CHAPTER 4

A status report on Part D for 2009

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Chapter summary

Part D uses competing private plans to deliver outpatient prescription drug benefits. Organizations that sponsor plans compete for market share by offering benefits that will meet beneficiaries' prescription drug needs at attractive premiums. Sponsors bear insurance risk for some of their enrollees' benefit spending. Under this approach, sponsors must balance enrollees' need for access to medications with the desire to make a reasonable financial return.

Each year, sponsors submit plan bids for providing Part D benefits. Part D sponsors may change plans' benefit designs, formularies, and cost-sharing requirements. Policymakers need to stay informed about changes to ensure that Part D meets the broader goal of giving beneficiaries access to appropriate drug therapies. Year-to-year changes in bids and enrollee premiums give policymakers information about how well sponsors are managing drug benefit costs for beneficiaries and for taxpayers.

In this chapter

This chapter describes Part D enrollment in 2008 and plan offerings for 2009: benefit designs, premiums, formularies, and cost-sharing requirements. The chapter also reports on one aspect of Part D intended to promote quality: medication therapy management programs (MTMPs).

Patterns of enrollment in 2008—As of January 2008, 90 percent of Medicare beneficiaries received some form of drug coverage. Fifty-eight percent of all Medicare beneficiaries enrolled in Part D plans; 32 percent had drug coverage at least as generous as Part D through employer-sponsored plans or other sources. Twenty-one percent of Medicare beneficiaries received Part D's extra help with premiums and cost sharing (called the low-income subsidy (LIS)). An estimated 2.6 million beneficiaries eligible for the LIS were not enrolled to receive it (about 6 percent).

Plan offerings for 2009—In 2009, the number of stand-alone prescription drug plan (PDP) options declined by 7 percent, but beneficiaries can still choose among a median of 49 PDPs. Sponsors are offering 6 percent more Medicare Advantage–Prescription Drug plans (MA–PDs) than in 2008. MA–PDs provide combined medical and drug benefits, and they continue to be more likely than PDPs to include enhanced benefits (basic and supplemental drug coverage in one package).

For 2009, Part D premiums are significantly higher than in 2008. If enrollees stayed in the same plan, they saw premiums rise by an average of $6 to nearly $31 per month (24 percent). However, CMS reassigned some LIS enrollees to lower premium plans and other individuals changed plans voluntarily, which dampens the average increase.

Each plan sponsor manages a formulary—the list of drugs it may cover, cost-sharing tiers, and whether a drug is subject to tools such as prior authorization. For 2009, we estimate that more than 80 percent of enrollees are in plans that use one generic tier and separate tiers for preferred and nonpreferred brand-name drugs. More than 80 percent of enrollees have a specialty tier for high-cost drugs or biologics. For 2009, the median enrollee

in a plan with a specialty tier must pay 33 percent coinsurance for those drugs. Cost sharing tended to rise among PDPs for 2009. Copays for the median enrollee in a PDP rose to $7 per 30-day supply of a generic drug, $38 for a preferred brand-name drug, and $75 for a nonpreferred brand. MA–PD cost sharing was more likely to remain at 2008 levels, with the exception of increased coinsurance for specialty-tier drugs.

LIS premium subsidies and beneficiary reassignments—For 2009, fewer premium-free PDPs will be available to enrollees who receive the LIS: 308 plans qualified, compared with 495 in 2008. CMS moved to a new method for setting the maximum amount Medicare will pay in premiums on behalf of LIS enrollees.

CMS estimated that it needed to reassign about 1.6 million LIS enrollees to new plans for individuals to avoid paying some of the premium: nearly 1.2 million to a plan offered by a different sponsor and just under 0.5 million to a plan offered by the same sponsor. Another 0.6 million LIS enrollees previously picked a plan on their own and were responsible for switching themselves into a qualifying plan for 2009 or begin paying part of the premium. When beneficiaries switch to a plan in which the person's current drugs are not listed on the new plan's formulary, the beneficiary needs to obtain transition supplies of the drug, seek a formulary exception, pay for the drug out of pocket, or change medication.

Medication therapy management programs—PDPs and MA–PDs must implement MTMPs to improve the quality of pharmaceutical care for enrollees with multiple chronic conditions and high drug costs. Costs for MTMPs are included as an administrative expense in plan bids. All PDPs and MA–PDs are required to offer MTMPs to enrollees with several chronic conditions who take multiple drugs and are expected to average at least $4,000 per year in drug costs. CMS does not provide much guidance on designing or implementing these programs.

In conducting our review of MTMPs, we examined research evaluating those programs and available data on MTMPs operating in Part D. 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. MTMPs differ in 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. A small percentage of beneficiaries are enrolled in MTMPs, and we do not have sufficient data to determine whether the programs are increasing the quality of pharmaceutical care to them.

A number of interviewees want CMS to require plan sponsors to measure and report specific outcomes. More standardized collection and reporting of outcome measures could be used to determine whether programs are meeting their goals of improving the quality of pharmaceutical care, what patient populations benefit from these programs, and what interventions are most successful. In October 2008, CMS announced that it had contracted with Optimal Solutions to help identify standardized outcomes that all Part D sponsors could measure and to help the agency identify MTMPs that have the most positive impact on medication use. This research has the potential to answer many important questions about Part D medication therapy management. The Commission will closely follow the results, but we are unlikely to know the results from this study for several years. ■

In its fourth year of operation, Medicare Part D has more than 25 million enrollees and helps pay for their drugs at an annual cost of about $50 billion. Part D uses competing private plans to deliver outpatient prescription drug benefits. Part D was based on the premise that sponsoring organizations would compete for market share by offering plans with benefits that would meet beneficiaries' prescription drug needs at attractive premiums. While Medicare bears much of the risk for the benefit, sponsors also bear insurance risk for some of their enrollees' benefit spending. Under this approach, sponsors must balance enrollees' need for access to medications with the desire to make a reasonable financial return. The broader goal for Medicare is to ensure that program beneficiaries have access to appropriate drug therapies at a cost that is reasonable to enrollees and to taxpayers.

This chapter examines Part D program performance in terms of beneficiary enrollment for 2008 and plan benefit designs for 2009. We also report on one aspect of Part D that is intended to promote quality, known as medication therapy management.

Background on Part D program design

Unlike the traditional Medicare fee-for-service program, Medicare Part D sets prices for providing drug benefits through competition among private plans. A potential advantage of this design is that CMS does not have to set prices administratively. Experience shows the difficulties of administratively setting Medicare prices accurately and making refinements as needed. Mispricing has led to misallocation of investment resources and has had large effects on the organizational structure and cost of health care delivery over time.[1]

Nevertheless, Part D's competitive approach has limitations and must be monitored to ensure that it works as intended. Over time, the success of Part D may depend on beneficiaries' willingness to switch among competing plans. When the program began in 2006, beneficiaries tended to choose plans with low premiums, which led many sponsors to bid more competitively for 2007. In later years, plans with the most enrollees have had some of the largest premium increases, yet only about 6 percent of enrollees have switched plans voluntarily each year. (This rate is comparable to the rate of plan switching observed in the Federal Employees Health Benefits program.) While large in percentage terms, the dollar amount of premium increases typically has been $5 to $10 per month—perhaps not enough to justify incurring other costs of switching plans. There may be a tipping point after which higher premiums will lead enrollees to reconsider their choices. If not, sponsors will have less incentive to compete on premiums, making it difficult for Part D to achieve program savings, as intended.

One central reason why relatively few Part D enrollees have switched plans voluntarily may be that most are satisfied with the program (CMS 2008b). Medicare subsidizes Part D enrollees' drug spending, thereby saving most beneficiaries money. CMS estimated that in 2007, enrollees saved an average of $1,200 compared with individuals without prescription drug coverage. Enrollees who receive extra help with premiums and cost sharing through the low-income subsidy (LIS) saved an average of $3,350, according to CMS (CMS 2007).

Many beneficiaries who receive the program's LIS follow a different enrollment path, which can have implications for Part D program performance.[2] For 2006, LIS enrollees who did not choose a plan for themselves were randomly assigned to plans with premiums at or below regional benchmarks. So long as a plan's premium falls below the required benchmark, LIS beneficiaries pay reduced or no premiums and cost sharing if they remain in the plan. However, LIS beneficiaries may be reassigned to a different plan each year if their current plan's premium is too high.[3] An original goal of this approach was to provide an incentive for plan sponsors to bid low enough to qualify as premium-free to LIS beneficiaries and thereby gain or retain those enrollees.

The chance that enrollees may switch plans—either because they believe their premium is higher than the plan's value to them or through CMS's reassignment process—was intended to give plan sponsors an incentive to control drug spending and bid low. Beneficiaries who do not receive the LIS gain from this approach if they can find an alternative plan that provides their medications at a more affordable premium. Individuals who receive the LIS gain from the approach insofar as it makes continuing Part D's assistance with premiums and cost sharing more financially sustainable for taxpayers. At the same time, there are other costs to individuals who switch plans—transition issues as they navigate new coverage rules. For example, if a new plan does not cover or requires prior authorization for a medication, some enrollees may have difficulty obtaining the drugs they have been using and could face significant increases in out-of-pocket spending.

Part D drug plans

Beneficiaries can obtain Part D benefits in one of two ways: through a prescription drug plan (PDP), which is "stand alone" in that it offers a drug-only benefit package, or through a benefit within a Medicare Advantage (MA) plan, known as a Medicare Advantage–Prescription Drug (MA–PD) plan, which offers a combined benefit package of medical services and prescription drugs. PDPs are required to be available regionwide within 1 of 34 Medicare-designated PDP regions in the United States. In contrast, MA–PDs are generally local, operating on a countywide basis. Regionwide MA–PDs are an exception; if available, they operate in 1 of 26 Medicare-designated MA regions in the United States. Regionwide MA–PDs are available in 22 of the 26 regions.

Medicare payments to Part D plan sponsors

Medicare's payments to Part D sponsors are based on plans' annual estimates of expected benefit costs plus administrative costs including profit. Sponsors' estimates of expected costs take the form of bids. Medicare pays sponsors a monthly amount per enrollee, adjusted for the health status of the plans' enrollees. A sponsor's monthly payment is based on the nationwide average of plan bids for providing basic drug coverage. The nationwide average plays a pivotal role in premiums charged to beneficiaries: Enrollees in a plan whose sponsor bid more than the nationwide average must pay a premium that is higher by the difference between their plan's bid and the average; those in a plan whose sponsor bid lower than the nationwide average pay a premium that is lower by the difference between their plan's bid and the average.

Part D includes several financial protections to limit plan sponsors' exposure to risk. For each Medicare enrollee in a plan (either stand-alone PDP or MA–PD), current law calls for Medicare to provide sponsors with a subsidy that averages 74.5 percent of basic coverage for beneficiaries. That average subsidy takes two forms:

- ***Direct subsidy***—a monthly payment to sponsors set as a share of the national average bid, adjusted for the financial risk of the individual enrollee, based on the individual's health status; and
- ***Individual 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.

In addition, Medicare establishes "risk corridors" that define how much risk a sponsor is exposed to, given the dollar level of the plan's expected costs. Under risk corridors, Medicare limits sponsors' potential losses or gains by financing some of the higher-than-expected costs or recouping excessive profits. CMS sets risk corridors separately for each plan. The corridors were narrow initially to encourage sponsors to participate in Part D, but they widened in 2008, increasing the amount of insurance risk that sponsors face. The Secretary may further widen the corridors in 2012.

Medicare also pays expected cost sharing and premiums for enrollees who receive the LIS. These program costs are above and beyond the 74.5 percent amount by which Medicare subsidizes basic Part D benefits. According to estimates by the Medicare Trustees, aggregate spending for the LIS has been at nearly the same level as aggregate spending for direct subsidy payments—about $18 billion each in 2008 (Boards of Trustees 2008).

Sponsors' monthly payments include the direct subsidies, expected reinsurance, and LIS cost sharing. Although sponsors receive essentially the same direct subsidy per enrollee (modified by risk adjusters), the level of subsidies granted through the other payment mechanisms differs from plan to plan. Subsidy dollars provided through individual reinsurance and LIS cost sharing vary depending on the characteristics of individuals each plan enrolls as well as whether a sponsor's losses or profits trigger provisions of its risk corridors. (See *MedPAC payment basics: Part D payment system* at http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_PartD.pdf.)

Under Part D's per enrollee payment arrangement, the accuracy of risk adjustment is key to effective program performance, particularly with respect to LIS enrollees. As long as Medicare's risk-adjusted payments for LIS enrollees more than cover plans' benefit costs, sponsors have an incentive to bid low to keep or attract these beneficiaries. But if risk adjusters do not compensate sponsors adequately for LIS enrollees, an incentive may exist for sponsors to bid higher to avoid LIS enrollees—especially if non-LIS enrollees are not sensitive to rising premiums. Findings from Commission-sponsored research on risk adjustment suggest that adding information about enrollees' past drug utilization could improve the performance of CMS's current risk adjusters for Part D and for LIS enrollees (see text box). Because a subset of

Risk adjustment under Medicare Part D

Under Part D, Medicare pays organizations that sponsor Medicare Advantage–Prescription Drug (MA–PD) plans and stand-alone prescription drug plans (PDPs) a monthly prospective payment for each enrollee based on plan bids. Because bids represent sponsors' expected costs of providing a basic benefit for an enrollee of average health, CMS adjusts payments to sponsors to account for enrollees' demographic characteristics and health status. CMS further adjusts payments for beneficiaries receiving the low-income subsidy (LIS) and for those who are institutionalized to account for their higher expected costs. Accurate risk adjustment is important because it removes any incentive a sponsor may have to attempt to enroll only healthier individuals.

CMS assigns risk scores to each enrollee by using the prescription drug hierarchical condition category (RxHCC) model developed before 2006. It is similar to the hierarchical condition category (HCC) model used for the Medicare Advantage program. Both models use age, gender, disability status, and medical diagnoses from administrative claims data to predict expected costs in the following year.

Both RxHCC and HCC models group thousands of diagnosis codes into disease groups that are similar clinically and in terms of expected costs. For related disease conditions, they rank order the disease groups in hierarchies so that only the highest cost group is included for the purpose of assigning risk scores. Neither model uses information on past drug utilization to predict future costs.

The RxHCC model differs from the HCC model in that it predicts drug spending rather than medical spending. In addition, the RxHCC model uses more diagnoses to create disease categories: about 5,000 compared with about 3,000 for the HCC model. Finally, the RxHCC model classifies diagnoses into disease groups based on drugs used for treatment, so the disease groups do not necessarily overlap with those used for the HCC model.

The payment adjustments for LIS and institutionalized populations are multipliers applied to risk scores assigned by the RxHCC model, and they are intended to capture factors unique to these populations that lead to higher drug utilization. For example, LIS and institutionalized enrollees pay no or reduced cost sharing. For the LIS, the multipliers are 1.08 and 1.05 for individuals eligible for full and partial subsidies, respectively. For institutionalized status, they are 1.08 and 1.21 for aged and disabled individuals, respectively.[4]

Under a Commission contract, researchers led by John Hsu, M.D., of Kaiser Permanente Northern California, evaluated the performance of the current RxHCC model and the effects of including drug information. The contractor used Part D claims data from selected large sponsors of PDPs, so the data are not representative of the entire Part D program. The analysis focused on PDPs, as LIS recipients make up nearly half of total PDP enrollment, compared with less than 20 percent of total MA–PD enrollment. The objectives of the analysis were to determine:

- how well RxHCC scores predict plan drug benefit spending;
- to what extent including prior-year drug information raises the RxHCC model's predictive power, and the tradeoffs of doing so; and
- how benefit spending compares for LIS and non-LIS enrollees with similar risk scores.

The analysis was based on Part D claims data for noninstitutionalized individuals enrolled in PDPs in 2006 and 2007. It included only individuals who were enrolled in plans continuously during 2007 to capture a full year of drug utilization. For LIS enrollees, it included only those individuals who received the subsidy for the entire year. The data included more than 1 million individuals, with about one-third receiving the LIS.

