CHAPTER 7

Part D plan offerings

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Chapter summary

Part D uses a market-based approach in which private plans deliver Medicare prescription benefits and assume some risk for the drug spending of their enrollees. The law gives organizations that sponsor Part D plans flexibility in designing and administering drug benefits within certain restrictions. For 2006, nearly 80 organizations are offering 1,429 prescription drug plans (PDPs) on a stand-alone basis:

- 9 percent use the defined standard benefit, 48 percent have the same actuarial value as basic coverage but a different benefit design, and 43 percent include enhanced benefits (basic coverage plus some supplemental coverage).
- 15 percent include coverage in the defined standard benefit's coverage gap, typically for generic drugs.
- 66 percent have no deductible or a reduced deductible.
- Nearly 90 percent of the 1,429 PDPs are offered by 16 organizations, which often use the same benefit structure, cost sharing, and formulary among their different plans.

In this chapter

Another 1,303 Medicare Advantage–Prescription Drug plans (MA–PDs) are available nationwide, but access to specific plans varies depending on the county in which a beneficiary lives:

- 7 percent use the defined standard benefit, 29 percent have actuarially equivalent basic benefits, and 64 percent include enhanced benefits.
- 28 percent include coverage in the coverage gap, typically for generic drugs.
- 83 percent have no deductible or a reduced deductible.
- Nearly 40 percent of MA–PDs charge no additional premium for Part D coverage beyond what they charge for Parts A and B services.

As of mid-April 2006, CMS estimated that 27 million of the 43 million Medicare beneficiaries (61 percent) either signed up for Part D plans or had prescription drug coverage through employer-sponsored coverage under Medicare's retiree drug subsidy. Another 3.5 million beneficiaries (8 percent) were federal or military retirees who receive drug coverage with at least the same value as the Part D benefit. All of the more than 7 million individuals who are dually eligible for Medicare and Medicaid or who are already enrolled in a Medicare Savings Program within their state are deemed eligible for Part D's low-income subsidy (or "extra help") that pays for some or all of their premiums and cost sharing. About 1.7 million other non-Medicaid beneficiaries with low incomes and assets qualified for Part D's low-income subsidy.

Both MA–PDs and PDPs use formularies to manage the cost and use of prescription drugs. The most frequent tier structure distinguishes preferred and nonpreferred brand name drugs and includes a specialty tier for very expensive drugs, biologicals, and injectables. Plans that distinguish between preferred and nonpreferred brand name drugs charge median copays of $5 to $7 for generics, $22 to $29 for preferred brands, and $50 to $55 for nonpreferred brand name drugs. About 60 percent of all Part D plans have a specialty tier and charge a median of 25 percent to 30 percent coinsurance

for them. Beneficiaries may not appeal the cost-sharing amounts for drugs on a specialty tier.

The median Part D plan lists about 1,000 drugs, with MA–PDs typically listing somewhat more drugs than PDPs. Among all plans, those that offer nonpreferred brand tiers generally list more drugs than plans with only brand and generic distinctions. Our analysis shows little difference in formulary size between plans that are and are not eligible for auto-enrollees. Note that the number of drugs on a plan's formulary does not necessarily represent beneficiary access to needed medications. Unlisted drugs may be covered through the nonformulary exceptions process, which for some plans may be relatively easy, but for other plans may be more burdensome for enrollees and physicians. Alternatively, on-formulary drugs may not be covered in cases where a plan does not approve a prior authorization request.

Most Part D plans apply drug utilization tools, such as prior authorization, to selected drugs. Plans use these tools for drugs that are expensive, potentially risky, or to encourage use of available lower cost therapies. Our analysis shows that Part D plans typically apply prior authorization to less than 10 percent of the drugs on their formularies and use step therapy for a very small share of drugs concentrated in selected therapeutic categories.

In the coming years, the Commission will continue to analyze aspects of cost, quality, and access under Part D. With further data, we would like to examine how plans' benefit designs and formularies affect enrollee plan choice (by characteristics of beneficiaries and plans), beneficiary access to medications, beneficiary out-of-pocket spending, beneficiary health outcomes, and Medicare program spending. Additionally, the Commission will examine how Part D is meeting the needs of special populations, such as those residing in long-term care facilities, and study the consequences of plans' formulary changes and utilization management tools—such as prior authorization—on beneficiaries, pharmacists, and physicians. ■

Part D, Medicare's new outpatient prescription drug benefit that began in January 2006, is a departure from traditional Medicare. Like the Medicare Advantage (MA) program, Part D differs from Medicare's fee-for-service (FFS) program for Parts A and B services because it uses competing private plans that are at risk for some of their members' benefit spending. The new program encourages both MA plans that include prescription drug benefits—Medicare Advantage–Prescription Drug plans (MA–PDs)—and new stand-alone prescription drug plans (PDPs) to participate. The latter are plans that offer drug benefits without a broader package of medical benefits. Organizations offering Part D plans submit bids to CMS to provide Part D benefits. CMS calculates the national average of bids for basic Part D benefits and then Medicare pays plans the same capitated amount per enrollee based on a percentage of the national average, adjusted for the risk of the individual enrollee. (For more detail about Part D payments to plans and how Medicare subsidizes Part D, see MedPAC 2005b, 2005c.) Plans may also receive additional payments from Medicare for members who qualify to receive Part D's low-income subsidies (also called "extra help") or who have drug spending high enough to trigger individual reinsurance subsidies.[1]

Rather than Medicare specifically defining Part D benefits, organizations that sponsor plans have flexibility in designing and administering drug benefits within certain restrictions. This approach has the advantage of providing a range of plan options that could potentially better suit each individual beneficiary's needs. The approach also lets plans use different mixes of management tools—such as formulary designs—to balance enrollees' desire for access to drug therapies with the need to control benefit costs. At the same time, allowing flexibility in Part D benefit designs means that CMS must monitor plans to help ensure that some do not try to avoid enrolling beneficiaries with higher prescription drug spending.[2] The agency must also strive to ensure that its risk adjusters capture differences in individuals' benefit spending on Part D drugs.

Organizations that offer private plans negotiate prices for pharmaceuticals and pharmacy services, and the results of these negotiations affect plan bids and premiums. Since plans are at risk for some of their members' drug spending, some policymakers believe that delivering Part D benefits through competing private plans will lower Medicare payments and Part D premiums and may help to constrain cost growth. Others believe that a delivery system that is more like traditional Medicare would provide beneficiaries with better access to prescription drugs, less administrative burden, and lower prices.

Part D's market-based approach also means that beneficiaries who are most familiar with traditional Medicare face new challenges. They must choose among dozens of plans available in their local area, each with somewhat different benefit structures, cost-sharing requirements, premiums, and networks of pharmacies. (Plans must also include long-term care pharmacies in their networks. We provide background about the services they provide and how Part D may affect that industry in the text box on page 150.) Plan options differ in important dimensions that are often not obvious or easy to understand. As a result, CMS and others are challenged to provide even the most knowledgeable beneficiaries with sufficient information to help them make informed choices. (Chapter 8 describes some of those challenges.) In addition, some Medicare beneficiaries may be unfamiliar with the tools that private plans use to manage drug benefits such as formularies and tiered cost sharing, formulary exceptions processes, prior authorization, and grievance and appeals procedures. Individuals may face issues related to the use of these tools as they transition from their previous drug benefits to their new Part D coverage and, over time, if they switch among Part D plans or if their plans exit the market (MedPAC 2004).

Part D's structure and initial levels of enrollment

Policymakers sought to design Part D to promote adequate access to appropriate drug therapies for Medicare beneficiaries while encouraging efficiency, quality, and cost control. Before Part D began, the majority of the noninstitutionalized Medicare population had prescription drug coverage through current or former employers, Medicaid, MA plans, and certain medigap policies.[3] The relative generosity of those sources of coverage varied considerably, ranging from comprehensive Medicaid coverage with low cost sharing to medigap policies that typically had higher cost-sharing requirements, an overall limit on the dollar value of their benefits, and generally were not subject to formularies and management tools. Beneficiaries with employer-sponsored policies had relatively generous coverage but were also typically subject to pharmacy benefit management tools, including limited formularies. Beneficiaries with no prescription

Long-term care pharmacies

In order to meet the prescription drug needs of beneficiaries who live in long-term care (LTC) facilities (nursing homes and skilled nursing facilities), such facilities contract with long-term care pharmacies (LTCPs). Approximately 3.5 million Medicare beneficiaries (9 percent) live in an LTC facility (Lewin Group 2004). Many have poor overall health with multiple chronic conditions and require 24-hour nursing care. Their health status also means that they are more likely to use a large number of prescription drugs, which increases the probability of adverse drug events. Beneficiaries residing in LTC facilities take an average of 8 to 10 medications per day, compared with 5 to 6 for Medicare beneficiaries who live in the community.

LTCPs generally offer services beyond those provided by retail pharmacies. Among these are specialized compounding and packaging; alternative forms of drug administration (e.g., unit dosing, liquid dosing, chewable tablets, infusion services, or parenteral administration); 24-hour access to a pharmacist; medication delivery (including emergency deliveries); medication and treatment carts; and medical records management. Because of the relatively complex nature of these services, most LTC facilities tend to contract with a single LTCP to provide these services. Under the Part D program, LTCPs are subject to "any willing pharmacy" provisions. These provisions mean that plans must offer standard contracting terms and conditions, including performance and service criteria, for LTCPs specified by CMS. Plans must also provide members with convenient access to LTCPs—all plan enrollees in an LTC facility must be able to access their covered Part D drugs through an LTCP in the plan's network. If LTCPs contract with as many plans as are available in a region, it is possible that even if a facility has residents who are enrolled in different Part D plans, LTC facilities will be able to continue to contract with a single LTCP.

Before the Part D benefit was introduced, LTCPs generally were reimbursed through four primary sources: Medicaid, Medicare Part A, private insurance, or self-pay. The LTCP market represents about $8 billion in annual revenues (Leavitt 2005). Medicaid has been by far the largest source of revenue for LTCPs, accounting for 60 percent to 65 percent of their revenues, with the other three sources of revenue accounting for a little over 10 percent each. Most, if not all, of the revenues that previously came from Medicaid will now come from individual prescription drug plans (PDPs) and Medicare Advantage–Prescription Drug plans (MA–PDs) under the Part D program, while additional shares of both private pay and private insurance revenue may also be replaced by Part D. Therefore, most LTCPs face a sea change in the source of a majority of their revenues. Now, state Medicaid payment rates and rules are being replaced by payment rates, formularies, and other management tools for PDPs and MA–PDs.

continued on next page

drug coverage generally had no supplemental coverage to Medicare at all or purchased medigap plans that did not cover prescription drugs.

Program structure

A combination of stand-alone PDPs and MA–PDs deliver the Part D benefit throughout the United States and in U.S. territories. Organizations can offer PDPs in one or more of 34 geographic regions; regional MA–PDs may operate in one or more of 26 MA regions; and local MA–PDs may operate in various service areas (one or more counties) throughout the country. Plans bear some risk for their enrollees' drug spending and compete for enrollees on the basis of premiums, benefit structures, access to specific drug therapies, pharmacy networks, and quality of services. To encourage Medicare beneficiaries to enroll, the government subsidizes premiums by nearly 75 percent and provides additional premium and cost-sharing subsidies for beneficiaries who have low incomes and assets. A late-enrollment penalty similar to that for Part B also provided an incentive for beneficiaries to enroll during an initial open enrollment period, which ended on May 15, 2006.[4]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) defines a standard

Long-term care pharmacies (cont.)

The change from Medicaid to Medicare reimbursement is important because many of the additional services described above are provided by LTCPs at no extra charge to LTC facilities (Lewin Group 2004). LTCPs have not traditionally charged for such services because those costs were covered partly by the margin between Medicaid payment rates and the cost of acquiring drugs and supplies. In addition, LTCPs—particularly the four largest chains—have traditionally collected rebates from drug manufacturers, based on their ability to direct market share to specific drugs. These rebates have also helped to finance additional services. One might argue that the ability of LTCPs to provide these additional services at no charge may indicate that payment rates for drugs were too high and that the competitive pressures created by the Part D program will result in lower prices to both Part D and non-Part D enrollees.

