicaid Services 2009f). Recent changes in the law affect the types of resources that SSA considers when beneficiaries apply for the LIS, and it estimates that more than 1 million are newly eligible as a result (Social Security Administration 2010).[3]

In 2007, Part D enrollees were more likely to be female and minority than the overall Medicare population (see Table 5-A1 in the online appendix to this chapter, available at http://www.medpac.gov). Compared with PDP enrollees, beneficiaries enrolled in MA–PDs were less likely to be disabled and more likely to be Hispanic, reflecting in part the demographics of areas where MA–PDs are located. LIS enrollees were more likely to be female, minority, and disabled beneficiaries under age 65 than Medicare beneficiaries overall.

Part D enrollment varies geographically. In each of the 34 PDP regions across the country, 2007 enrollment ranged between 40 percent and 68 percent of Medicare beneficiaries (Figure 5-A1 in the online appendix to this

chapter). Part D enrollment tends to be lower in states with large employers that receive Medicare's RDS, such as Michigan and Ohio. In parts of the West (Nevada, New Mexico, Colorado, and California), Florida, and parts of the Northeast (Pennsylvania and West Virginia), 40 percent or more of enrollees are in MA–PDs (Figure 5-A2 in the online appendix to this chapter). By comparison, in other parts of the Northeast, Midwest, and in the South central states, fewer than 20 percent of Part D enrollees are in MA–PDs.

The number of beneficiaries receiving the Part D LIS also varies considerably by region. In 2007, 50 percent or more of enrollees in Alaska, Maine, New Hampshire, Mississippi, Alabama, Louisiana, and Tennessee received the LIS (Figure 5-A3 in the online appendix to this chapter). By comparison, no more than 30 percent of enrollees in the upper Midwest and several central western states received the LIS. Participation rates in the Part D LIS reflect factors such as underlying rates of poverty and health status, the degree to which state outreach efforts were successful at enrolling eligible individuals, and how states set eligibility criteria. For example, states can increase the numbers of beneficiaries who may join a Medicare Savings Program by not counting certain types of assets or sources of income in their eligibility criteria for Medicaid benefits (Medicare Payment Advisory Commission 2008).

Distribution of enrollment across plan types

Most Part D enrollees are in plans other than the Part D standard benefit; those plans are actuarially equivalent to the standard benefit or are enhanced in some way. Actuarially equivalent plans have the same average benefit value as defined standard plans but a different benefit structure (both actuarially equivalent and defined standard plans are referred to as basic benefits).[4] For example, a plan may use tiered copays (e.g., charging $7 per generic prescription and $50 for a prescription of a brand-name drug) rather than 25 percent coinsurance. Alternatively, instead of having a deductible, a plan may use cost sharing equivalent to a rate higher than 25 percent. Once a sponsor offers at least one PDP with basic benefits in a region, it may also offer a plan with enhanced benefits—basic and supplemental coverage combined, with a higher average benefit value. Medicare does not subsidize supplemental benefits; enrollees must pay the full premium for the additional coverage.

In 2009, 63 percent of PDP enrollees were in actuarially equivalent basic plans, most with tiered copays. Another 26 percent of PDP enrollees had enhanced benefits—the typical enhancement being a lower deductible rather than benefits in the coverage gap.[5] MA–PD enrollees were also predominantly in plans that use copays, and 94 percent were in enhanced plans.

Enrollees in PDPs are more likely to have a deductible than enrollees in MA–PDs. In 2009, about 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 $295 deductible. By comparison, 95 percent of MA–PD enrollees had no deductible. This situation reflects, under the Part C payment system (which is used to pay MA plans), the ability of MA–PDs to use 75 percent of the difference between the plan's benchmark payment and its bid for providing Part A and Part B services (known as Part C rebate dollars) to supplement benefits or lower premiums. Many MA–PDs use some of their Part C rebate dollars to enhance their Part D benefit by charging no deductible, providing benefits in the coverage gap, or reducing their premium.

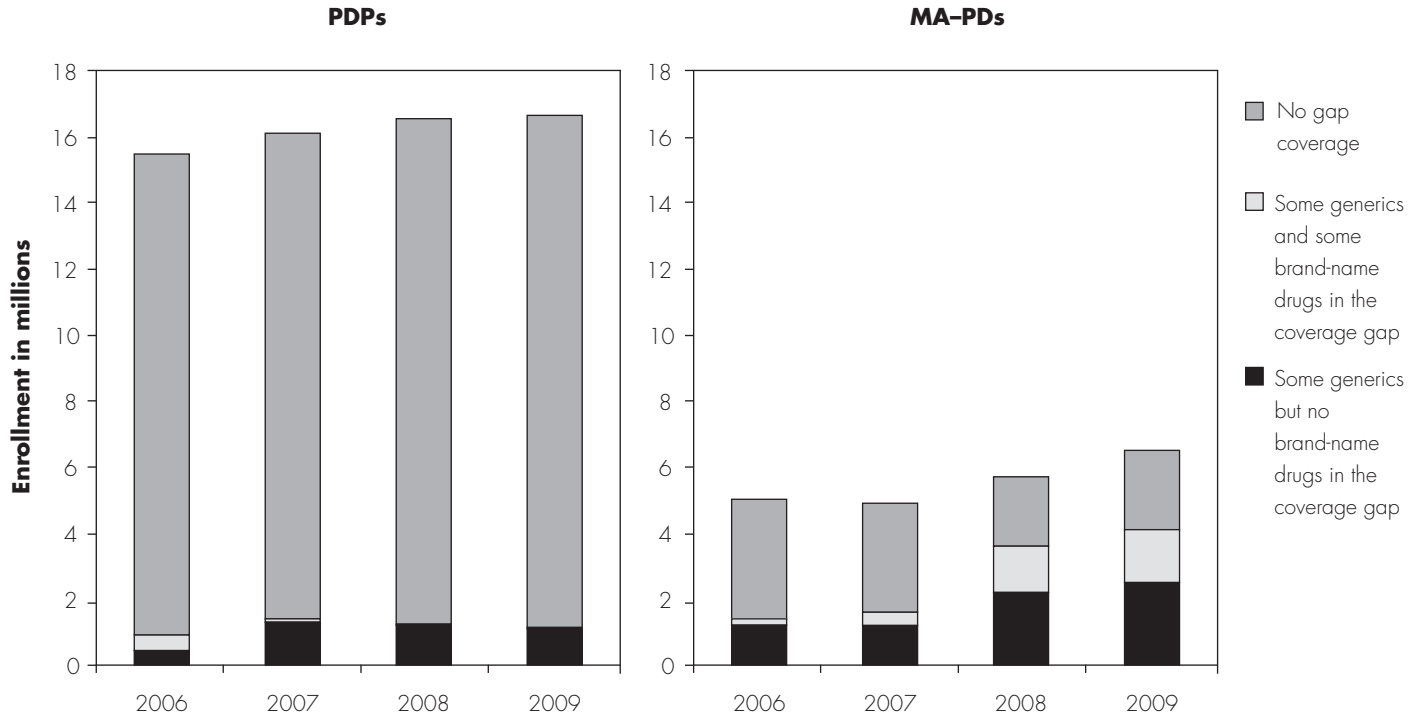
A similar pattern of differences between PDPs and MA-PDs holds for benefits in Part D's coverage gap (Figure 5-2, p. 288). In 2009, only 7 percent of PDP enrollees (1.1 million beneficiaries) were in plans that offered benefits in the coverage gap, usually for generic drugs rather than brand-name drugs. However, 45 percent of PDP enrollees received Part D's LIS, which effectively eliminates their coverage gap. By comparison, 63 percent of MA–PD enrollees (4.1 million beneficiaries) were in plans offering gap coverage, generally covering generics but not brand-name drugs.

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

Prescription drugs are used widely by beneficiaries. According to the Commission's analysis of 2007 prescription drug event data, nearly 92 percent of Part D plan enrollees filled at least one prescription during the year. Enrollees filled an average of 3.9 prescriptions per month, with considerably higher average utilization among those who received the LIS (4.6 per month) than among beneficiaries who did not (3.4 per month). While LIS enrollees tend to have a greater disease burden than non-LIS enrollees, under Part D they have much lower cost sharing, ranging from no copays to about $6 per prescription for dual-eligible beneficiaries who have the most comprehensive benefits. Other LIS enrollees pay

FIGURE 5–2

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 for 2009.

15 percent coinsurance. By comparison, in 2009, median copays for non-LIS enrollees were about $7 per generic prescription and more than $75 per prescription for nonpreferred brand-name drugs.

