CHAPTER 1

Monitoring the implementation of Part D

RECOMMENDATION

The Secretary should have a process in place for timely delivery of Part D data to congressional support agencies to enable them to report to the Congress on the drug benefit's impact on cost, quality, and access.

COMMISSIONER VOTES: YES 15 • NO 0 • NOT VOTING 0 • ABSENT 2

CHAPTER 1

Monitoring the implementation of Part D

In this chapter

- Description of the Part D benefit
- Performance measures for evaluating Part D implementation
- Paying plans, setting premiums, and enrollment in Part D
- The Medicare discount drug card and beneficiary outreach for Part D
- Formulary exceptions and the appeals processes
- Looking forward: Electronic prescribing and other areas of future research

This chapter examines some of the issues that will arise as CMS implements the Medicare drug benefit. We examine performance measures, premium variation, outreach and enrollment, and beneficiary grievance and appeals protections. Building on the work of other purchasers, CMS must determine how to measure the performance of plan sponsors and the overall drug benefit. Part D enrollees will face different premiums across the nation. Medicare will provide the same subsidy to plans on behalf of each enrollee, and enrollees will pay more if their plan's benefit spending is higher. Plans may be able to reduce geographic variation in premiums by managing enrollees' use of drugs. Nevertheless, higher premiums might lead to lower enrollment in some parts of the country. CMS will auto-enroll beneficiaries dually eligible for Medicare and Medicaid in Part D, but the agency may find it difficult to reach and enroll other low-income individuals.

On January 1, 2006, Medicare will begin a voluntary outpatient drug benefit known as Part D. A combination of stand-alone prescription drug plans (PDPs) and Medicare Advantage (MA)–Prescription Drug plans (MA–PDs) will deliver the benefit. In each of 34 geographic regions, plans will compete for enrollees on the basis of annual premiums, benefit structures, degree of access to specific drug therapies, and quality of services. Plans will bear some risk for their enrollees' drug spending. In order to encourage Medicare beneficiaries to enroll, the government will subsidize premiums by nearly 75 percent and will provide additional subsidies for beneficiaries who have low incomes and assets.

In this chapter, we describe issues related to CMS's implementation of the Medicare Part D benefit and discuss strategies for monitoring and evaluating this new benefit in the future. Because the policy goals of appropriate access, high quality, and reasonable cost sometimes compete with one another, Medicare must strike a balance among them.

Our research on drug benefit implementation issues suggests the following key findings:

- In the commercial market, purchasers rank cost as a top priority in evaluating the performance of their plan's drug benefit management. To evaluate drug benefit quality, purchasers use measures that track enrollees' access to pharmacies, needed drugs, and safe utilization. Purchasers also review measures on member satisfaction and on benefit administration, such as claims processing accuracy. For Part D, CMS intends to construct and use performance measures, but it has not yet selected or announced them for either short- or long-term analysis.
- CMS will be collecting a large amount of data on Part D, including drug use and plan benefit information. Congressional agencies will need Part D data to report to the Congress about the impact of Medicare payment policies on cost, quality, and access.
- Premiums for Part D will, in percentage terms, vary more across geographic regions than per capita drug spending due to the method of calculating enrollee premiums required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Plans may be able to reduce today's geographic variation in spending, somewhat, by managing enrollees' use of prescription drugs. Nevertheless, higher Part D premiums might lead to lower enrollment in some parts of the country.
- Because CMS will automatically enroll beneficiaries who are dually eligible for Medicare and Medicaid, these individuals could represent a disproportionate share of early enrollees in Part D plans. The share of dual eligibles varies considerably among each region's Medicare population. An open question remains: How will differences in the proportion of each region's Medicare population that CMS auto-enrolls affect geographic variation in Part D premiums?
- In the case of the Medicare discount drug card, CMS and other state agencies experienced difficulty in targeting outreach strategies to beneficiaries who are disabled, low income, less educated, or living in long-term care facilities. Auto-enrollment proved far more effective than voluntary enrollment and accounted for a larger share of the overall enrollment in the discount card program.
- Health plans and pharmacy benefit managers (PBMs) have well-established processes that involve the use of prior authorization and other techniques to manage drug utilization. Most plan members do not appeal denied formulary exceptions. Physicians frequently decide, when told of the prescribed drug's nonformulary status, that the formulary drug is acceptable. When physicians pursue requests, plans report very high approval levels. However, given the increased level of drug utilization likely to occur in 2006, the volume of appeals may increase.
- Beneficiaries who are dually eligible for Medicare and Medicaid will have fewer appeal rights under Part D than they currently have under Medicaid. For example, Medicaid programs must continue to provide ongoing drug treatment to beneficiaries while an appeal is underway. Part D plans will not face this requirement, and beneficiaries may be unfamiliar with new processes for appealing formulary decisions. When dual eligibles begin receiving their drug benefit from Part D plans, some of these individuals may be taking drugs that are not on their plans' formulary. Plans must develop transition policies that are adequate to ensure that beneficiaries continue to receive medications and do not delay or stop treatment because they face unfamiliar formulary exceptions processes.

Description of the Part D benefit

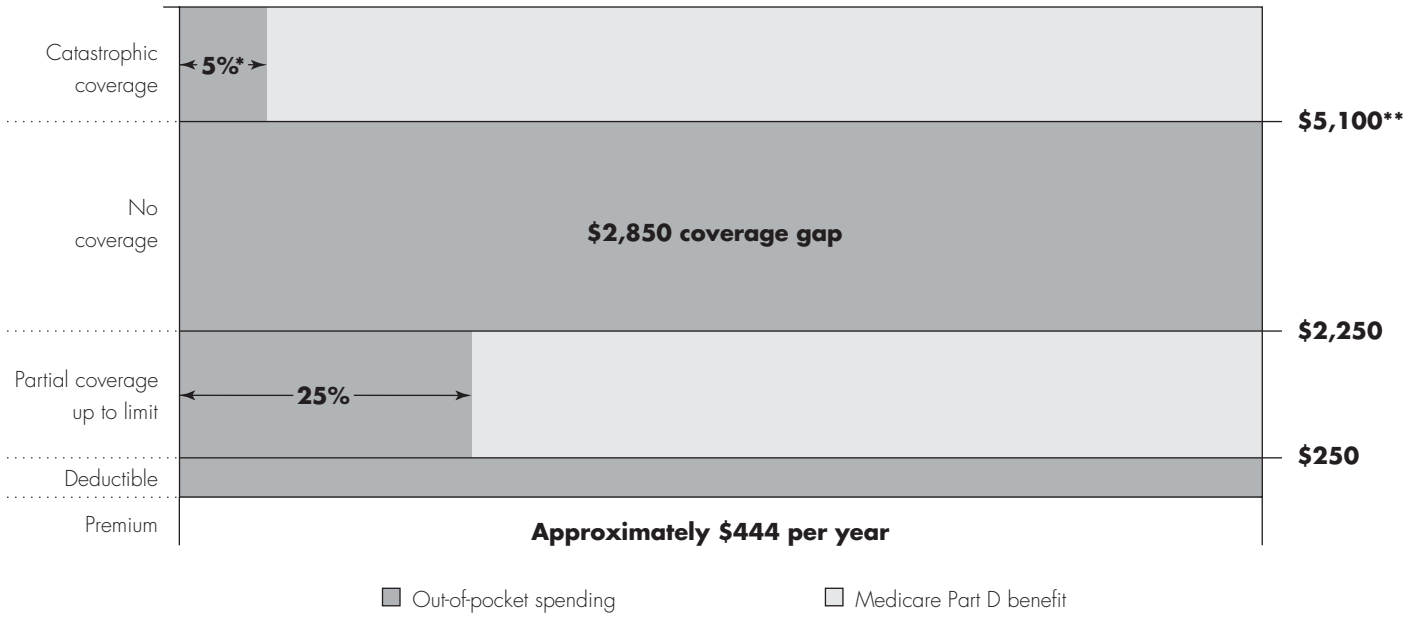
The MMA defines a standard drug benefit under Part D and describes the conditions under which private plans may offer alternative benefit designs. In 2006, the standard benefit will include:

- a $250 deductible;
- coverage for 75 percent of allowable drug expenses up to a benefit limit of $2,250;
- a $3,600 catastrophic limit on true out-of-pocket spending[1] (or $5,100 in total drug expenses for enrollees without supplemental drug coverage); and
- about 5 percent coinsurance for drug spending above the catastrophic limit (Figure 1-1).[2]

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 would also need to adhere to their plan's formulary, prior authorization, and formulary exceptions processes in order to receive credit for their out-of-pocket spending toward the $3,600 catastrophic limit.

Although the MMA explicitly lays out the structure of this standard Part D benefit, the law also permits plans to offer alternative coverage. For example, a plan could use tiered copayments rather than coinsurance, provided that cost sharing averages 25 percent of allowable drug spending above the deductible and below the benefit limit. The law permits other variations from the standard benefit—such as having a deductible lower than $250—provided that the alternative benefit meets certain tests of actuarial equivalence. CMS expects that enrollee premiums for these basic benefits will average $37 per month in 2006, but each plan's specific premium could vary.

FIGURE 1-1 **Standard drug benefit in 2006**



Note: Benefit structure applies for an enrollee who has no supplementary drug coverage.
* Cost sharing above the catastrophic cap is the greater of either 5 percent coinsurance or a copay of $2 for generic drugs, or $5 for brand-name drugs.
**Equivalent to $3,600 in out-of-pocket spending: $250 (deductible) + $500 (25% cost sharing on $2,000) + $2,850 (100% cost sharing in the "coverage gap").

Source: MedPAC analysis.

TABLE 1-1 **Out-of-pocket spending under the low-income drug benefit, 2006**

Beneficiary income	Premium	Deductible	Copayments*	Coverage gap
Dual eligibles, up to100% FPL	none	none	$1–3	none
Other dual eligibles and others, 100–135% FPL	none	none	$2–5	none
135–150% FPL	sliding scale	$50	15% of drug cost	none

Note: FPL (federal poverty level). Low-income beneficiaries must meet an asset test to qualify for low-income subsidies. In 2006, assets must be no greater than $10,000 for an individual or $20,000 for a couple.
*Plans may not charge copayments to dual eligibles who live in long-term care facilities.

Source: CMS 2005g.

The law provides additional subsidies for low-income beneficiaries. Medicare will begin providing primary drug coverage for individuals who are dually eligible for Medicare and Medicaid. Dually eligible individuals who earn incomes up to 100 percent of poverty will have no deductibles and nominal copays. CMS will randomly assign them to drug plans if they do not choose a plan by January 1, 2006, and these beneficiaries will be able to change plans at any time. Low-income beneficiaries who do not qualify for Medicaid may also receive subsidies: Individuals who earn incomes below 150 percent of poverty and who meet an asset test will receive full or partial coverage for premiums and cost-sharing and will not face a coverage gap (Table 1-1).

Medicare beneficiaries will likely see a variety of benefit designs available in the market. MA–PDs may offer broader coverage than the basic benefit (for example, by filling in the coverage gap) without charging an additional premium.[3] If a PDP or MA–PD meets the requirement of offering basic Part D coverage, it may also offer supplemental coverage for an additional unsubsidized premium. Even two competing plans—both offering the standard benefit—may appear somewhat different from one another because they can include different mixes of preferred and nonpreferred drugs on their formularies.

Performance measures for evaluating Part D implementation

Policymakers will need to monitor the implementation of the new Medicare drug benefit to evaluate plan performance and to measure how well Part D meets cost, quality, and access objectives for pharmaceutical care. Employers and government agencies use performance measures to evaluate how well health plans and PBMs manage the drug benefits they purchase.

MedPAC staff convened a panel of experts to discuss performance measures and to identify ways in which policymakers could use measures to monitor the Part D program over time and evaluate participating plans' performance. Under contract, Georgetown University researchers organized the panel and facilitated the meeting's full-day discussion. The panelists represented health plans, PBMs, employers, pharmacies, consumers, quality assurance organizations, and researchers.

The panelists were unable to reach a consensus on a specific set of performance measures that should be used for Part D plans, or even for drug benefits in the commercial market. However, they did discuss several areas of performance that purchasers (e.g., employers) consider when selecting and monitoring the health plan or PBM that manages their drug benefits. These areas of performance measures were:

- cost control,
- access to needed medications and quality assurance,
- benefit administration and management, and
- enrollee satisfaction.

Table 1-2 lists these areas of performance and, for illustrative purposes, provides an example of a measure in each area. Purchasers use many additional (and often more detailed) measures to assess health plan or PBM performance in managing drug benefits. Also, as we

TABLE 1-2

Examples of performance measures purchasers use to evaluate drug benefit management

Measurement areas	Examples
Cost control	
Plans' drug spending	Average drug spending per member per month (risk-adjusted)
Out-of-pocket drug spending	Average annual out-of-pocket spending on covered drugs (risk-adjusted)
Pharmacy discounts on drugs	Average rate of discount on brand and generic drugs
Pharmacy dispensing fees	Dispensing fees for brand and generic drugs
Manufacturer rebates	Total aggregated rebates as a percentage of total drug spending, annually
Drug utilization	Average number of prescriptions per member per year, by therapeutic category
Generic use	Ratio of generic drugs to total drugs that have an available generic
Formulary adherence	Ratio of preferred to nonpreferred brand-name drugs covered
Access and quality assurance	
Pharmacy network	Ratio of preferred network pharmacies to all pharmacies in service area
Enrollee refill adherence	Percentage of members who refill chronic medications
Formulary review process	Average time P&T committee takes for initial review of new drug
Prior authorization and nonformulary exceptions	Average time for plan decision on prior authorization request
Appeals process and rates	Percentage of appeals that are overturned
Point-of-sale electronic messaging to pharmacists	Frequency of updates to clinical safety messaging software
Utilization of drugs contraindicated for the elderly	Percentage of drugs contraindicated for the elderly on prior authorization
Adverse drug interactions, events	Number of adverse drug interactions and/or adverse drug events per 1,000 members
Drug utilization review	Presence of screening to identify drugs filled beyond maximum therapeutic duration
Electronic prescribing use	Percentage of prescriptions submitted through e-prescribing per year
Benefit administration and management	
Claims processing	Percentage of claims processed accurately per year
Eligibility determination	Percentage of claims processed for ineligible individuals per year
Data management for coordination of benefits	Accuracy of benefit-spending calculations
Enrollee satisfaction	
Enrollee survey results	Member satisfaction rates
Call-center availability	Hours per day that the call center is open
Call-center response times	Abandonment rates (percentage of time caller hangs up while on hold)
Grievance reporting	Average number of complaints reported per 100 members per year
Plan retention and disenrollment	Percentage of enrollees who voluntarily disenrolled

Note: P&T (pharmacy and therapeutics). The measures included in the second column are examples meant for illustrative purposes. Drug benefit purchasers (e.g., employers) may use many other more detailed measures to assess health plan or pharmacy benefit manager (PBM) performance. In some cases, results from these measures can be interpreted differently, depending on other plan variables.