In its instructions to Part D plans for contract year 2007, CMS expressed concern about the continued payment of rebates to LTCPs providing drugs as part of a Part D plan's network (CMS 2006). CMS believes that any rebates to participants in the Part D program ultimately should accrue to the government and beneficiaries through lower premiums. CMS also noted that rebates paid to LTCPs could be in violation of federal anti-kickback standards. CMS requires that all Part D plan sponsors include a provision in their pharmacy contracts in which pharmacies must fully disclose to the sponsor any rebates from drug manufacturers.

Further, the change from a single payer for a majority of LTC facility residents to multiple payers may have implications for beneficiaries, LTCPs, LTC facilities, and Part D plans. In particular, all of these stakeholders face challenges as beneficiaries transition among plans—initially from their Medicaid coverage to enrollment in Part D, as well as when some beneficiaries switch among Part D plans. There may also be administrative burden associated with coordinating between different plans' formularies and complying with CMS requirements regarding the availability of nonformulary drugs.

The Commission will monitor the experience of LTCPs with the Part D program and examine this issue in more detail in future work. ■

drug benefit under Part D, which an organization may offer. For 2006, the defined standard benefit includes:

- a $250 deductible;
- coverage for 75 percent of covered drug expenses up to an initial coverage limit of $2,250;[5]
- a coverage gap with 100 percent beneficiary cost sharing between the initial coverage limit and an out-of-pocket threshold reached when the enrollee has accrued $3,600 of true out-of-pocket costs (or $5,100 in total drug expenses for enrollees without supplemental drug coverage);[6] and
- beyond the out-of-pocket threshold, the greater of either 5 percent coinsurance or copays of $2 for generic or preferred brand name drugs and $5 for brand name drugs.

These threshold amounts will increase each year by CMS's estimate of the annual change in drug spending per person. For 2007, the values are as follows: a $265 deductible, $2,400 initial coverage limit, and a $3,850 out-of-pocket threshold. Above the catastrophic threshold, copayment amounts will increase to $2.15 for generics or preferred brand name drugs and $5.35 for other drugs.

The law gives organizations substantial flexibility beyond the defined standard benefit. Plans may, for example, offer a basic plan that has the same actuarial value as the defined standard benefit but with a different design. A plan could offer a tiered cost-sharing design with different copays by tier—such as for generic, preferred brand name, nonpreferred brand name drugs, and specialty drugs—between the deductible and the $2,250 initial coverage limit. However, cost-sharing requirements under such a tier structure would need to have the same

actuarial value as the 25 percent coinsurance required under the defined standard benefit. Alternatively, a plan could lower or eliminate its deductible but require cost sharing greater than 25 percent. Plans that offer such actuarially equivalent benefits must meet certain tests to comply with the law. CMS evaluates plan benefit designs to help ensure that competition among plans is based on premiums for comparable benefits rather than selection among enrollees. However, tests of actuarial equivalence do not go so far as to require comparable formularies. Even two competing plans in which both plans offer the defined standard benefit may be somewhat different from one another because they can include different mixes of preferred and nonpreferred drugs on their formularies or have differences in their pharmacy networks. CMS also reviews plan formularies to assure that enrollees have access to certain medications and to ensure that plans do not discriminate against any particular type of beneficiary.

Organizations offering basic Part D coverage (the standard benefit or one that is actuarially equivalent to it) may also choose to offer enhanced alternative coverage. Enhanced coverage combines a basic benefit with supplemental benefits. Supplemental coverage could include either reductions in cost-sharing requirements that increase the actuarial value of the benefit package, coverage of drugs that are specifically excluded as Part D drugs under the MMA, or both. For example, a plan might include zero or reduced cost sharing for generic drugs in the coverage gap. However, the enrollee must pay for all of these additional benefits through a supplemental premium and any additional cost sharing required by the plan. Plans must assure CMS that their premium for supplemental coverage takes into account higher basic drug spending induced by the supplemental coverage.

Part D includes a low-income subsidy (LIS) that provides assistance for out-of-pocket spending by individuals with low incomes and assets. In 2006, individuals who do not receive Medicaid must have an income below $14,355 for a single person or $19,245 for a married couple to be eligible. (These values are 150 percent of the federal poverty level, or FPL.) Assets must be no greater than $10,000 for an individual or $20,000 for a couple, excluding the beneficiary's primary residence and vehicles. Individuals who receive both full Medicaid and Medicare benefits (called dual eligibles) and other beneficiaries with incomes of up to 135 percent of the FPL who meet asset tests may be eligible to have Medicare pay their entire premiums and significantly reduce their copays for plans that qualify to receive such enrollees. These beneficiaries have copays ranging from $1 to $5 if they live in community settings. Full-benefit dual eligibles residing in long-term care facilities have no cost sharing. Individuals with incomes between 135 percent and 150 percent of the FPL who meet the asset test may qualify for sliding-scale premium assistance and reduced cost sharing. Both groups are effectively exempt from Part D's coverage gap—the range of drug spending between Part D's initial coverage limit and its catastrophic threshold in which beneficiaries would normally pay 100 percent coinsurance. One should note, however, that unless a beneficiary successfully obtains a formulary exception, all Part D enrollees only receive benefit coverage for drugs that are listed on their plan's formulary.

These subsidies are applicable only to Part D plans with premiums that are at or below a certain threshold level calculated for each region.[7] That threshold amount is designed to assure that beneficiaries who qualify for the LIS are enrolled in lower priced plans, while ensuring that at least one stand-alone PDP is available to them. Participating organizations pay attention to the LIS thresholds because those amounts determine whether their plans are eligible to be randomly assigned beneficiaries through CMS's auto-enrollment process—virtually guaranteeing those plans some initial enrollees. Auto-enrollment saves plans marketing costs, and qualifying organizations can count on Medicare paying for all or much of those enrollees' premiums and cost sharing. CMS auto-enrolled about 6 million beneficiaries who are dually eligible for Medicare and Medicaid to begin Part D coverage on January 1, 2006—the date that their primary prescription drug coverage through Medicaid officially ended.[8] In a process similar to that for duals, CMS also helped enroll about 1 million of the 1.7 million other individuals who qualified for Part D's LIS as of April 30, 2006.

Enrollment in Part D and other sources of drug coverage

The program's initial open enrollment period began on November 15, 2005, and ran through May 15, 2006. Early projections of prescription drug coverage for 2006 varied. The Congressional Budget Office (CBO) estimated about 37 million (87 percent) of all Medicare beneficiaries would have coverage, while CMS's Office of the Actuary (OACT) estimated 41 million (94 percent) (CBO 2004, 2004 Technical review panel on the Medicare Trustees Report). Both sets of numbers include beneficiaries who enroll in Part D as well as those with primary drug

TABLE 7–1 **Part D enrollment and other sources of drug coverage in early 2006**

	Millions enrolled as of			
	1/13/2006	2/11/2006	3/18/2006	4/18/2006
Enrollment that leads to Medicare program spending:				
Voluntary enrollees in stand-alone PDPs	3.6	4.9	6.4	8.1
Enrollees in MA–PDs (including some duals)	5.1	5.3	5.7	5.8
Individuals dually eligible for Medicare and Medicaid and auto-enrolled in Part D plans	5.6	5.7	5.8	5.8
Individuals covered by Medicare retiree drug subsidy	6.4	6.4	6.2	6.8
Subtotal	20.6	22.3	24.0	26.5
Enrollment that does not lead to Medicare program spending:*				
Estimated federal retirees in TRICARE and FEHB	3.1	3.1	3.5	3.5
Total	23.8	25.4	27.6	30.0

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage prescription drug [plan]), FEHB (Federal Employees Health Benefits program). TRICARE is the health program for military retirees and their dependents. For calendar year 2006, CMS projects that an average of 43.1 million beneficiaries will be enrolled in Medicare Parts A and/or B. Columns may not sum due to rounding.
*In addition, CMS estimates that 5.8 million Medicare beneficiaries have drug coverage of equal or greater value to Part D benefits through the Department of Veterans Affairs, Indian Health Service, former employers that do not receive Medicare's retiree drug subsidy, or through current employers.

Source: CMS press releases dated as shown above.

coverage through employer-sponsored health plans, through which the sponsor receives Medicare's retiree drug subsidy (RDS). Medicare provides a tax-free subsidy to employers for 28 percent of each eligible individual's drug costs that fall within a specified range of spending. These projections exclude beneficiaries with retiree drug benefits through the Federal Employees Health Benefits (FEHB) and TRICARE programs, which cover federal and military retirees and their dependents, as well as other sources of coverage. (Although beneficiaries with FEHB and TRICARE coverage have drug benefits that are equal or greater in value to the Part D benefit (called creditable coverage), those programs do not participate in the RDS.) The Medicare trustees most recently estimated that 31 million Medicare beneficiaries (73 percent) would have Part D or RDS coverage on May 15, 2006 (Boards of Trustees 2006).[9]

As of mid-April 2006, CMS estimated that 26.5 million of the 43 million Medicare beneficiaries (61 percent) either had signed up for Part D plans or had prescription drug coverage through employer-sponsored coverage under the RDS (Table 7-1). Voluntary enrollees in stand-alone drug plans numbered 8.1 million, or 19 percent of the 43 million. Individuals who are dually eligible for Medicare and Medicaid and enrollees in MA–PDs each numbered 5.8 million, and each group made up 13 percent of the 43 million. Individuals whose employers receive the RDS in return for remaining the primary payer of prescription drug coverage made up 6.8 million (16 percent) of the 43 million. Those four groups directly affect Medicare program spending.

Other Medicare beneficiaries have creditable drug coverage, but that coverage does not affect Medicare program spending. For example, 3.5 million beneficiaries (8 percent) were federal retirees who receive drug coverage through FEHB or TRICARE. Another 5.8 million others (13 percent) had prescription drug coverage through the Department of Veterans Affairs, Indian Health Service, former employers that are not a part of Medicare's RDS, or through current employers because the individual is still an active worker (data not shown).

The Commission did not receive information about enrollment levels in specific Part D plans in time to include it in this report. However, data on enrollment levels by plans' parent organizations are shown on page 165.

Defining Part D organizations and plans

Throughout this chapter we define an organization as an entity—usually a combination of an insurer or medical plan with a pharmacy benefit management firm and a network of pharmacies—that offers one or more Part D plans. A plan is a specific combination of benefits offered to all Medicare beneficiaries who live within a prescription drug plan (PDP) region or Medicare Advantage prescription drug plan region. When an organization chooses to offer a plan nationwide, it actually offers 34 different PDPs (one for each geographic region), even if those plans share the same benefit design, formulary, and structure of tiered copays. CMS guidance limits each organization to offering no more than three types of plans in each region. As a result, some larger organizations are offering as many as 102 plans (3 plans multiplied by 34 regions) across the PDP regions, plus additional plans offered in the U.S. territories or designed for specific employer groups. For 2007, CMS had considered limiting each organization to two plan types per region, but ultimately decided to continue permitting organizations to offer up to three PDPs in each region if one of those plans includes benefits in the coverage gap (CMS 2006). ■

Enrollment in Part D's low-income subsidy program

Prior to the start of Part D, projections of enrollment in the LIS program also varied. OACT estimated that 10.9 million out of 14.5 million eligible Medicare beneficiaries would participate in the LIS program in 2006—all 7.2 million dual eligibles, qualified Medicare beneficiaries (QMBs), and specified low-income Medicare beneficiaries (SLMBs), as well as 3.7 million other individuals who did not previously participate in Medicaid. By comparison, CBO estimated that fewer nonduals would enroll in the LIS program, for total enrollment (dual and nondual) of 8.7 million in 2006. The Medicare trustees currently estimate that 9 million Medicare beneficiaries will be eligible for Part D's LIS program in 2006 (Boards of Trustees 2006).