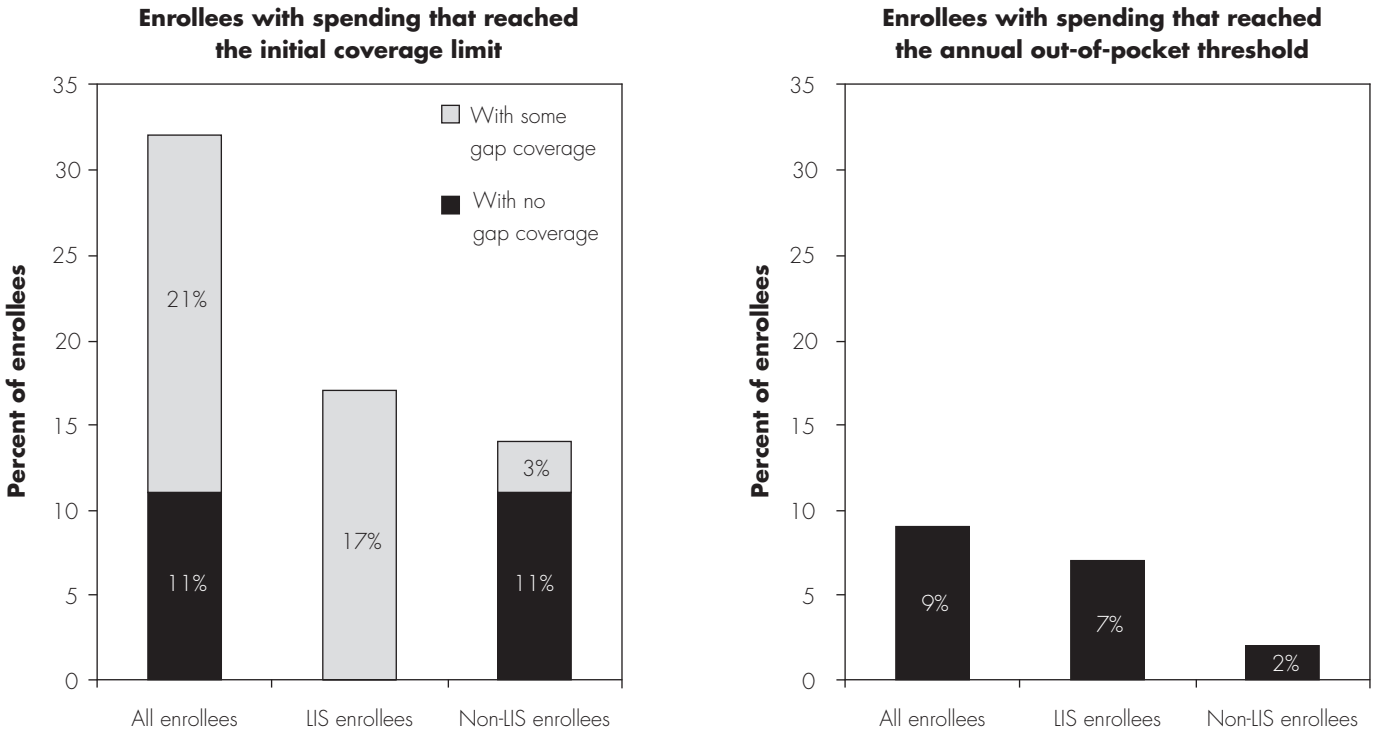
In 2007, nearly a third of Part D enrollees (8.3 million) had benefit spending high enough to put them in the coverage gap, but only 1 in 10 paid 100 percent cost sharing (Centers for Medicare & Medicaid Services 2008). In Part D's coverage gap, most non-LIS enrollees face 100 percent of the plan's negotiated cost of the drug, unless they are in a plan that provides some benefits in the gap. In 2007, about 2.9 million beneficiaries (11 percent of Part D enrollees) were exposed to 100 percent cost sharing in the coverage gap (left-hand side of Figure 5-3). Another 0.9 million non-LIS beneficiaries (3 percent of Part D enrollees) were in enhanced plans that provided some benefits in the coverage gap—usually limited to generic drugs. LIS enrollees, for whom the gap is eliminated, accounted for more than half of the enrollees with higher spending (4.5 million, or 17 percent of all Part D enrollees). About 9 percent of Part D enrollees had spending that reached Part D's catastrophic threshold (right-hand side of Figure 5-3). Of these 2.3 million individuals, nearly 2 million (7 percent of Part D enrollees) received the LIS.

Different effects of coverage gap on LIS and non-LIS enrollees

To provide a qualitative look at beneficiary experiences with Part D, the Commission evaluated 12 beneficiary focus groups in 3 markets (Baltimore, Chicago, and Seattle) from July to August 2009. Groups averaged eight participants. Six groups were composed of LIS recipients, and six were composed of beneficiaries who reached or anticipated reaching the coverage gap in 2009 or had reached the gap in previous years. Although focus groups cannot provide the precision or comprehensiveness of quantitative findings, they enable us to gain more real-time knowledge of how the benefit is working.

FIGURE 5–3

About 1 in 10 Part D enrollees faced 100 percent cost sharing in the coverage gap during 2007



Note: LIS (low-income subsidy). Part D enrollees who receive the LIS do not face a coverage gap. In 2007, Part D enrollees reached the initial coverage limit at $2,400 in benefit spending. If they had no supplemental coverage, an enrollee reached the annual out-of-pocket threshold at $3,850 of out-of-pocket spending. Some percent of non-LIS enrollees who reached the catastrophic threshold may have had some gap coverage. Sums may not add to totals due to rounding.

Source: CMS 2008.

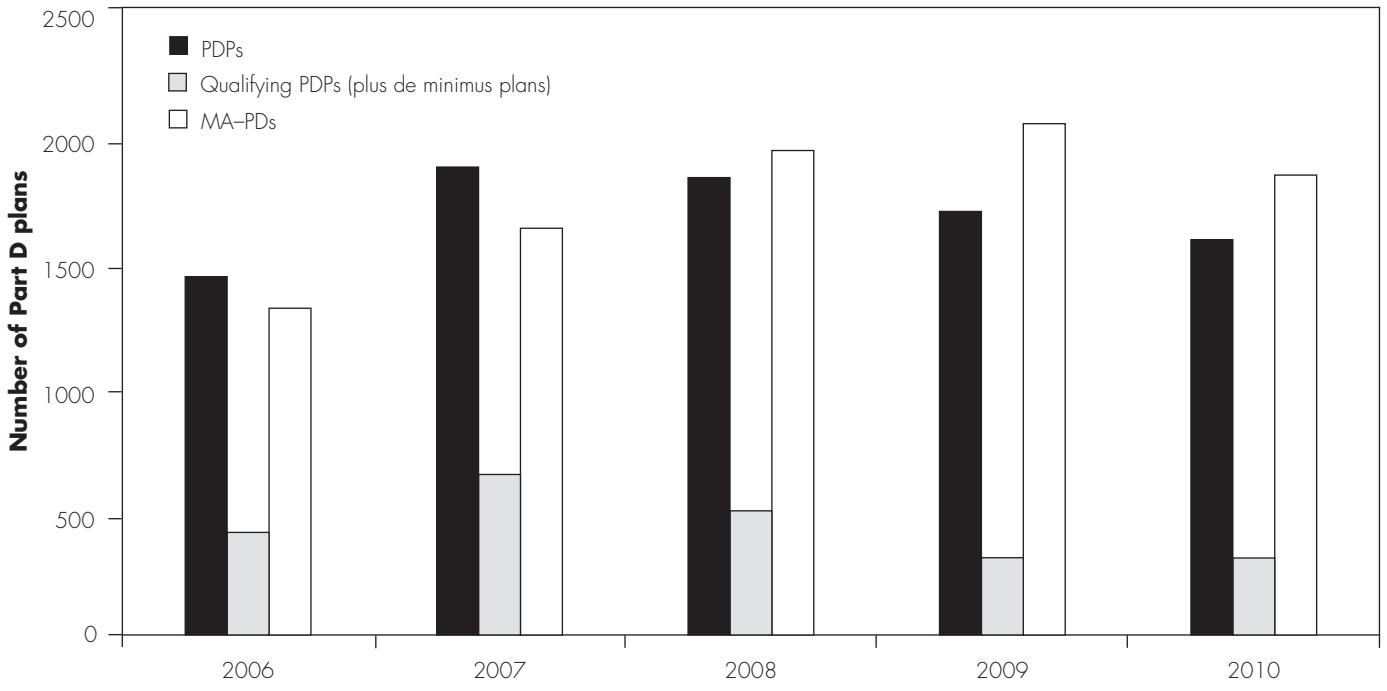
LIS beneficiaries, who do not face a gap in their coverage, generally reported good access to their medications. A few individuals reported a delay in getting their drugs because they switched plans or their plan's formulary changed, but these problems were resolved. Only one beneficiary in the LIS groups mentioned that the cost of drugs was a problem.

Conversely, non-LIS beneficiaries who reached the coverage gap were very conscious of costs and sought to minimize them in various ways. One participant who reached the coverage gap in January and two participants who did not reach the gap until November continued to purchase and use medications as they had before they reached the limit. However, in each focus group, other participants reported multiple strategies to lower their costs. Those strategies included seeking drug samples from their physicians, switching to generic alternatives, using mail-order pharmacy service to lower their copays, asking for higher dosages of their medications and splitting pills to last twice as long, discontinuing one or more of their drugs, taking pills every other day, asking drug companies for assistance, purchasing drugs from Canada, comparing pharmacy prices for their drugs, and purchasing generic drugs from Walmart or similar stores that sell some generic prescriptions for $4. In the latter case, the idea was to postpone reaching the coverage gap by not using their Part D insurance for these purchases.

Some beneficiaries carried out these strategies in collaboration with their physicians, but others did not. For example, some never told their physicians they had stopped taking certain drugs. Focus group participants were more likely than in previous years to report that they told their physicians they could not afford to keep taking some medications. In many cases, the physician suggested alternative drugs or other strategies to ensure that patients continued to receive treatment.

FIGURE 5–4

Numbers of Part D plans decreased somewhat in 2010



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]. Qualifying PDPs are plans for which low-income subsidy (LIS) enrollees pay no premium because the plans' premiums are at or below a regional premium threshold. De minimus plans are plans that CMS permitted to retain their LIS enrollees because the plan premium was within a small variance from the regional LIS premium threshold.

Source: CMS landscape files and Part D bid data.

Many focus group participants reported that they used these strategies without apparent adverse consequences. However, others reported some additional costs or adverse effects. For example, some beneficiaries reported needing additional physician visits to monitor the effects of changes to their drug regimen. Others experienced side effects from the new medications or had poorer control of their condition. Some continued on replacement drugs while others went back to their original regimens.

