CHAPTER 1

Implementing the Medicare drug benefit: Formulary and plan transition issues

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Implementing the Medicare prescription drug benefit will raise many policy questions that the Commission and others will consider. In this chapter, we examine formulary systems and what issues arise when drug plans enter or exit markets or beneficiaries switch plans.

In establishing formulary systems, plans must balance a cost-effective approach with beneficiaries' access to medically necessary medications. This chapter examines therapeutic category definitions, the structure and decision-making process of pharmacy and therapeutics committees, the appeals process, and the need for independent drug-to-drug comparison studies. As beneficiaries choose plans, and as plans enter and exit markets, key issues include the prior approval process and informing physicians, pharmacists, and beneficiaries of differences in formularies, cost sharing, and other procedures. Employers and plan sponsors in the private sector credit smoother transitions to adequate time for data transfers and communication with those affected by the changes. Physicians and pharmacists need comprehensive information because they usually are beneficiaries' point of contact.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created Medicare Part D, a voluntary prescription drug benefit scheduled to begin in 2006. Given the size and complexity of the legislation, the cost and value of the benefit will, in large part, be determined by a series of upcoming regulations to be issued by CMS and the responses of states, beneficiaries, and stakeholders to the challenges and opportunities provided by the law. MedPAC is studying a range of topics relating to the drug benefit. Our goal is to inform policymakers about potential implementation issues, including those that might require Congressional action in the future.

In this chapter, we examine two key questions:

- How will formularies and formulary systems be established and maintained?
- What issues arise when beneficiaries move from one drug plan to another or when drug plans enter and leave the program?

For some of these issues, analysis is difficult because minimal data are available and little scholarly research has been done. We have used a variety of methods to gain insight into these questions, including structured interviews with relevant stakeholders, site visits, beneficiary focus groups, and analysis of relevant literature.

We found that formulary design affects the variety and number of drugs available to beneficiaries as well as the ability of drug plan sponsors to manage the benefit and control costs. When therapeutic categories are broad, competition within categories is enhanced, but the number of drugs on the formulary may be more limited. On the other hand, when plans use formularies with narrow categories, they have less ability to steer enrollees to the most cost-effective drugs and negotiate lower prices with manufacturers. The MMA requires an exceptions process to allow enrollees to obtain medically necessary medications not on their plans' formulary. Most plans currently have exceptions processes, but there is considerable variation in the ease with which such exceptions are reviewed and granted. Formularies can change frequently, responding to therapeutic advances, market competition, and deliberations by plans' pharmacy and therapeutics (P&T) committees. Plan selection of formulary drugs is based on a variety of information sources, but notably lacking are studies which directly compare the effectiveness of one drug to another.

As drug plans enter and exit markets and enrollees switch plans, formulary changes are one of the issues that will have to be addressed. Findings from our study of drug plan changes in the private market can inform policymakers of implementation challenges they will confront. Although some private sector transition experiences are not relevant to Medicare, our findings indicate the importance of ensuring that contractors have sufficient time to implement new drug plans, transfer data, and communicate with patients and others affected by the changes. CMS should ensure that contracts with drug plans include criteria for entering and leaving markets, including timely transfers of data. Of critical importance, beneficiaries (or their caregivers), physicians, and pharmacists must have advance notice of changes in formularies, cost sharing, and other procedures that differ across plans.

Examining formulary systems and drug plan transitions provides insight into some of the key components of the law, including benefit structure, beneficiary education, the grievance and appeals process, and the elements needed to ensure effective competition among plans. Yet this chapter encompasses only a few of the significant issues that must be addressed before the program begins in 2006. In the coming year, MedPAC intends to analyze additional issues including how the drug benefit will be implemented in nursing homes and other long-term care facilities. We also intend to monitor the implementation and effectiveness of the Medicare discount card program to gain further insight into the challenges and opportunities involved in establishing the Medicare drug benefit.

Formulary implementation issues

The MMA allows plans offering Medicare drug coverage to develop and use formularies to manage the costs and use of prescription drugs. Indeed, plans participating in the upcoming Medicare drug benefit are likely to use formularies to designate the coverage or tiered cost-sharing status of prescription drugs. To the extent that formularies help control the costs of drugs, they can be a key to the success of the overall Medicare drug benefit. However, attention to formulary implementation is important to ensure beneficiary access to a range of

needed medications. The MMA allows the Secretary to regulate some features of formulary design and use, but he may not require a particular formulary or price structure for the reimbursement of covered Part D drugs.