All individuals who are dually eligible for Medicare and Medicaid or who are already enrolled in a Medicare Savings Program within their state (QMBs and SLMBs) are deemed eligible for Part D's LIS. However, enrolling other non-Medicaid beneficiaries is proving more difficult. The Social Security Administration (SSA), which determines eligibility for the LIS program, received nearly 5 million applications for the LIS program. A number of those applications were denied because beneficiaries had income or assets that were too high, or the SSA received a duplicate application. As of April 30, 2006, 1.7 million non-Medicaid beneficiaries with low incomes and assets qualified for the LIS program. Some of these individuals did not realize that they must apply for the LIS program and then also enroll in a specific Part D plan. For this reason, CMS auto-enrolled individuals in plans who qualified for the LIS but had not yet chosen a plan themselves.

Part D plan offerings for 2006

This section describes the degree of variation that exists among Part D benefits and premiums for 2006. Throughout this chapter we exclude plans that are exclusive to certain groups of enrollees, such as plans available only to employer groups, Programs of All-Inclusive Care for the Elderly, special needs plans, and demonstrations. We also limit the analysis to plans offered within the 50 states. Although much variation exists, our analysis reveals patterns in the structure of benefit designs that organizations have chosen to offer.

Plan entry, benefit designs, and premiums among PDPs

Although 1,429 PDPs are available across the country, most of those plans are offered by 16 larger actors in Part D—that is, organizations or groups of organizations offering at least one plan nationwide or a total of 30 or more plans in one or more of the 34 regions (the text box defines organizations and plans). In many cases, those organizations offer the same two or three benefit structures in the regions of the country in which they participate, and they typically use the same formulary. While individual

TABLE 7–2

Characteristics of PDPs in 2006

	All types of benefits	Basic benefits: Defined standard	Basic benefits: Actuarially equivalent	Enhanced benefits
Total number of plans	1,429	132	689	608
Distribution of plans (in percent):				
Plan type	100%	9%	48%	43%
Type of deductible				
Zero	58	N/A	18	40
Reduced	8	N/A	5	3
$250	34	9	25	0
Cost-sharing structure before the initial coverage limit				
Uses 25% coinsurance	9	9	0	0
Uses tiered cost sharing	91	N/A	48	43
Copays	21	N/A	8	13
Coinsurance	3	N/A	2	0
Both	67	N/A	38	30
Coverage in the gap				
Generics	13	N/A	0	13
Generics and brands	2	N/A	0	2
None	85	N/A	48	27
Offers mail-order pharmacy services	91	8	43	40

Note: PDP (prescription drug plan), N/A (not applicable). Percentages are not weighted by plan enrollment. The PDPs described here exclude plans offered in U.S. territories. Benefits labeled actuarially equivalent to Part D's standard benefit include what CMS calls "actuarially equivalent standard" and "basic alternative" benefits. Plans with "gap coverage" include some benefits in the range of beneficiary drug spending above the standard benefit's initial coverage limit and below its out-of-pocket threshold. Part D's defined standard benefit requires the enrollee to pay 100 percent coinsurance in this coverage gap.

Source: MedPAC based on CMS plan benefit design and landscape data.

beneficiaries still face many plan options, the degree of variation across the country may not be as large as 1,429 PDPs might suggest. Although availability varies by county, MA–PDs are offering an additional 1,303 plans around the country.[10] MA–PDs are more likely than PDPs to offer enhanced (supplemental) benefits and charge no deductible, often at no additional premium beyond the monthly premium that the enrollee pays for medical services.

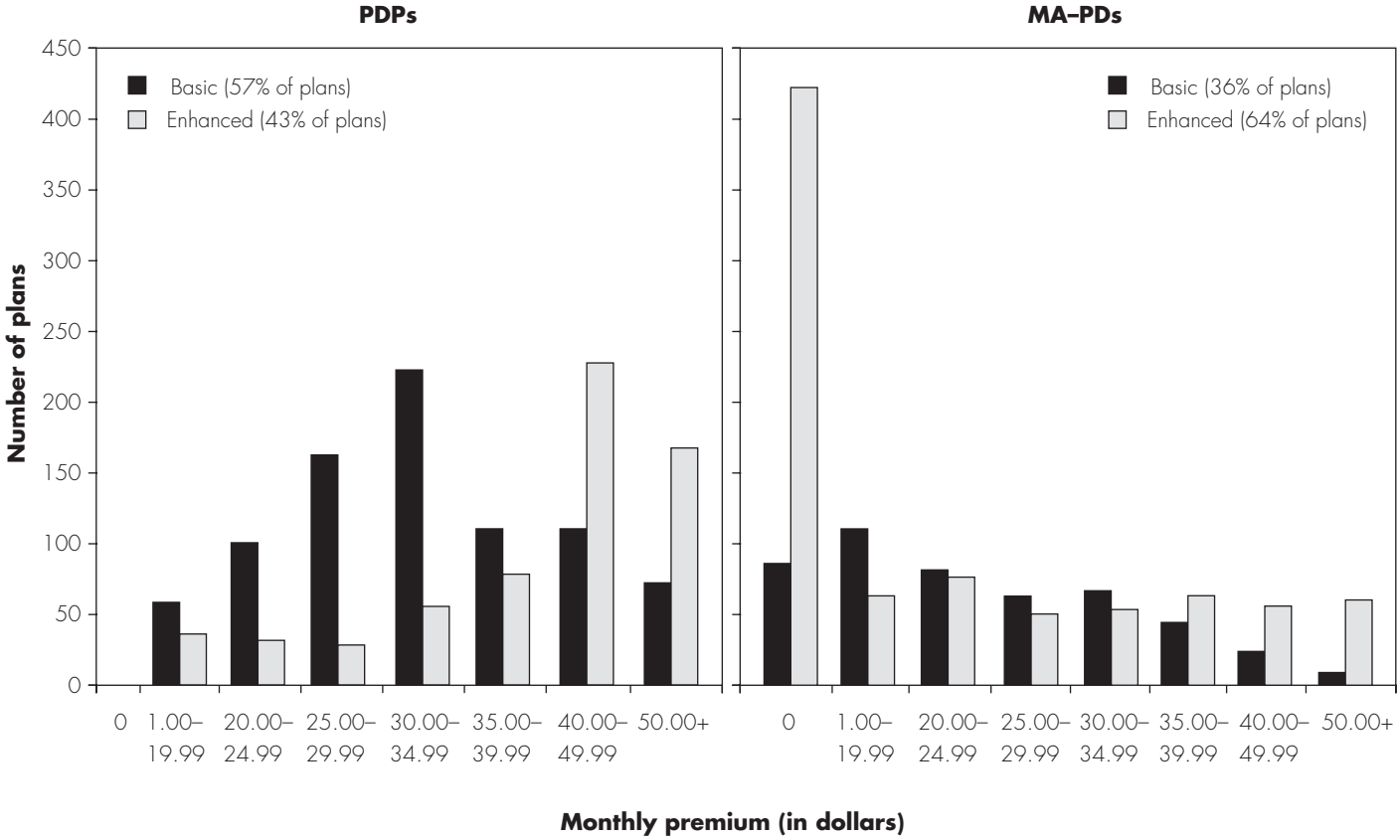
Characteristics of PDPs offered by all organizations

A relatively small number of organizations (16) accounts for 1,225 of the 1,429 PDPs offered among the 34 regions, and nearly 60 other organizations are offering the remaining 204 PDPs. In this section, we provide statistics for all 1,429 PDPs. Note that this analysis is not weighted by each plan's enrollment. Few plans use Part D's standard benefit design; instead, many offer a reduced or no deductible design and most use tiered cost sharing.

Among all PDPs, 57 percent provide basic benefits—either Part D's standard benefit design (9 percent) or a benefit that is actuarially equivalent to the standard benefit (48 percent) (Table 7-2). The remaining plans are enhanced (43 percent); they include basic benefits and supplemental coverage.

Organizations may be testing the waters by trying several different benefit designs. Still, the design of a sizable number of PDPs reflects a widely held perception that beneficiaries do not want to pay deductibles. About 58 percent of all PDPs do not charge a deductible, 34 percent use the standard benefit's $250 deductible, and the remainder use deductibles that are less than $250.

FIGURE 7–1 **Distribution of PDP and MA–PD premiums for basic and enhanced plans in 2006**



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage prescription drug [plan]). Distributions are not weighted by beneficiary enrollment. Total number of PDPs is 1,429, which excludes plans offered in U.S. territories. Total number of MA–PDs is 1,303, which excludes demonstration programs, 1876 cost plans, and plans offered in U.S. territories. MA–PD enrollees must pay any other Medicare Advantage premiums in order to obtain Part D prescription drug coverage. Benefits labeled basic include Part D's standard benefit design as well as benefits that are actuarially equivalent to standard benefits. Enhanced plans include supplemental coverage.

Source: MedPAC based on CMS plan benefit package and landscape data.

No enhanced plans use the standard benefit's deductible, and many actuarially equivalent plans charge no deductible either. A plan could charge no deductible yet maintain actuarial equivalence to the standard benefit by charging higher cost sharing or lowering the benefit's initial coverage limit.

Most plans (91 percent) use cost-sharing tiers rather than Part D's defined standard benefit with flat 25 percent coinsurance. This probably reflects organizations' judgment that beneficiaries will prefer the relative predictability of fixed-dollar copays over coinsurance. However, 67 percent of all PDPs use a combination of copays (usually for lower price tiers) and coinsurance (typically for specialty drugs on higher price tiers). Some plans use copays for preferred drugs but charge coinsurance for nonpreferred drugs or for prescriptions filled at out-of-network pharmacies. Relatively few PDPs offer any coverage in the standard benefit's coverage gap.

Among all basic PDPs (defined standard benefits and those that are actuarially equivalent) in our analysis, the simple average monthly premium is $33. By comparison, CMS officials have noted that beneficiary premiums are expected to average $25 a month (McClellan 2006). The reason for this difference is that the $25 figure is weighted by Part D enrollment. CMS auto-enrolled beneficiaries in Part D plans with lower price premiums, which partly explains the difference in averages. Additionally, CMS's administrator also noted that the majority of beneficiaries who were not dually eligible for Medicare and Medicaid

TABLE 7–3 **Premiums and cost-sharing requirements among PDPs in 2006**

	Basic benefits		
	Defined standard*	Actuarially equivalent	Enhanced benefits
Monthly premium			
Minimum	$2	$14	$5
Maximum	85	63	105
Median	28	32	44
Mean	26	35	43
Deductible			
Minimum	250	0	0
Maximum	250	250	150
Median	250	250	0
Median cost sharing for:			
Plans with generic/brand tier structure			
Generic copay	N/A	5	7
Brand copay	N/A	28	30
Specialty tier coinsurance (where applicable)	N/A	25%	25%
Plans with generic/preferred brand/nonpreferred brand tier structure			
Generic copay	N/A	$7	$5
Preferred brand copay	N/A	22	26
Nonpreferred brand copay	N/A	55	50
Specialty tier coinsurance (where applicable)	N/A	25%	30%

Note: PDP (prescription drug plan), N/A (not applicable). Values do not reflect plan enrollment. The PDPs described here exclude plans offered in U.S. territories. Cost sharing is for median cost sharing among plans that use tiered cost sharing before the initial coverage limit. Benefits labeled actuarially equivalent to Part D's standard benefit include actuarially equivalent standard and basic alternative benefits.
*Part D's defined standard benefit has a $250 deductible (in 2006) and 25% coinsurance below the initial coverage limit.

Source: MedPAC based on CMS plan benefit package and landscape data.

selected plans with premiums below the national average premium (McClellan 2006).

Turning again to the simple (unweighted) distribution of plans' premiums, note that at the median, premiums for enhanced plans run about $10 more per month than premiums for basic benefits (left-hand side, Figure 7-1). Within each category of basic and enhanced plans, there is quite a bit of variation among premiums. Some enhanced benefits cost less than $20 per month in certain regions, while a handful of basic plans cost more than $75 per month. Across all types of PDP benefits offered in the 34 regions—including both basic and enhanced packages—the plan with the lowest premium is a defined standard benefit at a cost of just under $2 per month, while the highest premium plan provides enhanced coverage for about $105 per month (Table 7-3).

Plans that are actuarially equivalent to the defined standard benefit have median and mean premium values that are $5 to nearly $9 higher, respectively, than those for the defined standard benefit.[11] This occurs even though, by design, they have the same expected benefit value. The higher average premium could reflect a higher willingness to pay among beneficiaries for the relative predictability of fixed copays over coinsurance. This result may also reflect higher costs for providing a benefit with fixed-dollar copays than one with coinsurance; a benefit design with copays could put a plan at greater risk for increases in pharmaceutical prices.