Researchers used RxHCC risk scores based on demographic and medical diagnosis information from 2006 data to predict drug spending in 2007. They also introduced two types of variables regarding 2006 drug use: whether an enrollee filled one or more prescriptions for any drug within a given therapeutic

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Risk adjustment under Medicare Part D (cont.)

class, and the dollar amount of each enrollee's prior-year drug spending. Performance was measured as the amount of variation in actual plan liability (adjusted R-squared) explained by risk adjusters using a linear regression model, the mean absolute dollar amount of prediction error, and how well the model predicted spending for the lowest cost and highest cost enrollees (Hsu 2008).

For the PDPs included in the analysis, RxHCC scores based on CMS's current approach explained slightly less than one-quarter of the total variation in plan benefit spending for LIS and non-LIS enrollees (Table 4-1). Adding information about an individual's drug use in the previous year significantly raised the predictive power of the risk adjusters. For both LIS and non-LIS enrollees, regression models that included risk scores and past drug use explained slightly more than 40 percent of the variation in actual spending for basic Part D benefits.[5] When the contractor included each individual's dollar amount of drug spending from the previous year in the model, the regression explained about 50 percent and 60 percent of the variation for the non-LIS and LIS populations, respectively.

CMS's current multipliers compensate plans 5 percent to 8 percent more for the benefit costs of LIS enrollees compared with non-LIS individuals with similar health status. To evaluate those multipliers, the research team compared the actual plan benefit spending of LIS and

TABLE 4–1

For a limited sample of PDPs, adding drug information raises the predictive power of Part D adjusters

	Mean absolute prediction error (in dollars)		Percent of variation explained (adjusted R^2)	
	Non-LIS enrollees	LIS enrollees	Non-LIS enrollees	LIS enrollees
RxHCC score	$520	$612	0.21	0.24
RxHCC score plus drug class information	403	516	0.42	0.41
RxHCC score plus drug spending	392	451	0.52	0.60

Note: PDP (prescription drug plan), LIS (low-income subsidy), RxHCC (prescription drug hierarchical condition category). Plan benefit spending values are for 2007. Drug class information refers to indicators for whether the enrollee filled a prescription in each of 48 therapeutic classes during 2006. Drug spending reflects an annualized estimate of the dollar value of each enrollee's drug spending. Mean absolute prediction error is the average absolute value of actual plan benefit spending minus what the regression model predicted for plan benefit spending. Adjusted R^2 is a value between zero and one that describes the amount of variation in actual plan benefit spending explained by the regression model. A value of zero means the model does not explain any of the variation and a value of one means that it explains all the variation.

Source: Hsu 2008.

Part D plans were analyzed, CMS needs to test whether the results apply more generally to all plans.

Part D benefit package

Medicare law sets out a defined standard benefit structure for the program's initial year, but the benefit parameters change over time at the same rate as the annual change in average total drug expenses of Medicare beneficiaries (Table 4-2, p. 282). For 2009, the defined standard benefit includes a $295 deductible and 25 percent coinsurance until the enrollee reaches $2,700 in total covered drug spending, after which a coverage gap exists in which the enrollee is responsible for the full discounted price of covered drugs (usually without reflecting manufacturers' rebates) up to $4,350 in true out-of-pocket spending (defined as out-of-pocket spending that excludes cost sharing paid by sources of supplemental coverage, such as employer-sponsored policies).[6] An individual with no

Risk adjustment under Medicare Part D (cont.)

non-LIS enrollees in their sample of plans, controlling for health status as measured by CMS's current RxHCC risk adjusters. They found that the ratios of actual plan benefit spending for LIS enrollees compared with non-LIS enrollees were considerably higher than the amounts suggested by the current multipliers. However, when the researchers added prior-year drug information to RxHCC scores in their regression model, the current multipliers more closely approximated the ratio of benefit spending between LIS and non-LIS enrollees for individuals with similar risk scores.

Overall, the results of the analysis indicate that adding information about the prior year's drug use has the potential to raise the predictive power of the risk adjusters and that the use of this information would have implications for how well LIS multipliers compensate plan sponsors for LIS enrollees. However, this analysis was conducted on a subset of PDPs—CMS should evaluate whether the results apply more generally for all Part D plans.

Decision makers must weigh certain tradeoffs before adding drug information to the Part D risk adjustment methodology. On the positive side, risk adjusters that predicted enrollees' drug spending with more accuracy could mitigate incentives for sponsors to encourage lower cost individuals to enroll and higher cost individuals to disenroll. More accurate risk adjusters could also mitigate incentives for sponsors to put tight restrictions on the use of certain drugs. At the same time, it may not be advisable to remove the cost control and efficiency incentives built into the concept of prospective payment. If Medicare were to base plan payments on risk-adjusted amounts that too closely predicted actual spending, the result would scarcely differ from using a system of cost-based reimbursement, defeating the purpose behind Medicare's use of prospective payment. Adding information about an enrollee's past drug spending raises the risk adjuster's predictive power but also reduces sponsors' incentives to control drug spending, as higher spending would lead to higher payments the next year. Because of these effects on incentives, policymakers may want to evaluate carefully the tradeoffs of adding information about past drug spending to Part D's risk adjustment model using data from all plans.

Other concerns relate to budgetary implications and timing. Any changes to Part D risk adjustment should be considered in the context of their effects on overall payments to sponsors to ensure that those changes are budget neutral. It takes time to make certain that revised risk adjusters are budget neutral and capture incentives that policymakers think are desirable for the program. CMS is evaluating the RxHCC model and, if the agency chooses to revise it, those changes would be in place for the 2011 benefit year. (CMS would need to have a new risk adjustment system ready in spring 2010 for plan sponsors to prepare and submit bids in June 2010 for the 2011 benefit year.) Given the complexity of the task, it seems unlikely that CMS could revise the RxHCC model to include drug information on a faster timetable. ■

other source of drug coverage reaches the true out-of-pocket limit at about $6,154 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 from $2.40 to $6.00 per prescription.

Patterns of enrollment in 2008

Enrollment patterns as of January 2008 suggest that the vast majority of Medicare beneficiaries receive some form of drug coverage. However, an estimated one-sixth of financially limited beneficiaries eligible for the LIS were not enrolled to receive the subsidy. In 2008, the two sponsors with the largest concentration of enrollment in PDPs lost market share because premiums for some

TABLE 4–2 **Parameters of the defined standard benefit increase over time**

	2006	2007	2008	2009
Deductible	$250.00	$265.00	$275.00	$295.00
Initial coverage limit	2,250.00	2,400.00	2,510.00	2,700.00
True out-of-pocket spending limit	3,600.00	3,850.00	4,050.00	4,350.00
Total covered drug spending at true out-of-pocket limit	5,100.00	5,451.25	5,726.25	6,153.75
Minimum cost sharing above true out-of-pocket limit:				
Copay for generic/preferred multisource drug prescription	2.00	2.15	2.25	2.40
Copay for other prescription drugs	5.00	5.35	5.60	6.00

Note: For 2009, most parameters increased by about 7.5 percent, reflecting about a 6 percent trend in per capita spending for Part D benefits as well as about a 1.5 percent increase for prior year revisions.

Source: CMS, Office of the Actuary.

of their plans were too high to qualify as free to LIS enrollees.

Nine in 10 Medicare beneficiaries have Part D or equivalent drug coverage

As of January 2008, about 90 percent of Medicare beneficiaries were either enrolled in Part D plans or had creditable drug coverage—which means they had credit for having prescription drug benefits through non-Medicare sources at least as generous as basic Part D coverage. Specifically, nearly 58 percent of all beneficiaries—more than 25 million individuals—were enrolled in Part D plans: 17 million (40 percent) in PDPs and 8 million (18 percent) in MA–PDs (Figure 4-1). Nearly 7 million other beneficiaries (15 percent) received primary prescription drug coverage through former employers. In return, those employers received a tax-free subsidy from Medicare for some of their drug costs (called the retiree drug subsidy). Combined, Medicare subsidizes the prescription drug spending for 73 percent of beneficiaries.

Another 17 percent of Medicare beneficiaries had other sources of creditable drug coverage that Medicare does not subsidize. About 12 percent of individuals had primary drug coverage through the Federal Employees Health Benefits Program, TRICARE, the Department of Veterans Affairs, Indian Health Service, or current employers (in the case of individuals who are still active workers). About 5 percent had creditable coverage through other sources. That leaves 10 percent (4.6 million beneficiaries) without drug coverage or with coverage of lesser value than Part D.

A sizable minority of eligible beneficiaries did not enroll for Part D's extra help (LIS)

As of January 2008, an estimated 12.5 million Medicare beneficiaries (nearly 30 percent) were eligible for extra help (CMS 2008a). About 9.4 million of those 12.5 million received the subsidy, and another 0.5 million had other sources of creditable coverage. CMS estimates that another 2.6 million Medicare beneficiaries were eligible for extra help but did not sign up. We do not know the degree to which some of those individuals were enrolled in Part D or were among the 10 percent of Medicare beneficiaries without drug coverage.

Among those beneficiaries receiving the subsidy, their enrollment in Part D plans was similar to the enrollment proportions for traditional Medicare and MA plans. Nearly 8 million beneficiaries with Part D's LIS (84 percent) were enrolled in stand-alone PDPs, while about 1.5 million (16 percent) were in MA–PDs.

The percent of LIS enrollees in any given plan can affect how the sponsor manages drug utilization. In aggregate, LIS enrollees make up a much higher percent of enrollment in PDPs (about 45 percent) than in MA–PDs (18 percent).[7] A key tool that many sponsors use to control drug spending is differential cost sharing—charging different copays for drugs on lower and higher cost-sharing tiers to steer enrollees toward generic and preferred brand-name drugs. Because LIS enrollees face low or no cost sharing, sponsors of Part D plans that have higher proportions of LIS enrollment must use tools other than differential copays to manage benefit spending. Those tools include the design of the plan's formulary (the list

of drugs it may cover) and administrative measures to manage utilization such as prior authorization (preapproval before coverage), quantity limits (on the number of doses covered in a given time period), and step therapy requirements (enrollees must try specified drugs before moving to other drugs).

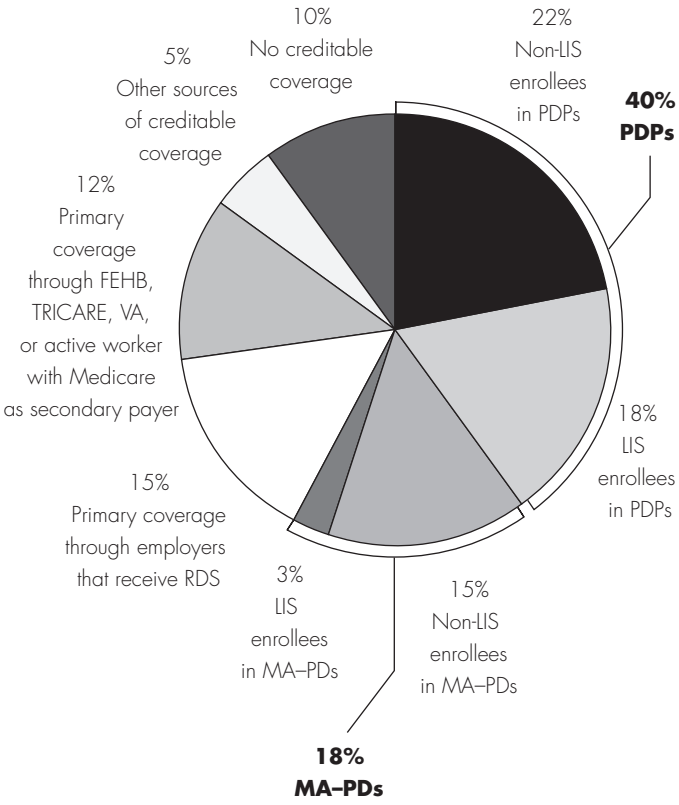
Largest PDP sponsors lost some market share in 2008

In 2006 and 2007, Part D enrollment in PDPs was concentrated among a relatively small number of sponsors, with the top two (UnitedHealthcare and Humana) accounting for nearly half of PDP enrollment. For 2008, those two firms remained dominant, but their market shares declined because of reassignments of LIS enrollees to lower premium plans. As of October 2008, UnitedHealthcare and Humana held a combined 41 percent of the 17.4 million members in the PDP market (23 percent and 18 percent, respectively), compared with 48 percent the year before (Figure 4-2, p. 284). Universal American, which acquired MemberHealth in 2007, was the third largest PDP sponsor in 2008 with 11 percent of the market.

Among organizations that sponsor MA–PDs, market shares changed little in 2008 (Figure 4-3, p. 285). The same two organizations that had the largest PDP membership also had the greatest market shares of enrollment in plans that cover both medical and drug benefits. (The plans with combined medical and drug coverage are predominantly MA–PD plans but also include cost plans, Program of All-Inclusive Care for the Elderly plans, and demonstrations. Our enrollment figures here also include MA–PDs that are open only to employer groups.) In 2008, UnitedHealthcare and Humana account for 17 percent and 15 percent, respectively, of the 8.6 million members in combined coverage plans.

FIGURE 4–1

In 2008, about 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. Other sources of creditable coverage include programs such as retiree coverage for employers not enrolled in the RDS, certain medigap policies, and state pharmaceutical assistance programs.

Source: CMS Management Information Integrated Repository data as of January 18, 2008.

Plan offerings for 2009

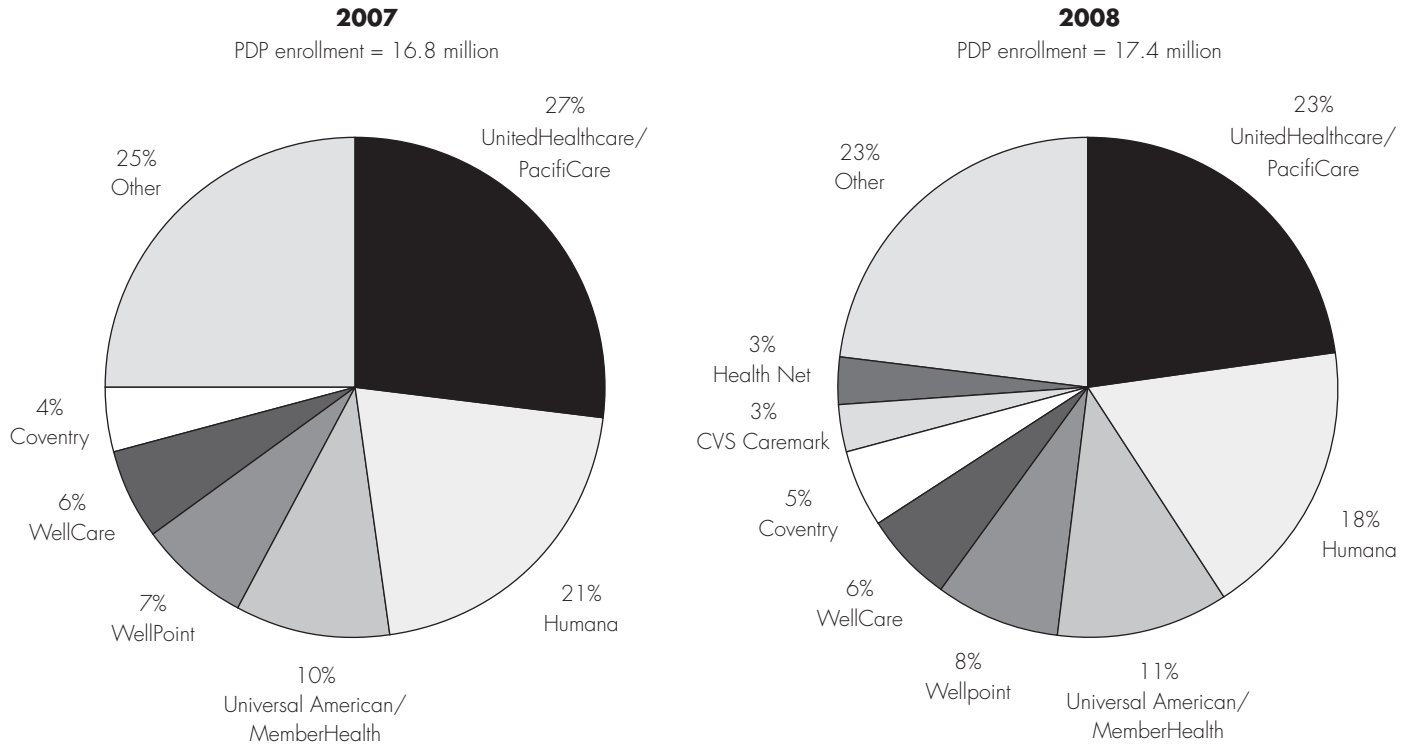
Each year, organizations that sponsor Part D plans may change benefit designs, formularies, and cost-sharing requirements. These changes are important to monitor to ensure that Medicare beneficiaries who participate in Part D have reasonable access to appropriate medication therapies. Annual changes in plan bids and enrollee premiums are also important to monitor as indicators of plan performance.