Source: MedPAC analysis.

discuss later in this chapter, results from these measures can be interpreted in different ways, depending on other plan variables.

Under Part D regulations, CMS will collect data that CMS and other policymakers could use for performance measurement in most of these areas. For example, CMS will have information on beneficiaries' drug utilization and spending, plans' pharmacy network breadth, claims processing accuracy, and beneficiary satisfaction rates. In addition, CMS will have medical claims data for risk adjusting many of these measures. In its Part D regulations, CMS states that it will develop plan performance measures for the drug benefit, but the agency has not yet selected these measures or determined how they will be used.

Considering the complexity of implementing a drug benefit of this size, policymakers may expect some initial challenges and difficulties that likely will be resolved over time. Therefore, both short- and long-term analyses of Part D will be important. Indeed, evaluation at the start of the benefit can help identify the most useful measures to implement in the coming years. Once appropriate measures are selected and constructed, CMS could release some publicly, use some to determine financial awards in a pay-for-performance model, or factor some into future plan contracting decisions. Ultimately, CMS may use performance measures across the entire enrolled population to evaluate the drug benefit's implementation and make operational adjustments, where needed.

Cost control

Most panelists agreed that purchasers rank cost as a top priority in evaluating the performance of their health plan's or PBM's drug benefit management. In general, PBMs and health plans control drug benefit costs by negotiating with pharmacies and pharmaceutical manufacturers and by managing members' drug utilization. Although purchasers can track overall drug spending totals, their ability to evaluate plan performance on specific cost-control activities—such as formulary design—varies.

Negotiations with pharmacies and pharmaceutical manufacturers

PBMs and health plans establish retail pharmacy networks with which they negotiate discounts on prices for brand-name and generic drugs. Plans and PBMs also include negotiated dispensing fees in their pharmacy contracts; these fees can include incentives for substituting generic for brand-name drugs, when available (Mercer 2003b). Plans and PBMs provide purchasers with information on their negotiated dispensing fees. Similarly, CMS will require Part D plans to submit dispensing fee data. This information might serve as an indicator to CMS of how well plans negotiate with their pharmacy network to lower costs.

Some expert panelists noted that because generic substitution is an effective cost-control tool, purchasers commonly examine plans' generic dispensing rates—the number of covered generics as a percentage of total covered drugs or as a percentage of total covered drugs for which generics are available. CMS will collect generic dispensing rate data by plan and could use this information as one measure of plans' ability to control costs. CMS will also have drug claims data to allow calculation of generic dispensing rates for the Medicare population.

In addition to contracts with pharmacies, the majority of PBMs and health plans that provide pharmacy benefit services establish contractual relationships with pharmaceutical manufacturers to receive rebates. These rebates are typically based on target volumes of drug sales. Plans and PBMs provide purchasers with some information to show how much purchasers gain through rebates. For example, measures may show total dollars saved or the negotiated percent discount off the published average wholesale price. Panelists agreed that PBMs and health plans may share some portion of their rebate revenues with purchasers but do not always clearly disclose actual numbers. Several panelists commented that purchasers devote considerable resources verifying reported rebates, but they find this task difficult because PBMs generally consider the data to be proprietary.

Under Part D, Medicare will require plans to report aggregate rebates confidentially in order to estimate transaction prices. Plans will apportion a share of their total rebates to Part D utilization and report that amount. Previous lapses in government oversight of Medicaid drug pricing and manufacturer rebates highlight the challenge that Medicare will face in reviewing and auditing rebate information (GAO 2005). A few panelists suggested that CMS will need to monitor fraud and abuse and assert its right to audit participating plans. They noted previous legal actions filed against PBMs regarding misrepresentation of their cost-saving methods and objectives.

Drug utilization management

A plan's drug spending reflects the type and amount of drugs that members take. Drug utilization measures focus on both aspects. The National Committee for Quality Assurance (NCQA) has developed a few performance measures on drug utilization that employers can use when evaluating health plan performance. For example, NCQA collects data on plans' total prescription drug costs, the average cost of prescriptions per member per month, the total number of prescriptions, and the average number of prescriptions per member per year (NCQA 2005). Under Part D, CMS will collect data on some of these same measures. In combination with health claims data, these metrics will allow CMS to calculate risk-adjusted

spending and utilization trends for Part D to determine how well the drug benefit controls costs over time. These measures will also allow for some general drug-spending comparisons among Part D plan sponsors.

Much of the panel discussion on cost control focused on the broad set of activities that health plans and PBMs use to manage the drugs that members take. Among other goals (such as safety), these activities can steer enrollees toward specific drugs that the plans and PBMs determine are the most clinically appropriate and cost effective. For example, formulary design features—including drug lists, tiered cost sharing, step therapy, and prior authorization policies—can influence members' drug utilization. The MMA states that Part D plans are expected to use a variety of drug utilization management activities, some of which they currently employ with their commercial clients.

Health plans and PBMs commonly use drug utilization review (DUR) to manage the costs associated with enrollees' drug utilization. Such DUR activities may include screening for overutilization of drugs. These screens can help plans and PBMs achieve cost savings (in addition to improving safety) by automatically reviewing instances in which enrollees refill prescriptions beyond their maximum therapeutic timeframe.

Several panel experts suggested performance measures that assess the impact of utilization activities. For example, formulary compliance measures examine rates at which members take preferred over nonpreferred brand-name drugs. Physician prescribing and patient preferences strongly influence these rates, but health plans and PBMs have several tools to educate physicians and members on the rationale for distinguishing drugs by preferred and nonpreferred tiers. Generic dispensing rates also provide a measure of drug utilization management. Experts in our panel emphasized that physicians have considerably more impact on members' drug choices than do plans' utilization management activities. Health plans, particularly those in group staff models, typically communicate more with their prescribing physicians and thus may have more opportunities to influence prescribing patterns than do independent PBMs.

Out-of-pocket spending

Many group health purchasers also monitor enrollees' out-of-pocket spending as it affects enrollee (employee) satisfaction. In general, plans' success at lowering some drug prices will reduce their members' out-of-pocket spending on those drugs. However, depending on enrollee utilization, some drug utilization tools—such as tiered cost sharing—that lower *purchaser* costs may raise enrollee out-of-pocket costs. In their reports to purchasers, PBMs and health plans often separate out-of-pocket spending from the benefit's covered spending.[4]

Some experts on the panel stated that beneficiaries are extremely interested in how Part D will affect their out-of-pocket spending, including premium payments. Participating plans will submit data to CMS that will enable the agency to compute beneficiaries' average out-of-pocket spending on covered drugs. These calculations will be essential for policymakers' evaluation of Part D over time. CMS could also calculate and monitor average, risk-adjusted, out-of-pocket spending by plan. When making enrollment decisions, this kind of information might help beneficiaries determine which plans can give them the best value.

Access and quality assurance

The Congress established Part D to improve Medicare beneficiaries' access to needed medications, and included provisions in the program to encourage safe utilization. Panelists described a variety of measures that drug benefit purchasers use to evaluate enrollee access to medications, and whether the covered medications they take are appropriate and safe. Because pharmaceuticals are so central to effective medical treatment, some purchasers also may consider access to prescription drugs a measure of plan or PBM quality. Under Part D, plans will have financial incentives to control costs, highlighting the need for access and quality measures. CMS will be collecting some relevant data that can be used to develop access and quality measures for plans and—for the Medicare drug benefit, overall.

Pharmacy access

Some panelists noted that pharmacy access is a major factor in plan and PBM selection—both for group health plan purchasers and for individuals who are purchasing their own drug coverage. Measures of pharmacy access evaluate members' ability to obtain their medications conveniently. When making contracting decisions, purchasers often request detailed reports on the locations of the pharmacies in health plan and PBM networks. For example, employers may compare employee zip codes to the locations of plans' pharmacies.

Under Part D, Medicare requires a minimum level of pharmacy access based on standards set for the TRICARE program—the program that insures members of the U.S. military and their dependents. This standard specifies maximum average distances to plans' network pharmacies within a state, based on the type of geographic area (rural, urban, or suburban). In general, these minimum pharmacy access standards are adequate for most beneficiaries, but some beneficiaries who live in rural areas may have to travel more than 15 miles to reach a network pharmacy. Some panelists stated that Part D plans with broad pharmacy networks will likely attract more consumers because beneficiaries tend to focus heavily on the convenience of a plan's pharmacy network when selecting a plan.

Although plans may have many pharmacies in their network, and minimum access standards exist, Medicare may still need to monitor beneficiary access to pharmacies. In particular, plans can distinguish between preferred and nonpreferred pharmacies in their overall networks by offering lower cost sharing for preferred pharmacies. In such circumstances, access to preferred pharmacies may not meet TRICARE standards in some areas. To identify access problems (if they exist), CMS could examine beneficiary distances to preferred and nonpreferred pharmacies by zip code.

Access to needed medications

To ensure that drug utilization management programs do not prevent enrollees from obtaining needed medications, purchasers can examine measures that show enrollees' access to drugs. For example, purchasers may examine the number of drugs plans list on their formulary. However, several panelists cautioned that formulary designs do not directly reveal drug access. In practice, enrollees may have either greater or lesser access to drugs than a formulary's drug list suggests—that is, plans can cover drugs that are *off* the formulary and, alternatively, can require prior authorization for drugs that are *on* the formulary.

The panelists considered other performance measures that could reflect access, but many again noted that the data might be ambiguous. For example, the ratio of formulary to nonformulary drugs covered might be a useful measure, but it is difficult to interpret. A high share of nonformulary use could indicate that the plan employs a flexible exceptions process to ensure that members get the drugs they need. Alternatively, this high share could indicate that the formulary is out of date or that physicians do not find it acceptable. A low exception ratio may mean that physicians consider the plan's process for granting a nonformulary exception too onerous—or, alternatively, that the formulary is relatively unrestrictive and well-accepted by physicians. A plan's rate of overturned appeals has similar caveats.

Panelists discussed some approaches that Medicare could use to measure access to medications under Part D. Some panelists suggested that CMS evaluate exception rates within selected therapeutic categories. This measure could show whether beneficiaries can obtain necessary drugs for a given condition. Others suggested access measures on the frequency of claim denials at the point of sale, and whether enrollees later obtained an alternative drug or got their plan to cover the drug through a prior authorization or formulary exception.

Some purchasers use other access measures to examine member adherence to treatment regimens, particularly for chronic conditions (Berman 2005). CMS could use claims data to calculate the average number of times per year that members refill their monthly prescriptions, by therapeutic class. By carefully analyzing beneficiary access to medications by therapeutic category, CMS could also examine how differences in variables, such as formulary design and cost sharing associate with differences in adherence rates.

Part D addresses access concerns for people who have expensive, chronic conditions by prohibiting plans from excluding from their formulary whole classes of drugs used to treat expensive conditions, such as AIDS. CMS will require Part D sponsors to submit for review formularies and other drug management utilization programs, such as step therapy rules that encourage the use of low-cost medications before covering high-cost medications for a given medical condition. During the bidding process, CMS intends to review plans' drug utilization management requirements to ensure that beneficiaries receive appropriate and timely access to medically necessary drugs. CMS's review of drug utilization programs, including formularies, is consistent with that of group health purchasers; these purchasers require their contracted PBM or health plan to demonstrate their formulary's cost effectiveness and clinical appropriateness, thus ensuring that members can obtain the drugs they need (Mercer 2003b).

Quality assurance

By facilitating access to appropriate medications, health plans and PBMs go a long way toward ensuring health care quality. Many purchasers also look at measures that evaluate the safety and appropriateness of medication dispensing and prescribing. Integrated health plans are usually accredited and have built-in incentives to manage their drug benefits to avoid medical complications. Part D regulations require plans to develop and submit an explanation of their own quality assurance systems, but these regulations do not require specific quality assurance performance measures.

The need for quality assurance measures and systems to reduce medication errors and adverse drug interactions is well documented for the elderly population (Booz Allen Hamilton 2004, Goulding 2004, Fick et al. 2003, Beers 1997). However, peer-reviewed literature does not reach consensus on methods for determining which drugs are appropriate for the elderly, and under which circumstances. NCQA has recently proposed some prescription drug measures to examine safe drug utilization in its health plan accreditation process (see text box, p. 12). One of its proposed measures assesses how well health plans reduce their elderly members' use of drugs that are contraindicated for elderly people. CMS will have the data needed to implement this kind of quality assurance measure. With its medical and drug claims data, CMS also could begin to examine the frequency of emergency room visits due to adverse drug events and drug-to-drug interactions, depending on the adequacy of claims' diagnosis information.

A common tool that health plans and PBMs use for quality assurance is point-of-sale electronic messaging to alert pharmacists about safety concerns before dispensing particular drugs. Claims processing systems typically screen for potential drug interactions, overuse, incorrect dosage, allergy contraindications, and clinical abuse or misuse. Performance measures, therefore, often examine whether plans employ these types of alerts, whether the alerts are up to date with best clinical practice, and whether pharmacists find the messages clear and easy to understand.

Some panelists indicated that pharmacists receive a large number of messages and alerts. This barrage of messages may lead some pharmacists to ignore many alerts in order to fill prescriptions in a timely manner. One recent report to CMS noted that too many redundant messages and outdated warnings may cause pharmacists to disable electronic messaging features or routinely override messages (Booz Allen Hamilton 2004). The Academy of Managed Care Pharmacy (AMCP) has published guiding principles on electronic messaging systems. One principle suggests that plans and PBMs revise their claims processing systems to eliminate the number of redundant messages that pharmacists receive per claim, such as the following two similar messages: "drug not covered for females" and "drug not covered for patient gender." By eliminating such redundancies, plans and PBMs could improve pharmacists' ability to focus on important clinical safety alerts.

The expert panelists agreed that physician prescribing remains the most important and influential component of quality assurance in drug utilization. Accordingly, health plans and PBMs are exploring ways to educate physicians at the moment in which they prescribe medication therapies. Electronic prescribing (e-prescribing) technology can help physicians make safe prescribing decisions, prescribe formulary medications, and reduce errors due to illegible handwriting. We discuss e-prescribing further on page 33.