TABLE 7–4

PDPs offered in 2006 by organizations with at least one nationwide plan

Organization and plan name	Regions in which plan is offered	Plans qualifying for auto-enrollment	Type of benefit	Range of monthly premiums	Deductible	Cost sharing by tier at in-network preferred pharmacies	Gap coverage
Aetna							
Medicare Rx:							
Essentials	34	6	Actuarially equivalent	$28–$39	$250	$5/$25	None
Plus	34	0	Enhanced	37–50	0	$7/$35	Generics
Premier	34	0	Enhanced	52–67	0	$2/$20/$40	Generics
Cigna							
CIGNATURE Rx:							
Value Plan	34	7	Actuarially equivalent	30–37	250	$4/$20/$40	None
Plus Plan	34	0	Enhanced	40–42	0	$5/$30/$50	None
Complete Plan	34	0	Enhanced	43–51	0	$5/$30/$50	Generics
Coventry							
AdvantraRx:							
Value	34	0	Enhanced	18–25	0	$10–$15/$36–$60	None
Premier	34	0	Enhanced	29–38	0	$5–$10/$20–$40/ $50–$70	None
Premier Plus	34	0	Actuarially equivalent	40–50	0	$5/$20–$40/$54–$70	None
Medco							
YOURx Plan	34	19	Actuarially equivalent	27–36	250	$4/$17/75%/25%	None
MemberHealth							
Community Care Rx:							
Basic	34	23	Actuarially equivalent	26–33	250	0%/25%/45%	None
Choice	34	0	Actuarially equivalent	34–41	250	$4/$20/$40	None
Gold	34	0	Enhanced	38–45	100	$4/$25/$50	None
PacifiCare							
PacifiCare:							
Saver Plan	34	31	Actuarially equivalent	19–35	0	$8/$22/$47–$53/33%	None
Select Plan	34	2	Actuarially equivalent	30–49	0	$8/$22/$56–$73/33%	None
Comprehensive Plan	2	0	Enhanced	37–41	0	$8/$22/$53–$54/33%	Generics
Complete Plan	32	0	Enhanced	34–55	0	$8/$22/$22–$54/$53/ 33%/33%	Generics

Note: PDP (prescription drug plan). Benefits labeled actuarially equivalent to Part D's standard benefit include actuarially equivalent standard and basic alternative benefits. Plans that "qualify for auto-enrollment" have premiums that are at or below threshold values calculated by CMS for each PDP region. Plans with "gap coverage" include some benefits in the range of beneficiary drug spending above the standard benefit's initial coverage limit and below its out-of-pocket threshold. Part D's defined standard benefit requires the enrollee to pay 100 percent coinsurance in this coverage gap.

Source: MedPAC based on CMS plan benefit package and landscape data.

TABLE 7–4 **PDPs offered in 2006 by organizations with at least one nationwide plan (cont.)**

Organization and plan name	Regions in which plan is offered	Plans qualifying for auto-enrollment	Type of benefit	Range of monthly premiums	Deductible	Cost sharing by tier at in-network preferred pharmacies	Gap coverage
Silverscript							
SilverScript	34	27	Actuarially equivalent	$24–33	$250	$7–$9/25%/25%	None
SilverScript Plus	34	0	Actuarially equivalent	49–63	100	$7–$8/$22–$25/ $60–$62/25%	None
Unicare							
Medicare Rx:							
Rewards	34	34	Actuarially equivalent	17–31	250	$5/$25/25%/25%	None
Rewards Plus	33	0	Enhanced	26–39	0	$10/$30/25%/25%	None
Rewards Premier	33	0	Enhanced	35–52	0	$10/$30/$60/30%/30%	Generics
United							
AARP Medicare Rx	34	33	Actuarially equivalent	23–30	0	$5/$28/ $55–$56/25%	None
United Health Rx	4	4	Actuarially equivalent	21–23	50	$7/$23/$54/25%	None
United Medicare MedAdvance	34	28	Actuarially equivalent	27–32	0	$10/$23/$52–$55/25%	None
WellCare							
WellCare:							
Signature	34	33	Actuarially equivalent	17–33	0	$0/$0/$62-$73/ $62–$73/30%–33%	None
Complete	34	0	Enhanced	33–51	0	$0/$0/$15/$50/30%	None
Premier	34	0	Enhanced	35–54	0	$0/$0/$30/$60/30%	None

Note: PDP (prescription drug plan). Benefits labeled actuarially equivalent to Part D's standard benefit include actuarially equivalent standard and basic alternative benefits. Plans that "qualify for auto-enrollment" have premiums that are at or below threshold values calculated by CMS for each PDP region. Plans with "gap coverage" include some benefits in the range of beneficiary drug spending above the standard benefit's initial coverage limit and below its out-of-pocket threshold. Part D's defined standard benefit requires the enrollee to pay 100 percent coinsurance in this coverage gap.

Source: MedPAC based on CMS plan benefit package and landscape data.

Plans that use tiered cost sharing tend to charge fixed-dollar copayments rather than a percentage coinsurance of the prescription's price. Among plans that use a generic/brand name tier structure, median copays for generic drugs are $5 to $7, and those for brand name drugs are $28 to $30. Plans that distinguish between preferred and nonpreferred brand name drugs have the following median copay values: $7 to $5 for generics, $22 to $26 for preferred brand name drugs, and $55 to $50 for nonpreferred brand name drugs. As we discuss in greater detail later in the chapter, many plans use a separate tier for higher-cost specialty drugs, such as biologics. PDPs that incorporate a specialty tier into their tier structure tend to charge 25 percent to 30 percent coinsurance. Based on CMS guidance, plan enrollees may not appeal payment of a lower tier's cost-sharing requirement for such specialty drugs.

Organizations with nationwide participation

Ten organizations have at least one plan in all 34 of the PDP regions (Table 7-4). The offerings of these 10 organizations account for nearly 900 of the 1,429 PDPs available across the 34 regions. None of these organizations offer Part D's standard benefit design.

Instead, most use tiered copays or a combination of copays and coinsurance and keep the standard benefit's $2,250 initial coverage limit. Many of the plans have equivalent actuarial values to the standard benefit, but charge no deductible or a deductible lower than the standard benefit's $250. While most of these sponsoring organizations chose to offer one or more enhanced plans, fewer than half of those enhanced plans provide coverage in the standard benefit's coverage gap. As discussed in Chapter 9, beneficiaries in many regions have access to at least one MA–PD that includes coverage in the gap. The enhanced plans that do provide such coverage tend to cover generic drugs but not brand name drugs.

Organizations use different combinations of cost-sharing tiers and coverage approaches for their different benefit packages. For example, Aetna Medicare Rx Essentials lists a smaller number of drugs on its formulary than its Medicare Rx Premier product. The Medicare Rx Essentials product includes a $5 copay for a tier-one drug and $25 for a tier-two drug, where tiers generally correspond to covered generic and brand name prescriptions. Aetna Medicare Rx Premier's formulary charges $2 for a tier-one, $20 for a tier-two, and $40 for a tier-three drug (covered but nonpreferred drugs).

While they are not national plans, another six organizations are major participants in Part D; they offer 30 or more PDPs across the 34 regions (Table 7-5). A few of these entities offer a larger total number of plans than do some of the 10 organizations with nationwide offerings. Combined, these "near-national" entities contribute more than 300 of the 1,429 PDPs available across the 34 regions. Several of these organizations offer the defined standard benefit. Thirty-one Humana PDP Complete plans provide coverage in the standard benefit's coverage gap and cover generic and brand name drugs.

Characteristics of plans that qualify for auto-enrollees

About 29 percent of all PDPs qualified to receive auto-enrollees in 2006. Since the LIS threshold amounts are calculated among premiums for basic benefits (or the portion of enhanced benefits associated with basic coverage), no plans with enhanced benefits were assigned auto-enrollees. As a result, auto-enrolled members are much more likely to be assigned to a plan that uses Part D's defined standard benefit than not. Plans that qualified for auto-enrollees in 2006 are somewhat less likely to use tiered cost sharing: 76 percent do so versus 91 percent among all PDPs. This is because more plans that qualified for auto-enrollees use the defined standard benefit with 25 percent coinsurance.

The potentially higher cost-sharing liability of coinsurance might be a cause for concern if those LIS enrollees were paying for most of their plans' cost-sharing requirements. However, since the LIS covers most of the out-of-pocket spending for these enrollees, the more relevant issue is how the formularies of plans that qualify for auto-enrollees compare with those that did not. We discuss this issue in greater detail later in this chapter.

Geographic variation in plan entry and premiums

All regions of the country experienced strong plan entry among stand-alone Part D plans. Every region has at least 27 PDPs offering Part D coverage and the median number of plans per region is 43. Alaska has the fewest, with 27 plans, while the Pennsylvania-West Virginia region has the most, with 52 PDPs (Table 7-6, p. 162). Similarly, Medicare beneficiaries who qualify to receive Part D's LIS also have a broad choice of PDPs available. For example, Arizona and Florida had the fewest PDPs qualifying for auto-enrollees (6), while Virginia, South Carolina, and Texas each had 16 PDPs qualifying. All regions but Alaska have at least one PDP available with a monthly premium of $20 or less.

Although the average monthly premium in each region varies, the variation is not as large as one might have expected. The simple average (that is, not weighted by enrollment) monthly premium for basic benefits varies by as much as $10: Mean basic premiums range from $28 to $38 (Table 7-6, p. 162). Similarly, unweighted monthly premiums for enhanced benefits range between $37 and $48.

Offerings by MA–PDs

In addition to PDPs, which offer Part D drug coverage separately to beneficiaries in the FFS program, private health plans are offering 1,303 MA–PDs around the country. In order to enroll in an MA–PD plan, beneficiaries must elect to have their health care services (e.g., hospital and physician care) provided by the MA–PD. As discussed in Chapter 9, MA–PDs are available to practically all beneficiaries nationwide, and as of mid-April 2006, about 13 percent of the Medicare population was enrolled in MA–PD plans. The vast majority of these are offered at a local level; that is, availability varies depending on the county in which a beneficiary lives.

TABLE 7–5 **"Near-national" organizations with 30 or more PDPs among the 34 regions**

Organization and plan name	Regions in which plan is offered	Plans qualifying for auto-enrollment	Type of benefit	Range of monthly premiums	Deductible	Cost sharing by tier at in-network preferred pharmacies	Gap coverage
American Progressive							
Prescription Pathway:							
Bronze	1	1	Defined standard	$25	$250	25%	None
Silver	8	0	Actuarially equivalent	34–41	250	$5–$6/$27–$28/25%	None
Gold	8	0	Enhanced	46–52	0	$5–$6/$27–$28/25%	None
Platinum	7	0	Enhanced	64–69	0	$6/$24/$40/25%	None
Marquette							
Prescription Pathway:							
Silver	22	0	Actuarially equivalent	34–43	250	$4/$29/25%	None
Gold	22	0	Enhanced	46–54	0	$4/$29/25%	None
Platinum	22	0	Enhanced	62–71	0	$4/$26/$42/25%	None
Pennsylvania Life							
Prescription Pathway:							
Bronze	31	25	Defined standard	24–34	250	25%	None
Silver	31	0	Actuarially equivalent	34–43	250	$5/$28/25%	None
Gold	31	0	Enhanced	46–54	0	$5/$28/25%	None
Humana							
Humana PDP:							
Standard	31	30	Defined standard	2–18	250	25%	None
Enhanced	31	0	Enhanced	5–25	0	$7/$30/$60/25%	None
Complete	31	0	Enhanced	39–73	0	$7/$30/$60/25%	Generics, brands
Sterling							
Sterling Prescription Drug Plan	32	0	Actuarially equivalent	49–61	100	$10/$22–$28/ 40%–50%/25%	None
United American							
UA Medicare Part D Prescription Drug Coverage	31	2	Actuarially equivalent	30–41	0	$9/$30/$60/33%	None

Note: PDP (prescription drug plan). Benefits labeled actuarially equivalent to Part D's standard benefit include actuarially equivalent standard and basic alternative benefits. Plans that "qualify for auto-enrollment" have premiums that are at or below threshold values calculated by CMS for each PDP region. Plans with "gap coverage" include some benefits in the range of beneficiary drug spending above the standard benefit's initial coverage limit and below its out-of-pocket threshold. Part D's defined standard benefit requires the enrollee to pay 100 percent coinsurance in this coverage gap.