Number of stand-alone PDPs remained relatively stable

In 2007 and 2008, the typical Medicare beneficiary had 50 to 60 PDP options to choose from in addition to MA–PD options. Although the total number of PDPs in 2009 declined slightly (7 percent)—1,689 compared with 1,824 in 2008—the median number of plans available in a PDP region is 49. Alaska has the fewest available (45), while the Pennsylvania–West Virginia region has the most (57).

FIGURE 4–2

Market shares of the top two PDP sponsors declined somewhat in 2008



Note: PDP (prescription drug plan). Enrollment numbers for 2007 are as of July and those for 2008 are as of October.

Source: CMS data on monthly enrollment by plan for 2007 and 2008. http://www.cms.hhs.gov/MCRAdvPartDEnrolData/EP/list.asp#TopOfPage.

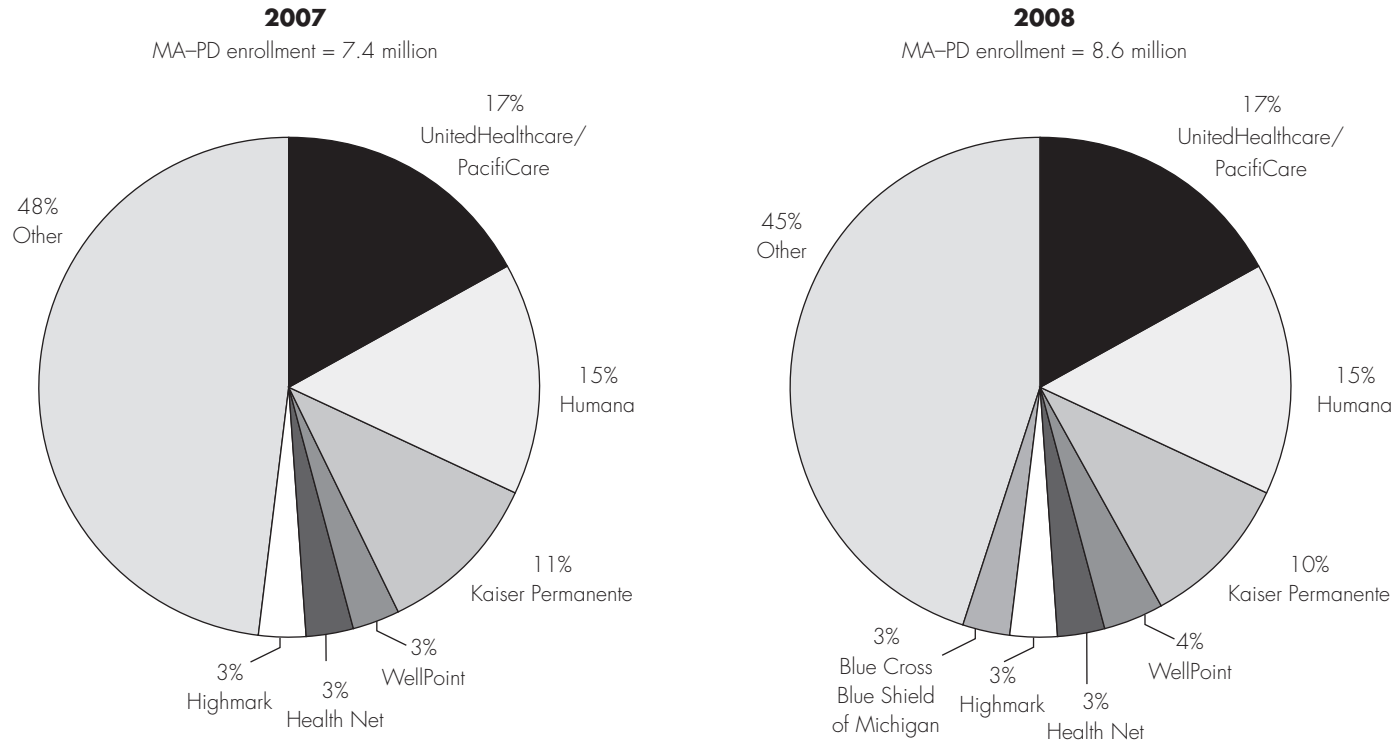
Table 4-3 (p. 286) shows plan type, benefit, deductible, gap drug coverage, and enrollment characteristics for PDPs in 2008 and 2009.

The decline in the number of PDPs reflects organizational mergers and acquisitions as well as withdrawals of certain benefit designs. For example, UnitedHealthcare and PacifiCare merged in 2006; under CMS guidance, the organization was required to reduce its combined number of plans per region over a three-year period. In addition, several organizations—including Sterling, Longs Drug Stores (RxAmerica), and Coventry (First Health)—withdrew PDPs from the market that covered generic drugs for beneficiaries whose spending had reached the coverage gap. In 2008, 16 organizations that offered one or more PDPs in each of the 34 PDP regions continued to account for 86 percent of PDP enrollment. At least one organization, BravoHealth, greatly expanded its PDP offerings for 2009—operating nearly nationwide with PDPs in 32 regions.

In general, the distribution of PDP benefit designs did not change much between 2008 and 2009, except for the smaller number of plans providing benefits for beneficiaries whose spending reached the coverage gap. Plan sponsors continue to offer more actuarially equivalent benefits or enhanced benefits than the defined standard benefit package. Actuarially equivalent plans have the same average benefit value as defined standard plans but a different benefit structure. For example, a plan may use tiered copays rather than 25 percent coinsurance. Or a plan may have no deductible but use cost-sharing requirements that are equivalent to a rate higher than 25 percent. Both defined standard benefit plans and plans that are actuarially equivalent are known as "basic benefits." Once a sponsor offers at least one 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. Medicare does not subsidize these supplemental benefits; enrollees in

FIGURE 4–3

Market shares among MA–PD sponsors remained stable in 2008



Note: MA–PD (Medicare Advantage–Prescription Drug [plan]). Enrollment numbers for 2007 are as of July and those for 2008 are as of October. Includes Medicare Advantage, employer-only, cost, Program of All-inclusive Care for the Elderly, and demonstration plans that offer Part D coverage.

Source: CMS data on monthly enrollment by plan for 2007 and 2008. http://www.cms.hhs.gov/MCRAdvPartDEnrolData/EP/list.asp#TopOfPage.

enhanced plans must pay the full value of that coverage as part of their premium.

In 2008, 61 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, nearly all with tiered copays rather than coinsurance. One reason for the wide prevalence of such plans is that tiered copays are an effective tool sponsors use to steer enrollees toward generic and preferred brand-name drugs for which the sponsor receives manufacturer rebates. Some enrollees may prefer copays to coinsurance because of their predictability. Another 23 percent of PDP enrollees had enhanced benefits. Typically, PDPs enhance coverage by charging no deductible rather than by providing benefits in the coverage gap.[8] (Sponsors can enhance benefits in other ways as well—e.g., covering drugs not allowed under basic Part D benefits such as weight-loss medications and over-the-counter products.) In 2008, more than half of PDP enrollees paid no deductible (51 percent) or a lower deductible than that in Part D's defined standard benefit (4 percent). Only 7 percent of PDP enrollees were in plans that offered gap coverage, usually for generic rather than brand-name drugs. However, 45 percent of PDP enrollees received Part D's LIS, which effectively eliminates their coverage gap.

For 2009, plan sponsors have generally kept benefit designs similar to those for 2008. A slightly smaller share of PDPs have the defined standard benefit structure (10 percent in 2009 compared with 12 percent in 2008), and 53 percent of PDPs are enhanced plans with a higher average benefit value, compared with 51 percent in 2008. A smaller proportion of PDPs have no deductible for 2009, but many PDPs charge a lower deductible than the defined standard benefit amount of $295.

The most noticeable change among benefits for 2009 is that a smaller share of PDPs provides gap coverage. In 2008, about 29 percent of plans included some gap coverage—usually some or all generic drugs but no brand-

TABLE 4–3

Characteristics of PDPs

	2008				2009		
	Plans		Enrollees (as of October 2008)		Plans		
	Number	Percent	Number (in millions)	Percent	Number	Percent	Percent of estimated enrollment[a]
Total	1,824	100%	16.5	100%	1,689	100%	100%
Type of organization							
National[b]	1,589	87	14.2	86	1,496	89	88
Near-national[c]	0	0	0.0	0	32	2	1
Other	235	13	2.3	14	161	9	11
Type of benefit							
Defined standard	217	12	2.7	17	170	10	7
Actuarially equivalent[d]	682	37	10.0	61	628	37	66
Enhanced	925	51	3.7	23	891	53	27
Type of deductible							
Zero	1,065	58	8.4	51	934	55	49
Reduced	150	8	0.7	4	189	11	6
Defined standard[e]	609	33	7.4	45	566	34	46
Drugs covered in the gap							
Some generics but no brand-name drugs	528	29	1.2	7	413	24	7
Some generics and some brand-name drugs	1	<0.5	<0.5	<0.5	3	<0.5	0
None	1,295	71	15.3	93	1,273	75	93

Note: PDP (prescription drug plan). The PDPs and enrollment described here exclude employer-only plans and plans offered in U.S. territories. Sums may not add to totals due to rounding.

a. Assumes enrollees remained in the same plan in which they were enrolled in 2008 if offered in 2009. Nearly 98 percent of October 2008 PDP enrollees who were within the scope of our analysis were in 2008 plans that could be matched to 2009 plans. Some beneficiaries enrolled in or were reassigned to a different plan for 2009.

b. Reflects total numbers of plans for the 16 organizations with at least 1 PDP in all 34 PDP regions.

c. Totals for organizations offering 30 or more PDPs across the country, but without 1 in each PDP region.

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

e. $275 in 2008 and $295 in 2009.

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

name medications. For 2009, that share fell to 24 percent. While relatively few PDP enrollees are in enhanced plans with gap coverage, some of those individuals had to switch plans because the plan's sponsor withdrew them from the market—presumably because those plans were costlier and less profitable to the sponsor than expected.

More MA–PDs offer enhanced benefits than PDPs

As in 2008, sponsors offered a larger number of MA–PDs in 2009 than the year before: 2,039 plans for 2009 compared with 1,932, or 6 percent more (Table 4-4). (Our analysis here excludes employer-only plans, cost plans, Program of All-Inclusive Care for the Elderly plans, demonstrations, and plans for beneficiaries who do not

TABLE 4–4

Characteristics of MA–PDs

	2008				2009		
	Plans		Enrollees (as of October 2008)		Plans		
	Number	Percent	Number (in millions)	Percent	Number	Percent	Percent of estimated enrollment[a]
Total	1,932	100%	5.7	100%	2,039	100%	100%
Type of organization							
Local HMO	1,025	53	4.1	72	1,126	55	73
Local PPO	353	18	0.5	8	430	21	8
PFFS	520	27	0.9	17	449	22	16
Regional PPO	34	2	0.2	4	33	2	3
Type of benefit							
Defined standard	79	4	<0.1	1	92	5	1
Actuarially equivalent[b]	132	7	0.3	6	161	8	4
Enhanced	1,721	89	5.3	93	1,786	88	95
Type of deductible							
Zero	1,665	86	5.3	94	1,797	88	94
Reduced	45	2	0.1	2	104	5	3
Defined standard[c]	222	11	0.2	4	138	7	3
Drugs covered in the gap							
Some generics but no brand-name drugs	661	34	2.2	38	701	34	40
Some generics and some brand-name drugs	327	17	1.4	25	355	17	27
None	944	49	2.1	37	983	48	33

Note: MA–PD (Medicare Advantage–Prescription Drug [plan]), PPO (preferred provider organization), PFFS (private fee-for-service). The MA–PDs and enrollment described here exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, demonstrations, and Part B-only plans. Sums may not add to totals due to rounding.

a. Assumes enrollees remained in the same plan in which they were enrolled in 2008 if offered in 2009. About 97 percent of October 2008 MA–PD enrollees who were within the scope of our analysis were in 2008 plans that could be matched to 2009 plans. New plan entrants are credited with no enrollment. Note that some beneficiaries enrolled in a different plan for 2009.

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

c. $275 in 2008 and $295 in 2009.

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

have Part A coverage. A separate section below describes special needs plans (SNPs).)

Offerings through MA–PDs differ systematically from PDPs. The law allows MA–PDs to use 75 percent of the difference between an MA plan's benchmark payment and its bid for providing Part A and Part B services (called Part C rebate dollars) to supplement its package of benefits or lower its premium. Many MA–PDs use some of their rebate dollars to enhance their Part D benefit or to reduce the portion of their plan premium associated with drug coverage.

The dominant type of MA–PD organization is the HMO, making up more than half of all MA–PDs. Last year, a sizable growth occurred in the share of MA–PDs that were private fee-for-service (PFFS) plans. Between 2008 and 2009, PFFS MA–PDs noticeably declined, in both number

(from 520 to 449) and percent (from 27 percent to 22 percent). In their place, sponsors offered more HMOs and local preferred provider organizations.

MA–PDs continue to be more likely than PDPs to include enhanced drug benefits. In 2009, 88 percent of MA–PDs include enhanced benefits, compared with 53 percent of PDPs (Table 4-3, p. 286). As with PDPs, MA–PDs enhance (supplement) benefits mostly by eliminating or lowering the deductible. Compared with PDPs, however, a larger proportion of MA–PDs provide coverage of some or all generic drugs in Part D's coverage gap—52 percent in 2009 compared with about 25 percent of PDPs. About 17 percent of MA–PDs cover some (often preferred) brand-name drugs as well as generics, while 34 percent provide gap coverage for generic drugs only.

In 2009, SNPs increasingly offer the defined standard benefit as compared with other benefit types

In 2008, more than a million beneficiaries were enrolled in SNPs. The Congress created SNPs to provide a common framework for existing plans (including demonstrations) for special needs beneficiaries and to expand beneficiaries' access to and choice among MA plans. SNPs generally function like and are paid the same as other MA plans. In addition, they must provide Part D benefits.[9] Unlike other MA plans, SNPs can target certain types of enrollees—beneficiaries dually eligible for Medicare and Medicaid (dual eligibles), institutionalized beneficiaries, and beneficiaries with severe or disabling chronic conditions. In practice, however, some individuals other than those categories of beneficiaries also enroll in SNPs. In 2008, the Congress placed a moratorium on new SNPs but also extended the authority of SNPs to target enrollment to certain populations (with new restrictions) until December 31, 2010.

Just under 60 percent of SNPs serve dual eligibles, and these beneficiaries make up 66 percent of SNP enrollees (Table 4-5). Chronic condition SNPs are the next most common type, making up about 30 percent of plans and 21 percent of total SNP enrollment. The vast majority of SNPs are HMOs; PFFS plans are ineligible to operate as SNPs.