Health plans typically focus more broadly on quality assurance than PBMs because they provide an integrated benefit package and seek accreditation. Health plans have a greater opportunity to integrate measures of pharmaceutical quality with broader measures of quality of care. A number of organizations measure and evaluate health plans' quality assurance programs for accreditation purposes. Because PBMs usually are not independently accredited, they do not necessarily evaluate their performance on the same specific measures, but PBMs may adopt practices that are consistent with the accreditation standards required of their client health plans (Booz Allen Hamilton 2004).[5] Also, health plans are typically at risk if prescription drug utilization or underutilization results in medical complications; thus, health plans have built-in incentives to monitor and improve the safety of members' prescription drug utilization. PBMs are not usually at risk for medical costs—such as hospitalizations—that are associated with underutilization of needed medications or unsafe drug utilization. Additionally, PBMs that are not integrated within a health plan or insurer do not typically collect data on their enrollees' health status and health care utilization.

To encourage plans to connect health outcomes with prescription drug use, the MMA requires that all Part D plans offer a medication therapy management program

(MTMP) to targeted beneficiaries—namely, those who have multiple chronic conditions, are taking multiple medications, or have high expected drug expenses. MMA introduced the MTMP to improve therapeutic outcomes through activities such as pharmacist consultations. These consultations could include a review of member beneficiaries' full drug regimens to detect the potential for adverse drug interaction as well as patterns of prescription drug overuse and underuse. In the early stages of the Medicare drug benefit, CMS will allow plans to determine the methods and types of providers they will use to implement MTMP services. CMS is delaying the collection of performance measures for these programs but will require plans to report some operational data, such as the numbers of eligible and participating beneficiaries. Considering that the MMA expects MTMPs to improve

Current and proposed drug utilization and quality measures in HEDIS

The Health Plan Employer Data and Information Set (HEDIS) is a set of standardized performance measures designed to allow purchasers and consumers to compare managed care organizations on the basis of quality. HEDIS is a model for emerging systems of performance measurement in other areas of health care delivery. The National Committee for Quality Assurance (NCQA), a not-for-profit organization that evaluates and publicly reports on the quality of managed care organizations, maintains HEDIS.

In 2006, health plans will report on more than 60 HEDIS performance measures, including measures that assess appropriate medication treatment for patients with asthma, depression, heart attack, and other conditions. Below are some of NCQA's current and proposed HEDIS measures that relate specifically to prescription drugs:

- **Outpatient drug utilization.** This current measure summarizes data on outpatient utilization of prescription drugs. It includes the total cost of prescriptions, the average cost of prescriptions per member per month, the total number of prescriptions, and the average number of prescriptions per member per year.

- **Antibiotic utilizations.** For 2006, NCQA proposes to look also at possible overutilization of selected antibiotics known to contribute to antibiotic drug resistance compared with overall antibiotic use. The measure provides information on outpatient antibiotic use by drug class, including total and average number of antibiotics per member per year and average days per antibiotic prescription.

- **Pharmacotherapy management of chronic obstructive pulmonary disease (COPD) exacerbations.** This proposed measure assesses whether members who were discharged home following a COPD exacerbation episode treated in the emergency department or in an inpatient hospital setting received systemic corticosteroids within 7 days and/or bronchodilators within 21 days.

- **Drugs to be avoided in the elderly.** Among health plan enrollees age 65 and older and in Medicare, proposed HEDIS measures include two rates: (1) the percentage who received at least one prescription for a drug to be avoided in the elderly, and (2) the percentage who received prescriptions for at least two different drugs to be avoided in the elderly. The first rate assesses the extent to which elderly patients have had some exposure to potentially harmful drugs. The second rate further assesses if elderly patients have been exposed to multiple harmful drugs. NCQA identifies drugs to be avoided in the elderly population based on clinical journal publications and clinical consensus.

- **Annual monitoring of patients on persistent medications.** This proposed patient safety measure would assess whether adults taking medications for chronic conditions are receiving timely monitoring to prevent potential problems associated with persistent use of these drugs, including drug toxicity, electrolyte imbalances, renal failure, and liver damage. ■

therapeutic outcomes, performance measures that assess reductions in adverse health events due to drug-to-drug interactions may be an important future measure.

Benefit administration and management

Purchasers rely on health plans and PBMs for administrative functions such as processing prescription drug claims, managing drug identification cards, and adjudicating primary and secondary payer information. The expert panelists stated that performance measures for these tasks are relatively common, and CMS could monitor them under Part D.

Generally speaking, PBMs and health plans are able to process most drug claims almost instantaneously through electronic communication links with their network pharmacies, but delays and errors can occur. Many purchasers routinely look at the accuracy of their PBM's eligibility determinations, dispensing fee payments, and cost-sharing charges (Mercer 2003b). Many panelists noted that if CMS monitored these administrative tasks at the beginning of Part D implementation, beneficiaries may experience smoother enrollment into the Medicare drug benefit.

Under Part D, plans will need to provide pharmacies with drug price information so that they can calculate beneficiary cost sharing at the point of sale. Additionally, plans must provide monthly statements to beneficiaries explaining their year-to-date drug spending, if any. CMS will contract with a single company that will provide Part D plans and CMS with electronic information regarding other payers (e.g., employer-sponsored supplemental plans that wrap around the Medicare plan).[6] Plans will use this information to track members' out-of-pocket spending for covered drugs. CMS could implement performance measures on the accuracy of cost-sharing charges to ensure that beneficiaries are paying the correct amounts for their medications.

Enrollee satisfaction

Health plans and PBMs commonly measure member satisfaction rates and offer relevant performance guarantees to their clients. In addition to survey results, purchasers can also examine plans' call-center performance and disenrollment rates to evaluate member satisfaction. Panelists noted that both CMS and Part D plans could conduct some of these activities.

Satisfaction surveys

Health plans and PBMs routinely provide their current and potential clients with results of enrollee satisfaction surveys (Mercer 2003b). Purchasers typically determine their own target threshold for enrollee satisfaction, recognizing that they may not be able to compare rates between plans that use different survey instruments. However, purchasers can track enrollee satisfaction over time when the plan or PBM presents the purchasers with periodic survey results.

Under Part D regulations, CMS will conduct consumer satisfaction surveys of Part D enrollees and provide the results to beneficiaries as they are making enrollment decisions. CMS is reviewing possible survey instruments and anticipates working with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey that measures beneficiaries' experience with their prescription drug coverage.[7] Using this survey, CMS can obtain consumer satisfaction rates directly from beneficiaries.

Call center operations

Many panelists stated that the performance of plans' and PBMs' customer-service call centers plays an important role in influencing enrollee satisfaction. Purchasers commonly examine the length of time that callers wait on hold, as well as abandonment rates (the share of calls in which the caller hangs up while waiting on hold to talk with a service representative). Under Part D, CMS could collect the same performance measures that it currently collects for the discount drug card program—namely, hours of operation and call-center response times. Some panelists also suggested that CMS collect data on call centers' ability to serve non-English speakers.

Retention and disenrollment rates

By examining the extent to which members voluntarily stay in or disenroll from plans, CMS will have additional indicators of consumer satisfaction. Under Part D, beneficiaries will be able to switch plans once during the year, and more frequently if they are eligible for Medicaid or if they reside in long-term care facilities.[8] In general, plans with high retention rates are likely to show higher consumer satisfaction than plans with lower retention rates. In addition, Medicare can use this information to track beneficiary satisfaction with the Part D benefit, as a whole.

Data needs

As noted above, CMS will be collecting a large amount of data on Part D, including drug utilization and plan benefit information. In addition to claims and spending data, Part D sponsors must submit data on pharmacy discounts, aggregate pharmaceutical manufacturer rebates, generic dispensing rates, formulary design, prior authorizations, nonformulary exceptions, appeals, coordination of benefits for out-of-pocket determination, call-center operations, grievances, and enrollment/disenrollment. CMS will also collect satisfaction survey data from beneficiaries and additional health claims data from other providers. Therefore, CMS will have a rich and comprehensive set of data for Part D analysis. Indeed, CMS will have more robust information on Part D than it collects on Part C—the Medicare Advantage program.

CMS has stated that it intends to construct and use performance measures to monitor the Part D benefit. At this time, CMS has not yet selected these measures or determined how they will be used. In the long term, these uses could include (but are not limited to) releasing some measures publicly, using some measures to determine financial awards in a pay-for-performance model, or factoring some measures into future plan contracting decisions. In addition to using measures to assess plan performance, CMS could also use them to assess how well the overall benefit is meeting its objectives for the beneficiary population and could design operational changes accordingly.

At the start of the benefit, plans are likely to encounter several logistical challenges. Therefore, analysis of plan performance in the initial year should take these difficulties into consideration. Data analysis of the early stages of Part D will be essential to help policymakers identify and shape important and useful performance measures for the program over time.

In addition to CMS, congressional support agencies are charged with reporting to the Congress about the impact of Medicare payment policies on cost, quality, and access. Data on Part D are necessary for analyzing program performance and making policy recommendations. Therefore, CMS will need to develop a process for the timely dissemination of Part D data to congressional support agencies.

RECOMMENDATION

The Secretary should have a process in place for timely delivery of Part D data to congressional support agencies to enable them to report to the Congress on the drug benefit's impact on cost, quality, and access.

RATIONALE

Congressional agencies need these data to monitor and evaluate the new Part D benefit in the initial stages of the program and over the long term.

IMPLICATIONS

Spending

- This recommendation would not increase federal program spending.

Beneficiary and provider

- This recommendation would have no direct impact on beneficiaries. It also would not affect provider cost or administrative burden because it does not require submission of additional data.

Paying plans, setting premiums, and enrollment in Part D

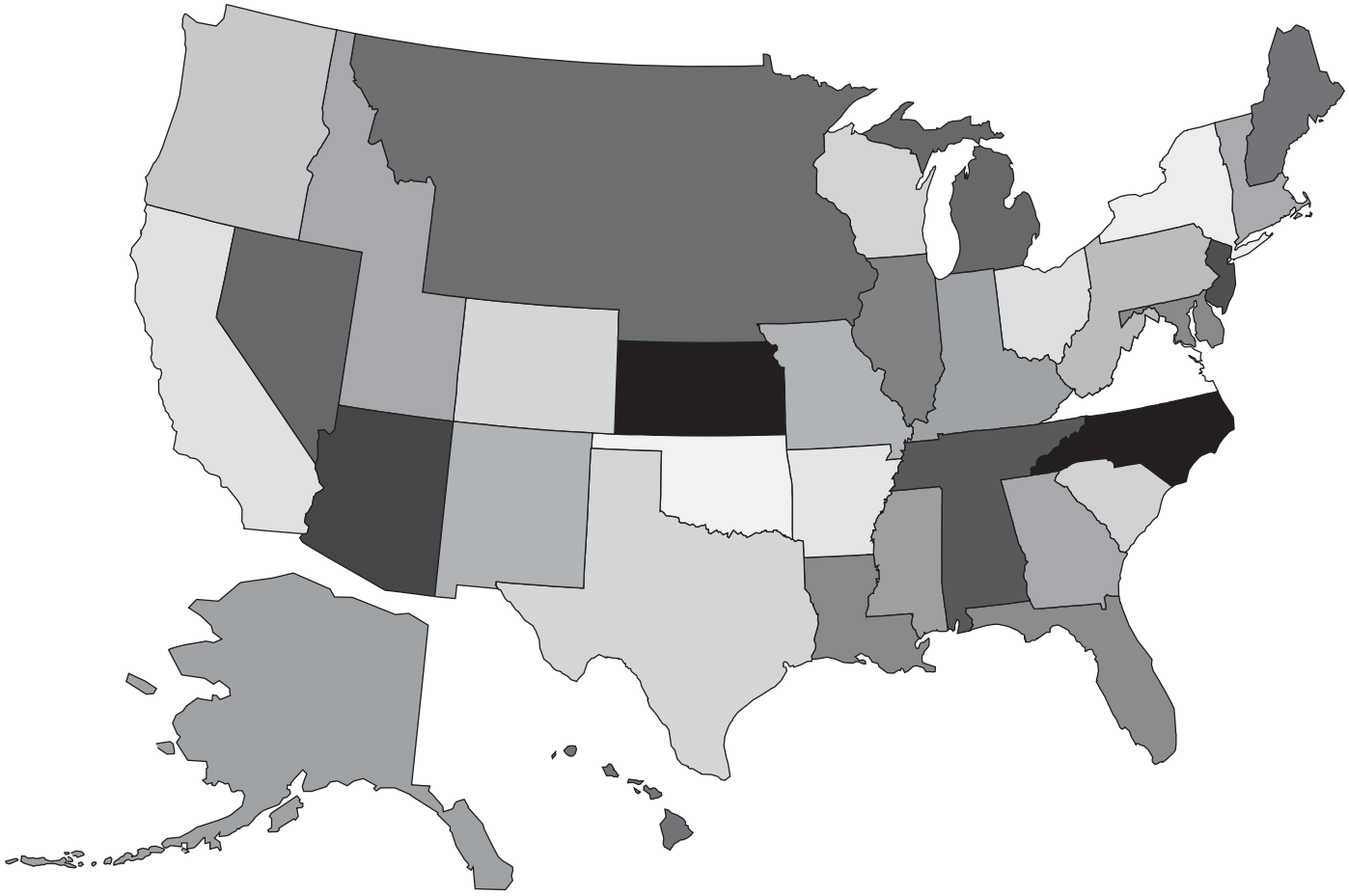
A number of private organizations have announced that beginning next year, they intend to offer PDPs nationwide, offer them in several PDP regions, or offer MA–PDs.[9] Although plan entry constitutes an important half of the equation in establishing Part D, uncertainty remains about how many Medicare beneficiaries will choose to enroll. Beneficiaries' decisions about whether to sign up for a Part D plan will depend, in part, on what premiums they must pay.

In this section, we review how CMS will pay Part D plans, how it will set enrollee premiums, and why premiums may vary across geographic regions. We discuss the following:

- ***Under Part D, enrollee premiums are likely to differ around the country.*** One implication of Part D's premium-setting approach is that beneficiaries who live in parts of the country with higher use of prescription drugs could face higher premiums than people who live in areas with lower use. Plans may be able to reduce this geographic variation by managing enrollees' use of prescription drugs. Nevertheless,

FIGURE 1-2

CMS established 34 PDP regions



Note: PDP (prescription drug plan).

Source: CMS 2005h.

higher Part D premiums might lead to lower enrollment in some parts of the country.

- ***Because CMS will auto-enroll beneficiaries who are dually eligible for Medicare and Medicaid, these individuals could represent a disproportionate share of early enrollees in Part D plans.*** The share of dual eligibles varies between 9 percent and 29 percent of each region's Medicare population. An open question remains: How will differences in the proportion of dual eligibles in each region's population affect geographic variation in Part D premiums?