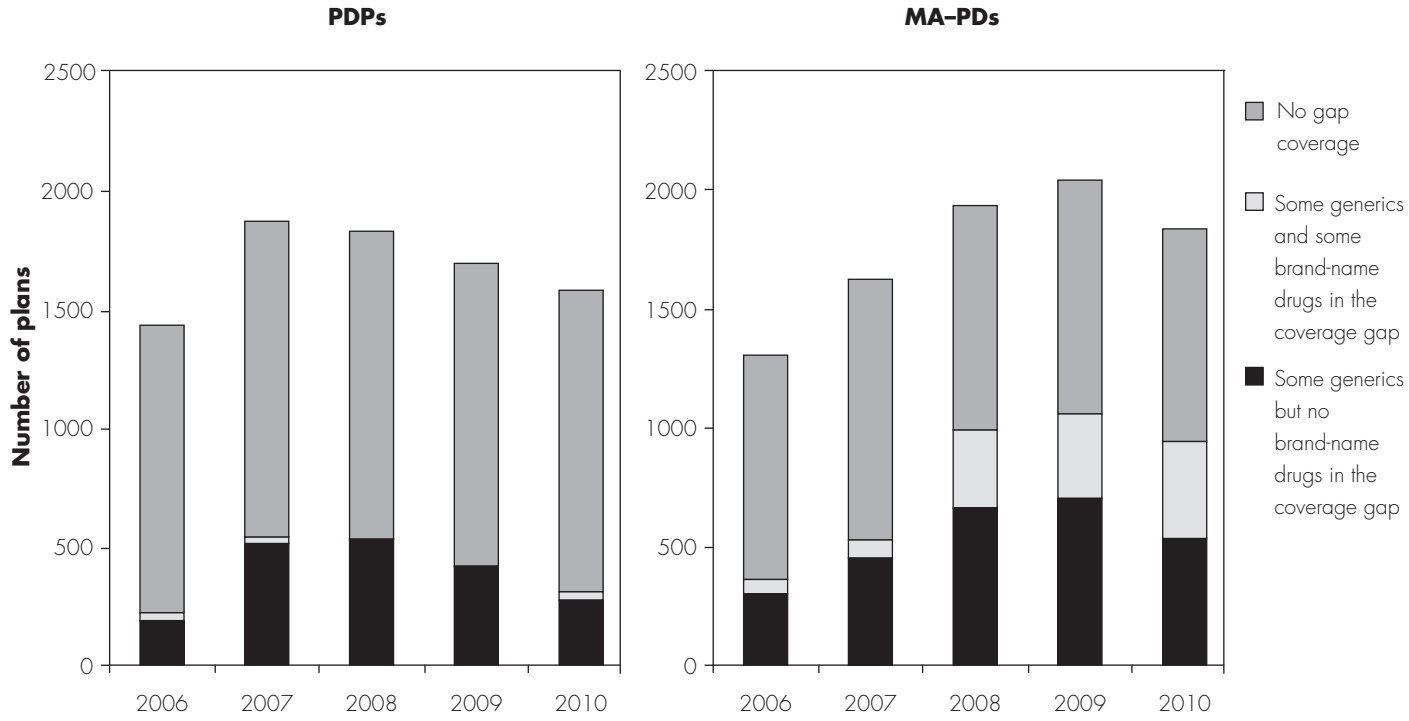
Broad availability of plans in 2010

Beneficiaries continue to have many choices of Part D plans in each region. In 2010, sponsors are offering a total of 1,576 PDPs, or about 7 percent fewer than in 2009 (Figure 5-4).[6] There are 1,834 MA–PDs available, or about 10 percent fewer than in 2009, reflecting a decline in the number of local health maintenance organizations as well as a drop by about one-third in the number of private FFS plans offered. CMS estimates that decisions by either plan sponsors or CMS not to renew contracts for the upcoming year affected nearly 400,000 MA–PD enrollees (Hill 2009). Still, Medicare beneficiaries continue to have 41 to 55 PDP options, along with many (sometimes dozens of) MA–PDs. The number of MA–PD plans available to a beneficiary varies by the county of residence.

For 2010, LIS enrollees have about the same number of PDPs available to them at no premium as in 2009. A total of 307 PDPs have premiums at or below the LIS monthly premium subsidy amount for their region, compared with 308 in 2009 (Figure 5-4). In addition, 133 MA–PDs and 295 MA special needs plans (SNPs) qualified as premium-free to LIS beneficiaries who enroll in them. Each region has at least four PDPs available to LIS enrollees at no premium. (See Table 5-A2 in the online appendix to this chapter.)

FIGURE 5–5

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]).

Source: MedPAC analysis of CMS landscape data for 2009.

Notable changes for 2010 in benefit design and formularies

Those beneficiaries who reexamined their options for the 2010 benefit year may have found some important changes in plan coverage, particularly if they were in PDPs that did not charge a deductible in 2009, if they received the Part D LIS, or if they were in a private FFS MA–PD.

Benefit designs

For the 2010 benefit year, organizations that offer PDPs tightened many of their plans' benefit designs, while the structure of drug benefits in MA–PDs held fairly steady. A smaller share of PDPs has no deductible in 2010—40 percent compared with 55 percent in 2009. The proportion of MA–PD offerings that charge no deductible is roughly the same in both years—about 90 percent.

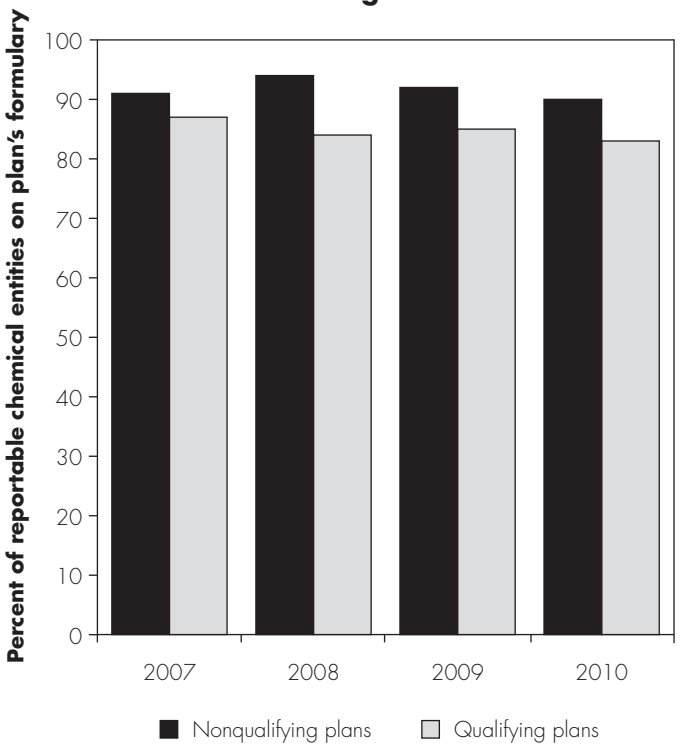
In 2010, a somewhat smaller percentage of PDPs provides gap coverage (Figure 5-5). In 2009, about 25 percent of PDPs (more than 400 plans out of nearly 1,700 PDPs) included some gap coverage—usually some or all generic drugs but no brand-name medications. For 2010, that share fell to 20 percent (about 300 PDPs out of nearly 1,600). In contrast, the share of MA–PDs with gap coverage held steady at just over 50 percent in 2010 (more than 900 plans out of nearly 1,800 MA–PDs); among those plans with such coverage, a slightly higher share cover some brand-name drugs (in addition to generics). Among both PDPs and MA–PDs, the share of plans offering coverage of all generic drugs has been declining, and a sizable share charge higher cost sharing for generics after the enrollee has reached the coverage gap (Hoadley et al. 2009c).

Plan formularies

In Part D, each plan sponsor operates one or more formularies—lists of the 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

FIGURE 5–6

Plans that qualify as premium-free to LIS enrollees tend to list fewer drugs on their formularies



Note: LIS (low-income subsidy). Excludes plans that qualified to keep LIS enrollees based on waivers for 2007 and 2008. Also excludes plans offered by WellCare because that sponsor's formulary data were not available at the time this analysis was prepared. Calculations are weighted by total plan enrollment. Number of nonqualifying plans: 2007 = 1,228, 2008 = 1,228, 2009 = 1,379, 2010 = 1,222. Number of qualifying plans: 2007 = 483, 2008 = 442, 2009 = 308, 2010 = 288.

Source: NORC/Georgetown University/Social and Scientific Systems analysis for MedPAC of formularies submitted to CMS and Part D enrollment data.

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 levels of cost sharing can lead to Part D premiums that are 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.

Under contract with the Commission, researchers at NORC at the University of Chicago, Georgetown University, and Social and Scientific Systems analyzed Part D formulary data. 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 broader grouping that encompasses all of a chemical's forms, strengths, and package sizes. The definition combines brand-name and generic versions of the same chemical entity (Medicare Payment Advisory Commission 2008).[7]