The distribution of SNP drug benefit designs changed significantly in 2009. Sponsors are offering fewer actuarially equivalent benefits: 67 SNPs, or 10 percent of all SNPs, down from 162 SNPs in 2008, or 23 percent. Sponsors offset this decline with defined standard benefit plans (230 SNPs, or 35 percent, in 2009 compared with 188, or 27 percent, in 2008). Similarly, the numbers and shares of zero- and reduced-deductible SNPs declined, while the proportion of SNPs that use the deductible from the defined standard benefit ($295 in 2009) grew significantly. Also, fewer SNPs cover some drugs for beneficiaries whose spending reaches Part D's coverage gap: 24 percent compared with 31 percent in 2008. These changes may not affect many enrollees in SNPs for dual eligibles and institutionalized beneficiaries, as most of these individuals face low or no copays and no gap in coverage. However, not all enrollees in SNPs for dual eligibles or for the institutionalized receive the LIS, and enrollees in chronic condition SNPs are affected as well.[10]

Enrollee premiums increased for 2009

If they remained in the same plan as last year, Part D enrollees pay an average of nearly $31 per month in 2009, up $6 (24 percent) from nearly $25 per month (Table 4-6, p. 290). The average PDP enrollee pays about $37 per month compared with $30 in 2008, a 25 percent increase. Similarly, the portion of MA premiums attributable to prescription drug benefits increased in 2009, with the average MA–PD enrollee (excluding SNPs) paying about $15 per month, compared with $12 in 2008—a 27 percent increase. (These amounts reflect MA–PDs' rebate dollars, which come from the MA payment system. Many MA plan sponsors apply rebate dollars from the MA payment system to lower or eliminate their premium for Part D benefits. In 2009, about two-thirds of MA–PDs charged no premium for drug coverage.)

The estimates above overstate the average premium increase that Part D enrollees experienced for 2009 because, at the time of publication, we did not know how many beneficiaries would change plans. Subsequently, CMS reassigned some LIS enrollees to lower premium plans, and other individuals changed to new plans on their own in response to rising premiums. These factors tend to dampen the average percentage increase.

According to CMS, the average portion of an MA–PD premium attributable to Part D benefits (before applying rebate dollars from the MA payment system) in 2009 is $11 less than the average PDP premium (CMS 2008b). Because bids for both PDPs and MA–PDs make up the overall national average bid and affect Medicare's payments to sponsors, lower average bids by MA–PDs somewhat reduce federal program spending for Part D.

A counterintuitive finding is that, at $22.12 per month, the average portion of MA–PD premiums attributable to Part

TABLE 4–5

Characteristics of SNPs and their drug coverage

	2008				2009		
	Plans		Enrollees (as of October 2008)		Plans		
	Number	Percent	Number (in millions)	Percent	Number	Percent	Percent of estimated enrollment[a]
Total	704	100%	1.1	100%	658	100%	100%
Type of SNP							
Dual eligible	401	57	0.7	66	383	58	66
Chronic condition	221	31	0.2	22	195	30	21
Institutionalized	82	12	0.1	12	80	12	12
Type of MA organization							
Local HMO	587	84	0.9	84	555	84	84
Local PPO	76	11	0.1	9	72	11	9
Regional PPO	41	6	0.1	8	31	5	8
Type of benefit							
Defined standard	188	27	0.3	28	230	35	40
Actuarially equivalent[b]	162	23	0.3	26	67	10	14
Enhanced	354	50	0.5	46	361	55	46
Type of deductible							
Zero	358	51	0.6	57	277	42	44
Reduced	69	10	<0.05	5	22	3	1
Defined standard[c]	277	39	0.4	38	359	55	55
Drugs covered in the gap							
Some generics but no brand-name drugs	117	16	0.2	21	39	6	13
Some generics and some brand-name drugs	99	15	0.1	8	119	18	9
None	488	69	0.7	71	500	76	78

Note: SNPs (special needs plans), MA (Medicare Advantage), PPO (preferred provider organization). SNPs are MA plans that are permitted to limit their enrollment to a targeted population such as beneficiaries with a specific chronic condition, dual eligibles, or the institutionalized. The SNPs and enrollment described here exclude employer-only plans and plans offered in U.S. territories. Private fee-for-service plans are not permitted to offer SNPs. Sums may not add to totals due to rounding.
a. Assumes enrollees remained in the same plan in which they were enrolled in 2008 if offered in 2009. About 99 percent of October 2008 SNP enrollees who were within the scope of our analysis were in 2008 plans that could be matched to 2009 plans. New plan entrants are credited with no enrollment. Note that some beneficiaries enrolled in a different plan for 2009.
b. Includes "actuarially equivalent standard" and "basic alternative" benefits.
c. $275 in 2008 and $295 in 2009.

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

D coverage is higher for plans with basic benefits than the average for plans with enhanced benefits ($14.78 per month). A predominant share of plans contributing to the overall MA–PD average of $15.15 is made up of MA–PDs that offer enhanced rather than basic benefits (90 percent). In most cases, organizations that sponsor MA–PDs do not offer basic and enhanced plans in the same area of operations. The average premiums for MA–PDs offering basic compared with enhanced benefits reflect a mixture of different plan sponsors and different MA payment rates.

TABLE 4–6

Comparison of Part D premiums in 2008 and 2009

	2008 enrollment (in millions)	Premium[a]		Change in premium	
		2008	2009	Dollar	Percent
PDPs					
Basic plans	12.8	$26.72	$32.98	$6.27	23%
Enhanced plans	3.7	40.65	48.42	7.77	19
All PDPs	16.5	29.86	37.27	7.41	25[b]
MA–PDs, excluding SNPs[c]					
Basic plans	0.4	21.88	22.12	0.24	1
Enhanced plans	5.3	11.23	14.78	3.55	32
All MA–PDs	5.7	11.97	15.15	3.18	27
SNPs[c]					
Basic plans	0.6	20.30	21.44	1.14	6
Enhanced plans	0.5	11.68	11.81	0.12	1
All SNPs	1.1	16.30	16.97	0.67	4
All plans					
Basic plans	13.7	26.31	32.21	5.90	22
Enhanced plans	9.5	22.73	29.26	6.53	29
All plans	23.3	24.85	30.88	6.03	24

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), SNP (special needs plan). The PDPs and enrollment described here exclude employer-only plans and plans offered in U.S. territories. The MA–PDs and SNPs and their enrollment described here exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B-only plans.
a. Values for plans offered in 2008 are the weighted average using October 2008 enrollment. Values for plans offered in 2009 are estimated and reflect enrollment levels of those plans as of October 2008. New plan entrants have no enrollment. Ninety-eight percent of October 2008 PDP enrollees, 97 percent of MA–PD enrollees, and 99 percent of SNP enrollees who were within the scope of our analysis were in 2008 plans that could be matched to 2009 plans. Note that some beneficiaries enrolled in a different plan or, in the case of some low-income subsidy enrollees, were reassigned automatically to a lower premium plan for 2009.
b. A 25 percent increase is counterintuitive because it is larger than the 23 percent and 19 percent increases for average basic and enhanced PDP premiums, respectively. However, the average PDP premium for 2009 reflects a higher proportion of enrollment in higher premium enhanced PDPs rather than basic PDPs because more enhanced plans could be matched with 2008 enrollment data.
c. Reflects the portion of Medicare Advantage plans' total monthly premium attributable to Part D benefits for plans that offer Part D coverage. MA–PD premiums reflect rebate dollars (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.

In 2009, CMS ended its demonstration that phased in the use of enrollment as a factor in calculating the Part D national average bid. Medicare law calls for weighting plan bids by their prior-year enrollment (called enrollment weighting). The national average bid is the amount CMS uses to set Part D enrollee premiums as well as Medicare's payments to sponsors. When setting premiums and payments for 2006, CMS weighted PDP bids equally because Part D was a new program without prior-year enrollment. For 2007 and 2008, CMS used its general demonstration authority to transition to enrollment weighting. This change led to a higher Medicare subsidy than the 74.5 percent called for by law, which increased the government's payments to sponsors and lowered enrollee premiums relative to the statutory requirement. This year (2009) is the first in which CMS used full enrollment weighting to set premiums and payments.

Low-income premium subsidies and beneficiary reassignments

In 2009, LIS enrollees have far fewer options of PDPs in which they pay no premium. A total of 308 PDPs have premiums at or below the LIS monthly premium subsidy amount for their region, compared with 495 PDPs in 2008 (Table 4-7). Unlike past years when each region had at least five PDPs available to LIS enrollees at no premium, in

TABLE 4–7

Fewer PDPs with no premium are available to LIS enrollees in 2009

		LIS monthly premium subsidy			Number of qualifying PDPs		
PDP region	**State(s)**	**2008**	**2009**	**Difference**	**2008**	**2009**	**Difference**
1	ME, NH	$31	$28	–$3	18	5	–13
2	CT, MA, RI, VT	29	32	3	14	12	–2
3	NY	24	28	4	15	9	–6
4	NJ	31	31	<–0.50	18	7	–11
5	DE, DC, MD	31	31	<0.50	18	11	–7
6	PA, WV	27	29	3	18	9	–9
7	VA	31	32	1	17	13	–4
8	NC	33	33	<0.50	17	11	–6
9	SC	31	32	1	20	15	–5
10	GA	30	29	–1	18	11	–7
11	FL	19	21	2	8	5	–3
12	AL, TN	28	30	2	15	12	–3
13	MI	30	32	2	17	11	–6
14	OH	27	28	2	15	6	–9
15	IN, KY	34	34	<0.50	17	12	–5
16	WI	31	38	7	16	16	0
17	IL	30	30	<–0.50	19	12	–7
18	MO	27	32	5	13	6	–7
19	AR	28	27	–1	18	12	–6
20	MS	31	32	<0.50	15	13	–2
21	LA	25	27	3	10	7	–3
22	TX	25	25	<0.50	15	14	–1
23	OK	28	29	1	13	8	–5
24	KS	31	34	3	17	10	–7
25	IA, MN, MT, NE, ND, SD, WY	31	33	3	16	9	–7
26	NM	19	21	1	11	7	–4
27	CO	25	30	6	12	8	–4
28	AZ	16	16	<0.50	7	2	–5
29	NV	17	20	4	5	1	–4
30	OR, WA	30	32	2	15	7	–8
31	ID, UT	34	37	4	14	9	–5
32	CA	20	25	5	9	6	–3
33	HI	24	25	1	10	5	–5
34	AK	36	36	<–0.50	15	7	–8
	Total	N/A	N/A	N/A	495	308	–187

Note: PDP (prescription drug plan), LIS (low-income subsidy), N/A (not applicable).

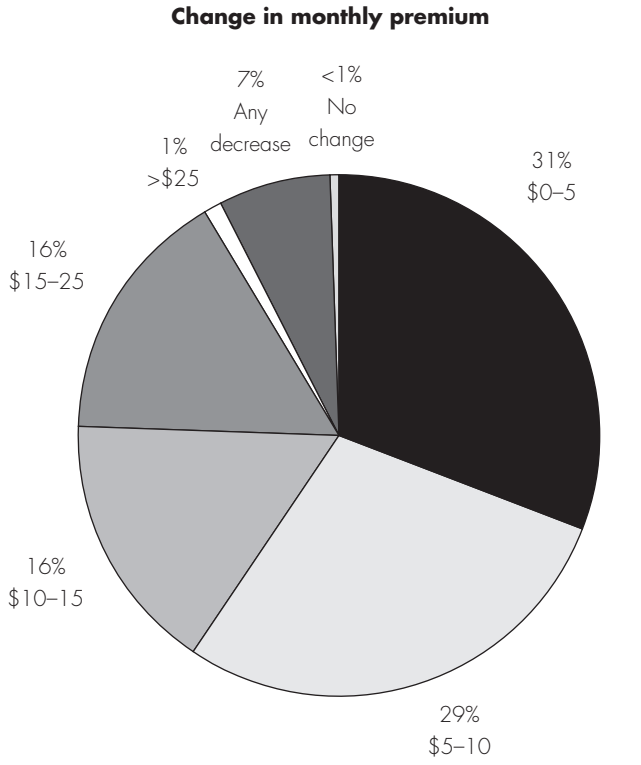
Source: MedPAC based on 2009 PDP landscape file and LIS enrollment data provided by CMS.

2009, two regions will have fewer than three (Nevada with one, and Arizona with two such PDPs), and every region but Wisconsin had a decline in the number of such PDPs.

Approximately 2.3 million LIS enrollees were affected by this 2009 turnover of qualifying plans. CMS expected to reassign an estimated 0.5 million beneficiaries to a qualifying plan offered by the same sponsor. Because many sponsors use the same formulary for all their plans, these reassigned individuals are less likely to face significant changes. Another 0.6 million LIS enrollees, who previously chose a plan on their own, were

FIGURE 4–4

Almost all PDP enrollees who do not receive the low-income subsidy pay higher premiums in 2009 if they stayed in the same plan



Note: PDP (prescription drug plan).

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

responsible for switching themselves into a qualifying plan or for paying a portion of the premium to remain in the same plan. CMS expected to reassign an estimated 1.2 million individuals (12 percent of LIS enrollees) to new plans offered by a different plan sponsor (CMS 2008g). By comparison, in 2008, a similar number of LIS enrollees (2.6 million) were affected by the turnover of qualifying plans. Compared with 2009, in 2008 more enrollees (1 million) were reassigned to plans offered by the same sponsor, while similar numbers switched themselves into a qualifying plan, paid part of the premium to stay in the same plan (0.4 million), or were reassigned to a new plan with a different sponsor (1.2 million).

Beneficiaries who switch plans and the physicians and pharmacies who serve them face transition issues as they change formularies. For example, the 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.) Enrollment and LIS eligibility information is transmitted through less than up-to-date data systems that must connect sponsors, states, CMS, the Social Security Administration, and pharmacies. At the point of service, pharmacists must know the beneficiary's plan and applicable copay. If these data links are not current, the beneficiary is not recognized as an enrollee or is charged a higher copay. A potential outcome is that enrollees may discontinue needed medication.

We do not yet know how reassigned beneficiaries have fared in past years. Despite a relatively large number of reassignments in 2008, there was little press coverage of problems for LIS enrollees at the start of the year. Future analyses of Part D claims information will enable us to see whether plan reassignments have led LIS enrollees to change their adherence to medication therapies, or whether there are noticeable effects on health outcomes and use of other services.

For 2009, CMS moved to a new method for setting LIS premium thresholds. Specifically, the agency set each region's threshold amount by weighting plan premiums by the number of their LIS enrollees. Previously, CMS was phasing in the weighted enrollment approach, which weighted premiums by overall plan enrollment and not just LIS enrollment. (The agency used its general demonstration authority to phase in weighting over time rather than moving to full enrollment weighting in 2007 as called for by law. Under the same demonstration, CMS carried out a "de minimis" 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 for 2009.) A reason for the change 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 therefore fewer PDPs with premiums below those thresholds. Because, on average, MA–PDs have fewer LIS enrollees than PDPs and PDPs tend to have higher premiums, weighting premiums by LIS enrollment would tend to raise regional thresholds.

The agency believes the new policy helped reduce the number of beneficiaries who had to be reassigned for 2009 relative to what would have happened under the previous method. Yet, even with the new method, LIS premium subsidy thresholds remain low in some parts of the country because in those areas relatively high shares of LIS beneficiaries are enrolled in MA–PDs.

Some LIS enrollees choose to remain in their current plan rather than be reassigned to a new one. To stay in their current plan, LIS enrollees need to pay the difference between their plan's premium and the threshold amount that Medicare covers in their region. The premium amount such individuals need to pay differs across plans, ranging between 6 cents and more than $47 per month. The most common amounts are between $3 and $5 per month.

Some enrollees who do not receive the LIS also live on fixed or limited incomes, and they too may find that they need to switch plans because of premium increases. We estimate that about 93 percent of non-LIS enrollees in PDPs faced a premium increase for 2009 (Figure 4-4). For about 7 percent of individuals, their plan's monthly premium decreased or stayed the same. Most individuals—about 60 percent—saw their PDP premium increase by less than $10 per month. However, about one-third of non-LIS enrollees were enrolled in PDPs with premiums that increased by $10 or more per month.