Source: MedPAC based on CMS plan benefit package and landscape data.

TABLE 7–6

Geographic distribution of PDPs in 2006

PDP region	States in the region	Number of PDPs: Total	That qualify for auto-enrollment	With monthly premium ≤$20	Mean premium for: Basic benefits	Enhanced benefits
1	ME, NH	41	14	1	$35	$44
2	CT, MA, RI, VT	44	11	4	31	42
3	NY	46	15	6	32	37
4	NJ	44	14	4	32	41
5	DC, DE, MD	47	15	3	33	45
6	PA, WV	52	15	2	34	45
7	VA	41	16	2	34	44
8	NC	38	13	2	37	46
9	SC	45	16	1	35	47
10	GA	42	14	1	34	43
11	FL	43	6	4	34	47
12	AL, TN	41	9	1	35	48
13	MI	40	14	1	34	43
14	OH	43	10	3	33	42
15	IN, KY	42	13	1	36	46
16	WI	45	14	4	31	41
17	IL	42	15	1	32	43
18	MO	41	10	2	34	43
19	AR	40	13	2	35	46
20	MS	38	12	2	36	47
21	LA	39	11	1	38	48
22	TX	47	16	2	33	44
23	OK	42	12	2	36	46
24	KS	40	11	2	34	42
25	IA, MN, MT, ND, NE, SD, WY	41	14	3	32	44
26	NM	43	8	6	29	41
27	CO	43	10	3	32	41
28	AZ	43	6	4	31	40
29	NV	44	7	3	30	40
30	OR, WA	45	15	5	31	41
31	ID, UT	44	14	3	34	44
32	CA	47	10	6	28	38
33	HI	29	8	3	31	37
34	AK	27	8	0	34	41
Total		1,429	409	90	33	43

Note: PDP (prescription drug plan). Mean values are not weighted by plan enrollment. The PDPs described here exclude plans offered in U.S. territories. Benefits labeled basic include Part D's standard benefit design as well as benefits that are actuarially equivalent to standard benefits. Enhanced plans include supplemental coverage. Plans that "qualify for auto-enrollment" have premiums that are at or below threshold values calculated by CMS for each PDP region.

Source: MedPAC based on CMS plan benefit package and landscape data.

However, 48 regional PPOs (4 percent of all MA–PDs) offer a package of Parts A, B, and D services to Medicare beneficiaries who live anywhere within the MA region.

Because of certain provisions in law and regulation, offerings through MA–PDs differ systematically from PDPs. For example, the law allows MA–PDs to use 75 percent of the difference between an MA plan's benchmark

TABLE 7–7

Characteristics of MA–PD drug benefits in 2006

	All types of benefits	Basic benefits		Enhanced benefits
		Defined standard	Actuarially equivalent	
Total number of plans	1,303	96	376	831
Distribution of plans (in percent):				
Plan type	100%	7%	29%	64%
Type of organization				
Local HMO	66	4	18	43
Local PPO	21	1	8	12
PFFS	10	1	2	7
Regional PPO	4	1	1	2
Type of deductible				
Zero	80	N/A	18	62
Reduced	3	N/A	2	1
$250	17	7	8	1
Cost-sharing structure before the initial coverage limit				
Uses 25% coinsurance	7	7	0	0
Uses tiered cost sharing	93	N/A	29	64
Copays	34	N/A	16	17
Coinsurance	0	N/A	0	0
Both	59	N/A	13	46
Coverage in the gap				
Generics	23	N/A	0	23
Generics and brands	5	N/A	0	5
None	72	N/A	29	36
Offers mail-order pharmacy services	96	7	27	62

Note: MA–PD (Medicare Advantage prescription drug [plan]), PPO (preferred provider organization), PFFS (private fee-for-service), N/A (not applicable). Local plans (HMOs, PPOs, and PFFS plans) select individual counties in which they operate. Regional PPOs must provide Medicare services throughout a CMS-defined region that encompasses one or more states. Percentages are not weighted by plan enrollment. The MA–PDs described here exclude demonstration programs, 1876 cost plans, and plans offered in U.S. territories. Benefits labeled actuarially equivalent to Part D's standard benefit include what CMS calls "actuarially equivalent standard" and "basic alternative" benefits. Plans with "coverage in the gap" include some benefits in the range of beneficiary drug spending above the standard benefit's initial coverage limit and below its out-of-pocket threshold. Part D's defined standard benefit requires the enrollee to pay 100 percent coinsurance in this coverage gap.

Source: MedPAC based on CMS plan benefit package and landscape data.

payment and its bid for providing Parts A and B services (called rebate dollars) to supplement its package of benefits or lower its premium. MA–PDs appear to have used this provision to lower the portion of their premium attributable to Part D or to supplement Part D's benefit. A much larger proportion of MA–PD plans provide enhanced benefits than do PDPs—64 percent of MA–PDs (Table 7-7) compared with 43 percent of PDPs (Table 7-2, p. 155). In addition, more than 500 MA–PDs (nearly 40 percent) charge no additional premium for Part D coverage beyond what they charge for Parts A and B services (right-hand side of Figure 7-1, p. 156).

MA–PDs are less likely to charge a deductible than PDPs. For 2006, 80 percent of all MA–PDs have no deductible (Table 7-7), compared with 58 percent of PDPs (Table 7-2, p. 155). They are similar to PDPs in that they are just as likely to use a tiered cost-sharing structure, but MA–PDs are somewhat more likely to use four tiers than their stand-alone counterparts. They are also more likely to provide coverage within Part D's coverage gap: 23 percent of

TABLE 7–8 **Premiums and cost-sharing requirements among MA–PD drug benefits in 2006**

	Basic benefits		
	Defined standard*	Actuarially equivalent	Enhanced benefits
Monthly drug premium			
Minimum	$0	$0	$0
Maximum	77	78	120
Median	23	24	0
Mean	25	21	16
Monthly total plan premium (including medical and drug premiums)			
Minimum	0	0	0
Maximum	202	179	260
Median	63	63	29
Mean	68	61	41
Deductible			
Minimum	250	0	0
Maximum	250	250	250
Median	250	0	0
Median cost sharing for:			
Plans with generic/brand tier structure			
Generic copay	N/A	5	7
Brand copay	N/A	30	30
Specialty tier coinsurance (where applicable)	N/A	25%	30%
Plans with generic/preferred brand/nonpreferred brand tier structure			
Generic copay	N/A	$5	$5
Preferred brand copay	N/A	29	28
Nonpreferred brand copay	N/A	55	50
Specialty tier coinsurance (where applicable)	N/A	25%	25%

Note: MA–PD (Medicare Advantage prescription drug [plan]), N/A (not applicable). Values are not weighted for plan enrollment. The MA–PDs described here exclude demonstration programs, 1876 cost plans, and plans offered in U.S. territories. Cost sharing is for median cost sharing among plans that use tiered cost sharing before the initial coverage limit. Benefits labeled actuarially equivalent to Part D's standard benefit include actuarially equivalent standard and basic alternative benefits.
*Part D's defined standard benefit has a $250 deductible (in 2006) and 25% coinsurance below the initial coverage limit.

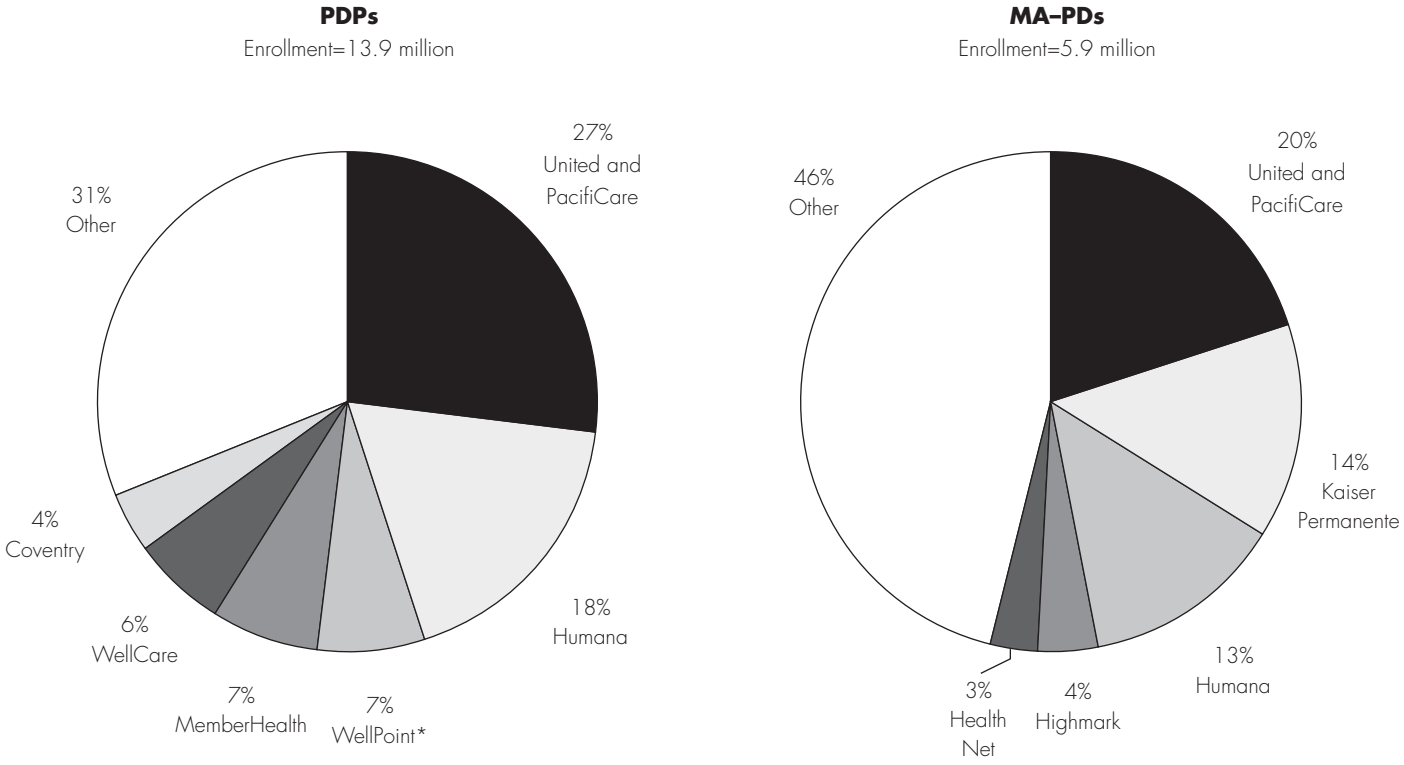
Source: MedPAC based on CMS plan benefit package and landscape data.

MA–PDs offer coverage of generic drugs, and another 5 percent of MA–PDs provide coverage of both generic and brand name drugs. By comparison, 13 percent of PDPs offered generic coverage in the gap and 2 percent covered generic and brand name drugs (Table 7-2, p. 155). The higher availability of drug coverage in the gap may prove attractive to beneficiaries and increase the proportion of beneficiaries enrolled in MA plans.

Many MA organizations have applied some of their rebate dollars toward the premiums of enhanced plans (Table 7-8). The median monthly premium for an enhanced MA–PD is essentially zero. However, as discussed in Chapter 9, not every beneficiary has access to a zero-premium enhanced plan; availability depends on the county in which they live.[12] Also, in order to obtain MA–PD coverage, enrollees must pay the Part B premium and any other premium amount charged by their plan for regular medical services. The median combined MA–PD premiums for medical services and prescription drugs range from $63 to $29 per month (Table 7-8).

FIGURE 7–2

Distribution of Part D enrollees by organization



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage prescription drug [plan]). Data are as of April 27, 2006.
*Includes Blue Cross Blue Shield New England Alliance, Blue Medicare Rx, and Unicare.