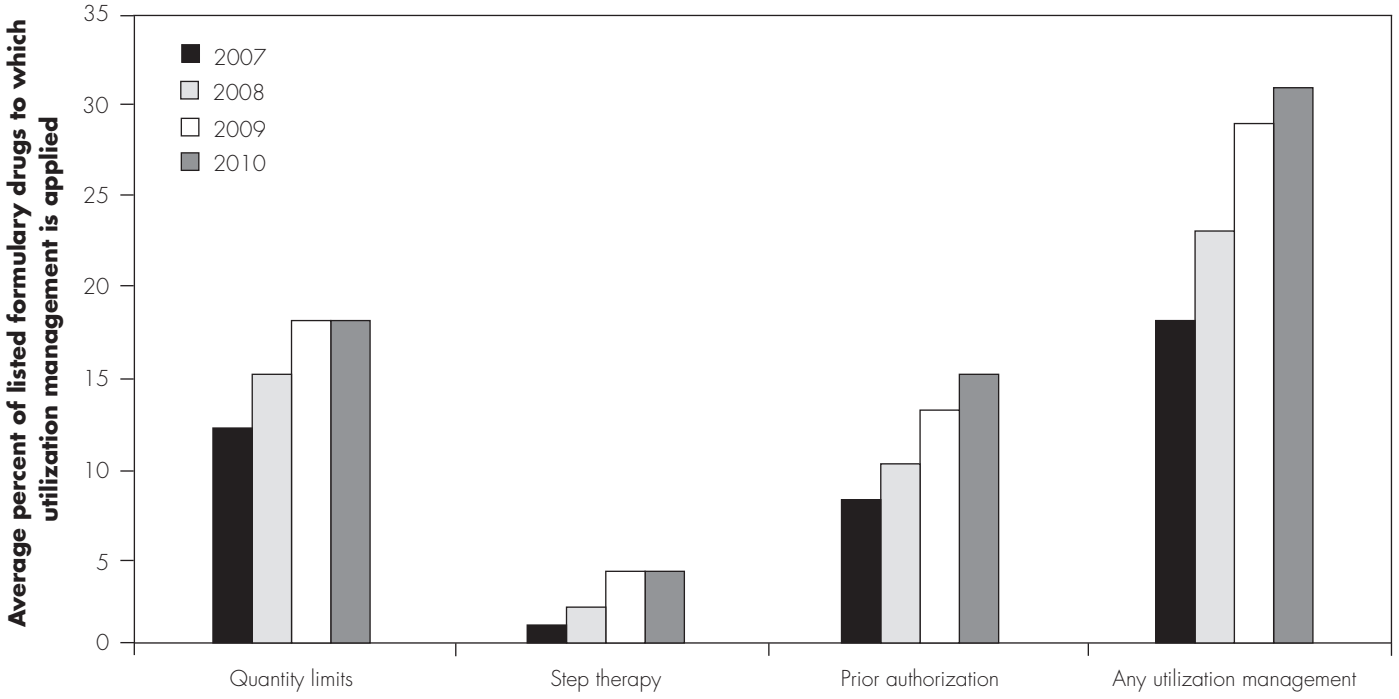
CMS data show that about 80 percent of all Part D enrollees are in plans that use: (1) a single cost-sharing tier for generic drugs; (2) two tiers for brand-name drugs (a preferred tier with lower cost sharing and a nonpreferred tier); and (3) a specialty tier for expensive products, unique drugs, and biologics.[8,9] Only about 10 percent or fewer of enrollees are in plans that use the 25 percent coinsurance of Part D's standard benefit design. The remaining enrollees are in plans that use other formulary structures.[10] (See Figure 5-A4 in the online appendix to this chapter.)

The number of drugs that sponsors list on a formulary is another way to view beneficiaries' access to prescription drugs under Part D, but caution is in order, as that number does not provide a complete picture. Plans' processes for nonformulary exceptions, prior authorization, quantity limits, and step therapy requirements can strongly affect access as well.[11] 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. Alternatively, some sponsors do not automatically cover drugs listed on their formulary if prior authorization is required before filling a prescription.

For 2010, the average PDP enrollee is in a plan that lists 88 percent of all distinct chemical entities on which CMS requires sponsors to report (referred to here as reportable drugs), while the average MA–PD enrollee is in a plan listing 90 percent (Figure 5-A5 in the online appendix to this chapter).[12] This relative breadth of the formulary for the average Part D enrollee has been stable since the program's inception.[13] Still, the number of drugs listed can vary considerably among plans, from 37 percent for plans with the smallest formularies to 100 percent for other plans.

FIGURE 5–7

PDP's use of utilization management tools has grown over time



Note: PDP (prescription drug plan). Calculations are weighted by total plan enrollment.

Source: NORC/Georgetown University/Social and Scientific Systems analysis for MedPAC of formularies submitted to CMS and Part D enrollment data.

Cost sharing for LIS enrollees is set statutorily and is much lower than for other enrollees. As a result, plan sponsors may need to use different strategies to manage drug utilization if they anticipate having a relatively high percent of enrollees who receive the LIS. Typically, sponsors rely on the differences they set between copays for drugs available on their formulary's tiers to steer enrollees toward using generic and preferred brand-name drugs. Because LIS enrollees face low or no cost sharing, sponsors with higher proportions of LIS enrollment may need to rely more heavily on a tighter formulary or utilization management tools, such as prior authorization. At the same time, large differences between the formularies of plans that qualify as free to LIS enrollees and those that do not could raise concern about inequitable access to drugs.

CMS data show that plans qualifying as premium-free to LIS enrollees tend to have somewhat smaller formularies than plans that do not qualify. In 2010, an LIS qualifying plan had, for the typical enrollee, an average of 83 percent of reportable drugs (chemical entities) listed on its formulary, compared with 90 percent for a nonqualifying plan (Figure 5-6).

The use of utilization management tools in Part D—including quantity limits, step therapy, and prior authorization—has grown over time (Figure 5-7). Sponsors use such tools for drugs that are expensive; potentially risky; or subject to abuse, misuse, or experimental use. They also want to encourage use of lower cost therapies. Some tools are more common than others. For example, all PDPs and MA–PDs use prior authorization for at least one drug on their formulary. For 2010, the average enrollee in a PDP faces some sort of utilization management for 31 percent of listed drugs—an increase from 18 percent in 2007. Quantity limits are used for 18 percent of drugs, step therapy for 4 percent, and prior authorization for 15 percent. The use of specific tools varies by drug class.

LIS enrollees and plan reassignments

Part D's LIS covers the cost of an enrollee's premium up to a specified amount. Each year, CMS sets an LIS

Do plan sponsors want low-income subsidy enrollees?

Many beneficiaries who receive Part D's low-income subsidy (LIS) follow a different enrollment path than other individuals. For 2006, LIS enrollees who did not choose a plan for themselves were randomly assigned to plans with premiums at or below regional benchmarks. Bidding low enough to win LIS enrollees may have been especially attractive to plan sponsors when CMS was launching Part D, because they did not know how much of the market they would have, nor did sponsors incur marketing costs for autoassigned members.

Now that Part D is in its fifth year, it may be important to ask whether plan sponsors are still seeking to enroll beneficiaries who receive the LIS. Some clearly do: The percentage of their members who receive the LIS is high in some plans and their sponsors appear to be profitable. Yet, other plan sponsors may not want LIS members because they tend to have poorer health and use more prescription drugs. In turn, more LIS members could lead a plan to have higher benefit spending and premiums.

In 2009, several sponsors lost considerable numbers of LIS enrollees because their plans' premiums were above regional benchmarks for LIS premiums. In asking what might have led to this result, the Commission cited the importance of good risk adjustment to effective program performance. As long as Medicare's risk-adjusted payments for LIS enrollees cover plans' average benefit costs, sponsors have an incentive to bid low to keep or attract those beneficiaries. But if risk adjusters do not compensate adequately for LIS enrollees, an incentive may exist for sponsors to bid higher to avoid LIS enrollees. Commission-sponsored research found that adding information about beneficiaries' past drug utilization could increase the explanatory power of Part D's risk-adjustment system (Medicare Payment Advisory Commission 2009b). CMS is exploring this idea.

Among plans for 2010, a number of prescription drug plan sponsors are offering basic and enhanced plans side by side in the same region, with premiums for basic plans higher than those for enhanced benefits(Hoadley et al. 2009a). This event is notable because LIS enrollees are assigned randomly only to plans that offer basic benefits—CMS cannot reassign them to enhanced plans that provide supplemental benefits. Offering enhanced plans with lower premiums allows sponsors to compete for non-LIS beneficiaries without being assigned new LIS enrollees. ■

premium threshold for each PDP region based on a weighted average of plans' premiums for basic benefits.[14] As long as a plan's premium falls below the required benchmark, LIS beneficiaries pay no premium or a reduced premium and cost sharing if they remain in the plan.[15] However, LIS beneficiaries may be reassigned automatically on a random basis to a different plan each year if their current plan's premium is too high. LIS enrollees may remain in their existing plan if they choose to pay the additional premium above the LIS benchmark; CMS refers to these individuals as "choosers."

Numbers of LIS reassignees

Nearly three million LIS enrollees were affected by the turnover of qualifying plans for 2010:

- CMS had to reassign an estimated 1.06 million LIS enrollees to plans offered by a different sponsor because their previous plan's premium did not fall below the 2010 threshold (Centers for Medicare & Medicaid Services 2009a). This number of reassignees is nearly the same as it was in 2009.
- Another 0.1 million were reassigned to a qualifying plan offered by the same sponsoring organization (Centers for Medicare & Medicaid Services 2009a). When sponsors use the same formulary for all their plans, these reassigned individuals are less likely to face significant changes.
- In late 2009, 1.7 million LIS members were enrolled in a plan they had selected (i.e., they did not remain in a randomly assigned plan) but that plan did not qualify

as premium-free for 2010 (Centers for Medicare & Medicaid Services 2009e). It is not yet clear how many of these "choosers" picked a new qualifying plan themselves for 2010 or are paying a portion of their premium to remain in the same plan.

For 2009, CMS used rulemaking authority to change the way it set the LIS premium thresholds to reduce LIS reassignments.[16] Even with this approach, however, the number of reassignees remained high for 2010, and CMS officials did not believe the policy change addressed the issue adequately. In August 2009, CMS announced that it was using general demonstration authority to further adjust LIS premium thresholds (Centers for Medicare & Medicaid Services 2009d). Under its general demonstration authority, CMS set the premium thresholds by first removing Part C rebate dollars from MA–PD premiums before averaging plan premiums. Without such an action, the agency estimates that the number of LIS reassignees for 2010 would have been twice as large (Hill 2009). CMS's Office of the Actuary estimated that the demonstration would cost $110 million in 2010.