The Secretary, the Congress, other policymakers, and stakeholders are likely to encounter a range of formulary-related issues as they implement the new Medicare drug benefit. Some MMA provisions establish detailed requirements on formulary policies and procedures, but others allow greater latitude in formulary development. This section provides a framework for understanding the impact of selected formulary implementation options. To research these issues, MedPAC staff interviewed experts and stakeholders on the topic (including representatives of health plans, pharmacy benefit managers (PBMs), drug manufacturers, physicians, Medicaid plans, the Veterans Health Administration (VHA), the Academy of Managed Care Pharmacy (AMCP), U.S. Pharmacopeia, and consumer advocacy groups), and consulted available research and publications.

This section begins by presenting background information on formularies—how they work and current practices of health plans and PBMs. Then we explore an array of formulary implementation considerations that arise under the new Medicare drug benefit. For example, therapeutic class structures of a formulary can affect ease of access to medications and drug costs. How beneficiaries learn about plan formularies and formulary changes also can affect access. How beneficiaries may obtain coverage for nonformulary drugs is an important issue, considering that nonformulary drugs will not count towards beneficiaries' out-of-pocket spending totals calculated in the drug benefit, unless they are granted a nonformulary exception.

Additionally, this section of the chapter describes the process of selecting drugs for a formulary and examines the research needs and opportunities for improving the information available to make appropriate choices. Provisions in the MMA recognize the need for independent, scientific research that compares the outcomes and clinical effectiveness of prescription drugs. Funding mechanisms may assist in accomplishing this goal.

What are formularies and how do they operate?

On its own, a formulary is a continually updated list of medications that a health plan or other payer will cover. Formularies are a component of a plan's overall formulary system, which is the set of policies and procedures that plans use to design, implement, and update their formulary. (See text box at the end of this chapter for a glossary of related terms.) A health plan covers all drugs listed on its formulary in some way; however, it may set different levels (tiers) of cost sharing or require that a particular condition is met before certain drugs or groups of drugs will be covered. Hospitals, health plans, PBMs, self-insured employers, and government agencies such as the VHA and Department of Defense (DoD) now widely use formularies. According to one study of employer-sponsored health benefits, 71 percent of workers with prescription drug coverage in 2003 were in plans with closed or partially closed formularies (KFF and HRET 2003).

Health plans have adopted formularies primarily to control continued double-digit growth in drug spending (AAHP 2002). This growth has been driven by three factors: greater use, newer and more expensive drugs replacing older therapies, and increases in manufacturers' prices. Formularies can lower drug costs for plans and enrollees by directing physicians and enrollees to lower-priced, cost-effective drugs. Also, plans gain the ability to negotiate lower prices with a manufacturer when they list the manufacturer's products on their formulary and show a resulting shift in market share (CBO 2002).

The drugs on a formulary may be selected from thousands of available drugs, and many prevalent health conditions now have multiple brand or generic drugs available. According to our analysis of Medline drug information listed on the National Library of Medicine's website, there are at least 6 different statins for use in lowering cholesterol, 5 selective serotonin reuptake inhibitors (SSRIs) to treat depression, and 12 angiotensin-converting enzyme (ACE) inhibitors to treat hypertension. These groups of drugs are among the most highly used, both in terms of volume of prescriptions and sales (Table 1-1 on p. 6 and Table 1-2 on p. 7).

Formulary structures

Most formularies are variations of two basic models: open or closed. In an open formulary, the plan provides coverage for all drugs in most, if not all, therapeutic classes; therefore, even drugs that are not listed on the formulary are covered. Although a payer with an open formulary encourages the prescribing of drugs that are listed, the physician has little incentive to do so. This