Prescription drug plan regions

In late 2004, CMS announced its decision to establish 34 separate PDP regions, or groupings of states (Figure 1-2). Stand-alone drug plans must offer the same benefit and charge the same premium to all Medicare beneficiaries who enroll within a given PDP region.[10] A single legal entity may offer PDPs in several or all regions; CMS considers each of that company's regional PDPs a separate plan. Entities that have drug plans in several regions may choose to use the same formulary everywhere that they operate, but they are not required to do so. However, the company must submit separate bids to CMS for each PDP; as a result, premiums for that entity's plans could vary across regions.

When creating the regions, CMS considered three factors. First, it looked for combinations of states in which sufficient numbers of Medicare beneficiaries live, in order to ensure that at least two PDPs would have an economically viable risk pool.[11] At the same time, CMS did not want to make the eligible population of regions too large—potential Part D plan offerors expressed concern about the degree of insurance risk to which they would be exposed, particularly during Part D's startup. Second, CMS aimed to keep PDP regions as compatible as possible with MA regions; in doing so, CMS would avoid beneficiary confusion and simplify operations for MA–PDs. Finally, CMS sought to group states that had similar average levels of drug spending.

Medicare's payments to plans

Each plan (stand-alone PDP and MA–PD) will submit bids annually to CMS by the first Monday in June. Those bids should reflect the plan's expected benefit payments plus administrative costs after they deduct expected federal reinsurance subsidies. (See text box on federal subsidies at the end of this chapter.) Plans will base their bids on expected costs for a Medicare beneficiary of average health; CMS will then adjust payments to plans based on the actual health status of the plans' enrollees.

CMS will pay plans a monthly prospective payment (called a direct subsidy) for each enrollee. This payment equals the plan's approved bid times the enrollee's risk adjustment factor, minus the enrollee's premium for standard coverage. In addition, CMS may pay plans monthly prospective payments for average estimated individual reinsurance on high-cost enrollees with drug spending above the true out-of-pocket threshold. CMS will also pay plans monthly prospective payments for beneficiaries who are enrolled in Medicare's low-income subsidy program. Although CMS will provide these payments prospectively each month, the agency will reconcile actual levels of enrollment, risk factors, levels of incurred allowable drug costs (after rebates and other discounts), reinsurance amounts, and low-income subsidies at the end of each year.

Enrollee premiums

The main reason that beneficiary premiums will vary among plans is that enrollees must pay for any difference between their plan's bid and the national average bid amount. CMS bases the direct subsidy on a national weighted average of plan bids. Thus, enrollees in costlier plans could face higher-than-average premiums for standard Part D coverage; similarly, enrollees in less expensive plans would pay lower-than-average premiums. This situation will likely happen within a given PDP region. Likewise, beneficiaries who live in a part of the country with higher-than-average spending on prescription drugs may find that all plans in their area charge premiums that are higher than the national average. The situation would be reversed in regions with lower spending.

To calculate Medicare's direct subsidy, CMS will average the bids of risk plans (MA–PDs and PDPs), weighting each bid by expected levels of enrollment. Enrollees will pay a portion of the national average bid plus any difference between their plans' bid and the national average. (See text box for an example of how CMS will calculate enrollee premiums.)

Policymakers disagree on the extent to which geographic variation in Part D premiums is appropriate and acceptable. Differences in opinion stem from whether one believes that the costs of geographic variation in drug benefits should be borne by the individuals who live in regions that use more prescriptions, or redistributed more broadly across all enrollees. Some believe that Part B's approach—in which enrollees pay the same premium everywhere—is the fairer approach. Others believe that—like the Part D benefit—it would be fairer for Medicare to provide the same federal dollar subsidy to plans (adjusted for each member's health status) and require enrollees to pay more if their region's benefit spending is higher.

Geographic variation in prescription drug spending

The specific way in which Part D premiums are calculated—with the enrollee premiums picking up the full difference from the national average—tends to magnify, in percentage terms, geographic variation in drug spending. (See text box on p. 18 for a simulation of premium variation for a sample of Medicare beneficiaries.) But to what extent does drug spending vary? Such variation could occur if prices for the same drugs differ around the country, or if prescription drug use varies geographically.

Variation in drug prices

Several factors suggest that drug prices should not vary much across the country. Many of the entities involved in making, delivering, and managing prescription drugs (such as pharmaceutical manufacturers, retail pharmacy chains,

and PBMs) are large organizations with national contracts. As a result, one might not expect to see much variation in retail prices for drugs, except perhaps for differences in transportation expenses or the cost of retail operations.

Past research finds only limited evidence of geographic variation in prices. One recent study analyzed retail prices of prescription drugs posted on the website for the Medicare-endorsed drug discount cards. Researchers

How will CMS calculate enrollee premiums for Part D?

As a hypothetical example, assume that three plans submit bids to offer Medicare's new prescription drug benefit in 2006, and each plan has one-third of the total expected enrollment in Part D (Table 1-3). Plan 2 expects to have monthly drug claims, administrative costs, and profits that are about average, while Plans 1 and 3 expect to have costs that are higher and lower, respectively. To submit their bids to CMS, each plan will calculate monthly costs for a Medicare beneficiary of average health, and then subtract an estimate of the average monthly amount of individual reinsurance subsidies that the plan expects to receive from Medicare for its enrollees.

CMS will calculate the average of submitted bids, weighted by the plans' share of total enrollment. From this nationwide average, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) specifies that plan enrollees must pay a base premium plus any difference between their plan's bid and the nationwide average bid. The basic enrollee premium equals the nationwide average times a factor with a numerator of 25.5 percent and a denominator of 100 percent minus CMS's estimate of the plan's revenues for Part D benefits that it receives from federal individual reinsurance. In the example below, this sum equals $37 per month. Thus, the enrollee's premium is the sum of the base premium plus the difference between his or her plan's bid and the national average bid. ■

TABLE 1-3

Example of how monthly enrollee premiums could vary for three prescription drug plans

	Plan 1	Plan 2	Plan 3
Plan's expected cost of drug claims, administration, and profit	$164	$146	$128
Plan's expected individual reinsurance subsidies	– 42	– 38	– 33
Plan bid submitted to CMS	$122	$108	$95
Plan's expected share of enrollment in Part D	33%	33%	33%
National average bid	$108	$108	$108
Base enrollee premium	$37	$37	$37
Amount by which plan's bid exceeds the national average bid	+ 14	– 0	– 13
Enrollee's monthly premium	$51	$37	$24
Enrollee's monthly premium divided by the base enrollee premium	**1.36**	**1.00**	**0.64**

Note: All bid costs are for basic Part D coverage for a Medicare beneficiary of average health. The national average bid is the average plan bid weighted by each plan's share of enrollment. The base beneficiary premium equals the national average bid multiplied by [0.255 / (1 – CMS's estimate of the percentage of total plan revenue attributable to individual reinsurance subsidies)]. This example assumes no adjustment of premiums for geographic differences in the prices of prescription drugs.

Source: MedPAC analysis based on data from CMS.

Premium variation for a sample of privately insured Medicare enrollees

To demonstrate how Part D premiums will be set, we asked Direct Research, LLC, to analyze a sample of medical and drug claims for privately insured individuals who are also enrolled in Medicare—totaling about 1 million people in 2001. These data are not representative of the Medicare population as a whole: On average, the individuals for whom we have claims have more years of education, higher incomes, more comprehensive medical and drug coverage, and somewhat better health status than the typical Medicare beneficiary.

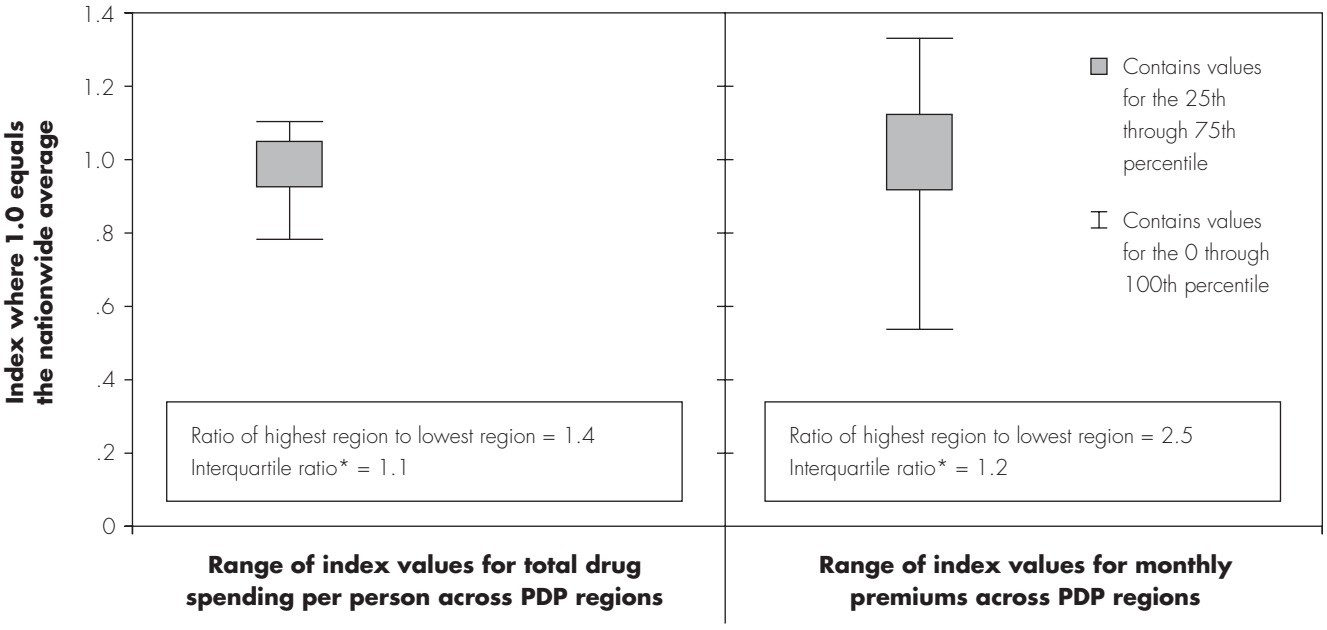
The data set includes the number and type of prescriptions filled at retail and mail-order pharmacies, by type of drug. For price information, we mapped nationwide average transaction prices for each national drug code (NDC) in 2001 medical expenditure panel survey (MEPS) data to NDCs listed on the private-payer drug claims. As is the case with many claims data sets, price information from MEPS excludes any manufacturers' rebates.

We used these data to examine two questions. First, how much geographic variation in drug spending exists? Second, what might premiums look like, assuming that all Part D plans have their region's average mix of enrollees? For each individual, we calculated the amount of Part D cost sharing that the enrollee would owe and what benefits a standard plan would cover, offset by federal individual reinsurance subsidies for people with very high drug spending. We calculated the average monthly cost per member for

continued on next page

FIGURE 1-3

Percentage geographic variation in drug spending and simulated premiums for a sample of privately insured individuals



Note: PDP (prescription drug plan). The nationwide averages have a value of 1.0, and regional values are depicted as an index relative to the nationwide mean. Premiums were estimated from privately insured prescription drug claims for individuals who are also enrolled in Medicare. Estimates assume that plan administrative costs are 5 percent of total enrollee drug spending. Premium estimates do not include assumptions about cost management savings or additional enrollee utilization associated with insurance coverage.
* The interquartile ratio is the value for the 75th percentile divided by the value for the 25th percentile. It measures the amount of variation across regions, an amount that is less influenced by extreme values.

Source: Direct Research, LLC, for MedPAC.

Premium variation for a sample of privately insured Medicare enrollees *(cont.)*

enrollees in each PDP region, adjusting for health status using risk indexes estimated with CMS's risk-adjustment model. We added costs to approximate a plan's administrative expenses. Finally, we estimated member premiums for each PDP region by following the MMA's formula—with members in each region paying the difference between their average plan costs and national average costs.

In percentage terms, our results suggest that enrollee premiums for this sample of individuals show more geographic variation than per capita drug spending (Figure 1-3). Across the 34 PDP regions, average per capita drug spending varies between a low of about 0.8 and a high of 1.1, where 1.0 equals the nationwide average. When ranked by drug spending per person, the highest-ranked region has spending that is 1.4 times that of the lowest-ranked region. In the middle of the distribution, regions at the 75th percentile have per capita spending that is 1.1 times that of regions at the 25th percentile. By comparison, the distribution of our simulated premiums is wider: ranging from about 0.5 to 1.3, where 1.0 equals the nationwide average. The highest ranked region has simulated premiums that are about 2.5 times those of the lowest ranked region, and the interquartile ratio for the distribution of premiums is 1.2. If the nationwide average Part D premium is $37 per month in 2006, enrollees like those represented by these claims data who live in regions that fall in the middle of this distribution (the interquartile range) might see premiums that vary by about $8 per month. Enrollees who live in most of the regions (spanning from the 10th percentile to the 90th percentile) might see premiums that vary by about $13 per month. Individuals who live in regions at the tails of this distribution would see greater variation in premiums.

In order to simulate premiums, we made a number of additional assumptions. We inflated each person's level of prescription drug spending in 2001 to 2006 levels, using nationwide projections of growth in drug spending. We estimated plan benefits as though no individuals would have supplemental drug coverage—and thus, they would reach Part D's catastrophic threshold at $3,600 in out-of-pocket drug spending. We did not include any adjustment of each person's spending levels to reflect changes in the relative generosity of their prescription drug coverage. Nor did we make any adjustments to reflect plan management that is more restrictive or less restrictive than that which already occurs in the underlying drug claims. It is possible that tighter management of prescription drug spending could lead to less geographic variation in spending than is observable today—and thus, premiums might not vary as much. We assumed that plan administrative costs would average about 5 percent of each region's total drug spending. Finally, these estimates are probably most sensitive to our assumption that Part D plans operating in each region have their region's average mix of enrollees. ■

found little or no variation in the lowest available price for the same drug across geographic regions (Bryant et al. 2004). On average, they found that retail prices were slightly lower in rural states; however, variation in prices across pharmacies within the same state was the more striking phenomenon. In an analysis of 1998 retail prices for 25 high-volume prescription drugs, researchers found that third-party payers in the Northeast and West were able to obtain greater discounts relative to cash customers than purchasers in the South and Midwest (Department of Health and Human Services 2000). In another study using 2002 data, researchers found only modest variation across the country in the average price of a prescription (Sager and Socolar 2004). However, researchers in that study did not control for differences in the mix of drugs used.