LIS choosers

Some LIS enrollees choose to remain in their current plan rather than be reassigned to a new one. If at any time LIS enrollees select a plan different from their random assignment, CMS no longer reassigns them. By one preliminary estimate, about 2.5 million LIS enrollees fell into this "chooser" category for 2010 (Hill 2009). Some of these individuals were in plans that qualified as premium-free for 2010, were in MA–PDs, or participated in state pharmacy assistance programs. There were 1.7 million in plans that did not qualify; they received a letter from CMS notifying them that they could either switch to a qualifying plan or remain in the same plan and pay the difference between the plan's premium and the threshold amount that Medicare covers in the region. The premium amount such individuals need to pay differs across plans, ranging from 10 cents to more than $86 per month. The most common amounts are $8 to $10 per month.

Effects of switching plans

Beneficiaries who switch plans and the physicians and pharmacies who serve them could face transition issues as they change formularies. For example, an enrollee may need to negotiate transition supplies of drugs and try to navigate different coverage rules. (Under CMS policy, during the first 90 days of a beneficiary's enrollment, sponsors are required to provide a 30-day supply of the enrollee's current medication, even if it is not covered on the plan's formulary, to give the enrollee time to obtain a substitute drug or request a formulary exception. In addition, dually eligible enrollees may change Part D plans monthly.) Enrollment and LIS eligibility information is transmitted through less than up-to-date data systems that must connect sponsors, states, CMS, SSA, and pharmacies. At the point of service, pharmacists must know the beneficiary's plan and applicable copay. A potential outcome is that enrollees may discontinue needed medication.

The Commission and CMS have begun investigating how the current process of reassignment affects LIS enrollees. Focus groups of LIS enrollees conducted for the Commission in 2009 did not report many problems resulting from switching from one plan to another. An empirical analysis conducted for CMS of reassignments completed early in the Part D program found that health outcomes—as measured by rates of mortality, hospitalizations, and emergency room use—were no different between LIS enrollees who had been reassigned and LIS enrollees who had not (Centers for Medicare & Medicaid Services 2009b). CMS and the Commission will continue to explore this issue.

Should policymakers take steps to reduce the number of LIS enrollees who must switch plans? Transitions between plans may be particularly challenging for dual-eligible beneficiaries, who tend to have more chronic conditions and use more prescription drugs. Some of these individuals have cognitive impairments and may lack family support to help them navigate the transition to a new plan's formulary. On the other hand, Part D enrollees who do not receive the LIS also face transition issues. For example, one estimate suggests that 27 percent of non-LIS PDP enrollees face a premium increase of $5 per month or more in 2010 if they do not change plans (Hoadley et al. 2009b). Some of those individuals will find such an increase unaffordable, will need to switch plans, and may need to change some medications or seek formulary exceptions. Additionally, enrollees who remain in the same plan may still face some transition issues if their plan's formulary changes from one year to the next

Costs of Part D

To review Part D's costs, we examined aggregate program spending, trends in plans' bid amounts, trends in the prices

TABLE 5–2

Medicare's reimbursements for Part D on an incurred basis

	Calendar year			
	2006	**2007**	**2008**	**2009***
In billions of dollars				
Direct subsidy	$17.6	$18.1	$17.5	$18.8
Reinsurance	6.0	8.0	9.7	10.9
Low-income subsidy	15.1	16.7	18.2	19.9
Retiree drug subsidy	3.8	3.7	3.7	3.7
Total	$42.5	$46.6	$49.1	$53.4
Annual percentage change				
Direct subsidy	N/A	2.6%	–3.3%	7.8%
Reinsurance	N/A	33.5	20.7	12.4
Low-income subsidy	N/A	11.0	8.8	9.1
Retiree drug subsidy	N/A	–2.7	–0.6	1.1
Total	N/A	9.5	5.4	8.7

Note: N/A (not applicable). 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, and $6.3 billion in 2009. Totals may not sum due to rounding.
*Estimated.

Source: MedPAC based on Table IV.B.10 of the Medicare Board of Trustees' report for 2009.

plans obtain for drugs at the pharmacy counter, enrollees' premiums, and plans' cost-sharing requirements.

Components of Part D plan payments

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

- Direct subsidy—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 catastrophic threshold. Reinsurance reduces risk for Part D sponsors by providing greater federal subsidies for the highest cost enrollees.
- Low-income subsidy—Medicare pays projected LIS benefits to the plan to cover expected cost sharing and premiums for enrollees who are eligible for the LIS.

The first two types of subsidies combined average 74.5 percent of the cost of basic Part D benefits. In addition, Medicare establishes symmetric risk corridors separately for each plan to limit a plan's overall losses or profits. Under risk corridors, Medicare limits each plan's potential losses or gains by financing a portion of any higher-than-expected costs or by recouping a portion of higher-than-expected profits.

Low-income subsidy: Largest share of Part D costs

Between 2006 and 2008, incurred reimbursements for Part D (including spending for the RDS) grew from $42.5 billion to $49.1 billion (Table 5-2). In 2008, the total was made up of $17.5 billion in direct subsidy payments to plans, $9.7 billion in payments for individual reinsurance, $18.2 billion for the LIS, and $3.7 billion in RDS payments. CMS's Office of the Actuary estimated that Part D spending totaled $53.4 billion in 2009 (Boards of Trustees 2009).

As of 2008, spending for the LIS was the largest component of Part D spending—$18.2 billion compared with $17.5 billion in direct subsidies. Moreover, substantial portions of other categories of spending were

made on behalf of LIS enrollees. Thirty-six percent of Part D enrollees receive the LIS. However, those 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.[17]

Notably, Medicare payments for individual reinsurance have grown considerably faster than other components of Part D spending. The Office of the Actuary attributes part of the very high growth rates in 2007 and 2008 to plans' relative inexperience at bidding and a lack of good claims information on which to base their bids. (Note, for example, that plan sponsors had to submit bids for 2008 benefits in June 2007—before CMS had finished reconciling with plans on final payments for the 2006 benefit year.) Another force behind the growth in reinsurance spending was the trend in costs for drugs in plans' specialty tiers, which typically are higher priced products that have fewer therapeutic substitutes. Although Part D plan sponsors have an incentive to control drug spending, the degree to which they can control spending is weaker for certain drugs. If one drug can be substituted for another, a plan can bargain with manufacturers that want their product placed on the plan's formulary in a favorable position (e.g., on a preferred vs. nonpreferred tier). But if a plan must cover an innovative drug that has no therapeutic substitute, it has little negotiating power over the drug's price.

National average bid: Rose 5 percent in 2010

Between 2009 and 2010, national average costs for basic Part D benefits were projected to grow at 5 percent. (Table 5-A3 in the online appendix to this chapter displays average bids by year and percentage changes in those bids.) Each component of Part D benefit spending is projected to grow at roughly the same rate. Last year, we expressed concern at the high rate of growth in plans' expected individual reinsurance payments, reflecting higher estimates for the cost of Part D's catastrophic coverage. This year, that component is projected to grow at a pace more in keeping with the rest of Part D benefits. Still, given that reinsurance makes up the fastest growing component of aggregate spending, the Commission will continue to watch this issue with interest.

Part D drug prices: A mixed picture

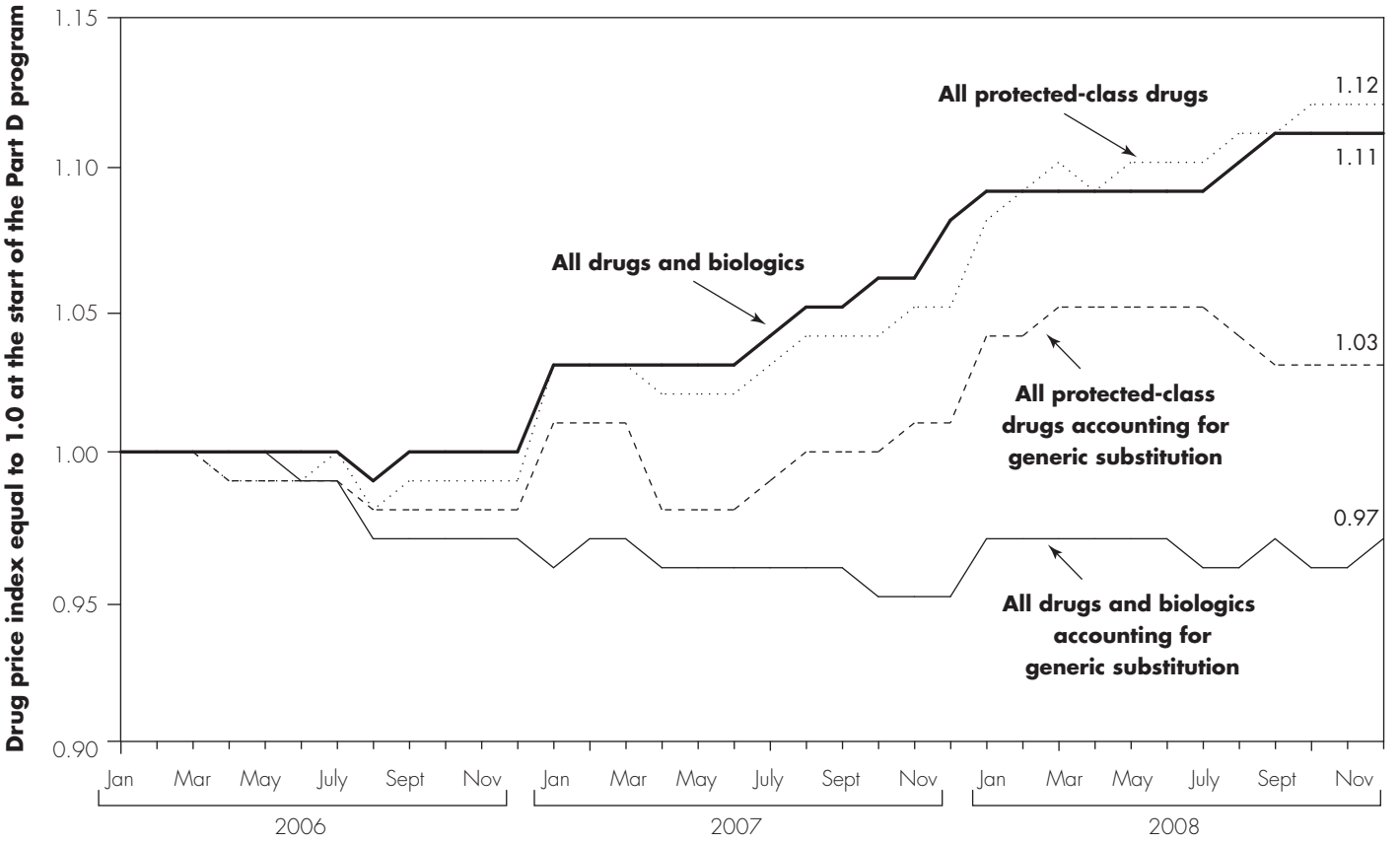
Most plan sponsors do not negotiate drug prices directly with pharmaceutical manufacturers.[18] Instead, sponsors set up contracts with a network of pharmacies with agreements on prices the plan will pay the pharmacy for drug ingredient costs and dispensing fees. In turn, pharmacies negotiate with manufacturers and wholesalers over the prices at which they will acquire drugs. Still, plan sponsors (or their pharmacy benefit manager (PBM) companies) play an important role by negotiating with manufacturers to receive retrospective rebates. If plan sponsors are successful at steering enrollees toward using certain brand-name drugs relative to other drugs for the same condition, manufacturers pay them an agreed upon amount per prescription. Sponsors and PBMs tend to use rebate revenues to offset plans' benefit spending (reducing plan premiums) rather than lowering the price of prescriptions at the pharmacy counter.