Plan formularies and cost-sharing requirements

The Medicare drug benefit requires plan sponsors to operate their own formularies—a list of drugs that plans may cover and the terms under which they will cover them—to manage the cost and use of prescription drugs.[11]

When designing formulary systems, sponsors strike a balance between providing enrollees with access to medications and controlling growth in drug spending by negotiating drug prices and managing utilization. Part D sponsors rely on clinicians—generally physicians and pharmacists who participate on a pharmacy and therapeutics committee—when deciding specific drugs to list on their formularies. Plan sponsors must also select the cost-sharing tier for each listed drug and whether any utilization management tools apply to the drug, taking into account clinical and financial factors (e.g., how decisions might affect the 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 be less attractive because it covers a limited number of drugs.

Each spring, Part D sponsors submit data to CMS on the list of drugs their plans may cover, cost-sharing tiers for the drugs, and whether each drug is subject to utilization management tools such as prior authorization.[12] CMS then uses that information, along with data from sponsors about formulary changes, to create files on a monthly basis that describe plan formularies. Researchers at NORC at the University of Chicago, Georgetown University, and Social and Scientific Systems—under contract with the Commission—used these formulary files to analyze Part D formulary structures and cost-sharing requirements. They found a large degree of variation across plan sponsors, but, in general, they also saw trends toward increasing the use of preferred, nonpreferred, and specialty tiers in formulary designs for 2009 and higher levels of cost sharing.

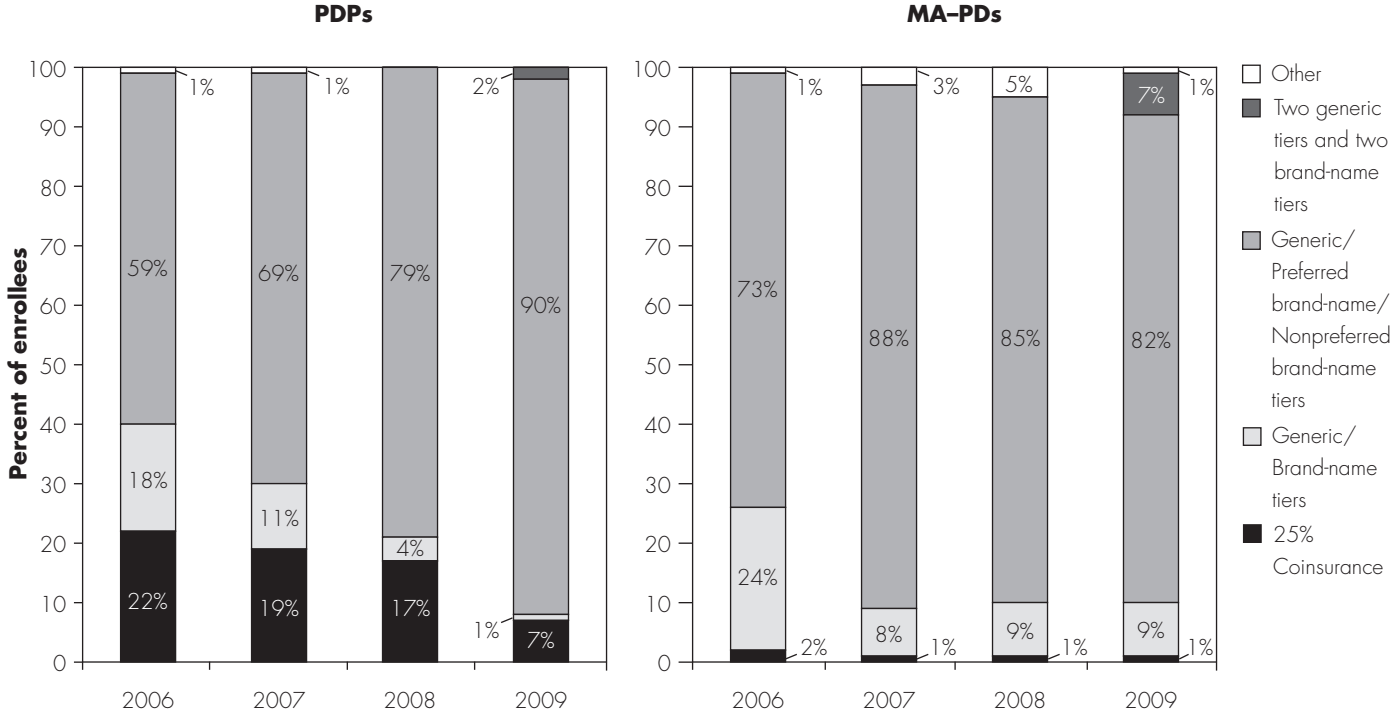
To conduct this analysis, researchers had to decide how to define a drug, as medication therapies come in a variety of forms and dosages. How drugs are defined can have a significant impact on formulary rules and standards. CMS generally requires that plan formularies include at least two drugs in each of its therapeutic categories and classes, unless only one drug is available. Yet, two products may be considered the same drug by one measure, while they are treated as separate entities by another. After considering several analytic approaches, our contractor conducted the research for this chapter by defining drugs 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.[13] (For more on the implications of how one defines a drug, see the Commission's March 2008 report (MedPAC 2008).)

Plan tier structures and cost-sharing requirements

CMS data show that most plans' formularies fall into three categories: 1) 25 percent cost sharing for all listed drugs (as in the defined standard benefit), 2) one generic and one brand-name tier, and 3) designs that include a generic tier and also distinguish between preferred and nonpreferred brand-name drugs.[14] Among these categories, most plans use the third category. In addition, CMS permits Part D plans to use a specialty tier for expensive products, unique drugs, and biologics; most plan formularies include a specialty tier.

FIGURE 4–5

Part D plans increasingly use formularies with tiers for generic, preferred brand-name, and nonpreferred brand-name drugs



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Calculations are weighted by enrollment. 2009 values were calculated using 2008 enrollment. PDPs exclude employer-only groups and plans offered in U.S. territories. MA–PDs exclude demonstration programs, 1876 cost plans, employer-only groups, special needs plans, and plans offered in U.S. territories. Most plans, except benefits that use the standard 25 percent coinsurance for all drugs, also have a specialty tier for higher price drugs.

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

By setting differential copays between preferred and nonpreferred brands, these formularies may give sponsors a stronger tool than two tiers for encouraging substitution among drugs within the same therapeutic class. Use of these designs in Part D has increased: The share of beneficiaries enrolled in a plan with a formulary using separate tiers for preferred and nonpreferred brands grew from 59 percent of PDP enrollees in 2006 to an estimated 90 percent in 2009, and from 73 percent of MA–PD enrollees in 2006 to an estimated 82 percent in 2009 (Figure 4-5).[15]

New for 2009, a noticeable number of sponsors introduced two tiers for generic drugs on their plans' formularies—with one often labeled as preferred or "value" generics—along with having two brand-name tiers (for preferred and nonpreferred brands). Using enrollment data from 2008, we estimate that about 2 percent of PDP enrollees and 7 percent of MA–PD enrollees are in plans with two generic tiers. Presumably, these formularies are in response to pharmacy chains and big-box stores such as Wal-Mart that offer low-cost generics (e.g., $4 for a 30-day supply) to all their customers. Another reason may be that some new generic drugs are much more expensive than older generics, and sponsors may want to place them on the generic tier that has a higher copay.

Most plans with benefit designs that differ from the defined standard benefit (which has flat 25 percent coinsurance for all listed drugs) include a specialty tier in their formulary design. In 2006, 82 percent of enrollees in nonstandard PDPs and 69 percent of enrollees in nonstandard MA–PDs were in plans that used such a tier. In 2008, those shares were 92 percent of enrollees in nonstandard PDPs and 96 percent of enrollees in nonstandard MA–PDs (Figure 4-6).[16] Most remaining enrollees were in plans that used coinsurance with cost-sharing requirements comparable to those of specialty

tiers. In 2009, the share of PDP enrollees in plans with a specialty tier appears to have declined to 82 percent from 92 percent a year earlier. However, this decline is largely due to changes in the formulary structure of one major sponsor that does not use a specialty tier. That sponsor switched from using the defined standard benefit for some of its plans (with flat 25 percent coinsurance) in 2008 to coinsurance tiers with cost sharing comparable to other plans' tiers for nonpreferred drugs. This means the sponsor's plans are excluded from the denominator in the bars representing PDPs for 2008 (because it used the defined standard benefit) but included in the denominator for 2009.

For 2006, CMS did not establish specific criteria for placing drugs on 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 on a specialty tier. In 2008 and 2009, only drugs with prices that exceed $600 per month may be on a specialty tier.

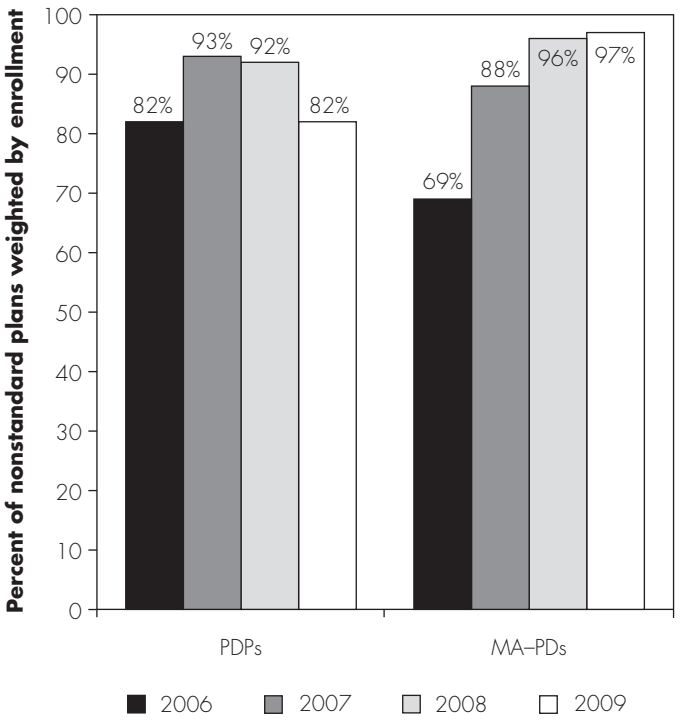
Broader use of specialty tiers has important implications for beneficiaries and plans. From an enrollee's perspective, cost-sharing requirements for specialty-tier drugs can be high (at least 25 percent of the plan sponsor's negotiated price before manufacturers' rebates) until the beneficiary reaches the catastrophic levels of spending in Part D's benefit that limit out-of-pocket spending. In addition, under CMS's regulations, enrollees may not appeal cost sharing as they can for other drugs such as those on nonpreferred brand tiers. Because the drugs on specialty tiers are often used to treat very serious illnesses such as rheumatoid arthritis, multiple sclerosis, some cancers, and hepatitis C, these patients could face relatively high cost sharing for medications on top of significant out-of-pocket costs for the rest of 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 add a specialty tier to limit the risk of attracting sicker enrollees who use very expensive drugs. Otherwise, those expensive drugs would be available for much lower copays.

Although there is wide variation across plans, for 2009, cost-sharing requirements tended to rise among PDPs. Copay levels for the median enrollee in a PDP rose to $7 per 30-day prescription for a generic drug, $38 for preferred brand-name drugs, and $75 for nonpreferred brands (Table 4-8, p. 296). Cost-sharing requirements have remained steadier for enrollees in MA–PDs. For 2009, the median enrollee in an MA–PD pays $5 for a monthly supply of generic drugs, $30 for preferred brand-name drugs, and $60 for nonpreferred brands.

Under CMS regulations, 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, sponsors may design a plan that uses 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 (CMS 2008h).

FIGURE 4–6

Most Part D plans use specialty tiers for some expensive drugs



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Nonstandard plans are those that do not use Part D's defined standard benefit, which has a flat 25 percent coinsurance rate for all listed drugs. Calculations are weighted by enrollment. 2009 values were calculated using 2008 enrollment. PDPs exclude employer-only groups and plans offered in U.S. territories. MA–PDs exclude demonstration programs, 1876 cost plans, employer-only groups, special needs plans, and plans offered in U.S. territories. Specialty tiers apply to expensive products and unique drugs and biologics for which enrollees may not appeal for lower cost sharing.

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

TABLE 4–8 **Median cost sharing for a month's supply of a prescription drug has risen among PDPs**

	PDPs				MA–PDs			
	2006	2007	2008	2009	2006	2007	2008	2009
Copay								
Generic	$5	$5	$5	$7	$5	$5	$5	$5
Preferred brand-name drug	28	28	30	38	27	29	30	30
Nonpreferred brand-name drug	55	60	72	75	55	60	60	60
Specialty-tier coinsurance	25%	30%	30%	33%	25%	25%	25%	33%

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Calculations are weighted by enrollment. 2009 values were calculated using 2008 enrollment. Generic copay values are for all plans that use dollar copays. Copay values for preferred and nonpreferred brand-name drugs are only for plans that use those tiers. PDPs exclude employer-only groups and plans offered in U.S. territories. MA–PDs exclude demonstration programs, 1876 cost plans, employer-only groups, special needs plans, and plans offered in U.S. territories. Specialty tiers apply to expensive products and unique drugs and biologics for which enrollees may not appeal for lower cost sharing.

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

For 2009, the median enrollee in either a PDP or an MA–PD with a specialty tier faces 33 percent coinsurance for those drugs. This situation shows that sponsors are making extensive use of the flexibility that Part D allows for actuarial equivalence in benefit designs, trading off a lower or no deductible for all plan members with higher cost sharing on specialty drugs used by a few enrollees (Hargrave et al. 2007). At the same time, this form of actuarial equivalence may raise out-of-pocket spending and disproportionately affect access for beneficiaries who use these high-cost drugs.

Formulary sizes and utilization management

The number of drugs that sponsors list on a formulary can be another way to analyze Part D plans. Note, however, that the number of drugs on a plan's formulary does not necessarily represent beneficiary access to medications. Plans' processes for nonformulary exceptions, prior authorization, quantity limits, and step therapy requirements can have a strong influence on access to certain drugs. For example, unlisted drugs may be covered through the nonformulary exceptions process, which may be relatively easy with some plan sponsors and more burdensome with others. Alternatively, the sponsor may not cover on-formulary drugs in some situations where it requires prior authorization before filling a prescription.

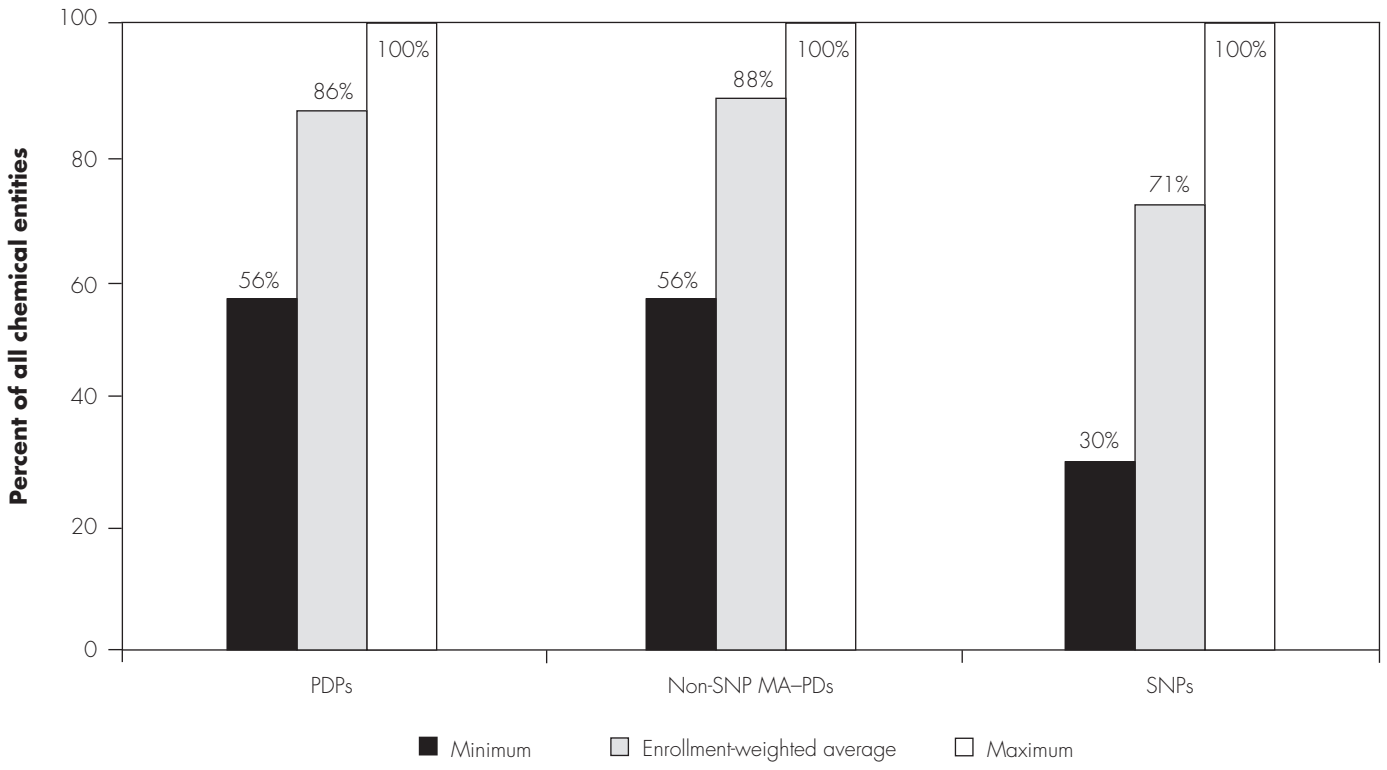
During 2009, enrollees in stand-alone PDPs and non-SNP MA–PDs have similar numbers of drugs listed on their plans' formularies. We estimate that the average PDP enrollee is in a plan that listed 86 percent of all distinct chemical entities on which CMS requires sponsors to report, while the average MA–PD enrollee was in a plan listing 88 percent (Figure 4-7). However, the number of drugs listed on any given plan's formulary can vary considerably, from 56 percent for plans with the tightest formularies to 100 percent for other plans.