Source: MedPAC based on CMS enrollment data.

Unlike for PDPs, there is little difference between the mean and median premium values for defined standard benefits and plans that are actuarially equivalent (Table 7-8). As is the case with PDPs, MA–PDs frequently use fixed-dollar copayments. However, it is also common to combine copays with coinsurance for certain tiers such as those for specialty drugs. Median cost-sharing amounts are similar to those used by PDPs. MA–PDs that use a generic/brand name tier structure typically charge $5 to $7 to fill a generic prescription and $30 for brand name prescriptions. Plans that distinguish between preferred and nonpreferred brand name drugs have the following median copays: $5 for generics, $29 to $28 for preferred brand name drugs, and $55 to $50 for nonpreferred brand name drugs. Plans often charge 25 percent coinsurance for specialty and higher priced drugs.

Enrollment by organization

As of late April 2006, Part D enrollment was concentrated among plans offered by a small number of parent organizations (Figure 7-2). Several of those organizations offer both stand-alone PDPs and MA–PDs. For example, United and PacifiCare (which merged recently) had 27 percent of the 13.9 million enrollees in PDPs and 20 percent of the 5.9 million enrollees in MA–PDs. Similarly, Humana had a considerable portion of both markets: 18 percent of PDP enrollees and 13 percent of MA–PD enrollees. As information on enrollment in specific Part D plans becomes available, the Commission will monitor those data to see how enrollment patterns affect plans' decision to enter or exit the market. Also, for 2007 and beyond, CMS will begin to weight Part D plans bids by enrollment when the agency calculates the nationwide

Guidance for plan formularies in 2006

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) designated the U.S. Pharmacopeia (USP)—a nongovernmental, nonprofit organization—to develop a model therapeutic classification system that plans could use to design their formularies. Plans were not required to use this model, but the USP Model Guidelines were used as the classification structure for 74 percent of the Part D formularies in place at the start of the Medicare drug benefit (USP 2006).[13] The 2006 USP guidelines provided the following therapeutic classification system:

- 41 broad therapeutic categories (e.g., cardiovascular agents),
- 137 pharmacologic classes (e.g., dyslipidemics), and
- 118 formulary key drug types (e.g., statins).

CMS's guidance on the formulary drug lists includes the following requirements:

- Plan formularies must generally include at least two drugs in each approved therapeutic category and class, regardless of the drug classification system used.[14]
- In specified categories and classes, formularies must include at least one drug from USP's category of key drug types.[15]
- Plans must list "all or substantially all" of the drugs listed in six drug categories: antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant, and HIV/AIDS drugs.[16]
- Plans may only have one specialty tier that may be designed for high-cost and unique drugs and biologicals, such as injectable drugs. Beneficiaries may not appeal the cost-sharing amount—generally limited to 25 percent—for drugs placed on a specialty tier.[17]
- Formularies should list drugs on a nonpreferred tier only when therapeutically similar drugs are available on a lower tier.

The text box on page 168 describes some of the challenges CMS faced, and will continue to face, when determining whether plans fulfill these requirements.

The MMA excludes certain categories of drugs from Part D coverage. These are the same categories of drugs that states have had the option to exclude from their Medicaid programs. Enhanced plans can cover these drugs, but beneficiaries must pay for this added coverage themselves, typically through premiums.[18]

All beneficiaries have the right to request Part D coverage of a nonformulary drug and to appeal denials. To obtain coverage for a nonformulary drug, the prescribing physician must provide a statement (and supporting documentation upon request) that the nonformulary drug is medically necessary because all drugs on the formulary would not be as effective for the enrollee or would have adverse effects. Plans may manage enrollees' drug utilization by requiring prior authorization or other action to obtain coverage for specific drugs.

During the early months of the drug benefit, CMS released several guidance documents on plan transition polices for new enrollees who were on medications which are nonformulary or require other action, such as prior authorization. CMS extended the general minimum transition period during which time plans had to temporarily cover such prescriptions and ensure that pharmacists did not encounter plan delays or denials for them. The extension increased the minimum transition period from 30 days to 90 days. ■

average plan bid, federal subsidies, and beneficiary premiums. Thus, patterns of enrollment in 2006 could lead to significant changes in beneficiary premiums for 2007.

Part D formularies

The Medicare drug benefit allows plans to develop and use formularies to manage the cost and use of prescription drugs. Indeed, all PDPs and MA–PDs participating in the new Medicare drug benefit use formularies to designate the coverage and tiered cost-sharing status of outpatient drugs. To the extent that formularies assist plans in encouraging safe, effective, and cost-conscious drug prescribing and utilization, they are a key to the success of the overall Medicare drug benefit. Attention to formulary implementation is important to ensure that beneficiaries have access to a range of needed medications. In our June 2004 report to the Congress, the Commission discussed formulary structure and design issues (MedPAC 2004).

In this section, we review statutory and regulatory standards for Part D formularies and present some descriptive analyses of the formularies that PDPs and MA–PDs submitted to CMS for the launch of the Medicare drug benefit. This early study provides some basic analysis and a beginning point for tracking changes in plan formularies over time. In the future, with enrollment and drug claims data, we will be able to examine how plan formularies affect enrollee plan choice (by beneficiary and plan characteristics), beneficiary access to medications, beneficiary out-of-pocket spending, Medicare spending, and beneficiary health outcomes.

At this point, we are able to examine the formularies and benefit designs that Part D plans submitted to CMS for use at the start of the drug benefit. For our analysis, researchers at the National Opinion Research Center (NORC) and Georgetown University examined all the formularies submitted to CMS beginning January 1, 2006. Findings from this analysis indicate that most Part D formularies distinguish between preferred and nonpreferred brand name drugs and include specialty tiers. Plan formularies typically list about 1,000 drugs (where the method for counting drugs is defined in the following section), but the number of drugs covered varies somewhat based on several plan characteristics, such as a plan's tier structure. Also, plans typically apply some utilization management tools to drugs in certain therapeutic categories.

Formulary designs

All MA–PDs and PDPs submitted their plan formularies to CMS for review and approval. CMS examined several factors to verify that the formularies met minimum standards. These standards were established to enhance beneficiary access to medications that may present unique therapeutic advantages in safety and efficacy, and to prevent plans from discouraging enrollment of beneficiaries with certain diseases—above and beyond the explicit prohibition of this practice in the MMA. The text box on page 166 describes these standards in more detail.

The text box on page 168 describes some of the challenges CMS faced, and will continue to face, when determining whether plans fulfill these requirements. In particular, the definition of what constitutes appreciable differences in drug products and entities can affect how formulary rules and standards are applied. Such definitions are not formally a part of current U.S. Pharmacopeia (USP) or CMS guidelines. For example, should oral and topical forms of a drug be counted separately? Should all available dosages of a drug be considered on a plan's formulary if at least one is listed? Decisions about whether or not different forms, strengths, and extended-release versions of a given drug are counted as one drug may affect the number and variety of products plans list. In general, CMS appears to have decided that a plan can not satisfy the requirement of two drugs per class by simply using two different forms or strengths of a given drug. The different versions of a drug can be treated differently, however, in terms of coverage and cost sharing.

For purposes of our analysis, we used a proprietary classification system developed by Medi-Span to translate the drugs that plans reported on their formularies into standardized drug entities. Different strengths and release mechanisms (e.g., regular vs. sustained release) are grouped into a single drug entity. Most forms of an entity (e.g., capsule vs. tablet) are typically counted as one drug, but some forms are considered separately if they are used for a notably different purpose. We differentiate between brand name and generic drugs. However, if a generic drug entity is available from several different manufacturers, all are counted as the same drug. Other researchers may categorize drug entities differently and thus obtain slightly different results. In our analysis, plan formularies are not weighted by beneficiary enrollment. We examined all drugs that plans listed and consequently did not select drugs by their frequency of use in the Medicare population.

Defining a drug

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.

The Food and Drug Administration's national drug codes (NDCs) are extremely exact and give a separate code for every possible combination of chemical ingredients, strength (e.g., number of milligrams), form, package size (how many doses are typically included in one container used by the pharmacy), and the firm that manufactures or distributes the drug. The U.S. Pharmacopeia (USP) coding, on the other hand, is more general and lists only chemical ingredients. Considerations such as brand name versus generic, strength, and (in most cases) form are absent from the USP scheme.

What drugs are counted

The absence of a clear-cut definition of which drug products should be considered different entities makes it considerably more difficult to interpret the statutory requirement that two drugs be covered in a given category or class. Some of the considerations that complicate this determination include the following:

- Should oral and topical forms be counted separately, especially if they are used to treat different conditions? It appears that the answer could be different for different drugs, as some appear in separate places in the USP classification and others do not.
- Should all versions of a drug (i.e., all NDCs) be covered if at least one is covered? In its June guidance to plans, CMS stated that it will not require all dosages to be included, or all manufacturers' versions of a multisource product to be included. In addition, CMS's guidance on displaying plan formularies makes it clear that plans may place different strengths of a drug on different cost-sharing tiers.
- How should extended-release versions of a drug be treated? It appears that CMS will neither require plans to cover extended-release versions of drugs, nor count them as an additional drug toward the coverage requirements.
- Should two chemically similar, but not identical, drugs count as two drugs? In the case of two chemically similar antidepressants with rather different treatment indications, CMS has allowed an exception to the requirement that plan formularies include all antidepressants and allowed plans to exclude one of these two drugs. ■

Source: NORC 2005.

Tier structures

We examined plan formularies to determine if there were differences in their designs associated with the following plan characteristics:

- national or non-national,
- eligible for auto-enrolled beneficiaries,
- basic or enhanced plans, and
- tier structure.

Plans submitted formularies to CMS with a variety of tier structures, ranging from one to eight tiers. However, not all tiers reflect cost-sharing differences for enrollees; some plan formularies include several tiers that, in fact, have the same cost sharing. For our formulary analysis, therefore, we delineate tiers only when they mark differences in cost sharing. Most plans' formularies fall into five tier structures, grouped into the following three categories:

- 25 percent cost sharing for all listed drugs;
- generic and brand name tiers (some with and some without an additional specialty tier); and
- generic, preferred brand name, nonpreferred brand name tiers (some with and some without an additional specialty tier).

TABLE 7–9

Most Part D plans distinguish between preferred and nonpreferred brands and include specialty tiers

	Distribution of plans by tier structures					
		Generic/brand		Generic/preferred brand/ nonpreferred brand		
Plan characteristics	25% coinsurance, all tiers	Without specialty tier	With specialty tier	Without specialty tier	With specialty tier	Other
All Part D plans	8%	11%	15%	19%	45%	2%
All PDPs	9	8	22	23	38	1
National, near-national	5	8	21	25	40	0
Non-national	31	3	28	12	21	4
Auto-enrollment	23	2	33	9	33	1
No auto-enrollment	3	10	18	29	40	0
Basic	16	5	25	18	36	1
Enhanced	0	12	18	30	40	0
All MA–PDPs	7	16	6	15	53	3
Local HMO	6	15	5	14	58	2
Local PPO	6	21	8	24	37	5
Regional PPO	29	8	15	10	38	0
PFFS	10	11	11	0	67	0
Basic	18	21	10	16	32	2
Enhanced	1	13	5	14	65	3

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage prescription drug [plan]), PPO (preferred provider organization), PFFS (private fee-for-service). The PDPs described here exclude plans offered in U.S. territories. The MA–PDs described here exclude demonstration programs, 1876 cost plans, and plans offered in U.S. territories. Auto-enrollment refers to PDPs that were eligible for automatically enrolled beneficiaries based on low-income status. Cost-sharing structures are for before the initial coverage limit of Part D. A specialty tier generally includes expensive products and unique drugs and biologicals, such as biotechnology drugs, for which enrollees may not appeal for lower cost-sharing amounts. Numbers may not sum to 100 percent due to rounding.

Source: National Opinion Research Center/Georgetown University analysis for MedPAC of formularies submitted to CMS for January 1, 2006.