TABLE 1-1

Leading 20 therapeutic classes by number of prescriptions, 2003

Rank	Class	Total U.S. prescriptions (in millions)	Percent growth	Percent market share
1	Codeine and combinations	148.3	6%	4.4%
2	SSRIs and SNRIs	139.6	11	4.1
3	HMG-CoA reductase inhibitors (statins)	123.4	6	3.6
4	Beta blockers	110.4	7	3.2
5	Ace inhibitors, alone	108.3	3	3.2
6	Proton pump inhibitors	94.9	14	2.8
7	Calcium blockers	89.1	–4	2.6
8	Oral contraceptives	85.6	0	2.5
9	Thyroid hormone, synthetic agents	83.4	5	2.5
10	Seizure disorder agents	77.4	9	2.3
11	Penicillins	72.8	0	2.1
12	Benzodiazepines	72.0	2	2.1
13	Antihistamines, capsules and tablets	59.6	–18	1.8
14	Macrolides and related agents	57.3	4	1.7
15	Antiarthritic agents, plain	57.2	–3	1.7
16	Beta agonists	56.3	–3	1.7
17	Antiarthritic agents, COX-2 inhibitors	53.9	3	1.6
18	Diuretics, other, noninjectable	53.7	0	1.6
19	Hormones, estrogens	51.4	–24	1.5
20	Muscle relaxants, nonsurgical	44.4	5	1.3

Note: SSRI (selective serotonin reuptake inhibitor), SNRI (selective serotonin/norepinephrine reuptake inhibitor), HMG-CoA (3-hydroxy-3-methylglutaryl coenzyme A), COX-2 (cyclo-oxegenase-2). Prescriptions are total dispensed prescriptions, including insulin, dispensed through chain, food store, independent, long-term care, and mail service pharmacies.

Source: IMS Health, National Prescription Audit™ Plus from October 2002 through September 2003.

arrangement usually has minimal impact on prescribing patterns, utilization, and the ability to negotiate manufacturer rebates.[1] On the other hand, in a closed formulary, the payer does not reimburse for drugs unless they are listed on the formulary or are covered through an exceptions process. In this type of formulary, the ability to shift prescriptions and gain rebates from manufacturers increases (AAA 2000).

In practice, most formularies are partially or selectively closed. Most formularies exclude certain types of drug classes completely, such as drugs that the Food and Drug Administration (FDA) has determined lack sufficient efficacy, and weight-loss, cosmetic, and other lifestyle drugs (AMCP 2000a). In addition, individual therapeutic classes may be open or closed. For example, a formulary may close the statin therapeutic class, only covering a few drugs within it, but leave other classes open, covering all available drugs within them.

Incentive-based formularies may be closed, open, or partially closed, and use price differentials or other financial incentives to influence drug choice by physicians and beneficiaries. For example, an incentive-based formulary allows coverage of nonpreferred drugs, but only at higher copay or coinsurance levels. In particular, a majority of commercial plans now offer three-tier incentive formularies. In this structure, the formulary may contain many drugs for each therapeutic class, but they are grouped into three tiers, each with different levels of cost sharing. This structure encourages cost-consciousness on the part of beneficiaries, as they typically pay the lowest copay for generic drugs, a midlevel copay for brand drugs preferred by the plan, and the highest copay for nonpreferred brand drugs. The prevalence of three-tier incentive formularies has steadily increased: In 2003, 63 percent of workers with employer-sponsored health benefits were enrolled in drug plans with this structure, up from 27 percent in 2000 (KFF and HRET 2003).

TABLE 1-2

Leading 20 therapeutic classes by sales, 2003

Rank	Class	U.S. sales (dollars in billions)	Percent growth	Percent market share
1	HMG—CoA reductase inhibitors (statins)	$13.5	10%	6.4%
2	Proton pump inhibitors	12.9	16	6.1
3	SSRIs and SNRIs	10.6	9	5.0
4	Antipsychotics, other	7.8	23	3.7
5	Erythropoietins	7.2	17	3.4
6	Seizure disorder agents	6.6	25	3.1
7	Antiarthritic agents, COX-2 inhibitors	5.2	9	2.5
8	Calcium blockers	4.4	–1	2.1
9	Antihistamines, capsules and tablets	3.8	–21	1.8
10	Codeine and combinations	3.1	14	1.5
11	Quinolones, systemic	3.1	7	1.5
12	Bisphosphonates	3.0	22	1.4
13	Insulin sensitizers	2.9	16	1.4
14	HIV—reverse transcriptase inhibitors	2.8	13	1.3
15	Ace inhibitors	2.8	–21	1.3
16	Oral contraceptives	2.8	4	1.3
17	Immunologic interferons	2.6	24	1.2
18	Newer generation antidepressants	2.6	9	1.2
19	Macrolides and related agents	2.5	10	1.2
20	Gastrointestinal anti-inflammatory agents	2.4	33	1.1

Note: HMG-CoA(3-hydroxy-3-methylglutaryl coenzyme A), SSRI (selective serotonin reuptake inhibitor), SNRI (selective serotonin/norepinephrine reuptake inhibitor), COX-2 (cyclo-oxegenase-2). U.S. sales are prescription pharmaceutical purchases, including insulin, at wholesale prices by retail, food stores and chains, mass merchandisers, independent pharmacies, mail services, nonfederal and federal hospitals, clinics, closed-wall HMOs, long-term care pharmacies, and others.