The MMA specifies that when calculating enrollee premiums, CMS may adjust the national average bid for geographic variation in prescription drug prices. CMS decided not to make such an adjustment in 2006 (CMS 2005a). The Department of Health and Human Services is looking into whether an adjustment may be necessary.

Variation in the use of prescription drugs

Geographic variation in Part D premiums will probably be more closely associated with variation in prescription drug use rather than variation in drug prices. In setting enrollee premiums, the MMA does not call for any geographic variation adjustment based on the use of prescription

drugs. However, the law does call on CMS to study whether this type of an adjustment would be appropriate and to report to the Congress by January 1, 2009.

Available evidence shows considerable variation in rates of use, as well as the mix of drug therapies that individuals use. For example, one study examined drug claims for insured individuals ages 18 to 64 during 2000 (Express Scripts 2002). After adjusting for age and gender, researchers found that the average annual number of prescriptions per member across states varied by 150 percent, with higher values in the South and Midwest and lower ones in the Northeast and West. The same study documented geographic variation in prescribing certain types of drug therapies. Calcium channel blockers, prescription cough/cold/allergy medicines, corticosteroids, and diuretics exhibited the widest variation. Similarly, another study documented variation in prescribing for nine drug classes for an insured population across a smaller geographic region—Michigan hospital service areas (Wennberg 2000). Among prescriptions for adults, researchers found the widest variation in antihistamines, anti-anxiety drugs, proton pump inhibitors, and statins.

Evidence of geographic variation in prescription drug spending

Various data sources provide information about prescription drug spending. These data sources include household surveys, manufacturer and retail surveys, and information from drug claims. Unfortunately, each of these data sources has limitations that complicate the analysis of geographic variation for the Part D benefit.

The limitations vary depending on the particular data set. Data from nationally representative surveys include too few individuals to estimate geographic variation; surveys of sales provide too little information about individual people; and claims data—which typically include many individual observations—are not fully representative of the Medicare population. The most widely used household surveys are designed to capture very detailed information about use of, and spending on, health care services from a limited number of respondents. However, these surveys do not include enough individuals to allow for an analysis of drug spending at the state level.[12] Surveys of manufacturers and retail outlets (including brick-and-mortar and sometimes mail-order pharmacies) serve as another source of information, but they only allow one to look at aggregate levels of retail sales or sales by type of drug, rather than drug spending per individual.[13] Insurers, health plans, PBMs, and some public payers (including Medicaid and state pharmacy assistance programs) collect very detailed drug claims. Currently, however, neither private nor public drug claims data sets are fully representative of the Medicare population. Beneficiaries who have either Medicaid or retiree coverage probably use more prescription drugs, on average, than the Medicare population as a whole, because those individuals either have more comprehensive coverage, are sicker, or both.

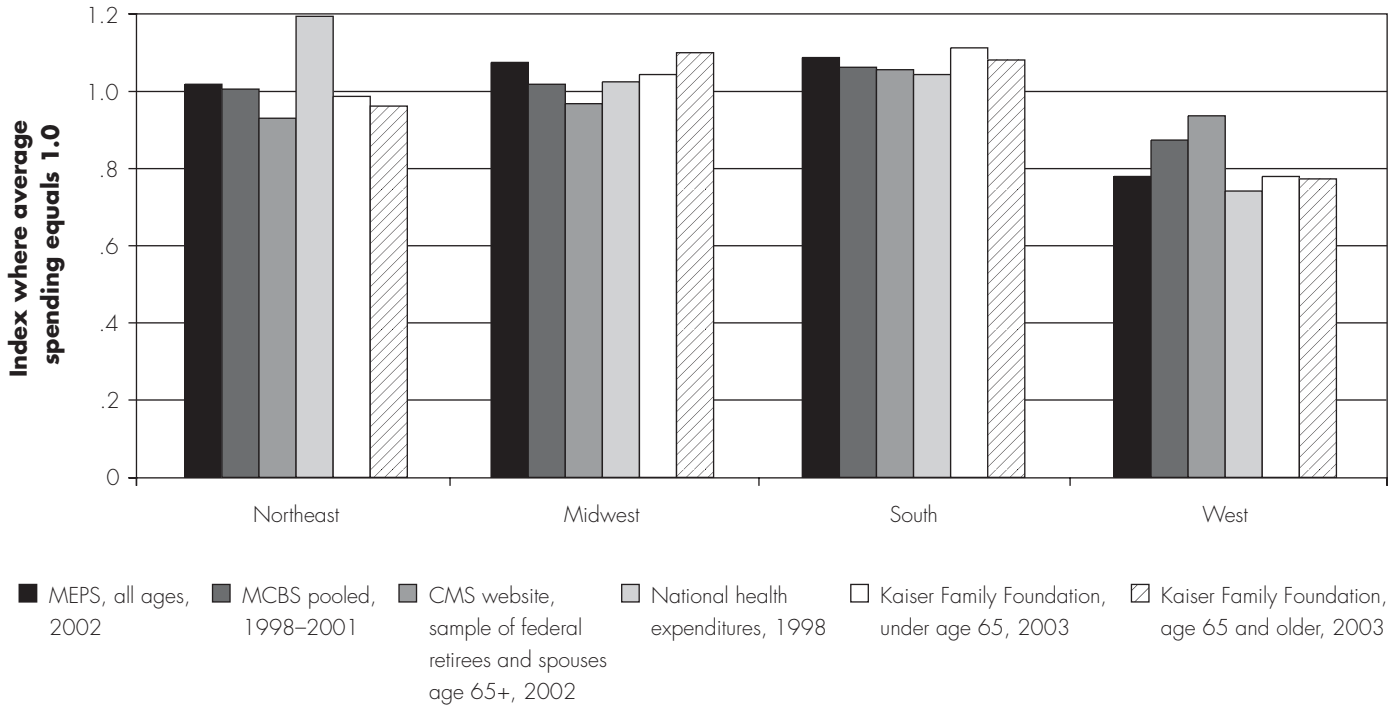
For Part D, CMS will require private plans to submit certain data from their drug claims to allow the agency to make and reconcile payments, build risk adjusters, and perform periodic audits. However, no such data are available today. CMS is using the same types of data described above—particularly the Medicare Current Beneficiary Survey, as well as Medicaid and private-payer drug claims.[14] The agency has also made much of its data available to organizations that are considering bidding to become Part D plans.

Due to the lack of a gold standard among drug data sets, plans face a very difficult task in constructing their initial bids for Part D. Some potential entrants—such as MA plans, insurers, and PBMs—can use their own existing claims information to help in that effort. Nevertheless, a plan's current data probably do not fully represent the mixtures of enrollees that the plan will have after January 1, 2006.

Although no gold standard exists among drug data sets, publicly available data suggest geographic variation exists in prescription drug spending. However, patterns in that variation are not consistent and depend on which data source one uses. Figure 1-4 divides the country into four regions—the Northeast, Midwest, South, and West. We needed to aggregate the data by these regions because data limitations, such as survey sample sizes, make less aggregate estimates unreliable. For each data set, we calculated average per capita drug spending by state and then calculated an average per region, weighted by population. We did not adjust those values for differences in health status. The absolute levels of per capita drug spending differ across data sets because each source reflects somewhat different populations and time periods. For that reason, Figure 1-4 shows regional variation around an index value of 1.0, which represents the overall national average specific to each data set.

FIGURE 1-4

Geographic patterns of per capita drug spending vary by data source



Note: MEPS (Medical Expenditure Panel Survey), MCBS (Medicare Current Beneficiary Survey, Cost and Use file). The U.S. average per capita spending level for each data source equals one. MEPS data reflect a nationally representative sample of the U.S. population. MCBS data reflect a nationally representative sample of Medicare beneficiaries. We pooled MCBS observations during the 1998–2001 period to increase sample sizes before constructing the index. CMS provided average levels of drug spending by state for a sample of federal retirees and their spouses who are age 65 or older. CMS estimated per capita drug spending at the state level for people of all ages using a variety of data sources for its national health expenditures. The Kaiser Family Foundation's estimates of drug spending are based on 2003 VectorOne data from Verispan collected from retail pharmacies, third-party payers, and other sources.

Source: Direct Research, LLC, for MedPAC.

Although they show some geographic variation, the data sets do not tell precisely the same story. In general, the data show that per capita drug spending in the South is somewhat higher than the nationwide average and that spending in the West is lower than average. One data set suggests that people who live in the Northeast have the highest spending per person; other data show that individuals in the Midwest or South have the highest spending per person.

Why does prescription drug spending vary?

A number of factors are likely to be associated with geographic variation in drug spending, including the health status of the individuals who live in a region, the number of providers who operate in the area, regional differences in prescribing patterns, the average incomes of beneficiaries in each region, and the availability of health and drug coverage.

Generally, one would expect individuals who are in poorer health to use more prescription drug therapies. CMS's Part D risk-adjustment model supports this expectation (CMS 2005a). CMS adapted its hierarchical condition category (HCC) model, which uses demographic and diagnosis information from Medicare Parts A and B claims (or comparable information submitted by MA plans) to predict plan claims' liability for a standard Part D benefit.[15] The model predicts more than 20 percent of variation in drug spending across individuals, which is higher than the risk-adjustment models CMS uses to predict spending for Parts A and B benefits.

In order to evaluate average health status across PDP regions, we used CMS's risk-adjustment model and calculated indexes of Part D benefit spending using diagnosis codes in 2001 claims data for a 5 percent sample of fee-for-service Medicare beneficiaries.[16] With a nationwide average of 1.0, those indexes range from 0.87 to 1.05 across the PDP regions (Table 1-4). The region with the highest index shows predicted drug benefit spending that is 1.2 times that for the region with the lowest index. The interquartile ratio—a measure less influenced by the tails of the distribution—is 1.1. Regions with the lowest risk indexes tend to be in the West and Midwest, but those with the highest indexes include regions in the South, East, and Midwest.

Because Medicare beneficiaries are, on average, healthier in certain parts of the country than others and because drug spending relates to an individual's health status, risk-adjustment models can help to predict geographic variation in drug spending. But by their nature, predictions of health status from such models are imperfect. In other words, risk-adjustment factors do not reflect all of the variation in health status that exists among Medicare beneficiaries. Thus, the underlying health status of beneficiaries in a region probably accounts for more of the geographic variation in drug spending than researchers can predict. One key reason is that researchers build risk adjustors from claims data, which have some well-known limitations. For example, providers may not record diagnoses thoroughly or consistently on claims. They are most likely to report diagnoses when they are actively treating a beneficiary for a condition. If an individual has a condition that does not require active intervention in a given year, providers may not list the diagnosis information on his or her claims.

Other factors that may explain geographic variation in drug spending include the relative supply of providers, the composition of that workforce, and physician prescribing patterns in the area. Previous research suggests that spending for Medicare Parts A and B by state is positively correlated with the number of specialists per 10,000 population and negatively correlated with the number of general practitioners per 10,000 (Baicker et al. 2004). Likewise, the relative availability and composition of a region's physician workforce may also explain how many prescriptions a population uses, on average. Patterns of prescribing may differ across regions. For example, it may be acceptable to prescribe antibiotics more routinely in some parts of the country compared with others.

Average levels of income are also related to variation in prescription drug spending, but third-party coverage complicates that relationship. Medicare beneficiaries who

TABLE 1-4

Variation in characteristics of PDP regions

	Range of values	Ratio of highest region to lowest region	Interquartile ratio[a]
Region's HCC risk index for covered drug benefit spending[b]	0.87–1.05	1.2	1.1
Percentage of region's elderly population			
with income less than 100% FPL[c]	7–19%	2.8	1.5
with income less than 150% FPL[c]	14–34	2.4	1.4
Percentage of region's Medicare population			
that receives a Part B buy-in[d]	9–29	3.2	1.6
who also have employer-sponsored coverage[e]	22–55	2.5	1.2
who are enrolled in Medicare Advantage plans[f]	<0.5–32	159.4	6.5

Note: PDP (prescription drug plan), HCC (hierarchical condition category), FPL (federal poverty level).
[a] The interquartile ratio is the value for the 75th percentile divided by the value for the 25th percentile. It measures the amount of variation across regions, an amount that is less influenced by extreme values.
[b] Estimated using CMS's model and based on diagnoses in 2001 claims for a 5% sample of Medicare fee-for-service beneficiaries. The nationwide average is 1.00.
[c] Based on the 2000 census.
[d] "Part B buy-ins" are dual eligibles for Medicare and Medicaid. Their state Medicaid program pays their Part B premium.
[e] Data pooled from the 1999, 2001, and 2003 Current Population Surveys.
[f] CMS Medicare Advantage state and county penetration report files, June 2004.

Source: Direct Research, LLC, for MedPAC.

have very low incomes may qualify for Medicaid and may thereby receive fairly comprehensive prescription drug coverage. Likewise, people who earn higher incomes are more likely to have employer-sponsored retiree health benefits, which often include drug coverage. In general, individuals who have third-party drug coverage tend to pay lower prices for a given drug at the point of sale, but they also tend to use a costlier mix of drugs compared to individuals with no drug coverage (Department of Health and Human Services 2000).

Average incomes of Medicare beneficiaries and the availability of health coverage vary broadly across PDP regions. For example, in some regions as few as 7 percent of the Medicare population earn incomes below the federal poverty level, while in other regions nearly 20 percent fall below the poverty level. The share of each region's beneficiaries who are dually eligible for Medicare and Medicaid (as measured by the number whose states pay for their Part B premium) ranges between 9 percent and 29 percent. The availability of and enrollment in employer-sponsored health coverage or MA plans varies even more widely.

Geographic variation in each of these factors suggests that considerable variation could exist in drug spending and in Part D premiums. On the other hand, private plans' efforts to manage the Part D benefit could reduce geographic variation in drug spending and in premiums.

Who will enroll in Part D?

Although important, premiums for Part D plans are just one of several factors that Medicare beneficiaries will consider in deciding whether to enroll in the new program. Part D is quite complex, and the general level of Medicare beneficiaries' understanding about the new benefit and how it works will be important in their decision making. In order to encourage broad initial enrollment, Part D includes a penalty for late enrollment similar to that of Part B. However, many Medicare beneficiaries may not be aware of or understand that provision yet. Even those who know more about the late enrollment penalty may find its initial level—about $5 per month for those who postpone signing up until 2007—low enough to be worth delaying enrollment until they know more about the program. The Commission suggests that CMS move as quickly as possible to determine whether the penalty amount fairly reflects any higher costs associated with delaying enrollment (MedPAC 2004). CMS should inform Medicare beneficiaries of the penalty and how it could affect their premiums if individuals delay enrollment.