Shown in Table 7-9, our analysis found that 61 percent of PDPs and 68 percent of MA–PDs use the generic, preferred, and nonpreferred brand name structure; 30 percent of Part D plans distinguish only between brand name and generic drugs; and fewer than 10 percent have 25 percent coinsurance for all covered drugs. Enhanced plans almost never use this latter structure. PDPs with 25 percent coinsurance were more likely to be non-national, basic, and qualify for auto-enrollment (vs. no auto-enrollees).

As described in the text box on page 166, plans may have a specialty tier. For 2006, CMS did not establish specific criteria for placing drugs on a specialty tier but indicated that this tier could be used for expensive products and unique drugs and biologicals, such as biotechnology drugs. (For 2007, CMS defined the specialty tier more clearly and has stated that only Part D drugs with plan negotiated prices that exceed $500 per month may be placed on a specialty tier.) Beneficiaries may not appeal the cost-sharing amount for drugs listed on a specialty tier as they can for drugs on nonpreferred brand name tiers. Cost sharing for a specialty tier is generally limited to 25 percent below the initial coverage limit. Our analysis shows that about 60 percent of the PDPs and MA–PDs include a specialty tier in their formularies.[19] Among these plans, the median PDP lists 46 drugs on a specialty tier and the median MA–PD lists 90.

Plans that use tiered formularies can reduce their financial liability for expensive drugs by placing them on a specialty tier with higher beneficiary cost sharing than other tiers. If beneficiaries reach their annual out-of-pocket spending limits, however, plans must cover these drugs—along with all other medically necessary drugs—at significantly reduced cost-sharing levels.

Formulary sizes

The number of drugs that plans list on their formulary can be another starting place for analyzing Part D formularies. Note, however, that the number of drugs on a plan's formulary does not necessarily represent beneficiary access to needed medications. Plans' processes for nonformulary exceptions, prior authorization, and step therapy requirements can have a strong influence on access. For example, unlisted drugs may be covered through the nonformulary exceptions process, which in some plans may be relatively easy for enrollees and physicians, while for other plans it may be more burdensome. Alternatively, on-formulary drugs may not be covered in cases where a plan does not approve a prior authorization request. Also, a formulary's size can be deceptively large if it includes drugs that are no longer used in common practice.

As can be expected, we found that Part D formulary sizes vary somewhat. The median PDP lists fewer drugs than the median MA–PDs, but broadly speaking, they each typically list about a 1,000 drugs on their formularies, with brand name drugs making up a little more than half (Figure 7-3).[20] Among PDPs, the total number of drugs listed ranges from 618 drugs to 1,743, with a median of 957 drugs. Among MA–PDs, the total number of drugs listed ranges from 509 to 2,130, with a median of 1,096. Formularies that are very large approach open formularies, in which all or mostly all drugs are covered. The median plan appears to have many therapeutic categories that exclude some drugs.

When analyzing formulary size by plan type, we see some patterns. At the median, regional PPO and private FFS MA–PDs have the largest formularies, but these only represent 6 percent of the total number of Part D plans. Among PDPs, the non-national plans have the largest formularies. Plans that are eligible for auto-enrollment typically list almost the same number of total drugs and total brand name drugs as plans without auto-enrollment. It is somewhat reassuring that PDPs eligible for auto-enrollees (through lower bids to CMS) have similar formulary sizes—and in particular include similar numbers of brand name drugs—as other plans. Major differences could have signaled concern of inequitable access to drugs between auto-enrollees and other beneficiaries. While formulary sizes appear similar, further analysis of drug claims and utilization management tools by therapeutic category will be important for measuring beneficiary access to needed medications because formulary size alone does not directly measure access.

For both MA–PDs and PDPs, enhanced plans' formularies are also larger than basic plans' formularies, but this difference is small (particularly for PDPs). Enhanced plans appear to have focused more of their added benefits on other areas, such as coverage in the gap. Our previous analysis of plan benefit designs shows that 36 percent of enhanced PDPs and 43 percent of enhanced MA–PDs offer coverage in the gap (most offering coverage only for generic drugs).

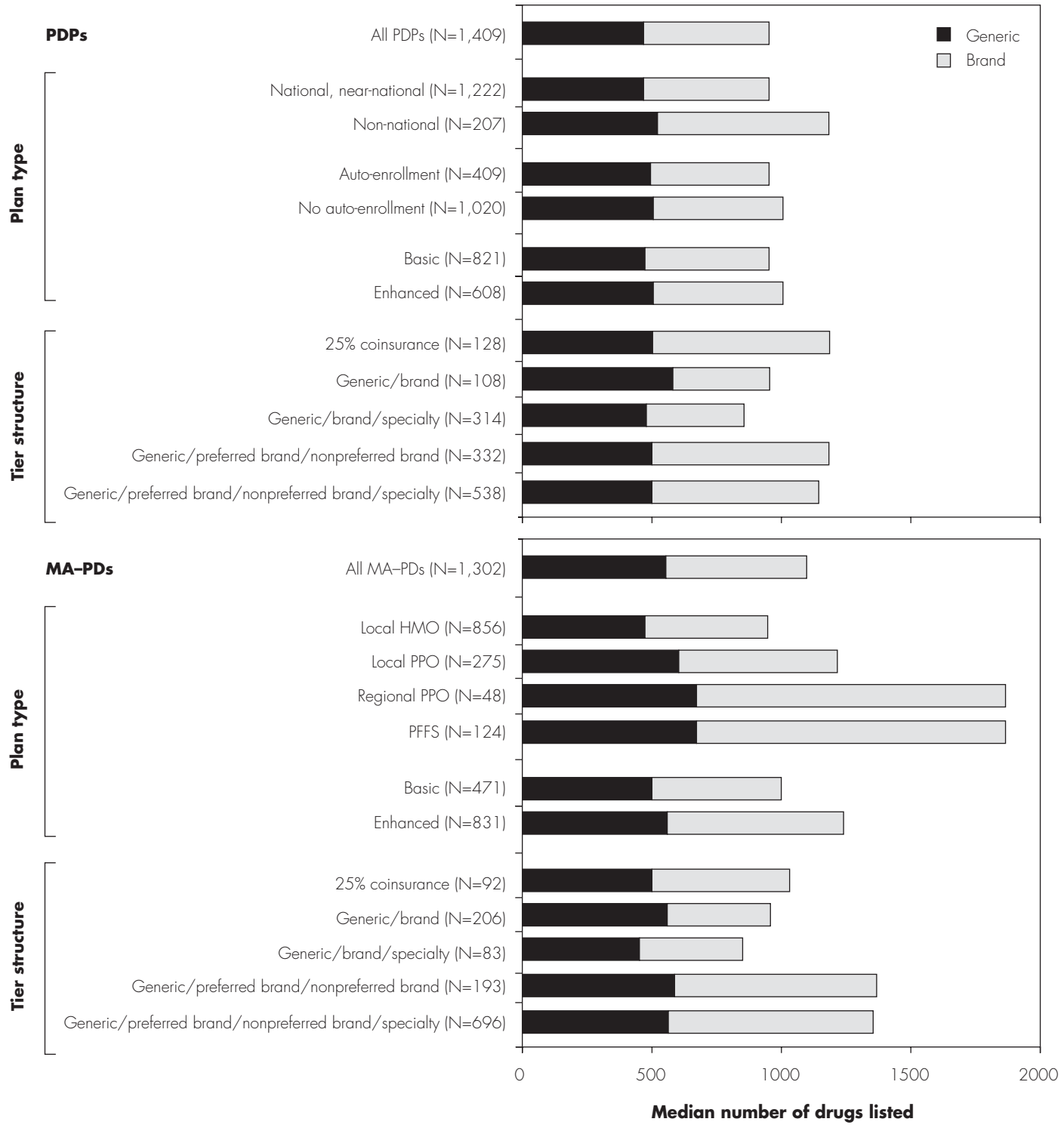
We see more variation in formulary size when we compare by tier structure. As shown in Figure 7-3, for both PDPs and MA–PDs, formularies that have preferred and nonpreferred brand name tiers list more brand name drugs overall than formularies that have a single brand name tier (whether or not they have a specialty tier). In other words, adding a nonpreferred brand name tier is associated with including more drugs on a plan formulary and specifically, more brand name drugs.[21] This finding is expected because plans generally take on less financial risk for drugs they place on nonpreferred and higher cost-sharing tiers.

We found that plans with specialty tiers do not necessarily list more brand name drugs. In fact, for PDPs, adding a specialty tier to a given tier structure is associated with including slightly fewer brand name listings at the median. However, among MA–PDs, plans that list the most brand name drugs are often those with a nonpreferred brand name tier plus a specialty tier. In some cases, some of the drugs plans place on specialty tiers are drugs that plans are required to list (e.g., some expensive oral anticancer drugs), but in other cases, plans may have listed drugs on the specialty tier that they may not have otherwise listed at all.[22]

In addition to regulatory coverage rules for certain therapeutic categories, the number of drugs listed in a therapeutic class also reflects the size of the class of drugs available in the marketplace. In classes with fewer drugs available, plans typically cover a larger share of them. Conversely, when there are more drugs available in a given class, plans are able to negotiate better prices by listing only selected drugs on their formulary. In addition,

FIGURE 7–3

Part D plans typically list about 1,000 drugs



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage prescription drug [plan]), HMO (health maintenance organization), PPO (preferred provider organization), PFFS (private fee-for-service). Occasionally, plans list some generic drugs on brand tiers and vice versa. Plans with "other" tier structures are not displayed. The PDPs described here exclude plans offered in U.S. territories. The MA–PDs described here exclude demonstration programs, 1876 cost plans, and plans offered in U.S. territories. Cost-sharing structures are for before the initial coverage limit of Part D. A specialty tier generally includes expensive products and unique drugs and biologicals for which enrollees may not appeal for lower cost sharing.

Source: National Opinion Research Center/Georgetown University analysis for MedPAC of formularies submitted to CMS for January 1, 2006.

TABLE 7–10

The share of drugs listed in a therapeutic category depends on category size and regulation

	Median percent of drugs listed by selected therapeutic categories			
	Cholinesterase inhibitors	Dyslipidemics	Opioid analgesics	Atypical antipsychotics*
Total drugs in category	4	20	61	6
Plan type:				
PDPs	75%	65%	39%	100%
MA–PDs	75	75	48	100

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage prescription drug [plan]). Descriptions of therapeutic categories are given in parentheses: cholinesterase inhibitors (antidementia agents); dyslipidemics (anticholesterol agents); opioid analgesics (narcotic pain relievers); atypical antipsychotics (nonphenothiazines). Occasionally, plans list some generic drugs on brand tiers and vice versa. The PDPs described here exclude plans offered in U.S. territories. The MA–PDs described here exclude demonstration programs, 1876 cost plans, and plans offered in U.S. territories.
*Under CMS regulation, plans are required to list all drugs in the atypical antipsychotic category.

Source: National Opinion Research Center/Georgetown University analysis for MedPAC of formularies submitted to CMS for January 1, 2006.

there are often more overlapping products in some of these larger classes (e.g., antibiotics or respiratory tract agents), meaning that plans may not see a need to cover all alternatives, even if negotiation is not a factor.

Table 7-10 shows that the share of drugs that plans list can decrease as class size grows. For example, in a therapeutic class with only a small number of drugs, such as cholinesterase inhibitors (within the class of antidementia agents), plans typically list a higher share of available drugs in the market. But in classes where there are many drugs available in the market, such as opioid analgesics, plans typically list a much smaller share on their formularies.

Note, however, that this table does not specify tier placement for plans' listed drugs. For example, further analysis (not shown on this table) finds that among plans that have nonpreferred tiers, the typical PDP plan lists 38 percent of the available brands for dyslipidemics (anticholesterol agents, including statins among others) on the preferred brand name tier and another 50 percent on the nonpreferred brand name tier.

In the six classes in which CMS requires that plans cover all or substantially all drugs (listed in the text box on page 166), plans predictably list a larger share of drugs. For example, in the class of atypical antipsychotics (listed in Table 7-10), both MA–PDs and PDPs typically list all of the available drugs. In some of these six classes, plans do not list all drugs because of allowed exceptions.