Source: IMS Health, National Sales Perspectives™ from October 2002 through September 2003.

Aside from excluding certain drugs, formularies may use mechanisms other than pricing differentials to direct utilization. For example, a drug may be listed on a formulary but require prior authorization by the plan or PBM. Also, some drugs may be designated as "first line": These drugs must be tried first and proven unsuccessful in treating a patient before a nonpreferred drug will be covered.

To accommodate medical need, most formularies have an exceptions process that provides access to and reimbursement for nonformulary drugs that a physician justifies as medically necessary for a patient's care (AMCP 2000a). Some stakeholders we interviewed stressed the importance of an exceptions process to a well-designed and functioning formulary. Exceptions processes are used more often with closed formularies than with tiered formularies. Most plans' exceptions processes require the physician to supply supporting evidence of their medical necessity claims, although one plan we interviewed does not. Most plans aim to resolve all exceptions claims within 48 hours. A plan we interviewed allows the prescribing physician or pharmacist to authorize a three-day emergency supply of a medication while the exceptions claim is being processed.

As a result of different structures and decisions, the number and types of drugs covered on formularies can vary greatly across the marketplace. A survey of HMOs found that the number of drugs on formularies ranges from fewer than 250 drugs to, in most cases, over 750 drugs (Formulary 2003). In the Medicare+Choice (M+C), now Medicare Advantage (MA), marketplace, the scope of the drug benefits offered has decreased markedly. A 2002 study found that 39 percent of M+C enrollees were in plans that limited coverage solely to generic drugs

(Achman and Gold 2003). However, starting in 2006, most types of Medicare Advantage plans are required to offer the Medicare drug benefit as an option.

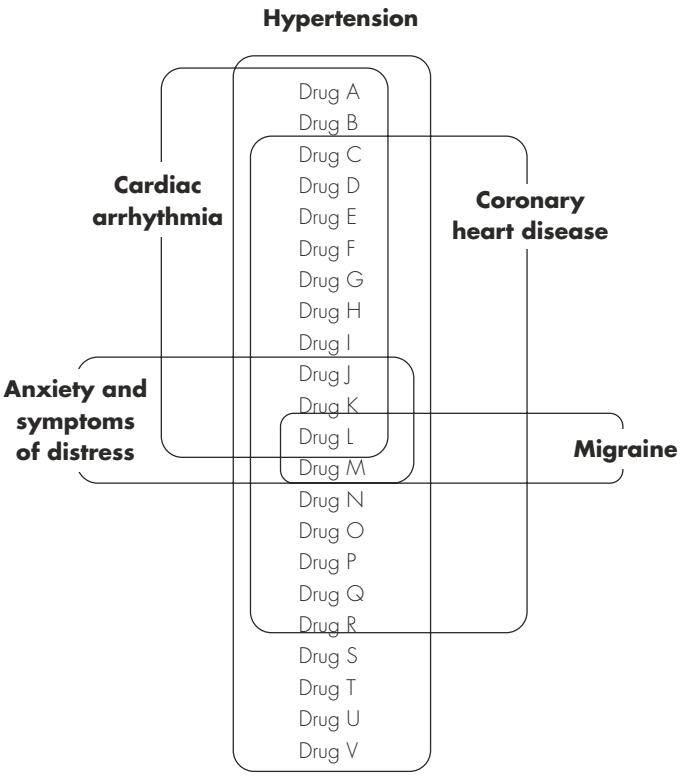
Therapeutic classes

The classification of drugs is complex and variable, with little consensus on the best methodology. Drugs can be classified on the basis of their therapeutic indications, the pharmacological mechanism by which they act, or at the most basic level, their chemical structure. Most classification systems place together drugs that produce similar clinical outcomes (lower cholesterol, alleviate depression) and have similar adverse reaction profiles. Stakeholders we interviewed stated that the classification systems are used as a framework for reviewing, selecting, and inducing price competition among drugs. Some plans offering a drug benefit create their own therapeutic classification system, while others use or modify systems available commercially.