Part D rules require plan formularies to cover at least two drugs in every therapeutic class and key drug type that are not therapeutically equivalent and bioequivalent, unless there is only one drug approved for that class. This policy protects beneficiaries who need a drug that is the only one available for treating a certain condition and allows competition in classes with multiple products. If a product is the only drug of its type, CMS generally requires Part D plans to cover it. For six drug classes in which access to a particular product may be especially important, Part D plans must cover "all or substantially all" drugs in the class. Those classes are antineoplastics, antidepressants, antipsychotics, antiretrovirals, anticonvulsants, and immunosuppressants used by transplant patients.[19] Between 2006 and 2008, prescriptions in these six classes accounted for 11 percent of total Part D claims and 22 percent of drug costs. Although plans must cover these drugs, they can still charge higher cost sharing for them, such as by placing them on tiers for nonpreferred brands. Sponsors can use requirements for prior authorization or step therapy with the intention of steering enrollees to preferred drugs only for beneficiaries who are just starting treatment on a protected-class drug.[20]

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 (Office of Inspector General 2007). Plan sponsors (and their PBMs) also regularly steer enrollees and negotiate rebates from manufacturers for brand-name drugs that have therapeutic alternatives. But like other purchasers, sponsors have had less success negotiating rebates for unique drug and biologic products.

FIGURE 5–8

Mixed success at drug prices obtained under Part D



Note: Chain-weighted Fisher price indexes.

Source: Acumen, LLC, analysis for MedPAC.

To track drug prices, the Commission contracted with researchers at Acumen, LLC, to construct a series of volume-weighted price indexes (Figure 5-8). 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 11 percent cumulatively between January 2006 and December 2008 (MaCurdy et al. 2010).[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 declined cumulatively by 3 percent between January 2006 and December 2008.[22]

An open question has been the degree to which plan sponsors can steer utilization within the six protected drug classes. 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 12 percent over the three-year period (Figure 5-8). Given their protected status, these drugs might have been expected to experience faster price growth, similar to what Acumen estimated for biologic products (Medicare Payment Advisory Commission 2009a). However, the observed 12 percent growth is influenced heavily by the experience of antidepressant medications, which account for about half of the volume in the six classes and had many generics in the market during this period. Our price index for the individual NDCs of those drugs fell by 11 percent (data not shown). Others of the six classes are made up almost entirely of brand-name drugs, and for these products, prices grew rapidly.

TABLE 5–3 **Comparison of weighted average Part D premiums in 2009 and 2010**

	2009 enrollment (in millions)	Average 2009 premium*	Average 2010 premium*	Percentage change in average premium
PDPs	16.6	$35.08	$37.67	7%
MA–PDs, excluding SNPs**	6.2	14.59	13.99	–4
SNPs**	1.1	16.55	21.68	31
All plans	23.8	28.91	30.52	6

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), SNPs (special needs plans). Estimates are preliminary and subject to change. The PDPs and enrollment described here exclude employer-only plans and plans offered in U.S. territories. The MA–PDs and enrollment described here exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B-only plans.
*Values for plans offered in 2009 reflect enrollment levels of those plans in February 2009. Values for plans offered in 2010 reflect enrollment levels of those plans as of January 2010. Note that January enrollment figures may not fully reflect all enrollment changes from the fall 2009 open enrollment period.
**Reflects the portion of MA plans' total monthly premium attributable to Part D benefits for plans that offer Part D coverage. MA–PD premiums reflect rebate dollars (75 percent of the difference between a plan's payment benchmark and its bid for providing Part A and Part B services) that were used to offset Part D premium costs.

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

For example, Acumen's index for the individual NDCs of antineoplastic drugs grew by a cumulative 31 percent (data not shown). When protected-class drugs were grouped to take generic substitution into account more directly, their prices grew by a cumulative 3 percent over the three-year period. Despite the drugs' protected status, plan sponsors appeared to have had success at moving enrollees toward generics for these drugs. However, we expect 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 branded drug. We lack rebate information to test that hypothesis.

Part D premiums: Average rose, but increases are smaller than last year

At the time of publication, we estimated that Part D enrollees in 2010 are paying, on average, $30.52 per month, up $1.61 (6 percent) from 2009 (Table 5-3). In 2010, the average PDP enrollee pays about $37.67 per month, or $2.59 more (7 percent) than in 2009. As in past years, premiums for the most popular PDPs increased more than others, but, in general, premium increases were smaller for 2010 than they were in 2009.

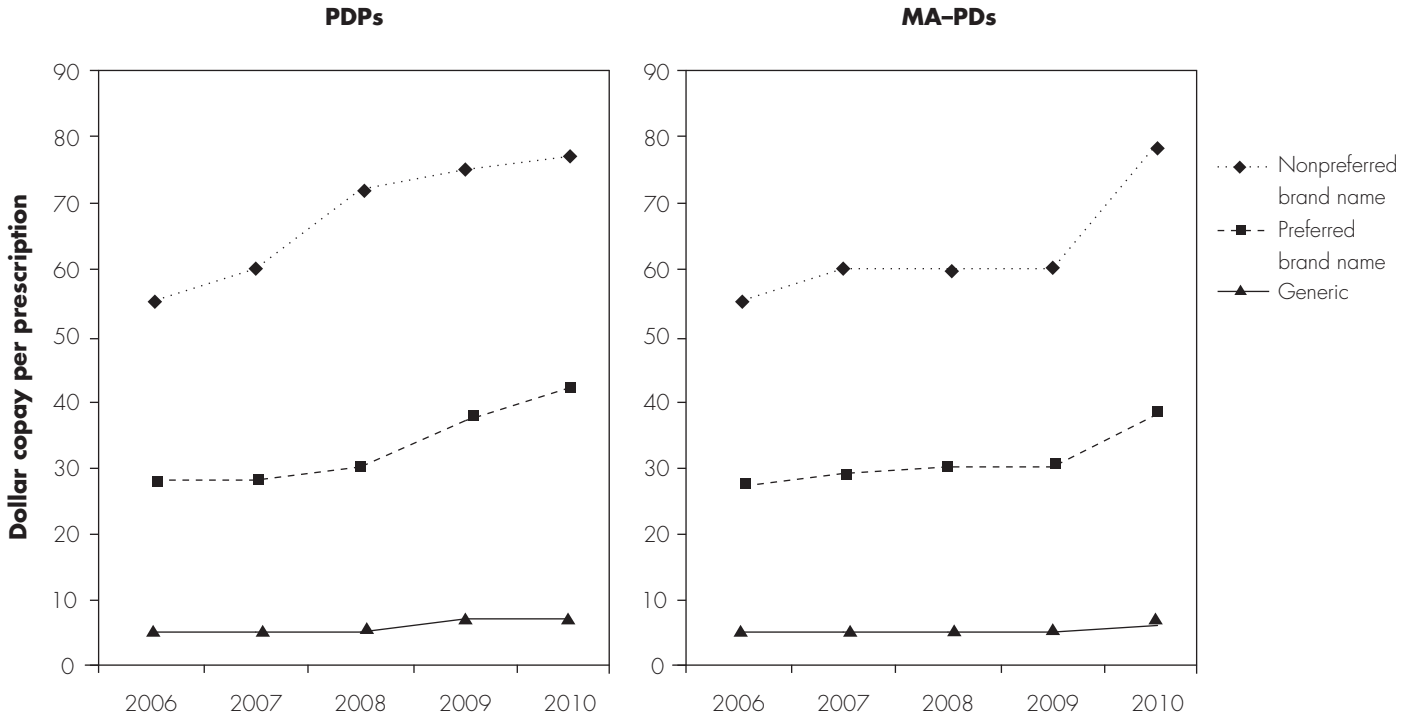
The portion of MA premiums attributable to prescription drug benefits declined by $0.59 (4 percent), with the average MA–PD enrollee paying $13.99 per month. (This amount reflects MA–PDs' rebate dollars that come from the MA payment system. Many MA plan sponsors apply rebate dollars to lower or eliminate their premium for Part D benefits. In 2010, about one-third of MA–PDs charge no additional premium for drug coverage after applying rebate dollars.) The drug benefit component of premiums for MA SNPs grew much more than for other types of MA plans, with average premiums increasing by 31 percent for 2010.