This year, we asked our contractor to also analyze the formularies of SNPs. Those plans show a distinctly different pattern from other MA–PDs in that they appear to have tighter formularies. We estimate that the average SNP enrollee is in a plan that lists 71 percent of the distinct chemical entities on which CMS requires sponsors to report (Figure 4-7). There is also more variation in the size of SNP formularies, with the tightest plan listing 30 percent of chemical entities. Most SNP enrollment is in plans designed for dual eligibles, and dual beneficiaries have no or low cost sharing because they receive the LIS. As a result, sponsors of SNPs may use tighter formularies more extensively to manage drug spending, as they cannot require LIS enrollees to pay differential copays between drug tiers to the same extent that they would with non-LIS enrollees. At the same time, LIS enrollees do not receive cost-sharing assistance for drugs not listed on a plan's formulary, so those individuals would either need to pay out-of-pocket for the drug or switch to a covered medication, which may be a cause for concern to the extent that sponsors fall on the lower end of the distribution in Figure 4-7.

The number of drugs listed on plan formularies varies widely. Our contractor looked for systematic differences on a variety of dimensions. Some of the findings include:

FIGURE 4–7

PDPs and non-SNP MA–PDs listed similar numbers of drugs on their formularies, but SNPs tended to list fewer drugs



Note: PDP (prescription drug plan), SNP (special needs plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Values reflect the percent of all distinct chemical entities listed within CMS's formulary reference file. The enrollment-weighted average is weighted by 2008 enrollment. PDPs exclude employer-only groups and plans offered in U.S. territories. Non-SNP MA–PDs exclude demonstration programs, 1876 cost plans, employer-only groups, and plans offered in U.S. territories. SNPs are one type of MA–PD. The numbers of plans are: PDPs (1,634), non-SNP MA–PDs (1,876), and SNPs (606).

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

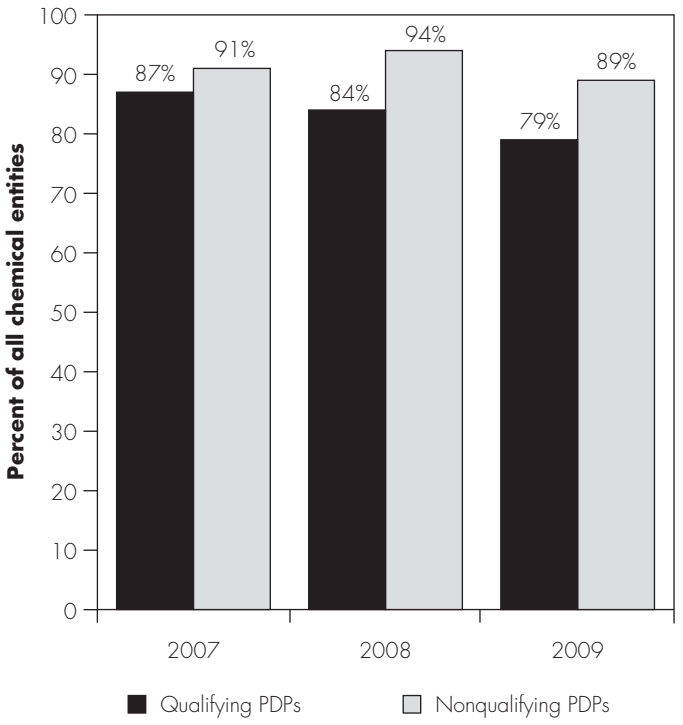
- PDPs that use more tiers tend to list more drugs but have similar numbers of drugs that are unrestricted (i.e., offered at preferred levels of cost sharing and not subject to utilization management) as PDPs with fewer tiers.
- PDPs with enhanced benefits do not tend to list more drugs covered by Part D than PDPs with basic benefits.
- PDPs with higher shares of enrollment in their region tend to have larger formularies.
- Among types of non-SNP MA–PDs, local HMOs tend to have modestly smaller formularies than PFFS plans or preferred provider organizations.

In an earlier analysis of 2006 Part D formularies, our contractor concluded that plans that qualified as premium-free to LIS beneficiaries listed about the same number of drugs as plans that did not qualify (MedPAC 2006). Since 2006, the gap in the size of formularies between PDPs that qualify and those that do not has widened. In 2007, there was a 4 percentage point difference in the average size of formularies for these categories of plans, weighted by enrollment (Figure 4-8, p. 298). In 2008 and 2009, that gap grew to 10 percentage points—79 percent of distinct chemical entities for qualifying PDPs compared with 89 percent for PDPs that did not qualify in 2009.

Formulary size alone does not directly measure access. Still, large differences may raise concern about inequitable access to drugs between LIS enrollees and other beneficiaries. At the same time, because LIS enrollees

FIGURE 4–8

Difference in sizes of formularies between PDPs that did and did not qualify as premium-free to LIS enrollees has widened



Note: PDP (prescription drug plan), LIS (low-income subsidy). Values reflect the percent of all distinct chemical entities listed within CMS's formulary reference file, weighted by enrollment. 2009 values were calculated using 2008 enrollment. Excludes plans that qualified based on de minimis waivers in place for 2007 and 2008. PDPs exclude employer-only groups and plans offered in U.S. territories. Medicare Advantage–Prescription Drug plans exclude demonstration programs, 1876 cost plans, employer-only groups, and plans offered in U.S. territories.

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

receive extra help with cost sharing, qualifying plans may limit the size of their formularies as a key way to manage drug spending.

Part D plan sponsors apply utilization management tools—including prior authorization, step therapy, and quantity limits—to selected drugs. Sponsors use such tools for drugs that are expensive; potentially risky; or subject to abuse, misuse, or experimental use or to encourage use of lower cost therapies. Some tools are more common than others. For example, all PDPs and almost all MA–PDs use prior authorization for at least one drug on their formulary. For 2009, the average enrollee in either a PDP or an MA–PD faces some sort of utilization management for 26 percent of the drugs listed on a plan's formulary—an increase from 18 percent in 2007 and 23 percent in 2008. Prior authorization is used for 12 percent of drugs, step therapy for 3 percent, and quantity limits for 16 percent. The use of specific tools varies by drug class. For example, in 2006 Part D formularies, 70 percent or more of drugs listed in the therapeutic class of immune suppressants required prior authorization, while fewer than 5 percent of renin angiotensins (selected hypertension drugs) had similar requirements (MedPAC 2006).

Payments to plan sponsors

Year-to-year trends in the national average bid give policymakers information about how well sponsors are managing drug benefit costs for beneficiaries and taxpayers. However, those trends are an imperfect measure of performance for several reasons. First, bids are projections of sponsors' estimated costs, not actual costs. For example, in 2005, when sponsors were preparing bids for Part D's first benefit year, they had little information on which to base their bids. The large reconciliation payments that sponsors made to Medicare for the 2006 benefit year indicate that many sponsors bid too high. Even though 2009 represents the fourth round of bidding under Part D, some analysts argue that sponsors have only just acquired sufficient claims experience on which to base some aspects of their bids.[17] A second reason for caution is that under the demonstrations described earlier, CMS phased in enrollment weighting over time rather than moving to full enrollment weighting in 2007. Thus, year-to-year trends reflect changes in weighting as well as trends in benefit costs. (Table 4-9 displays average bids by year and percentage changes in those bids measured two ways: The first four columns show averages that reflect CMS's payment demonstration, which phased in enrollment weighting. The last three columns show values using full enrollment weighting.)

Between 2008 and 2009, the projected trend in Part D benefit costs appears high: 11 percent per person (Table 4-9). (This percentage increase is the sum of each year's national average monthly bid amount plus sponsors' average expected reinsurance payments for plan enrollees with catastrophic levels of drug spending. The increase also reflects full enrollment weighting of plan bids for both years.) Over the same period, the percentage increase for the national average monthly bid amount alone (i.e.,

TABLE 4–9

Average prospective monthly payments per enrollee for basic coverage

	Amounts used as the basis for prospective payments				Fully enrollment-weighted amounts		
	2006[a]	2007[b]	2008[c]	2009[d]	2007	2008	2009
Amounts in dollars							
National average monthly bid							
Base beneficiary premium	$32.20	$27.35	$27.93	$30.36	$26.23	$27.28	$30.36
Monthly payment to plans	60.10	53.08	52.59	53.97	50.36	52.02	53.97
Subtotal	92.30	80.43	80.52	84.33	76.59	79.30	84.33
Expected individual reinsurance	33.98	26.82	29.01	34.73	26.27	27.68	34.73
Total average benefit cost	126.28	107.25	109.53	119.06	102.86	106.98	119.06
Annual percent change							
National average monthly bid							
Base beneficiary premium	N/A	–15%	2%	9%	–19%	4%	11%
Monthly payment to plans	N/A	–12	–1	3	–16	3	4
Subtotal	N/A	–13	0	5	–17	4	6
Expected individual reinsurance	N/A	–21	8	20	–23	5	25
Total average benefit cost	N/A	–15	2	9	–19	4	11

Note: N/A (not applicable). 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. At the start of Part D, 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 analysis based on CMS releases of Part D national average monthly bid amounts and base beneficiary premiums for 2006 through 2009, as well as other data provided by CMS.

without expected reinsurance) is 6 percent—similar to the rate of increase in general drug costs measured in the national health accounts. Thus, higher estimates of costs for catastrophic coverage account for much of the 11 percent projected increase in overall Part D costs. CMS believes this increase reflects more about sponsors' improved ability to project catastrophic spending from their claims experience than an excessive trend. Nevertheless, the Commission will keep a close eye on these components of plan bids.

Each year, CMS reconciles its prospective payments to Part D sponsors by comparing data on actual levels of enrollment, enrollee risk factors, levels of incurred allowable drug costs (after drug rebates and other discounts), individual reinsurance amounts, the LIS, and risk corridors. For 2007, CMS expected to collect $18 million—compared with $4.3 billion collected for 2006—from plan sponsors in reconciliation payments for lower actual costs than expected (Table 4-10, p. 300). The lower amounts for 2007 suggest that sponsors improved their ability to bid more accurately after a year's experience providing Part D benefits.

The 2007 reconciliation amount of $18 million nets out several types of Part D payments. It accounts for nearly $600 million that sponsors owe Medicare from risk corridors that limit plans' profits and losses, plus $187 million and $407 million that CMS owes sponsors for prospective payments that were not high enough for individual reinsurance and LIS cost sharing, respectively. Table 4-10 shows some of the largest amounts owed to and by Medicare for 2007.

TABLE 4–10 **Largest estimated reconciliation amounts by sponsoring organization**

	2007 reconciliation amounts (in millions)			
	Risk corridors	Individual reinsurance	Low-income cost sharing	Total (in millions)
Total for all organizations	–$599	$187	$407	–$18
Top organizations that owe Medicare:				
UnitedHealthcare/PacifiCare	–190	–110	–290	–590
Wellpoint	–59	–45	–130	–230
CVS Caremark	–43	–33	–51	–130
NewQuest Health Solutions	–25	–40	–44	–110
Health Net	–12	22	–77	–67
Top organizations that Medicare owes:				
MemberHealth	54	167	225	446
Humana	–78	–150	593	358
Universal American	–27	109	70	152
CIGNA	40	53	40	133
Health Care Service Corporation	–3	59	65	122

Note: The low-income cost sharing, reinsurance, and risk sharing amounts may not equal the total reconciliation amount because of rounding and an adjustment made for budget neutrality in the Part D Payment Demonstration program.

Source: CMS 2008c.

Medication therapy management programs

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires PDPs and MA–PDs to implement medication therapy management programs (MTMPs) to improve the quality of pharmaceutical care high-risk beneficiaries receive. Legislators intended MTMPs to improve medication use and reduce adverse events for beneficiaries taking multiple medications. Neither the legislation nor subsequent CMS regulations provide much guidance on how these programs should be designed or implemented. Currently, sponsors' MTMPs differ on the number and type of chronic conditions and prescriptions a beneficiary must have to be eligible, how beneficiaries are targeted and enrolled, the kinds of interventions provided to enrollees, and the outcomes sponsors measure. A small percentage of beneficiaries are enrolled in MTMPs, and we do not have sufficient data to determine whether the programs are increasing the quality of pharmaceutical care to participants.

In conducting our review of medication therapy management, we examined research evaluating MTMPs in general and available data on MTMPs under Part D. 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.

Pharmacists' medication therapy management services vary

Clinical pharmacists have been providing medication reviews and other clinical services to patients for years, but no generally accepted definition existed in 2006, when Part D was implemented, of what constituted an MTMP (see text box). Private employers and some state Medicaid programs have programs in which pharmacists or other medical providers educate patients about their chronic conditions and medication use, examine their drug regimens for potential drug interactions or other inappropriate prescribing, analyze lab results to see if medications are achieving desired therapeutic outcomes, and encourage patient adherence to their drug regimens. Some programs focus on collaboration between physicians

Defining medication therapy management

Since the start of the Medicare drug benefit, pharmacists, pharmacy representatives, and health insurers have been seeking to develop consensus on what constitutes medication therapy management services. Groups of these stakeholders have collaborated on defining core aspects of effective medication therapy management programs (AMCP 2008). For example, 11 stakeholder organizations identified 5 core elements of a medication therapy management service model provided by pharmacists (American Pharmacists Association and National Association of Chain Drug Stores Foundation 2008). They include:

- ***Medication therapy review***: The pharmacist gathers data including relevant medication history, assesses physical and overall health status, reviews and assesses laboratory data, evaluates the patient to detect symptoms that could be attributed to adverse events, and identifies and prioritizes medication-related problems.
- ***Personal medication record***: The pharmacist creates a list for each patient of all the medications and supplements the patient is taking. The record can include questions for patients to ask their physicians about the medications.
- ***Medication-related action plan***: The plan is a list of actions for patients to take to manage their therapy (e.g., reminders of how and when they should take their medication).
- ***Intervention and referral***: The pharmacist contacts the patient's physician to report potential medication problems (e.g., the pharmacist may determine that the patient has medication-related side effects and contact the prescribing physician).
- ***Documentation and follow-up***: The pharmacist documents services provided in a consistent manner and schedules a follow-up appointment as necessary. ■

and pharmacists to ensure that patients receive the most appropriate drug regimen for their conditions. Other programs emphasize patient education. For example, some employer-sponsored pharmacy management programs are designed to increase employee productivity by teaching individuals to manage chronic conditions like asthma and diabetes. These programs generally target working-age patients and individuals with a single chronic condition and their experiences may not be relevant for Part D MTMPs (Bunting et al. 2008, Bunting and Cranor 2006, Fera et al. 2008).