More than six million Medicare beneficiaries—over 15 percent of the Medicare population—are eligible for Medicaid (MedPAC 2004). These individuals may represent a disproportionate share of early enrollees in Part D because CMS plans to auto-enroll them into plans at the end of 2005. As Table 1-4 shows, the percentage of each region's Medicare population that consists of dual eligibles varies considerably around the country. It is unclear how differences in the proportion of each region's Medicare population that CMS auto-enrolls will affect geographic variation in Part D premiums.

There is even greater uncertainty about how many other types of Medicare beneficiaries will enroll in Part D plans. Currently, Medicare beneficiaries get drug coverage from a variety of sources. In 2001, just over 30 percent of the Medicare population had retiree drug coverage. Decisions by these individuals about whether to enroll will depend on how their former employers respond to the introduction of Part D. About one-quarter of beneficiaries currently have individually purchased Medigap policies, and their response to Part D is also uncertain. Only a small share of those Medigaps currently include prescription drug coverage—this share makes up less than 10 percent of total enrollment in standard Medigap policies. It is unclear how many beneficiaries who purchase Medigap policies without drug coverage will be willing to pay an additional premium to enroll in Part D plans.

MedPAC plans to monitor enrollment trends in Part D. CMS will hold Part D's initial open enrollment period from November 15, 2005, through May 15, 2006. During that time, beneficiaries will likely receive a lot of information about Part D, both from CMS and from individual plans operating in each region. As we shall see in the next section, CMS will have to make that information easy to obtain and understand to ensure broad participation in Part D.

The Medicare discount drug card and beneficiary outreach for Part D

Before beneficiaries can enroll in Part D plans, they must learn about the program and the choices they face. In the months before Part D becomes effective, CMS, the states, beneficiary advocates, and drug plans must educate beneficiaries about the new drug benefit. In 2004, Medicare beneficiaries became eligible to enroll in the

Medicare-sponsored discount drug card program. Beneficiaries who earned incomes below 135 percent of the federal poverty level could receive additional subsidies. By implementing the drug card program, CMS provided states with some early experience in reaching Medicare beneficiaries and counseling them about prescription drug plan choices. We interviewed individuals who participated in these efforts to determine what lessons they learned that could improve outreach efforts for Part D.

Elderly and disabled Medicare beneficiaries will begin enrolling in Medicare prescription drug plans in November 2005.[17] To begin receiving benefits by January 1, beneficiaries must navigate a tight timeframe. CMS, the Social Security Administration (SSA), state Medicaid programs, and beneficiary advocates will have little time to educate beneficiaries about their choices, help those who are qualified apply for low-income subsidies, and help beneficiaries make informed decisions. State Medicaid officials and beneficiary advocates have found it particularly difficult to inform low-income Medicare beneficiaries about their health insurance options.

In this section, we examine the challenges that state officials and beneficiary advocates face in educating beneficiaries about the discount drug card program. Next, we assess the relevance of this experience for the outreach efforts designed to inform dual eligibles—and other beneficiaries who are eligible for low-income subsidies—about their choices in 2006.

We draw four key lessons from state experiences with the discount drug card:

- ***CMS and drug plans must provide accurate, easily obtainable information about plan options.*** Counselors emphasized that beneficiaries need timely and accurate information. In the first weeks and months of the discount card program, counselors and beneficiaries encountered difficulties using the web-based tool, inaccuracies in the information that CMS provided, and changes in plan offerings. This confusion may have deterred enrollment in the discount card program.

- ***CMS should design federal outreach efforts so that they direct beneficiaries to state outreach and enrollment activities.*** States currently are responsible for providing prescription drug coverage to many individuals who will need to enroll in drug plans under Part D, including dual eligibles and enrollees in State Pharmacy Assistance Programs (SPAPs). To avoid confusion and ensure access to information and counseling, CMS should send materials to Medicare beneficiaries that indicate sources of assistance available in the state in which they reside—including Medicaid, SPAPs, and State Health Insurance Assistance Programs (SHIPs)—state-based organizations that receive federal funds to provide information and counseling about insurance issues to Medicare beneficiaries.

- ***CMS needs to develop better strategies for conducting targeted outreach to Medicare populations.*** State officials found it difficult to reach low-income beneficiaries, individuals with disabilities, enrollees with low literacy, and beneficiaries with limited English proficiency. Interviewees emphasized the importance of one-on-one counseling to explain eligibility for complex programs such as Part D and noted that adequate resources for SHIPs are crucial. However, even with enhanced funding, SHIPs will not be able to counsel all beneficiaries who need help understanding their choices under Part D. CMS will need to inform physicians and pharmacists about the program because they often serve as trusted intermediaries for beneficiaries.

- ***CMS should consider auto-enrollment for prescription drug coverage and low-income subsidies for selected Medicare populations.*** Federal, state, and private outreach efforts were relatively ineffective in enrolling large numbers of beneficiaries in the discount card program. For example, of the estimated 7.3 million Medicare beneficiaries who were eligible to enroll in the transitional assistance program in 2004, only 1.5 million actually enrolled. Auto-enrollment was far more effective than voluntary enrollment and accounted for a large share of the overall enrollment. SPAPs and Medicaid officials, as well as SHIP directors and counselors, suggested that auto-enrollment will be a critically important step in the success of Part D.

The Medicare discount drug card program

The MMA included the discount drug card program to provide temporary assistance with the cost of prescription drugs to Medicare beneficiaries until the Part D benefit begins in 2006. In exchange for an annual fee of up to $30,

drug card enrollees receive discounts off the retail price of prescription drugs. The cost of the card and the discounts vary depending on the card a beneficiary selects and the drugs a beneficiary uses. Different cards offer different combinations of discounts on different drugs, and discounts also vary across pharmacies. Beneficiaries could enroll in a discount card at any time without penalty, but once they enroll they could only change cards once—between November 15 and December 31, 2004.

Medicare beneficiaries who earn incomes below 135 percent of the federal poverty level can also receive transitional assistance. Those who qualify do not have to pay enrollment fees and they receive a credit of $600 per year on their discount cards.[18] Beneficiaries who are enrolled in Medicaid or other public or private insurance plans (except for SPAPs) cannot enroll in the card program and are not eligible for the subsidy.

Similar to Part D, the discount drug card program is voluntary. Before the program began, federal government agencies, state agencies, and private plans all engaged in efforts to inform beneficiaries about available cards and subsidies and to facilitate enrollment. CMS and SSA sent mailings to all Medicare beneficiaries about the discount card and the availability of transitional assistance. These mailings informed beneficiaries that they could call a federal customer service line or use Medicare's website to obtain comparative information on discount cards. In addition, the federal government provided new funding to SHIPs to help beneficiaries who sought assistance in making choices about the discount cards. The private companies that sponsored Medicare-approved drug discount cards also marketed their cards to the Medicare population and received enrollment applications for the cards and for the low-income subsidy.

CMS implemented the program quickly. The agency approved card sponsor applications on March 26, 2004. Beneficiary enrollment began on May 3, and cards became effective on June 1. Beneficiaries could choose from 39 national cards as well as other regional cards. CMS estimated that 15.4 million beneficiaries were eligible for the program, including 7.3 million who were eligible for transitional assistance. Despite beneficiary education and outreach efforts by CMS, SHIPs, and SPAPs,[19] enrollment was lower than expected. By December 2004, 5.8 million beneficiaries had enrolled in discount card programs, including 1.5 million who were also receiving transitional assistance (CMS 2004).[20] The majority of these individuals were enrolled automatically through their MA plan or SPAPs.

MedPAC contracted with researchers at the National Opinion Research Center (NORC) and Georgetown University to examine state experience in helping to implement the drug card. They focused on the successes and challenges of outreach strategies and how these experiences might inform implementation of the Medicare drug benefit. Between March and September 2004, researchers conducted structured interviews with 46 state officials, pharmacists, and beneficiary counselors in 26 states.

State outreach strategies

In early interviews that researchers conducted before CMS implemented the discount card program, state officials indicated that states would conduct outreach activities, contingent on federal funding. These interviews revealed that the level of effort and resources committed to outreach would vary across states. For example, some SHIP programs are well-funded and supplement their staff through a large base of volunteer counselors in a wide variety of field locations. Other programs may have few volunteers and few outreach sites.

None of the interviewees suggested that they would implement outreach efforts to enrollees in Medicare Savings Programs, which include the Qualified Medicare Beneficiary (QMB) program and Specified Low-Income Medicare Beneficiary (SLMB) program. Few of these state officials had developed plans to target disadvantaged, frail, and isolated populations with information about the discount card. SHIP officials suggested that they had little capacity to identify beneficiaries who were potentially eligible for transitional assistance in their state.

Because Medicaid recipients were not eligible for the discount card, SHIPs and SPAPs primarily conducted the outreach for the discount drug card program. SHIPs typically conducted broad, community-based outreach to increase awareness about the discount card and low-income subsidy programs, and responded to requests for assistance and information. SPAPs generally undertook a more targeted approach. They actively reached out to their enrollees to ensure funding for those who were eligible for transitional assistance subsidies.

In general, SHIPs:

- tried to increase community awareness of the discount card and other prescription drug assistance programs, and
- included information about the cards and transitional assistance as part of their normal counseling services.

In general, SPAPs:

- sent direct mailings to their members providing information about the discount cards, and
- sometimes chose to auto-enroll their members in a preferred drug card program.

State experience with the discount card

With some exceptions, SHIP counselors reported low levels of interest in the cards and low levels of voluntary enrollment in both the discount card and transitional assistance programs. They identified a number of factors that limited voluntary enrollment, including a perception by beneficiaries that the program was too complex and offered relatively little savings to enrollees. SHIP counselors suggested that outreach efforts had failed to reach many of the low-income individuals who would benefit most from the $600 annual subsidy.

Interviewees emphasized the importance of one-on-one counseling for Medicare beneficiaries. In interviewees' experience, direct mailings, call centers, and website information all posed problems for communicating important information to beneficiaries. According to counselors, beneficiaries routinely receive large amounts of direct mail that advertise drugs and other health care services and items. As a result, official state mailings might attract no more attention than any other form of advertising. Low literacy, limited English proficiency, and limited understanding of health care programs also interfere with beneficiaries' ability to comprehend and act on direct mail instructions.

Additionally, counselors expressed concern that the 1-800-Medicare call center operators provided too much information, rather than helping beneficiaries narrow their options. Counselors also worried that these operators were conveying inaccurate information. In a 2004 study conducted by the GAO, researchers received inaccurate answers to 29 percent of their questions and could not obtain any answer 10 percent of the time. Among other recommendations, GAO suggested that CMS provide more thorough testing of contractors' ability to answer questions and monitor the accuracy rate for frequently asked questions.

Lastly, counselors expressed mixed feelings about the Medicare web-based decision tool that CMS developed. The agency intended this database—The Prescription Drug and Other Assistance Programs—to allow beneficiaries to compare discount cards. Counselors found this tool useful in their offices but inaccessible to most elderly beneficiaries. Even beneficiaries who were computer literate and had Internet connections in their homes were unlikely to have the high-speed connections necessary to use the drug card website.

On the other hand, some counselors reported that the publicity over the discount card created new opportunities for beneficiary education. Beneficiaries who did not previously know about the SHIP's resources came for counseling sessions and were screened for eligibility for other programs. Depending on the state, this could include Medicaid or SPAP screening, and screening for nonhealth programs such as energy assistance.

By comparison, SPAPs experienced success with auto-enrollment and facilitated enrollment in a preferred card or cards. In cases in which programs auto-enrolled beneficiaries, programs gave beneficiaries the choice of opting out of the program after enrollment. Eleven states used auto-enrollment to sign up their program recipients for a specific or preferred discount card or cards (Fox 2005). For example, New Jersey auto-enrolled all members who were eligible for transitional assistance into a preferred card program unless those members explicitly opted out of the program. Connecticut required all state program members who were eligible for transitional assistance to apply for a discount card and supplied them with a list of all the cards available within the state (Rutgers Center for State Health Policy 2004). States that used auto-enrollment achieved high participation rates in a short period of time—these rates ranged from 80 to 90 percent of eligible members. Conversely, the five states that encouraged members to voluntarily enroll in the discount card program experienced much lower enrollment rates, ranging from 2 to 40 percent (Fox 2005).

Lessons learned for implementing Part D

Interviewees suggested that the challenges of implementing the discount card program—and the resulting low levels of voluntary enrollment, especially

of beneficiaries who were eligible for the low-income subsidies—were likely to become more problematic in 2006 with the implementation of Part D. SHIP counselors worried about the program's complexity and noted that elderly Medicare beneficiaries would likely be confused by the drug benefit design, including the deductible, coverage gap, and catastrophic coverage. Interviewees noted that any changes to the operation of the benefit—for example, mid-year changes to the formularies—would compound the already formidable challenges to beneficiary education. SHIP counselors indicated that beneficiaries could feel overwhelmed by the number of choices they face and thus may fail to enroll in a program that could provide them with significant benefits.

Many interviewees acknowledged that their organizations are designed to assist a mainstream elderly population. However, the organizations are less equipped to effectively counsel hard-to-reach groups such as those in nursing homes or other long-term care settings; younger beneficiaries with disabilities; and members of racial and ethnic minorities who face linguistic, cultural, and educational barriers. Interviewees stressed the need for targeted strategies to reach these populations. They suggested that CMS should develop strategies that include physicians and pharmacists who experience daily contact with beneficiaries.

Interviewees repeatedly stressed the success of auto-enrollment in reaching low-income populations. When CMS implements Part D, the agency will auto-enroll Medicare beneficiaries who are also eligible for comprehensive Medicaid benefits in plans. CMS will not use auto-enrollment for other groups but will develop alternative mechanisms to facilitate enrollment for some other low-income groups. In particular, CMS may use such mechanisms to target individuals who are enrolled in the Medicare Savings Program if they have not enrolled in a Part D plan by May 2006. SPAPs had requested CMS to give them the authority to auto-enroll their members, but CMS did not accept this recommendation (CMS 2005b). CMS should monitor enrollment by low-income groups in Part D and increase auto-enrollment, if necessary.

Once beneficiaries enroll in Part D plans, they will have to learn how to use plan procedures to ensure that they receive needed drugs. In the next section, we examine plan formulary exceptions and appeals processes.

Formulary exceptions and the appeals processes

Medicare Advantage drug plans (MA–PDs) and stand-alone Medicare prescription drug plans (PDPs) can use techniques developed in the commercial market to control cost and enhance the quality of the drug benefit. These techniques include formulary development, tiered copayment benefit structures, prior authorization, pharmacy networks, and mail order pharmacies. Plans must establish formulary exceptions and appeals processes to ensure that these techniques do not deprive beneficiaries of access to needed medications.