As mentioned earlier, formulary size gives some insight into plan differences, but it does not directly measure access to medications. Some drugs listed on a formulary may require further plan approval and alternatively, unlisted drugs can be covered through a nonformulary exceptions process. We will not be able to compare actual differences in utilization and access until we have drug claims data. With claims information, we can begin to assess coverage rates of drugs between plans, particularly if we also know rates of drug claim denials.

Utilization tools

Most Part D plans apply drug utilization management tools to selected drugs. These tools include prior authorization (plans require pre-approval before coverage), step therapy (enrollees must try specified drugs before moving to other drugs), and quantity limits (plans limit the number of doses of a particular drug covered in a given time period). Plans use these tools for drugs that are expensive, potentially risky, subject to abuse, misuse, 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 (98 percent) use prior authorization for at least one drug on their formularies. The median plan applies prior authorization to 9 percent of the drugs on its formulary (Table 7-11). Step therapy is less commonly used among Part D plans and those that use it do so for a smaller proportion of drugs.[23] Again, use of these tools varies by drug class.

As found in current health plan practices, our analysis shows that Part D plans typically require prior authorization in therapeutic categories with high-cost drugs and drugs with elevated safety risks. For example, PDPs and MA–PDs that use prior authorization typically require this tool for most of the drugs in the immune suppressant category for expensive rheumatoid arthritis drugs. In addition, plans are likely applying prior authorization restrictions in this category (and several other categories) to assist in determining whether the drugs should be covered under Part B.[24]

Plans also use prior authorization and step therapy for selected drugs in classes where lower cost or over-the-counter drugs are available. For example, in the class of proton pump inhibitors (PPIs) (medications that reduce stomach acid), PDPs typically apply prior authorization to half of their listed PPIs, and if they use step therapy at all, they apply it to all of them. Similarly, MA–PDs also use prior authorization and step therapy at high rates in this therapeutic category. For atypical antipsychotic drugs—a category with both high- and low-cost drugs—PDPs and MA–PDs also appear similar in their application of prior authorization and step therapy. (Under CMS instructions, plans can only apply utilization tools in this category to new-start enrollees—those not already taking a drug in the category.) Plans use step therapy considerably less often than prior authorization. In some therapeutic categories, we found differences between MA–PDs and PDPs in step therapy rates, but differences do not appear systematic.

In general, one might have expected MA–PDs to apply more utilization management tools to their formularies than PDPs because MA–PDs may serve a population more accustomed to such tools for other health services. However, PDPs and MA–PDs often use the same kind of organizations—pharmacy benefit managers (PBMs)—to administer their drug benefits. Thus, similarities between the two are somewhat predictable. In fact, in some cases, PDPs and MA–PDs used the same PBM and submitted formularies that were identical. Nevertheless, PDPs are a new kind of product for a new benefit and we expect their formularies to evolve over time. MA–PDs have more experience taking on risk for a drug benefit, but formulary guidelines and standards for Part D are relatively new.

TABLE 7–11 **Part D plans concentrate prior authorization in selected categories**

Therapeutic category	Median percent of listed drugs subject to prior authorization, among plans that use it	
	PDP	MA–PD
All drugs	9%	9%
Atypical antipsychotics*	33	33
Dyslipidemics	13	17
Immune suppressants*	83	71
Metabolic bone disease agents	17	17
Molecular target inhibitors*	75	75
Opioid analgesics	12	9
Oral hypoglycemics	17	11
Proton pump inhibitors	50	75
Renin-angiotensins	2	4
Reuptake inhibitors*	5	5

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage prescription drug [plan]). Descriptions of selected therapeutic categories are given in parentheses: atypical antipsychotics (antipsychotics, nonphenothiazines); dyslipidemics (anticholesterol agents); immune suppressants (rheumatoid arthritis agents); opioid analgesics (narcotic pain relievers); oral hypoglycemics (blood sugar level agents); proton pump inhibitors (stomach acid reducers); renin-angiotensins (selected hypertension drugs); reuptake inhibitors (selected antidepressants). The PDPs described here exclude plans offered in U.S. territories. The MA–PDs described here exclude demonstration programs, 1876 cost plans, and plans offered in U.S. territories.
*Plans may only apply prior authorization to new-start enrollees—those not already taking a drug in these categories.

Source: National Opinion Research Center/Georgetown University analysis for MedPAC of formularies submitted to CMS for January 1, 2006.

Formulary changes

Throughout 2006, plans may remove a drug from their formularies, move a drug to a higher cost-sharing tier, or impose new restrictions at any point during the year, as long as they notify affected enrollees, pharmacists, and physicians at least 60 days prior to the change. However, starting in 2007, enrollees who are on medications must have continued coverage for the remainder of the year for their medications and, thus, are exempt from formulary changes during the year. (Some exceptions apply, such as removing formulary drugs that have been withdrawn from the market by either the Food and Drug Administration or a product manufacturer.)

Looking ahead

In 2007, CMS, health plans, pharmacists, and beneficiaries will have had a year of experience with Part D. In addition to working out operational details for this new benefit, CMS will adjust plan subsidies for 2007 based on enrollment-weighted figures from 2006. This may result

in significant changes in premiums for the coming year. For example, if 2007 plan bids are similar to 2006 bids and enrollees cluster in lower-premium plans, the federal subsidy based on the enrollment-weighted average bid will be proportionately lower and beneficiaries' premiums will rise. Some plans may exit if their enrollment is low, and other plans may choose to enter the market. Additionally, some low-income beneficiaries may need to switch plans if their plan no longer qualifies for the low-income premium subsidy, as determined through the bidding process.

In the coming years, the Commission will continue analyzing aspects of cost, quality, and access under Part D. We would like to examine how benefit design and plan formularies affect:

- enrollee plan choice (by characteristics of beneficiaries and plans),
- beneficiary access to medications,
- beneficiary out-of-pocket spending,
- Medicare spending, and
- beneficiary health outcomes.

These analyses will help policymakers construct performance measures to monitor the implementation of the new Medicare drug benefit, as the Commission has discussed previously (MedPAC 2005c). Additionally, the Commission will examine how Part D is meeting the needs of special populations, such as those residing in long-term care facilities. A high priority for future analysis will also be to examine the impact of plans' formulary changes, utilization management tools (such as prior authorization), and nonformulary exceptions processes on beneficiaries and physicians. ■

Endnotes

1 Medicare subsidizes 80 percent of an individual's drug spending above the defined standard benefit's out-of-pocket threshold; enrollees pay 5 percent cost sharing and their plan covers the remaining 15 percent. Individual reinsurance acts as a form of risk adjustment by providing greater federal subsidies for the highest cost enrollees. In addition, Medicare establishes symmetric risk corridors separately for each plan to limit a plan's overall losses or profits. Under risk corridors, Medicare limits a plan's potential losses (or gains) by financing some of the higher-than-expected costs (or recouping excessive profits). These corridors are scheduled to widen, meaning that plans should bear more insurance risk over time.

2 CMS reviews plans' benefit designs and formularies with the goal of ensuring that plans do not substantially discourage enrollment by any class of enrollees.

3 In 2002, 18 percent of noninstitutionalized Medicare beneficiaries had no drug coverage. Thirty-four percent had coverage through employer-sponsored insurance, 14 percent through Medicaid, 12 percent through Medicare HMOs, 12 percent through medigap policies, and 10 percent through other sources such as the Department of Defense or Department of Veterans Affairs (Kaiser Family Foundation 2005). Although enrollment in the standardized medigap plans that include prescription drug coverage has been less than 6 percent of all standard policies, the percentage with prescription drug coverage through medigap plans may be higher because many individuals held pre-standard medigap policies.

4 Part D's late enrollment penalty is 1 percent of the base beneficiary premium for each uncovered month. The enrollee would pay this penalty each month for the rest of her life (or as long as she was enrolled in Part D), and the penalty would reflect each year's new (and presumably higher) base premium. An individual who postpones signing up until fall 2006 with coverage beginning on January 1, 2007, would pay a penalty of about $2 to $3 per month throughout 2007.

5 Enrollees with standard benefits will pay 100 percent coinsurance for drug spending greater than $2,250 but less than their catastrophic threshold. However, beneficiaries will be able to obtain their plan's discounted price for prescription drugs for drug spending in this coverage gap. They will need to adhere to their plan's formulary, prior authorization, and formulary exceptions processes to receive credit for their out-of-pocket spending toward the $3,600 catastrophic limit.

6 The term "true out of pocket" refers to a feature of Part D in which fewer federal subsidy dollars are directed toward enrollees who have supplemental coverage. Specifically, only certain types of spending on behalf of the beneficiary count toward the catastrophic threshold: the beneficiary's own out-of-pocket spending, that of a family member or official charity, supplemental drug coverage provided through qualifying state pharmacy assistance programs or Part D's low-income subsidies, and supplemental drug coverage paid for with Medicare Advantage rebate dollars under CMS's demonstration authority.

7 The low-income premium subsidy amount is calculated as the greater of the low-income benchmark premium (a weighted average of all PDP and MA–PD premiums for basic benefits in each region) or the lowest PDP premium for basic coverage.

8 Duals may select a different plan from the one to which they are auto-enrolled up to once per month.

9 Since fewer beneficiaries were enrolled at the start of 2006 than by May 15, OACT's average estimate of Part D and RDS coverage for 2006 is 29 million (Boards of Trustees 2006).

10 This number excludes demonstration programs, 1876 cost plans, and other plans not open to all Medicare beneficiaries such as employer-group plans and plans in U.S. territories.

11 The term actuarially equivalent refers to the expected value of each plan's benefit, not the expected value of the combination of benefit spending and enrollee premiums.

12 The relative magnitude of this difference between payments and bids varies geographically, based in part on how the Medicare+Choice program (the precursor to Medicare Advantage) paid particular counties. (For more on how the Medicare+Choice program categorized counties for payment purposes, see MedPAC 2005a.) Differences between payments and bids lead to different MA–PD premiums.

13 Plans that used the USP guidelines were granted safe harbor on the issue of discouraging enrollment of high-cost beneficiaries through their classification system.

14 Plans may list one drug in a category or class where only one drug is available.

15 CMS states, however, that plans may present a reasonable clinical justification for formularies that do not contain at least one drug for each of the USP formulary key drug types. If a USP formulary key drug type only includes drugs that are primarily covered under Part B, it is not CMS's expectation that these key drug types be represented on formularies.

16 Plans may apply utilization tools, such as prior authorization, for patients who start drug therapy in these categories (except for the HIV/AIDS category) during their enrollment in the plan.

17 For 2006, CMS did not establish specific criteria for drugs listed on a specialty tier, but indicated that it could be used for expensive products. (For 2007, CMS defined specialty tier more clearly and has stated that only Part D drugs with plan negotiated prices that exceed $500 per month may be placed on a specialty tier.)

18 For 2006, this list includes drugs that treat anorexia, weight loss, weight gain, fertility, cosmetic conditions, hair loss, symptomatic relief of cough and colds, most prescription vitamins and minerals, nonprescription drugs, barbiturates, and benzodiazepines. Most state Medicaid agencies covered benzodiazepines and continued to do so; they received the federal match for these expenditures. Beginning in 2007, Part D will not cover drugs used for the treatment of sexual or erectile dysfunction.

19 On the plan formulary data, CMS did not indicate which tiers were specialty tiers. Therefore, there may be some tiers that offer specialty-type drugs but do not claim this appeal exemption.

20 To meet the absolute minimum listing requirements for formularies, plans would have to list at least 425 drugs (NORC 2005).

21 Occasionally, plans list some brand name drugs on lower (generic) tiers and generic drugs on higher (brand name) tiers.

22 For example, among plans with specialty tiers, plans listed 60 percent of the drugs in the molecular target inhibitors class (part of the anticancer drugs) on their specialty tier.

23 We found that 25 percent of PDPs and 19 percent of MA–PDs use step therapy for at least one drug. CMS's website reports that higher percentages of plans are using step therapy.

24 Medicare Part B generally covers medications that can not be self-administered and that are administered by or under the supervision of a physician in the physician's office. Part B also covers oral anticancer drugs, hemophilia clotting factors, drugs furnished by dialysis facilities, drugs furnished as part of an outpatient procedure, and intravenous immune globulin provided in the home. Influenza, pneumonia, and hepatitis B vaccines are also covered under Part B.

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