Differences arise in classification systems for many reasons, one being that even drugs that act through the same pharmacological mechanism can have differing therapeutic indications. For example, drugs classified as beta-blockers are primarily used to lower blood pressure by decreasing the heart's output of blood.[2] However, some beta-blockers may be used to treat or prevent several heart conditions, such as angina or cardiac arrhythmia, because they selectively affect regions of the heart; still others may be used to treat migraines or anxiety. Small chemical differences between the drugs alter their appropriate uses, effectiveness, and safety profiles. Based on these differences, it would be possible to classify beta-blockers in one or several different therapeutic classes (Figure 1-1).

Additionally, drugs may act through different pharmacological mechanisms but achieve somewhat similar therapeutic outcomes. For example, commonly used antidepressants encompass several types of compounds that act by different methods: tricyclic antidepressants, SSRIs, monoamine oxidase inhibitors (MAOIs), and other agents. Some formularies separate antidepressants into these four different therapeutic classes, while others combine some or all of the classes. Some plan representatives we interviewed noted that, because only certain SSRIs work for some patients, they are careful to allow choice within that group of drugs. In another example, cyclo-oxygenase-2 (COX-2) inhibitors

FIGURE 1-1 **Beta-blockers may be grouped in one or several therapeutic classes**



Source: Adapted from presentation by Robert Guersen at Global Medical Forum Summit, December 5, 2003. http://www.globalmedicalforum.org/summits/us.

are a new form of nonsteroidal anti-inflammatory drugs (NSAIDs) for treating symptoms of arthritis (pain, inflammation, swelling, stiffness). Many plans classify COX-2 inhibitors as a class of drugs on their formulary and thus cover at least one (Doshi et al. 2004). However, some plans we interviewed do not classify them separately from other NSAIDs, and thus cover COX-2 drugs only through medical exceptions, citing their high cost and value only for people with gastrointestinal problems or other medical considerations. As these examples show, decisions about formulary inclusion depend on the classification system chosen and other system components.

Classification systems can change; they evolve to reflect the emergence of new drugs and clinical information. One plan noted that, when it chose among commercial classification systems, timely updates were a

consideration. In general, the drugs on a plan's formulary change much more frequently than the formulary's classification system.

Formulary development and drug selection

Formularies are usually developed and maintained by a body of medical experts known as a pharmacy & therapeutics (P&T) committee. All plans and PBMs we interviewed relied on the input of P&T committees for selecting their formulary. P&T committees differ, but they generally have physicians of varying specialities and pharmacists—with physicians usually outnumbering pharmacists. Our interviews revealed that physicians usually hold the majority vote on formulary decisions: In at least one case, pharmacists were present on the committee but could not vote on decisions. Some P&T committees used a voting process for selecting drugs, but others sought a consensus. Also, some plans and PBMs emphasized the independence of committee members. Some recruit experts from academia to serve as members and require or expect disclosure of conflicts of interest.

P&T committees choose whether a drug should be placed on the formulary and, when applicable, assign tier levels and other requirements such as prior authorization. Committees base these decisions on information about the effectiveness and safety of available drugs and net costs. Clinical information may include drug monographs obtained from medical references, therapeutic class reviews prepared by pharmacists, published studies, pharmacoeconomic studies, and internal drug utilization review. Most P&T committees place the greatest weight in their deliberations on published peer-reviewed articles, particularly those which focus on evidence-based clinical outcomes. P&T commmittees also rely on meta-analyses, including surveys of published literature prepared by a support staff of pharmacists or a contracted entity.

Pharmaceutical manufacturers may provide unpublished information to P&T committees upon request. In 2000, AMCP issued guidelines to standardize the format of the information drug companies provide to P&T committees. The guidelines call for drug companies to present a standardized "dossier" that contains detailed information on each drug's effectiveness, safety, economic value relative to alternative therapies (such as other drugs or treatment protocols), off-label indications, and any other relevant unpublished studies.