MedPAC staff interviewed physicians, beneficiary advocates, pharmacists and representatives from health plans, and pharmacy benefit managers (PBMs) about formulary exceptions processes and beneficiary appeals. In this section, we present findings from our research on how the private market and Medicaid handle requests for prescription drugs that are not on a plan's formulary or require prior approval. We compare current practice with requirements under the Medicare drug benefit.

We found the following key findings:

- Plans and PBMs currently have well-established processes to handle formulary exceptions and prior authorization requests. Accrediting organizations and states scrutinize these processes, and the processes are similar to those that CMS regulations prescribe.
- Patients usually do not appeal denied requests for formulary exceptions. Physicians frequently decide that the formulary drug is acceptable, when the pharmacist informs them of the nonformulary status of the prescribed drug. When patients and physicians pursue requests, plans report very high approval levels.
- The volume of appeals may increase under Part D.
- Beneficiaries who are dually eligible for Medicare and Medicaid will have fewer appeal rights under Part D than they currently have under Medicaid. For example, Medicaid programs must continue to provide ongoing drug treatment to beneficiaries while an appeal is underway. Part D plans will not face this requirement. When dual eligibles begin receiving their drug benefit from Part D plans, some may be taking

drugs that are not on their plans' formulary. CMS will need to monitor plan transition policies to ensure that beneficiaries continue to receive appropriate medications and do not delay or stop treatment because they face unfamiliar formulary exceptions processes.

Formulary exceptions: Current practice and Part D

Health plans and PBMs are experienced at handling requests for formulary exceptions. Requests for exceptions depend on the structure of the benefit. In a closed formulary,[21] drug coverage is limited to the specific medications that the plan places on the formulary. However, plan members sometimes may get an additional drug covered if the plan determines that the drug is medically necessary. In this case, a member—with physician support—requests a formulary exception. Plans may grant exceptions provided that the physician has shown that the covered formulary drugs are ineffective or will likely result in adverse consequences for the member.

In a tiered or incentive-based formulary, the plan charges different copayments for covered drugs. Typically, copayments differ for generic drugs, preferred branded drugs, and nonpreferred branded drugs, with generic drugs carrying the lowest copayments. Plans may limit access to nonpreferred drugs by requiring the member's physician to get prior approval from the plan before dispensing the drug. State Medicaid programs also may require prior authorization for many drugs, particularly in those states that have preferred drug lists.

Under the final regulations published January 28, 2005, CMS permits plans to use tools such as tiered copayments, closed formularies, prior authorizations, and step therapy to manage utilization and cost of the Medicare drug benefit. The regulations discuss plan procedures to handle requests for formulary exceptions and prior authorizations. CMS requires plans to establish processes and notify plan members of policies for obtaining formulary and copayment exceptions, but CMS does not mandate specific methods.

Currently, plans differ on the number of drugs they restrict and the rationale for requiring prior authorization. One interviewee emphasized that his plan placed on its prior authorization list only those drugs required to treat chronic conditions because beneficiaries refill prescriptions for these drugs multiple times. However, another interviewee reported that his plan placed some new antibiotics on its prior authorization list.

Interviewees gave many examples of cases in which a particular drug might require preauthorization. Some examples include:

- the drug is not on the plan's formulary (for closed formularies);
- a lower cost formulary drug is available;
- an equally effective over-the-counter medicine is available;
- a nonpreferred drug is heavily advertised and is subject to overutilization;
- the drug is a high-cost injectable;
- the request is for a larger quantity of the drug than plan administrators believe is clinically appropriate; and
- physicians prescribe the drug for a number of conditions without sufficient supporting medical evidence.

Because the formulary exceptions and prior authorization processes are generally the same, we do not distinguish in this section between the two. However, we remind readers that a plan's benefit package sometimes excludes entire specific categories or types of drugs. For example most private plans do not cover over-the-counter medications. In those cases, the plan would not consider those drugs part of the covered benefit and thus the formulary exceptions processes would not apply. Part D plans cannot cover drugs that Medicaid programs may exclude (such as weight loss drugs) and cannot cover drugs eligible for Medicare Part A or Part B coverage.

How does the process work?

Call centers serve as the first point of contact for formulary exceptions and prior authorization. Plan representatives in call centers—often pharmacy technicians—receive preauthorization requests from providers and use written protocols to determine if the request meets clinical guidelines for approval. The plan's pharmacy and therapeutics (P&T) committee usually approves the protocols. Many of our interviewees reported that call-center workers could approve requests but could not deny them. Pharmacists or physicians who work for the PBM or health plan usually review requests that do not

meet criteria stipulated in plans' protocols. (Some states mandate that only a physician can reject a request for prior authorization.) At this point, the plan may ask the prescribing physician for additional information. If the plan physician still rejects the request, the plan administrator will ask a medical director and/or pharmacist (who has not been involved in the original decision) to review the request. An additional negative decision would constitute a coverage decision, and a patient who wished to pursue the request would then go through the health plan's formal appeals process. As discussed below, all interviewees reported that prescription drugs rarely are the focus of formal appeals.

Many requests do not go through the entire internal process. Physicians frequently decide, after they learn of the prescribed drug's nonformulary status, that the formulary drug is acceptable. When physicians pursue requests, plans report very high levels of prior authorization approvals. Most interviewees indicated that the most common reason for initially rejecting a request was the lack of evidence of medical necessity. When providers supplied such evidence, plans granted most requests.

We found considerable variation in the extent to which plans rely on prior authorization. Some interviewees reported that the costs of reviewing prior authorization requests limit the utility of the process. Because plans must meet timeframe requirements for handling prior authorization requests, they determine call-center staffing based on the number of requests that staff must handle on a daily basis. Additionally, requests for prior authorizations and other exceptions pose a burden to plan members, physicians, and pharmacists. Plans may decide that the savings realized from these processes are outweighed by the negative effects on patient and provider relationships. Several interviewees reported that some drugs were taken off prior authorization lists because nearly all requests were approved. However, other interviewees cited specific cases in which clinical evidence indicated that a drug was being overused. In those cases, plans typically deny requests for exceptions.

The following cases are typical:

- One plan representative noted that the plan required prior authorization for all nonsedating antihistamines after one product in this class became available to patients over the counter. In order for members to receive coverage for any of the prescription products in this category, their physicians had to document that the over-the-counter medicine had not controlled their patients' allergies—a process known as step therapy. Our interviewee reported that the plan had to hire six new employees to handle the resulting volume of calls requesting exceptions. However, the plan calculated that it has saved $10 million because of this one decision.

- Several interviewees reported that they placed all medications in the cyclo-oxygenase–2 (COX–2) therapeutic class on the prior authorization list. Their plans received many requests for exceptions, but the plans believed that the drugs were overused compared with other pain medications and thus were only appropriate for a small group of high-risk individuals. Due to the high volume of requests for exceptions, the plan reviewed its criteria. However, plan physicians concluded that their original decision was clinically appropriate and they continued to deny requests for exceptions.

- Several interviewees reported placing human growth hormone on their prior authorization list. They covered the product in cases where clinical evidence of medical necessity was available. However, they did not want to cover it for lifestyle uses such as body building. In these types of cases, plans will often ask for additional clinical information to ensure that the physician is prescribing the product for a medically necessary reason.

- One interviewee pointed out that prior authorization can be useful even when the plan approves the request in nearly all cases. He noted that when a pharmacy notifies a physician that a patient's plan does not cover the requested drug—but covers other drugs to treat the same condition—the physician often agrees to prescribe the preferred drug without a request for prior approval ever reaching the call center.

State Medicaid programs often use prior authorization as their main cost management tool. These plans cannot use tiered cost sharing or closed formularies to move beneficiaries to preferred drugs. Placing drugs on a prior authorization list is one way in which Medicaid programs can affect physician prescribing patterns.

Interviewees reported that plans keep careful records on the results of their exceptions processes. Plans then use the data to evaluate their utilization management tools and to

weigh the costs and benefits of restricting use of particular medications. If a plan receives many requests for exceptions for a specific drug, it may ask its P&T committee to review the clinical evidence on the product and determine whether to change the drug's formulary status.

Managing prior authorization

Although all interviewees agreed that, ideally, providers would receive prior authorization before they write a prescription, this is often not the case. Most physicians see patients from a variety of health plans. Each plan will have its own formulary, prior authorization list, and specific procedures for obtaining approval. Recent research indicates that the majority of physicians do not know which drugs are on their patients' formularies (Shih and Sleath 2004).

Frequently, the need for prior authorization will only become apparent when a patient brings a prescription to a pharmacy. The pharmacist who is attempting to process the prescription will receive an electronic message from the PBM indicating that the drug cannot be dispensed as written. Pharmacists say that the exact content of the message differs depending on insurer and PBM. Some messages simply report that the plan does not cover the drug. Other plans provide suggested alternative covered drugs, or provide phone numbers that physicians can call to get prior authorization. Upon receiving the electronic message, the pharmacist usually contacts the prescribing physician. At this point, the physician may change the prescription to the plan's preferred drug or request prior authorization from the plan. Alternatively, the pharmacist may tell the patient that her plan does not cover the drug. Then the patient must decide whether to pay out of pocket for the requested drug, leave without any drug, or go back to her physician and ask for a drug that is on the plan's formulary.

In most cases, plans have little control over which actions the pharmacist and physician will take and only limited data on what actually happens. In one small study, researchers analyzed what happens to patients when pharmacies reject their nonformulary prescriptions (Cox et al. 2004). They found that the majority of health plan members eventually get a drug to treat their condition. About 40 percent of surveyed individuals got the formulary drug while 15 percent got prior authorization for the prescribed branded drug. A little over 10 percent received no medication for the treatment, and an equal share paid full price for the medication.

Pharmacists and physicians will most likely consider the prior authorization process unpaid additional work. Apart from the time it takes to contact physicians for prior authorizations, pharmacists report that the PBM or other electronic messaging company charges them a transmittal transaction fee for every message they must relay before a prior authorization is approved. One physician noted that two staff nurses each spend about one hour per day providing information for prior authorization requests. Further, plan members are likely to be unhappy with their health plan if they cannot get access to a drug that they believe is medically necessary or if they have to make multiple visits to the pharmacy to get a single prescription filled.

Plans try to alleviate provider burden in a number of ways, including notification, provider outreach, and automation:

- ***Notification.*** Plans and PBMs use a number of methods to inform plan members and providers about their formularies and exceptions processes. In some cases, members receive a notice at the pharmacy that details why the plan rejected their prescription, lists alternative formulary drugs, and notes the steps that the beneficiary should take if she wants to challenge the plan's decision. A recent court decision (*Hernandez v. Meadows*) requires the Florida Medicaid program to give beneficiaries written notice at the pharmacy if their prescriptions are rejected. Other states are considering similar requirements. (see text box).

- ***Provider outreach.*** Some plan interviewees reported spending much of their time meeting with network physicians and pharmacists. The goal was to explain their formulary and exceptions procedures, address provider complaints, and, ideally, convince providers that the evidence-based processes used to maintain the plan's formulary provide added value to clinicians. Some plans have experimented with giving physicians hand-held electronic devices that are loaded with the plan's formulary, thus enabling easy access when physicians write prescriptions.[22]

- ***Automation.*** Several interviewees told us that their plan tried to make the prior authorization process as seamless as possible. For example, pharmacists' computer systems may have automatic edits to check

that a plan member has tried a preferred drug before dispensing a nonpreferred drug to treat the same condition. Members who tried the preferred drugs can get the nonpreferred drug without a formal prior authorization. (However, this system cannot work for new plan members.)

If plans reject prior authorization requests, members can appeal the decision through the plan's general appeals process.

Appeals processes: Current practice and Part D

Under CMS regulations, beneficiaries may appeal many aspects of the exceptions process. Appeals may be filed by beneficiaries, their authorized representative, or their prescribing physician, but the prescribing physician must provide a supporting statement. Beneficiaries can appeal the following:

- failure to cover a Part D drug,
- a negative decision concerning an exceptions request,
- a negative decision on a request for lowered cost sharing for a drug,[23] and
- failure to provide a coverage determination in a timely manner.

Hernandez v. Meadows

In 2002, a coalition of advocacy groups filed suit against the Florida Medicaid Agency for failure to provide fair hearings and written notice to Medicaid enrollees when denying them coverage of prescription drugs. The plaintiffs claimed that the agency violated the Social Security Act and constitutional guarantees of due process, causing beneficiaries irreparable injury due to erroneous denials of coverage for necessary medications.

The settlement agreement—approved May 14, 2004—obligates Florida Medicaid to require posting of notices in pharmacies (Figure 1-5) and to provide pharmacy providers with informational pamphlets that they can distribute to Medicaid recipients when Medicaid denies payment for a prescription. In addition to posting notices in several languages within the pharmacy itself and providing recipients with written information explaining why Medicaid denied payment of a prescription, the state must also provide an ombudsman to help beneficiaries receive timely resolution of claim payment rejections. If reasonable efforts to do so fail, enrollees are entitled to a fair hearing.

The settlement also protects beneficiaries by requiring Medicaid to ensure payment for a temporary supply of medication for three business days in the case of an emergency or ongoing therapy. Additionally, if a beneficiary requests a hearing, he or she is entitled to payment for therapy from the date of the request until the hearing. Finally, Florida Medicaid agreed to pay the pharmacy for supplying a multisource brand drug to the enrollee if the prescriber writes on the script that the drug is medically necessary. The *Hernandez v. Meadows* settlement has become a model standard of beneficiaries' rights that advocates in other states are attempting to replicate. ■

FIGURE 1-5 **Notice required by *Hernandez v. Meadows* settlement**

IMPORTANT NOTICE TO MEDICAID RECIPIENTS

If your pharmacist has told you that Medicaid, or your Medicaid HMO, will not cover your prescription today, they must give you a written notice (pamphlet) explaining the reason. The notice will advise you what steps you need to take to correct the problem.

If you do not get a notice, call **1-866-490-1901**. If you do not receive a response, then call your local legal services/legal aid office.

AHCA
FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

Source: NHeLP, National Health Law Program, 2004.

Plans will have to meet quicker timeframes for making Part D coverage decisions than private plans typically require, although many interviewees said that their plans usually make decisions quickly. Plans must make initial Medicare coverage determinations no later than 72 hours after a member requests a determination and the physician provides necessary documentation. After the plan receives the request and necessary documentation, it must make an expedited coverage decision within 24 hours.