The estimates in Table 5-3 may somewhat overstate the average premium increase that Part D enrollees are experiencing in 2010, because they may not fully reflect how many beneficiaries changed plans. Because of our publication deadline, we used January 2010 data to develop the estimates in Table 5-3. However, that information may not capture final data on reassignments of LIS enrollees and beneficiaries who switched plans at the end of the open enrollment season.

For 2010, the average portion of an MA–PD plan's premium for Part D benefits (before applying rebate dollars from the MA payment system) is approximately $12.50 less than the average PDP premium. Bids for both PDPs and MA–PDs make up the overall national average bid that CMS uses as the basis for setting program payments. To the extent that MA–PD bids are lower because of better care management and efficiency, they may reduce federal program spending somewhat for Part D. However, lower MA–PD bids may also reflect differences in coding practices for members' underlying conditions or plans' ability to attract healthier members.

FIGURE 5–9

Median cost sharing for a month's supply of drugs has risen



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

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

Plans' cost-sharing requirements: Increased in 2010

Although there is wide variation across plans, for 2010, cost-sharing requirements rose overall (Figure 5-9). Copay levels for the median enrollee in a PDP remained flat at $7 per 30-day prescription for a generic drug but rose from $37 to $42 for preferred brand-name drugs and from about $75 to $76.50 for nonpreferred brands (Figure 5-9). Meanwhile, median copays for MA–PD enrollees rose to levels closer to copays charged by PDPs. For 2010, the median enrollee in an MA–PD pays $6 for a monthly supply of generic drugs, $38 for preferred brand-name drugs, and $79 for nonpreferred brands.

For 2010, the median enrollee in a PDP with a specialty tier faces 30 percent coinsurance for drugs in this tier, while the median MA–PD enrollee faces 33 percent.[23] 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 is permitted for other drugs, such as those on tiers for nonpreferred brands. Because drugs in specialty tiers are often used to treat serious chronic illnesses such as rheumatoid arthritis and multiple sclerosis, patients needing these drugs could face relatively high cost sharing for medications on top of significant out-of-pocket 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. Moreover, if most of a sponsor's competitors use specialty tiers, it may be important to use a specialty tier to limit the risk of attracting sicker enrollees taking very expensive drugs. Otherwise, those expensive drugs would be available for much lower copays.

Measuring plan performance in Part D

CMS collects data about performance and quality of Part D plans to help it monitor sponsors' operations and

help beneficiaries choose among plans. However, most of the quality measures relate to customer service and satisfaction more than patient safety and timely access to needed medicines. For 2010, CMS has changed its requirements for plans' medication therapy management programs (MTMPs), which are aimed at enrollees who take many prescription drugs.

Performance metrics for Part D

CMS collects quality and performance data for plan sponsors from several sources—the Consumer Assessment of Health Providers and Systems survey, agency monitoring of plans, and data furnished by sponsors. The agency is also beginning to use claims information as another source.

CMS makes selected performance measures available on the Medicare Prescription Drug Plan Finder at www.medicare.gov to help beneficiaries evaluate their plan options during Part D's annual open enrollment season (Table 5-A4 in the online appendix to this chapter). For 2010, 19 metrics are grouped into four domains:

- drug plan customer service (seven measures);
- member complaints, members who chose to leave, and audit findings (four measures);
- member experience with drug plans (three measures); and
- drug pricing information and patient safety (five measures).

Two measures in the last domain relate to patient safety.[24] The first captures elderly members' use of drugs that have a high risk of side effects when there may be safer drug choices.[25] The second is a measure of optimal treatment for diabetes patients.[26] Other patient safety measures are under review by organizations of stakeholders that focus on quality measurement, such as the Pharmacy Quality Alliance, and CMS may adopt them once they have been validated and endorsed. None of CMS's measures that are currently available captures whether enrollees got their prescribed drug or an alternative therapy without undue delay.

CMS aggregates individual scores for each of the 19 measures on the Plan Finder into a 5-star system based on adjusted percentile rankings of sponsors; 5 stars means excellent performance and 1 star reflects poor performance. CMS presents star ratings that combine individual scores within each domain as well as a summary ranking that represents overall performance. The distribution of PDP sponsor ratings ranges from 2.5 stars to 4.5 stars, while MA–PD sponsors range between 2.0 stars and 5.0 stars. Generally, LIS enrollees do not tend to be in plans run by sponsors with star ratings that differ systematically from those with more non-LIS enrollees (Figure 5-10, p. 302). Changes in the composition of the measures that CMS uses within its composite score make it difficult to compare plans' performance over time.

Changes for 2010 to Part D MTMPs

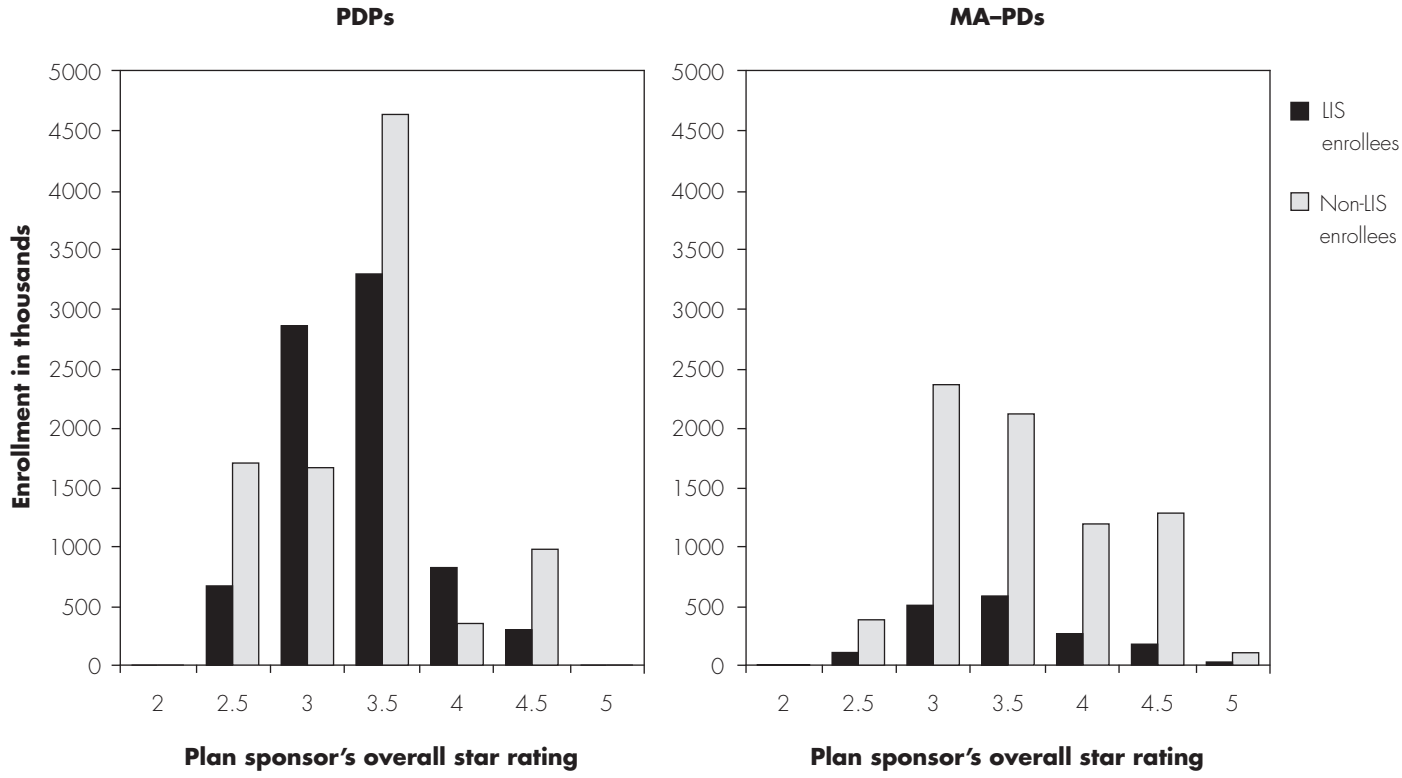
Medicare law requires PDPs and MA–PDs to include programs aimed at improving medication use and reducing adverse events for beneficiaries taking multiple drugs. During the first few years of Part D, sponsors received little guidance on how these MTMPs should be designed. As a result, sponsors' programs differed on many dimensions—the number and type of conditions and prescriptions a beneficiary had to have to be eligible for the program, how beneficiaries were targeted and enrolled, the kinds of interventions provided, and the outcomes measured. Only a small percentage of beneficiaries have enrolled in MTMPs, and sufficient data do not yet exist to determine whether the programs have been increasing the quality of participants' pharmaceutical care (Medicare Payment Advisory Commission 2009b).

On the basis of a review of MTMPs that operated during Part D's first three years, CMS modified plans' requirements for 2010 (Centers for Medicare & Medicaid Services 2009c). Sponsors must target beneficiaries for enrollment at least quarterly and enroll them using an opt-out method only. MTMPs must provide interventions for both providers and enrollees, including an annual comprehensive review of medications in the form of a person-to-person consultation. Sponsors set their own eligibility criteria, but they may not require that beneficiaries have more than three chronic conditions, and the programs must target at least four of seven core chronic conditions.[27]

Policy issues

Two features of Part D's design are intended to give competing plan sponsors an incentive to manage growth in drug spending and bid low: (1) the prospect of enrollees changing Part D plans voluntarily if premiums grow too high and (2) the opportunity for their plan to be premium-free to LIS enrollees. From the evidence on Part D

FIGURE 5–10 **2009 LIS and non-LIS enrollment by plan sponsors' star ratings**



Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Star ratings shown reflect a composite of 19 performance measures, where 1 star means "poor" and 5 stars means "excellent" performance. Sponsor scores are available for the 2010 version of the Medicare Prescription Drug Plan Finder tool available at www.medicare.gov.