The literature contains few large-scale evaluations of medication therapy management. Programs are difficult to compare because they differ in terms of goals, targeted populations, and interventions. Researchers have found some evidence that participation in MTMPs is associated with changes in intermediate quality indicators like improvements in hemoglobin A1c and low-density lipoprotein cholesterol levels (Abt Associates 2008). Evidence on cost savings is mixed. While most program organizers cite figures showing that MTMPs save money, analysts question the rigor of these evaluations. Program organizers tend to base larger savings estimates on medical costs that may have been avoided by more appropriate prescribing. Additionally, evaluations often do not take into account the cost of the interventions (Abt Associates 2008).

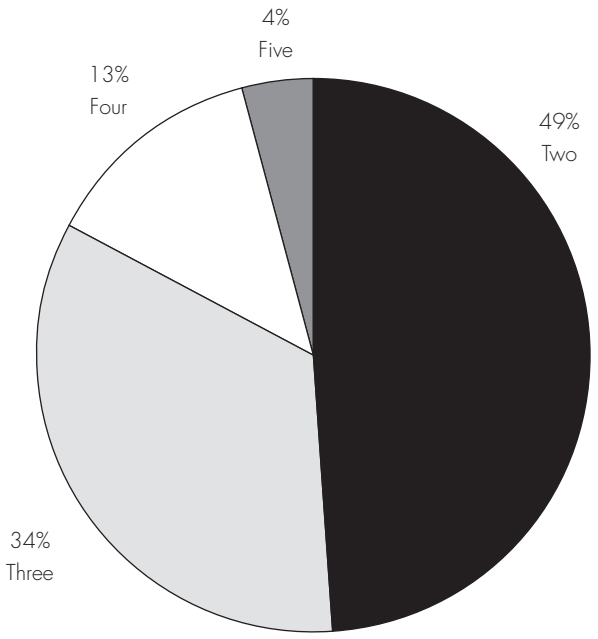
We interviewed several pharmacists who have been providing medication management services to private clients, some for more than a decade. Clients tend to be individuals with complex drug regimens, who contact the clinical pharmacist after receiving referrals from their physician, case manager, a friend, or a relative. Medication management services are generally not covered by insurance and clients pay out of pocket for medication reviews. In one case, a local area agency on aging sponsors the services periodically at a senior center, but most pharmacists we interviewed visit clients in their homes.

Although varying in the particulars, protocols for delivering services shared similarities among the pharmacists we interviewed. In general, we were told that the pharmacist:

- Contacts the client's primary physician and explains the kind of services that can be provided.

FIGURE 4–9

Most Part D MTMPs require that beneficiaries have at least two or three chronic conditions to qualify for MTMPs, 2008



Note: MTMP (medication management therapy program). In 2009, the percentage of plans requiring that beneficiaries have only two chronic conditions decreased and the percentage of plans requiring that beneficiaries have at least three chronic conditions increased.

Source: MedPAC analysis of data from CMS's (2008d) fact sheet.

- Examines the client's medical records, including lab results; visits the client to document all the drugs the client is taking, including over-the-counter medications and nutritional supplements; and questions the client about the reason for taking the drugs and the symptoms experienced.
- Sends a report to the client and the physician documenting potential drug interactions and inappropriate drugs or dosages and makes recommendations that may call for less expensive medications to replace other drugs or call for an additional drug.
- Documents all interventions and schedules follow-up visits with patients as appropriate. The pharmacist may also pay a follow-up visit if the client is hospitalized and the drug regimen changes.

Our interviewees pointed out that pharmacists are very familiar with drug side effects and interactions. No other health care professional receives as much training on the composition, mechanisms of action, and use and effect of drugs on the human body. Frequently, clients may be treated for problems that are actually caused by an interaction of drugs on their regimen. By changing the regimen, they may eliminate an additional medication used to treat the side effect.

As they interact with clients, pharmacists often educate patients. They explain why the physician prescribed a drug and how it should be taken (e.g., with food, in the evening). They emphasize adherence to therapy. Some teach patients with diabetes to monitor their blood sugar.

MTMPs under Part D must comply with federal requirements

Part D has led to an expansion in the use of MTMPs. The MMA requires plan sponsors to develop MTMPs to increase the clinical quality of pharmaceutical care. All PDPs and MA–PDs are required to offer MTMPs to their beneficiaries with multiple chronic conditions who take multiple drugs and are expected to average at least $4,000 per year in drug costs.[18]

Under the statute, a Part D sponsor must establish a program that:

- ensures optimum therapeutic outcomes for targeted beneficiaries through improved medication use,
- reduces the risk of adverse events,
- is developed in cooperation with licensed and practicing pharmacists and physicians, and
- establishes the fees to be paid to pharmacists or others for providing medication therapy management services.

Beneficiary participation is voluntary and individuals may not be denied medications for choosing not to participate in the program. Under Part D, beneficiaries do not pay for this service. Additional requirements include plan sponsors' responsibilities related to their Part D bids. Sponsors must provide a description of their MTMP as part of their annual bid. The program description includes eligibility requirements, enrollment methods, frequency and type of interventions, resources used providing the service, and method of documenting and measuring

outcomes (CMS 2008e). MTMP costs are considered administrative and are included in the bids.

In their bid submissions, sponsors must report the minimum number of chronic conditions a beneficiary must have to qualify for participation in the program. If the sponsor requires specific chronic conditions, they must be identified. The sponsor also must identify the number and type of covered Part D drugs required (e.g., sponsors may not consider drugs used to treat an acute condition as eligible for medication therapy management services). The sponsor must estimate the annual drug cost beneficiaries are likely to incur and describe their method of estimation.

Sponsors must also describe how their MTMP will operate. For example, sponsors must explain how they will identify qualifying beneficiaries and enroll and disenroll them from the program. They must detail how they predict annual drug costs based on monthly expenditures. The method must allow them to identify candidates for MTMPs before their drug expenditures reach $4,000. The sponsors describe the kinds of interventions enrollees receive (e.g., medication review), how frequently they provide services, and the recipient of the service (e.g., the beneficiary or the beneficiary's physician). Sponsors detail the type of provider who will perform program services (e.g., pharmacist, nurse, or physician) and whether the provider is employed by the sponsor or an outside contractor. In the case of outside personnel, sponsors must explain how fees will be established. Lastly, they must describe their method of documenting plan interventions and measuring outcomes.

Because of the lack of evidence on the dimensions of effective MTMPs, CMS provided minimal criteria or standards to sponsors when Part D began. CMS has not specified the content of the programs, who should offer them, or which individuals should be targeted. Sponsors determine the specific chronic conditions that apply. Sponsors also must measure outcomes of their programs, but each sponsor decides which outcomes to track and how to measure them.

Some interviewees question the appropriateness of the statutory and regulatory requirements. For example, individuals with multiple chronic conditions and high medical costs who might benefit from MTMP services may have annual expenditures below $4,000 if they have untreated indications, use generics to reduce their drug costs, or do not adhere to their medication regimen.

Part D's MTMP participation is small and sponsors' programs vary across several dimensions

CMS has not released enrollment figures for MTMPs, but according to sponsor officials, MTMP is a small program, with enrollment increasing slowly. In 2006, 6.6 percent of beneficiaries enrolled in a plan with an MTMP were enrolled in the program. In 2007, 10.8 percent of enrollees in Part D plans with MTMPs were eligible to receive program services and 8.4 percent were enrolled in their plan's program. Our analysis of 2006 Part D data suggests that 14 percent of beneficiaries enrolled in Part D (about 3.4 million beneficiaries) had Part D spending of $4,000 or more, the minimum spending required for program eligibility.

Currently, plan sponsors take varied approaches to MTMP. For example, sponsors:

- use eligibility criteria that range from less to more restrictive.
- use different enrollment methods.
- provide diverse services.
- provide services in various settings.
- collect a variety of outcome measures.

Details follow on eligibility criteria, enrollment methods, interventions, and outcome data collected.

Eligibility criteria

CMS requires sponsors to provide MTMP services to beneficiaries with multiple chronic conditions who are taking multiple drugs. Sponsors have interpreted this standard in different ways. The minimum number of chronic conditions required for beneficiaries to qualify ranges from two to five (Figure 4-9), and the minimum number of covered Part D prescriptions required for beneficiaries to qualify ranges from 2 to 15 (Table 4-11, p. 304) (CMS 2008d).

Despite the variation, we can identify some outliers. For example, most plans—83 percent—require that beneficiaries have two or three chronic conditions to qualify for medication therapy management services, whereas only 4 percent require that a beneficiary have at least five chronic conditions to be eligible for these services (CMS 2008d).

TABLE 4–11 **Minimum number of covered Part D drugs required by MTMPs, 2007**

Minimum number of covered Part D drugs	Number of MTMPs	Percent of programs		
		All MTMPs	MA–PDs	PDPs
2	46	6.5%	6.2%	7.8%
3	64	9.0	8.4	12.6
4	60	8.4	8.2	9.7
5	145	20.4	19.0	28.2
6	91	12.8	12.8	12.6
7	66	9.3	9.4	8.7
8	142	19.9	21.7	9.7
9	21	2.9	3.0	2.9
10	53	7.4	8.2	2.9
12	22	3.1	2.8	4.9
15	2	0.3	0.3	0.0

Note: MTMPs (medication management therapy programs), MA–PDs (Medicare Advantage–Prescription Drug [plans]), PDPs (prescription drug plans).

Source: CMS (2008d) fact sheet.

Sponsors also have discretion in determining which chronic conditions qualify for MTMP eligibility. According to a CMS fact sheet, 90 percent of 2008 MTMPs specify the chronic conditions that apply for program eligibility. The most frequently specified conditions in 2008 MTMPs were:

- diabetes
- heart failure
- hypertension
- dyslipidemia
- chronic obstructive pulmonary disease
- asthma
- rheumatoid arthritis
- depression
- osteoporosis
- osteoarthritis

The same conditions were the most frequently targeted in 2007. Figure 4-10 shows the percentages of MTMPs that specify each of the top 10 conditions in their eligibility criteria.

Plans also vary greatly in the designated minimum number of prescription drugs needed to qualify for their MTMPs. Most plans—89 percent—require fewer than 10 covered Part D drugs to qualify for their programs (CMS 2008d). The remaining 11 percent target only those beneficiaries who take 10 or more drugs, with two plans (which represent 0.3 percent of all plans) targeting only those who take at least 15 covered Part D drugs (CMS 2008d). Table 4-11 illustrates the distribution of prescription minimums across MTMPs.

Method of enrollment

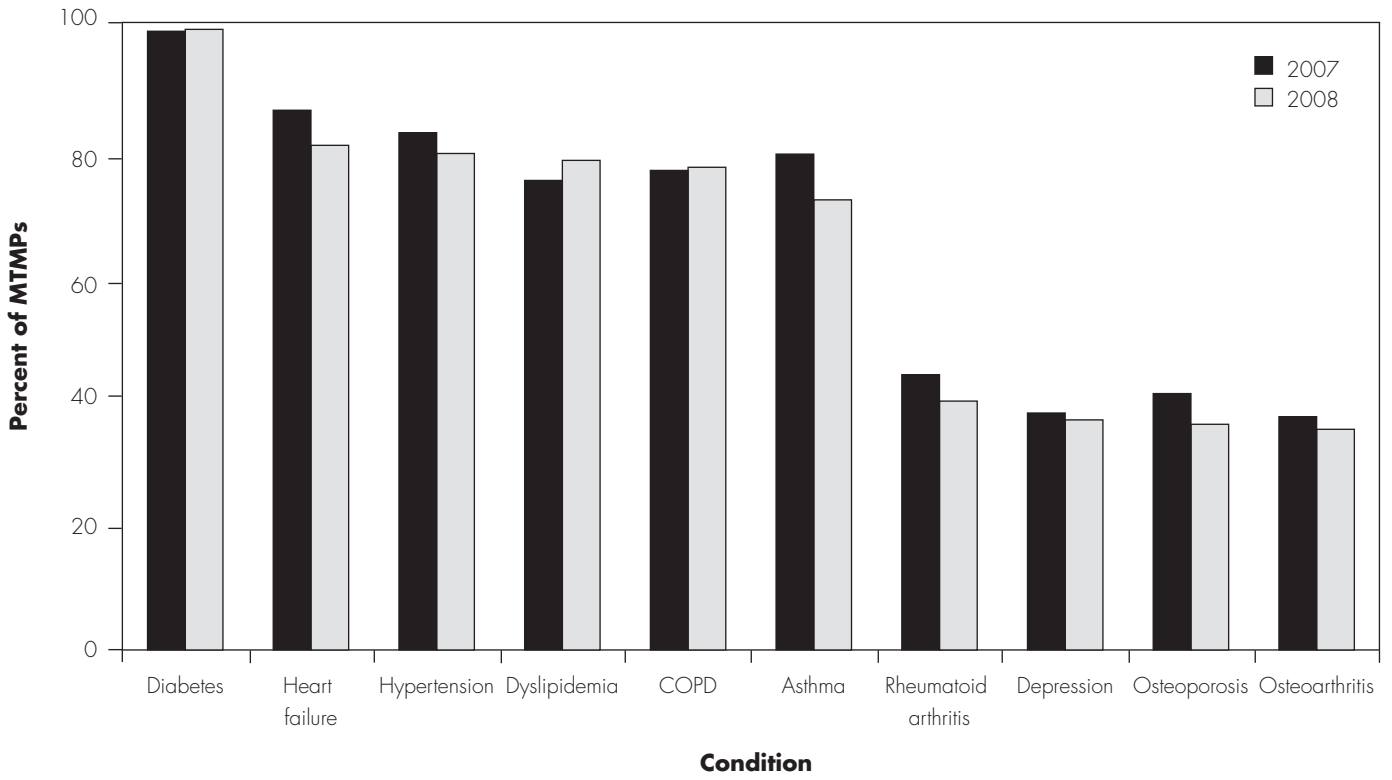
Sponsors use different techniques to enroll eligible beneficiaries in their MTMPs. CMS has sorted these enrollment methods into two basic categories—opt in and opt out (CMS 2008d). Under the opt-in model, beneficiaries who meet a set of designated eligibility criteria are contacted and asked to sign up for the MTMP. Those beneficiaries who choose to receive services are then considered enrolled. Under the opt-out model, sponsors reach out to beneficiaries until they actively indicate that they do not want to receive MTMP services. Although these two models represent two separate approaches in theory, the reality is more complex, and our interviews revealed that the enrollment methods of many sponsors cannot be so easily categorized.

Type of intervention

Each plan sponsor provides a unique set of services under its MTMP. While some sponsors focus on face-to-face

FIGURE 4–10

Nearly all MTMPs target diabetes



Note: MTMP (medication therapy management program), COPD (chronic obstructive pulmonary disease).

Source: CMS (2008d) fact sheet.

medication reviews conducted by community pharmacists, others rely on in-house call centers or educational newsletters (CMS 2008d). The 10 most common interventions in 2008 were:

- face-to-face interactions
- phone outreach
- medication reviews
- refill reminders
- intervention letters
- educational newsletters
- drug interaction screenings
- polypharmacy screenings
- disease-specific clinical initiatives
- medication profiles

Our interviewees disagreed about the most effective way to provide MTMP services. Some believed that beneficiaries benefited most from face-to-face interaction with community pharmacists. Others argued that centralizing the program at a call center allowed the sponsor to provide more specialized services to beneficiaries with specific conditions.

Once a beneficiary is enrolled in the program, the sponsor must arrange to provide MTMP services. Sponsors may target specific interventions based on the enrollee's health status or other factors. For example, a sponsor may provide face-to-face interaction only to a select group of enrollees that they believe will benefit from the encounter.