Currently, health plans and PBMs must meet various requirements for treatment of appeals. Different standards apply depending on the provider of the drug benefit and the state in which the plan is located. In the course of our interviews, plans frequently cited NCQA accreditation criteria and state Medicaid agencies' requirements. In addition, some states have mandated that all health plans that operate within their borders do one or more of the following:

- define processes for urgent and nonurgent appeals,
- set notification requirements,
- determine timeframes for responding to appeals and notifying members, and
- establish auditable records of appeals transactions.

Some systems require plans to have an external appeals process, as well.

Although all plan representatives with whom we talked described an appeals process that applied to their drug benefit, interviewees agreed that issues involving prescription drugs rarely became the focus of external appeals. One plan representative noted that he had not seen a single case involving prescription drugs go to external appeals in three years. One consumer advocate commented that plan members rarely challenged plan decisions on drugs because they did not know that they could appeal. Another advocate suggested that patients either got their drugs when they needed them or decided that they could get along without them.

However, beneficiaries did appeal decisions on some types of drugs. For example, interviewees indicated that members have appealed decisions involving injectable drugs that physicians prescribed for off-label uses. Additionally, beneficiaries sometimes appealed decisions on psychiatric drugs such as atypical antipsychotics.

Most health plans had little or no experience with appeals of cost-sharing requirements. One plan representative noted that his plan sometimes decided, informally, to reduce cost sharing for nonpreferred drugs when the plan determined these drugs to be medically necessary. For example, an interviewee from an integrated delivery system with its own pharmacies reported that pharmacists have the authority to lower copayments when a beneficiary cannot afford the required copayment. However, another interviewee reported that his plan never grants requests for lower copayments because drugs on the third tier were always considered covered—but only for the higher copayment. Plans set premiums based on projections of utilization across the different cost-sharing tiers.

Beneficiary advocates expressed particular concern that dual eligibles would not have the same appeal rights that they have under Medicaid. Currently, Medicaid recipients have the right to a pre-termination hearing before the program can reduce or end ongoing drug treatment. Medicaid programs must continue to provide the benefits at issue until the dispute is resolved (Rosenbaum 2004). No such right exists under Part D. As beneficiaries move from Medicaid coverage to Part D coverage, they may discover that the drug they have been taking for a chronic condition is not listed on their new plan's formulary. Advocates are concerned that beneficiaries will delay or stop treatment rather than initiate a formulary exception request or appeal.

CMS regulations require plans to develop a transition policy for new members who are already taking a particular drug that is not listed on their new plan's formulary. In guidelines issued on March 16 (CMS 2005b), CMS does not mandate any specific policies but does suggest that plan sponsors consider a range of strategies to address the needs of groups such as dual eligibles and individuals who have chronic conditions. One suggested strategy includes allowing a temporary one-time refill of a past medication while allowing the plan, the enrollee, and the physician to decide if a beneficiary can switch to a formulary medication. The transition supply could vary by drug, by individual medical needs, or by an individual's location (e.g., a long-term care facility). Although CMS had not issued these guidelines at the time of our interviews, a number of interviewees suggested that their plans already have informal processes in place to accommodate beneficiaries who move from one plan to another.

Part D issues related to exceptions and appeals

Our research suggests that a number of issues involving the exceptions and appeals processes will likely arise under the Medicare prescription drug benefit. Interviewees identified the following issues:

- ***Will plans have the resources to deal quickly with a potentially high volume of appeals?*** Plans may face a higher volume of appeals than is currently the case. For example, Part D regulations could cause more beneficiaries to appeal cost-sharing tiers. In addition, notification requirements that inform beneficiaries about their appeals rights may also generate increased activity. Lastly, expedited appeals would require a decision within 24 hours, a faster turnaround time than plans today commonly require. If expedited appeals become a frequent occurrence, plans may face a significant expense in managing the appeals and exceptions process.

- ***Will the benefit structure affect the plans' ability to use the exceptions process to steer utilization?*** One interviewee pointed out the potential difficulties of putting drugs on a nonpreferred third tier or using prior authorization. Part D plan members will have to pay 100 percent of the cost sharing for spending that falls below the deductible and above the initial benefit limit (Figure 1-1, p. 5). Members and their physicians may resent the additional burden of getting a drug preauthorized when they will still have to pay its full cost, albeit at the discounted price negotiated by the plan. However, prior authorization decisions will be particularly important to beneficiaries because only spending for drugs covered by their plan will count toward the benefit's out-of-pocket limit.

- ***How will plans distinguish between drugs that should be covered under Part B rather than Part D?*** Several interviewees noted that many drugs covered under Part B for some conditions or sites of care would be considered Part D drugs in other situations. For example, physicians prescribe oral antinausea drugs to treat the side effects of chemotherapy, but they also may prescribe these drugs for other cases of extreme nausea. Part B would cover the drugs only for the first situation. Although plans may use prior authorization for all medications that might be Part B drugs, interviewees suggest that this situation may be a complex issue that cannot be easily resolved.

- ***Will CMS publicly report plan appeals and grievances statistics?*** Regulations require that plans notify beneficiaries of appeal processes. Beneficiary advocates placed a high value on public disclosure of a drug plan's appeals record. They suggest that this would be an important quality measure for beneficiaries to use when choosing a plan. Our interviewees expressed disagreement on this issue. Some representatives of health plans and PBMs agreed that public reporting would be valuable. Others suggested that differences in plan policies on formulary management would make comparison of overall statistics meaningless. Instead, they suggested that the exceptions and appeals process should be transparent to beneficiaries so that plan members and physicians could evaluate the evidentiary standards that plans use to make coverage decisions. Plans would make public the conditions under which they grant formulary exceptions and the evidence required to meet these conditions.

CMS has announced its intention to examine all aspects of formulary development and management to ensure that plans do not discriminate against beneficiaries with high-cost medical needs. The agency may scrutinize plan use of tools such as prior authorization. In its review of plan submissions, CMS will have to balance carefully the need to ensure beneficiary access to necessary medications with the plans' ability to control unnecessary utilization. If plan sponsors believe that they will not be able to use tools like prior authorization to manage drug utilization, they may charge higher premiums or be reluctant to participate in the program.

Looking forward: Electronic prescribing and other areas of future research

Members of our expert panel and other interviewees agreed that the diffusion of e-prescribing technology would improve many of the access, quality, and cost issues we discuss in this chapter. Patients, physicians, pharmacists, and drug plans would save time and money if physicians could determine a drug's formulary status and get necessary prior authorizations when they write prescriptions. However, most interviewees agreed that diffusion of the technology is still slow (although some reported recent progress). Some physicians raised questions about the technology's cost and adaptability to the way in which physicians practice. One physician commented that

the version of e-prescribing used by a partner in his practice increased the time that his partner needed to write a prescription and thus reduced his productivity.

CMS issued a proposed rule (CMS 2005e) to promote the diffusion of e-prescribing. The rule proposes preliminary standards for electronic prescribing that could form the basis of final uniform standards for the technology—standards that would promote patient safety, quality of care, efficiency, and cost savings in the delivery of care. MedPAC intends to monitor these efforts as they move forward.

In the coming months, plans will be submitting bids to become PDPs or MA–PDs. By September 2005, CMS should make available information about plan offerings, including premiums, benefit designs, and formulary systems. MedPAC intends to analyze this data and describe its impact on enrollment in Part D plans. Depending on the availability of data, we will evaluate how the Medicare drug benefit meets the goal of ensuring a quality benefit at an affordable cost in the future. ■

Federal subsidies for the Part D drug benefit

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 designed Part D so that CMS would provide subsidies to serve three purposes:

- encourage beneficiary enrollment,
- encourage plan participation by reducing cost uncertainty, and
- reduce out-of-pocket liability for beneficiaries with low incomes and limited assets.

The forms of these subsidies are important because without high enrollment and limitations on risk, private entities might not want to offer a stand-alone drug plan.

Few examples of stand-alone drug plans exist today because beneficiaries, particularly those who have chronic conditions, can predict their drug spending fairly well. Enrollees would pick coverage that suits their prescription drug needs, thus raising the risk of adverse selection. Private plans might also be reluctant to offer drug-only coverage because they could find it difficult to predict growth in the use of new drug therapies, and, therefore, hard to set premiums reliably.

The Medicare program will provide a subsidy that averages 74.5 percent of standard coverage for all types of beneficiaries. That average subsidy will take two forms:

- **Direct subsidy**—a capitated payment calculated as a share of the adjusted national average of plan bids. Although no one can predict levels of enrollment in Part D, in general, high direct subsidies should lead to higher enrollment, which makes private entities more likely to offer a Medicare plan.
- **Individual reinsurance**—Medicare will subsidize 80 percent of drug spending above an enrollee's catastrophic threshold. Reinsurance acts as a form of risk adjustment by providing greater federal subsidies for the highest cost enrollees.

In addition, Medicare will establish symmetric risk corridors separately for each plan to limit a plan's overall losses or profits. Under risk corridors, Medicare limits a plans' potential losses (or gains) by financing some of the higher-than-expected costs (or recouping excessive profits). Also, plans that enroll low-income beneficiaries will receive a fourth type of subsidy to cover some of these enrollees' cost sharing and premiums.

Note that although plans will get essentially the same level of direct subsidy per enrollee (albeit modified by a risk adjuster to reflect health status), the level of subsidies granted through the other three mechanisms could differ substantially from plan to plan. Subsidy dollars will vary depending on the characteristics of individuals that each plan enrolls (e.g., income, health status, and supplemental coverage stats), as well as on how each plan structures its risk corridors. ■

Endnotes

1 The term "true out of pocket" refers to a feature of Part D which directs fewer federal subsidy dollars 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, under CMS's demonstration authority, supplemental drug coverage paid for with MA rebate dollars.

2 These threshold amounts in the standard benefit would increase each year by CMS's estimate of the annual change in drug spending per person. For example, CMS currently projects that by 2010, the standard benefit's deductible would be $331, the initial benefit limit would reach $2,980 rather than $2,250, and the catastrophic threshold would be $4,767 rather than $3,600 (Boards of Trustees 2005).

3 MA–PDs may use rebate dollars—that is, a portion of the difference between CMS's payment rates and a plan's bid for providing basic services covered by Medicare Parts A and B—to enhance the Part D benefit. Chapter 2 of this report provides further information about rebate dollars.

4 PBMs do not typically report members' spending on noncovered drugs, for which members pay fully out of pocket.

5 A few PBMs have received accreditation from quality assurance organizations for aspects of their business, such as specific disease management programs (Booz Allen Hamilton 2004).

6 When beneficiaries sign up for a Medicare Part D plan, they are required to report whether they also have prescription drug coverage through a third party.

7 In its Part D regulations, CMS notes that these surveys will likely be adapted from the Consumer Assessment of Health Plans Survey (CAHPS).

8 Under certain circumstances, individuals can switch plans more than once per year, such as when they move out of the area or when their plan discontinues offering the benefit.

9 CMS officials have commented that it is "highly unlikely" that CMS will need to use a fallback plan in the initial operation of Part D.

10 Some exceptions exist. Under employer waivers, for example, a PDP could have a separate risk pool and premium for the retirees of a specific employer.

11 If a region does not have at least one MA–PD and one PDP—or two stand-alone PDPs—available, CMS must contract with a fallback plan to offer Part D. MA–PDs and PDPs are known as risk plans because they will bear insurance risk on enrollees' benefit spending. Fallback plans will not bear insurance risk.

12 Two important household surveys that capture prescription drug spending are the Medical Expenditure Panel Survey (MEPS) and the Medicare Current Beneficiary Survey (MCBS). MEPS includes the noninstitutionalized U.S. population; it has fewer respondents who are Medicare beneficiaries than the MCBS. MCBS was specifically designed to represent the wide variety of individuals who make up the Medicare population. Household surveys are subject to the problem of recall bias—the notion that individuals may not recall accurately the number and type of prescriptions they got filled. Additionally, household surveys typically do not include information about rebates from pharmaceutical manufacturers—these rebates can lower prices for prescription drugs.

13 CMS uses such data from the Census Bureau and private survey organizations such as IMS Health to help it estimate nationwide prescription drug spending in the national health accounts. Other private companies, such as Verispan, similarly collect data from retail pharmacies and other sources.

14 According to CMS's 45-day notice to plans, the agency used drug claims for a sample of federal retirees and spouses who also have Medicare coverage to build initial risk adjusters for nondisabled beneficiaries and those who are not dual eligibles. For the latter two groups, CMS used Medicaid claims data (CMS 2005a).

15 CMS initially developed a model that predicts a person's total drug spending (plan benefit spending plus cost sharing), and then modified the model to predict Part D liability alone. This modification is particularly important given the peculiar structure of the standard Part D benefit, with a large range of spending for which the enrollee must pay 100 percent coinsurance. That coverage gap substantially reduces the amount of insurance risk that plans must bear. On average, benefit spending made up about 40 percent of total spending.

16 Each region's index is the average of predicted prescription drug spending divided by the predicted national average.

17 CMS will randomly assign those beneficiaries who are dually eligible for Medicare and Medicaid to plans beginning in October, although they will be able to switch plans at any time if their assigned plan does not meet their needs.

18 Low-income beneficiaries can still enroll for transitional assistance, but their credit is prorated depending on their date of enrollment.

19 SPAPs provide drug coverage or assistance to low-income elderly or persons with disabilities who do not qualify for Medicaid. As of March 2005, 39 states had established or authorized one of these programs (www.ncsl.org/programs/health/drugaid.htm).

20 As of March 4, 2005, enrollment had reached 6.3 million, with about 1.8 million beneficiaries receiving transitional assistance (CMS 2005d).

21 A closed formulary is defined as a list of specific drugs limited to only some of the commercially available products in each therapeutic class. An open formulary is defined as a comprehensive listing of medications typically including almost every commercially available product in each therapeutic class. A tiered or incentive-based formulary contains different cost sharing for preferred and nonpreferred brand-name drugs, as well as generic drugs, thereby giving patients a financial incentive to request preferred or generic medications. Most plans currently have open-tiered formularies, but we interviewed representatives from a number of organizations that also have closed formularies. For a more in-depth look at these issues, see MedPAC's 2004 *Report to the Congress*.

22 Health plans that have closed physician and pharmacy networks experience much less difficulty informing providers about the formulary. Physicians have only one formulary to keep in mind when they are writing prescriptions. Additionally, providers participate in developing the formulary and may have greater confidence in it. In some cases, these physicians may be able to prescribe nonformulary drugs without going through a prior authorization process.

23 Under the final rule, beneficiaries may appeal to reduce cost-sharing requirements for a nonpreferred branded drug to the level of cost sharing for a preferred branded drug. Beneficiaries may not appeal other cost-sharing requirements.

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