All plans we interviewed noted that studies that directly compare two or more drugs or classes of drugs in the treatment of a condition are limited and uncommon, despite their usefulness to plans, physicians, and patients. To address this demand, the National Heart, Lung, and Blood Institute of the National Institutes of Health recently completed a series of comparison studies on drugs that treat hypertension. These studies found that, in the majority of cases, generic diuretic compounds were just as effective in treating hypertension as more expensive ACE inhibitors and calcium-channel blockers (ALLHAT 2002). Both ACE inhibitors and calcium-channel blockers were among the top ten therapeutic classes by sales in 2003 (Table 1-2, p. 7).

Our interviews revealed that net cost seems to become a consideration at different points in the formulary process. Plans may first decide which drugs are therapeutically superior, equivalent, or inferior based only on effectiveness and safety, and then negotiate and consider pricing (including manufacturer rebates and discounts) among those they determine to be therapeutically equivalent. Others may take cost-effectiveness or pharmacoeconomic data into account while reviewing all available drug information.

Most P&T committees meet at least once a year, with many meeting quarterly (Formulary 2003). P&T meetings vary in length, from a minimum of three to four hours, to a full day, to a few days. Some committees stagger their reviews of therapeutic classes across meetings, effectively covering the formulary over the course of a year. Others may review the entire formulary once a year, or set their agenda based on when manufacturer contracts are up for renewal. Most plan representatives stated that their P&T committees reconsider drug selection as needed when generics or significant findings about safety or efficacy become available.

MMA formulary provisions: Issues and analysis

Most plans participating in the Medicare drug benefit will develop and use formularies to manage the costs and utilization of prescription drugs. The MMA stipulates some formulary-related provisions, but also enables the Secretary to regulate future policies on the topic. Plans are likely to have some latitude in designing and implementing formularies. The questions that follow in

this section raise the major issues that policymakers and stakeholders will encounter when drafting and reviewing formulary regulations and policies.

How will therapeutic class structures affect formulary development?

In implementing a formulary, the MMA allows plans to establish their own classification system of therapeutic categories and classes. However, a plan's therapeutic class structure may not be designed to discourage enrollment of beneficiaries with high expected drug costs, such as those with AIDS, mental illness, epilepsy, or other chronic conditions. Due in part to this concern, the MMA designated the United States Pharmacopeia (USP)—a nongovernmental, nonprofit organization—to develop a model classification system. Plans are not required to use USP's classification model, but if they do, they will be granted safe harbor on the issue of discouraging enrollment of high-cost beneficiaries. USP is required to consult with stakeholders when designing its model classification system for the Medicare drug benefit.[3]

The MMA requires that plans with formularies cover at least two drugs in each therapeutic category.[4] The structure of a plan's therapeutic categories, therefore, can have a major impact on which and how many drugs a plan covers. In particular, the specificity of a therapeutic class determines the number and mix of generic and brand drugs available. The MMA does not prevent plans from listing a drug on their formularies in more than one category. For example, plans may cover a beta-blocker in two therapeutic classes: hypertension and cardiac arrhythmia (Figure 1-1).

Some of the plan and PBM representatives we interviewed indicated that if, under the Medicare drug benefit, they use a formulary with narrow therapeutic classes, it would minimize their ability to contain costs for two main reasons. First, narrow drug classes are more likely than broad classes to have no generic or moderately priced drugs available. Second, these narrow drug classes are likely to reduce market competition within each drug class. Plans and PBMs maintain that without sufficient competition within a therapeutic category, they will have limited ability to negotiate for discounts and rebates from manufacturers, and thus will need to charge enrollees higher coinsurance or premiums. Plans further contend that formularies with broad therapeutic classes lower drug costs because they increase the likelihood that generics are included in the drug classes (AAHP 2002, AMCP 2004).

Consumer advocates and representatives of the pharmaceutical industry express concern that a broad classification system with too few therapeutic categories and classes can limit enrollees' access to medically necessary brand name drugs, particularly if the nonformulary exceptions process is too onerous for either the beneficiary or the prescribing physician, or both (NPAF 2003). For example, subpopulations of beneficiaries may be best served by new drugs with less risk of side effects. A formulary with a broad classification system may be less likely to offer these drugs. The industry is also concerned that if formularies use wide classes to steer beneficiaries away from new drugs, companies will be less willing to commit resources toward researching and developing new drugs (Danzon 2000).