Source: MedPAC analysis of CMS Part D performance and enrollment data.

reported for 2010 or the most recent year for which data are available, a number of policy issues emerge.

- Policymakers are ambivalent about beneficiary experiences with plan switching. Year-to-year changes in enrollment are part of the design of Part D: Plans that are able to manage drug spending and bid more competitively are supposed to be rewarded with more enrollment than plans that do not. Some analysts believe that too many LIS enrollees are reassigned each year to a different Part D plan, while others contend that too few non-LIS enrollees switch plans voluntarily. Concerns about LIS reassignees relate primarily to whether the change from one plan's formulary to another affects beneficiaries' adherence to their medicines. Early evidence suggests that there have not been many problems, but the issue needs further research. Concerns about non-LIS enrollees relate to their lack of switching, even in the face of significant premium increases. Only about 6 percent of Part D enrollees have switched plans voluntarily each year.[28] A greater willingness among enrollees to switch plans would make the incentives to bid low more credible to plan sponsors and help to keep growth in beneficiary premiums and program spending in check.

- Several factors related to Part D spending deserve closer attention. One is the LIS, which has become the single largest component of Part D program spending. A related concern is growth in spending for drugs and biologics that have few therapeutic substitutes, some of which are used disproportionately by LIS enrollees. The LIS population tends to be sicker, on average, and access to medications is critically important to help manage their conditions. The extra subsidies for obtaining prescription drugs that Medicare provides to low-income enrollees may help them avoid

exacerbating a medical condition that could otherwise lead to greater disability, greater use of other medical services, and higher Medicare spending. At the same time, fast growth in program spending for Part D's individual reinsurance reflects, in part, the difficulty of negotiating discounts and rebates for higher priced drugs. Also, for some drugs, there is questionable evidence about the appropriateness of therapies for certain beneficiaries. For the future, the Commission may explore ways to encourage greater use of generics and therapeutically equivalent products by LIS enrollees when providers believe it is medically appropriate to do so.

- The Commission is also concerned about the appropriateness and quantity of prescriptions used by beneficiaries. While on average Part D enrollees take three or four medications regularly, a considerable number take more, sometimes many more. In the past, the Commission has reported that Part D plans' MTMPs were inconsistent across plans and CMS lacked the outcome data needed to assess their effectiveness (Medicare Payment Advisory Commission 2009b). CMS has taken steps to set standards and to require sponsors to report data regularly so that the agency can evaluate MTMPs. Regular reviews of patients' drug regimens may help providers evaluate how well beneficiaries are tolerating multiple medications and adhering to appropriate therapies. We will continue to monitor whether plans' MTMPs are meeting this goal. In addition, the Commission may consider ways to shore up evidence on the effectiveness of drug and biological therapies for elderly patients and for beneficiaries with multiple comorbidities. ■

Endnotes

1 The share of Medicare beneficiaries enrolled in Part D plans grew slightly from the time the program began in 2006 to 2009, from 55 percent to 59 percent. Expanded enrollment in MA–PDs accounts for most of the growth.

2 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.

3 Specifically, SSA no longer considers the cash value of life insurance policies when evaluating assets, nor does it count assistance provided by others for household expenses as income.

4 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.

5 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 Part D, a handful of PDP sponsors offered 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.

6 The reduced numbers of PDPs reflect in part the continuing effects of consolidation among plan sponsors. For example, UnitedHealthcare and PacifiCare merged in 2006. Under CMS guidance, the organization was required to reduce its combined number of plans over a three-year period. Similarly, Universal American acquired MemberHealth in 2007.

7 Consider, for example, the case of paroxetine, an antidepressant also known under the brand-name Paxil®. Antidepressants are one of six protected therapeutic classes in which plans must cover all or substantially all drugs. By conducting the analysis at the level of chemical entities, plans are credited with including paroxetine on their formulary when they list the generic version (paroxetine hydrochloride), even if they do not list Paxil, the continuous release version Paxil CR®, or the brand-name drug Pexeva® (paroxetine mesylate) manufactured by a different company.

8 For purposes of this analysis, our contractor grouped plan-designated tiers into analytical tiers that were comparable to each other. For example, a plan might have two tiers that use 25 percent coinsurance each within their formulary. Since their cost sharing is the same, our analysis would combine these tiers into one group.

9 For 2006, CMS did not set criteria for placing drugs in a specialty tier. However, for 2007, CMS defined specialty tiers more clearly: Only Part D drugs with negotiated prices that exceeded $500 per month could be in a specialty tier. Since 2008, only drugs with prices that exceed $600 per month may be in a specialty tier.

10 The most common variations are plans that use one generic tier and one tier for brand-name drugs (i.e., they do not distinguish between preferred and nonpreferred brands), plans that use two generic tiers (e.g., value generics and nonpreferred generics at higher cost sharing), plans that use three tiers for brand-name drugs (e.g., they include a "value brand" tier with lower cost sharing than preferred brands), and plans with a separate tier for nonspecialty injectable drugs.

11 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.

12 The MA–PD value here excludes SNPs, which are made up primarily of enrollees with certain characteristics in common, such as being dually eligible for Medicare and Medicaid, residing in a long-term care facility, or having a specified chronic condition. Enrollees in SNPs tend to have much tighter formularies than beneficiaries in PDPs or MA–PDs. In 2010, the average SNP enrollee's plan lists 75 percent of all reportable chemical entities.

13 For 2010, CMS introduced a new reference file that defines the set of drugs for which sponsors must report on plan coverage. Although results for 2010 formularies are not strictly comparable to those in prior years, the change does not significantly affect the findings.

14 In 2007 and 2008, CMS used its general demonstration authority to phase in a weighting system based on each plan's total enrollment. Under the same demonstration, CMS carried out a "de minimus" policy: Plans with premiums within $1

or $2 of their regional threshold remained premium-free to LIS enrollees, but those plans were ineligible to receive newly assigned enrollees. CMS discontinued the demonstration in 2009.

15 Most LIS enrollees pay no premiums, but those with incomes between 135 percent and 150 percent of the federal poverty level pay a portion of their plan's premium.

16 Specifically, CMS began weighting plan premiums by their numbers of LIS enrollees rather than by plans' total enrollment. A reason for this approach was concern that, in areas where MA–PDs hold large shares of enrollment, the ability of MA–PDs to reduce their drug premiums with "rebate dollars" from the MA payment system would lead to lower regional thresholds and fewer PDPs with premiums below those thresholds. On average, MA–PDs have fewer LIS enrollees than PDPs and PDPs tend to have higher premiums; thus, the hope was that weighting premiums by LIS enrollment would tend to raise regional thresholds. However, the relative influence of MA–PD plans varies around the country. For example, more than half of Arizona beneficiaries who receive the LIS are enrolled in MA–PDs, compared with just 2 percent in the Maine–New Hampshire region. In approximately nine PDP regions, 20 percent or more of LIS recipients are enrolled in MA–PDs.

17 Direct subsidy payments for LIS enrollees are risk adjusted to reflect their higher average drug spending.

18 Exceptions include plan sponsors that own and operate their own pharmacies.

19 A provision of the Medicare Improvements for Patients and Providers Act of 2008 requires CMS to codify and, if appropriate, increase the number of protected classes. CMS is working on this process and some groups have requested inclusion of additional drug classes. For example, one manufacturer has suggested that drugs used to treat multiple sclerosis be considered a protected category.

20 Sponsors may, however, use prior authorization for protected-class drugs to establish whether Part B or Part D should pay for the drug.

21 By individual NDC, we mean prices across the exact same code that 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 Sponsors must limit cost sharing for specialty-tier drugs to no more than 25 percent of the negotiated price within the benefit's initial coverage limit. However, they may use higher coinsurance to help maintain actuarial equivalence to basic benefits—for example, in a basic plan that has no deductible or in one with a deductible that is lower than the defined standard benefit's deductible.

24 Other Part D performance measures are available but not on the Plan Finder. For example, each sponsor's generic dispensing rate is shown on the agency's website. Similarly, CMS posts other measures to its site that are still under development, are duplicative, or are limited by a small sample size. Among them, two are related to patient safety: a measure of drug–drug interactions and another of diabetes medication dosing. At CMS's Patient Safety Analysis website, which is available only to CMS and plan sponsors, sponsors can track their patient safety measures monthly and get more detailed information.

25 This measure calculates the percentage of Part D enrollees age 65 or older who filled at least one prescription for a drug with a high risk of serious side effects in the elderly. The measure was first developed by the National Committee for Quality Assurance through its Healthcare Effectiveness Data and Information Set and then adapted and endorsed by the Pharmacy Quality Alliance.

26 This measure evaluates whether patients who are under treatment for diabetes (identified by claims for insulin or oral antidiabetic medicines) and who receive an antihypertensive medication also receive an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker medication.

27 Core chronic conditions include hypertension, heart failure, diabetes, dyslipidemia, respiratory diseases, bone disease and arthritis, and mental health. Sponsors cannot set the use of more than eight Part D drugs as a criterion for eligibility. For 2010, CMS also lowered the dollar threshold of expected drug costs that sponsors use as another eligibility criterion from $4,000 to $3,000 and expanded plans' reporting requirements. For each enrollee in the plan's MTMP, sponsors must report the number of medication reviews completed, the number of prescriber interventions, and any resulting changes in therapy. The agency and its contractors will monitor and evaluate plans' MTMPs.

28 This proportion is similar to that in the Federal Employees Health Benefits (FEHB) program. However, unlike in FEHB, the decision to switch Part D plans does not affect the physician providers that the enrollee may see.

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