If the sponsor contracts with community pharmacies to provide MTMP, it provides the enrollee's name and contact information to the nearest participating pharmacist. The pharmacist contacts the beneficiary and arranges a time and place for a medication review. Generally, participating pharmacies set aside a room for private

consultations. Sometimes, the pharmacist meets with the beneficiary at his or her home.

CMS does not collect information on whether sponsors provide follow-up MTMP appointments to enrollees. Such appointments might be used to track the effect of changes in medication regimens or to monitor patient adherence to medication. Only one of the pharmacists we interviewed noted that he could provide a follow-up appointment each year to enrollees if necessary. Others reported that they provided medication reviews on an annual basis. Sponsors provided some services like medication newsletters monthly to MTMP enrollees.

Many MTMPs reach out to prescribers as well as beneficiaries. In fact, most MTMPs—about 90 percent—interact with both the beneficiary and the physician. However, about 10 percent of plans work with the beneficiary only and do not contact physicians (CMS 2008d). In these programs, if an enrollee is taking inappropriate drugs or drugs that are causing side effects, the enrollee is expected to discuss the issue with his or her physician at the next appointment. A number of studies have shown that collaboration between pharmacists and physicians increases the effectiveness of medication management (Stockl et al. 2008, Williams et al. 2004). The Commission is concerned that programs that do not report their findings to beneficiaries' physicians will have limited ability to improve the quality of care program enrollees receive.

Despite certain financial incentives, MTMPs in MA–PDs do not appear to outperform those in stand-alone PDPs

Despite structural incentives in MA–PDs for MTMPs to perform better than those in stand-alone PDPs, we found no evidence that PDPs, in the aggregate, provided less robust programs to their enrollees than MA–PDs. In principle, MA–PDs might save on medical costs if they provide enhanced MTMPs that increase beneficiary adherence to appropriate pharmaceutical regimens.

In contrast, stand-alone PDPs are at risk for increased drug spending and would not benefit if the enrollee's medical costs were reduced as a result of their programs. In fact, PDPs' administrative and utilization costs could increase if their MTMP protocols were successful in getting enrollees to adhere to therapy regimens.

However, sponsor officials we interviewed said they provided the identical MTMPs to their health plan and stand-alone drug plan members who meet their criteria for enrollment.

Moreover, CMS data indicate that PDPs tend to have more inclusive MTMP eligibility criteria than MA–PDs. About 56 percent of PDPs required a minimum of two chronic conditions, compared with about 48 percent of MA–PD plans that required two chronic conditions. Similarly, the minimum number of covered Part D drugs required for beneficiaries to qualify for services tended to be lower in PDPs than in MA–PDs (CMS 2008d).

In contrast, PDPs were less likely than MA–PDs to contact physicians as part of their MTMPs. Approximately 92 percent of MA–PD MTMPs—compared with only 78 percent of PDP MTMPs—included physician-targeted interventions (Figure 4-11) (CMS 2008d).

Most plans (98 percent) used pharmacists to furnish MTMP services. MA–PDs were more likely to employ in-house staff, whereas PDPs were more likely to use outside personnel to operate their MTMPs (CMS 2008d) (data not shown).

CMS collects minimal outcome data

Plan sponsors collected data on a wide spectrum of outcomes. These data ranged from process measures (e.g., number of outbound calls, interventions received, and eligibility) to economic measures (e.g., change in prescription costs) and quality indicators (e.g., change in therapy, adherence, and drug–drug interactions). Many plan sponsors also monitored patient satisfaction (CMS 2008d).

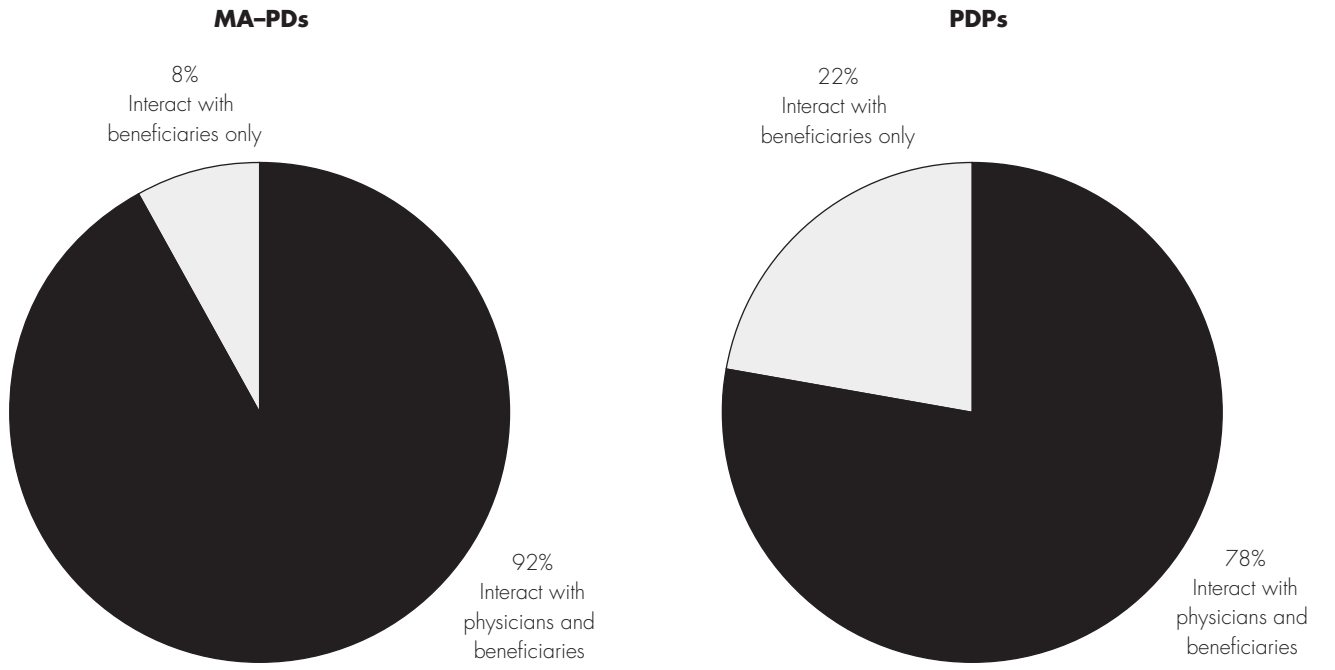
Although plan sponsors must report what outcome measures they collect and how they measure them in their annual bid, they do not report the outcomes to CMS. The agency currently collects limited data on MTMP outcomes. All sponsors must report:

- number of eligible beneficiaries,
- number of enrolled beneficiaries,
- method of enrollment,
- number of disenrolled beneficiaries and reason for disenrollment, and
- total prescription drug cost per MTMP beneficiary per month.

Since 2007, sponsors have been required to report the number of covered Part D 30-day equivalent prescriptions per MTMP beneficiary per month in addition to total prescription drug costs per beneficiary per month.

FIGURE 4–11

MA–PDs are more likely than PDPs to contact physicians, 2008



Note: MTMPs (medication therapy management programs), MA–PDs (Medicare Advantage–Prescription Drug [plans]), PDPs (prescription drug plans).

Source: CMS (2008d) fact sheet.

CMS has begun requiring sponsors to report the names of plan members enrolled in MTMPs. The agency expects to use this information to measure the effect of MTMP interventions on beneficiary health outcomes, drug costs, and other medical spending.

Lacking sufficient program data, suggested improvements to Part D MTMPs are based on anecdotal evidence

After two years, analysts have limited information about whether MTMPs are improving the quality of pharmaceutical care for beneficiaries with multiple medications. The small number of enrollees and the variety of eligibility, enrollment, intervention strategies, and outcome measures hamper systematic evaluations. For example, we do not know whether Medicare MTMPs:

- improve patient adherence to medication.
- result in more appropriate prescribing.
- affect drug spending.
- affect utilization of other medical services.

We also have no information on the average duration of enrollment within MTMPs and the extent to which enrollment is automatically rolled over each year.

For more in-depth knowledge of the program, Commission staff conducted about 30 interviews with pharmacists and representatives from health plan sponsors, pharmacy benefit managers, pharmacies, trade associations, companies that provide medication therapy management services for sponsors on a contract basis, and quality experts.[19] One theme we heard consistently was the need for more standardization. Interviewees discussed the need for greater uniformity in minimum program requirements, collection of outcomes data, and documentation. For many of our interviewees, these factors were important not only to improve the quality of MTMPs but also to enable them to convince their own organizations to invest in inclusive programs with multiple interventions.

Pharmacy representatives emphasized that MTMP practices increase their cost of doing business; many retail pharmacies are not willing to dedicate the time and space needed to participate in MTMPs without assured

payment. The stores must create a private space for counseling sessions between pharmacists and clients, reducing the space available for inventory. They may also have to increase staffing levels. A pharmacist cannot stop dispensing drugs to customers to provide medication therapy to enrollees. The pharmacist must make an appointment with the enrollee for counseling and the pharmacy must have another pharmacist dispensing drugs for the store.

In addition to these costs, pharmacy representatives emphasized that current practice results in high administrative costs. Pharmacists must be trained separately to participate in each plan sponsor's MTMP because sponsors use different types of documentation and different modes of reporting (e.g., some use web-based reporting platforms, others do not). These added costs affect the willingness of pharmacies to participate in multiple programs, especially given the small number of referrals each pharmacist is likely to receive.[20] Some interviewees suggested that stakeholders should work together to create a standard reporting platform and documentation template.

Some sponsor representatives argued that it is hard to make the business case within their companies in support of a multidimensional program when CMS approves programs that provide minimal interventions. For example, one sponsor representative who directs a program with inclusive eligibility requirements and a policy to provide multiple interventions to enrollees noted that without stricter requirements, he had to justify his program two ways. He had to answer questions from corporate officers about why their plan had such an inclusive program when others that were less inclusive (requiring enrollees to have 10 to 15 separate prescriptions each month) could be approved. At the same time, he had to answer to outside groups who questioned why the program did not provide more services.

Although CMS does not have the data to determine what eligibility standards or program structures are most effective, it has the authority to tighten minimum requirements when it reviews plan bids. For example, it could limit the number of prescriptions or conditions a sponsor could require for program eligibility or mandate certain types of interventions (e.g., sponsors must notify physician if they discover drug interactions).

CMS could also require program interventions when an enrollee transitions from one site of care to another (e.g., beneficiary is released from the hospital). One recent study found that about 7 percent of patients reported prescription-related problems within a few days of hospital discharge (Kripalani et al. 2008).

A number of interviewees suggested that sponsors be required to measure and report specific outcomes. More standardized collection and reporting of outcome measures could be used to determine whether programs are meeting their goals of improving the quality of pharmaceutical care, what patient populations benefit from these programs, and what interventions are most successful.

CMS proposes modifying MTMP requirements for 2010 by establishing more specific enrollment, targeting, intervention, and outcomes reporting requirements (CMS 2009). Under this proposal, all sponsors must:

- target beneficiaries for enrollment at least quarterly;
- enroll beneficiaries using an opt-out method only;
- limit eligibility requirements to no more than three chronic conditions and eight drugs;
- target beneficiaries with expected drug costs that exceed $3,000;
- provide a minimum level of services including interventions for both beneficiaries and providers and an annual medication review for beneficiaries; and
- measure and report outcomes on the number of medication reviews, provider interventions, and changes in therapy resulting from interventions.

CMS is examining the experiences of MTMPs over the past three years. It has established a work group within the agency and intends to analyze data to see which programs show the most positive impact on medication use. In October 2008, CMS announced that it had contracted with Optimal Solutions to help identify standardized outcomes that could be measured by all Part D sponsors (CMS 2008f). This research has the potential to answer many important questions about Medicare MTMPs. The Commission will closely follow the results of this project. ■

Endnotes

1 See, for example, the Commission's work on reassessing relative value units for physician services in Medicare's fee schedule (MedPAC 2006).

2 Dual eligibles and enrollees in Medicare savings programs are deemed into the LIS. Other Medicare beneficiaries may apply to receive the LIS through the Social Security Administration if they have low income and assets.

3 They may remain in their existing plan if they choose to pay the additional premium above the LIS benchmark.

4 If an individual is receiving the LIS and is also in a long-term care setting, only the multiplier for the institutionalized status applies as it is the higher of the two.

5 The regression model included dummy variables for 48 drug classes.

6 Drug manufacturers typically pay plan sponsors or their pharmacy benefit management companies rebates for placing their brand-name drugs on the plan's formulary or on a preferred cost-sharing tier and then for steering enrollees toward using those drugs. These payments are called manufacturers' rebates—a concept distinct from Part C rebate dollars that we describe later in this chapter from the MA payment system. Typically, Part D sponsors use manufacturers' rebates to lower their plans' premiums rather than lowering drug prices at the point of sale. For more on how drug manufacturers use rebates, see the Congressional Budget Office description (CBO 2007).

7 In 2006, dual eligibles and other LIS beneficiaries were randomly assigned to qualifying plans through an autoassignment process. Because most of them were in traditional Medicare rather than in MA plans, most were autoassigned to stand-alone drug plans rather than MA–PDs.

8 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 they experienced financial losses. In the following years, nearly all affected sponsors withdrew those products from the market.

9 Some MA plans do not provide drug benefits. For all other types of plans except SNPs and PFFS plans, once a sponsor offers an MA–PD in a service area, it may also offer an MA plan without drug benefits in the same service area. Sponsors of PFFS plans do not have to offer a plan option that includes Part D benefits, although many do.

10 Under past CMS guidelines, SNPs could enroll some individuals who were not dual eligibles, were not institutionalized, or did not have the chronic condition in question.

11 In non-Medicare markets, most formularies are variations of two basic models: open or closed. In an open formulary, a payer covers all drugs in most, if not all, therapeutic classes and may encourage enrollees to use preferred drugs through tiered cost sharing. In a closed formulary, the payer does not reimburse for drugs unless they are listed on the formulary or are covered through an exceptions process. Many payers have moved to a hybrid of open and closed formularies that uses three cost-sharing tiers: low copays for generic drugs, higher but still relatively low copays for preferred brand-name drugs, and significantly higher copays for nonpreferred brands. (Formularies are discussed more broadly elsewhere (MedPAC 2004).)

12 CMS reviews sponsors' formulary submissions, and sponsors that have not met CMS's requirements must supplement their formularies with additional drugs. After CMS approves formularies (in August), sponsors may include additional drugs throughout the year, but sponsors may not make negative changes (removing drugs, placing them on a higher copay tier, or adding utilization management) between the time of formulary approval and March 1 of the contract year. Similarly, sponsors may not make negative changes to their formulary after July of each year.

13 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®, its continuous release version Paxil CR®, or the brand-name drug Pexeva® (paroxetine mesylate) manufactured by a different company.

14 Plans submitted formularies to CMS with a variety of structures, ranging from one to eight tiers. However, not all tiers reflect cost-sharing differences for enrollees; some plan formularies include several tiers that have the same cost sharing. For our formulary analysis, we delineate tiers only when they mark differences in cost sharing.

15 The fact that a much larger percentage of PDP enrollees are in plans that use 25 percent coinsurance rather than tiered copays reflects the fact that recipients of Part D's LIS make up a much higher percentage of total PDP enrollment than MA–PD enrollment. For 2006, CMS autoassigned LIS enrollees randomly among plans that had premiums below regional threshold values. Plans with the defined standard benefit (which uses 25 percent coinsurance) tend to have lower premiums than plans with tiered copays.

16 On the plan formulary data, CMS does not indicate which were specialty tiers. Therefore, there may be some tiers that offer specialty-type drugs. Tiers for nonspecialty injectable drugs in some plan formularies are an example.

17 For example, CMS began requiring plan sponsors to include information about spending and use of drugs on specialty tiers beginning with the bid-pricing tool used for building 2008 bids.

18 Drug plans provided by PFFS plans are not required to offer MTMPs to their enrollees.

19 We also asked physicians and beneficiaries about MTMP in 2007 focus groups but none had any experience with the program.

20 For example, one pharmacist who has been providing MTMP services for two years told us that he had two patients in 2008.

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