AMCP has raised concerns regarding the classification system selected for the new Medicare drug discount card program. Set to run from June 2004 to the end of 2005, this program allows private entities to offer beneficiaries a Medicare-approved drug discount card, which will give discounts on selected drugs. CMS established 209 therapeutic categories for the Medicare drug discount card. These categories were selected primarily because they contain the drugs most commonly used by Medicare beneficiaries. AMCP states that the classification system CMS selected for the drug discount card contains narrowly defined drug classes with significant redundancy (AMCP 2004). As an example, AMCP points to the three chemical subclasses of calcium channel blockers. AMCP contends that this redundant classification system is not as effective in controlling costs as a broader one, with fewer therapeutic categories. Commenting on previously proposed drug discount card regulations, the Pharmaceutical Research and Manufacturers of America (PhRMA) has stated that aggregating therapeutic classes too much could impair beneficiaries' access to discounts on a sufficient range of drugs (PhRMA 2002).

The major implementation issue regarding therapeutic categories and classes will be whether USP's model is accepted by plans, PBMs, and other stakeholders. If plans decide not to use the model, they will need to show that their departure from the model is not designed to encourage or discourage certain beneficiaries from enrolling.

Another issue will be the level of coverage that will be offered within each therapeutic class. Although the MMA states that at least two drugs must be covered in each therapeutic class, the law does not specify a required tier of coverage for these drugs. Future regulations are needed to clarify whether any drugs within a therapeutic class must be covered at the most preferred level.

There are no formal accrediting agencies or accrediting requirements for plan formularies; thus, the quality of a plan's formulary and formulary system is not formally evaluated to ensure that they allow adequate access to necessary drugs. Recognizing this concern, Consumers Union has evaluated the value of drug benefits offered by Medicare managed care plans using its "prescription drug quality index" (Consumer Reports 1998). Further evaluation of the need and feasibility of formulary accreditation may be useful.

How can enrollees obtain coverage for nonformulary drugs?

The MMA requires that plans have a process for enrollees to request coverage for nonformulary drugs, or to reduce a nonpreferred drug's cost sharing to the most preferred level. For such exceptions, a prescribing physician must determine that a nonformulary or nonpreferred drug would be more effective and/or cause fewer or milder adverse side effects than a formulary or preferred drug. If beneficiaries are unable to obtain a nonformulary exception from the plan, they will have to pay high cost sharing, up to the full retail cost of the drug. Further, their costs for purchasing these drugs will not count toward their out-of-pocket spending totals—calculated to determine deductibles and catastrophic spending thresholds. Pharmacists may be the first people beneficiaries approach to learn about the nonformulary exceptions process, since they are often the first ones to explain to beneficiaries that their prescribed drug is not on the formulary.

If a beneficiary's request for a nonformulary drug or for a more preferred cost-sharing status of a drug is denied, the beneficiary may appeal. Plan sponsors must have meaningful grievance and appeals processes that conform to those for the Medicare Advantage program. These include requirements for determinations, reconsiderations, external review, and expedited decisions.

Our interviews and research revealed that plans currently use a continuum of methods for reviewing nonformulary exceptions. Exceptions processes are used more often with closed formularies than with tiered formularies, which involve obtaining preferred level cost sharing for a nonpreferred drug. Most require physicians to submit for approval medical documentation on why formulary alternatives will not be appropriate for a beneficiary, but some use less formal methods, including simple phone approval. Plans with more complex exceptions processes may also require the prescribing physician to document that the beneficiary tried the formulary alternative during a trial period and that either the beneficiary experienced an adverse reaction to the drug or the drug failed as a treatment alternative—often referred to as a step therapy requirement. Step therapy for hypertension was recently suggested in research sponsored by the National Institutes of Health (ALLHAT 2002). Physicians we interviewed cautioned, however, that the elderly and disabled population may not be well suited for some step therapy requirements, given their frailty and increased risk of adverse drug interactions.

Physicians also indicated to us that, although they usually were successful in obtaining nonformulary exceptions, the time spent on the phone was lengthy. Physicians commented that plans are more likely to grant nonformulary exceptions when physicians call than when a staff assistant calls. Additionally, specialists are more likely to obtain nonformulary approval for drugs within their specialty area than general practicioners.

Any burden associated with a medical exceptions process encourages formulary compliance (IOM 2000). Consumer advocates contend that, if the process for obtaining nonformulary exceptions is too burdensome, physicians may be less willing to prescribe nonformulary drugs, even when medically indicated. Alternatively, plan representatives expressed concern that, if nonformulary exceptions were too easy to obtain, the cost-control and drug-management mechanisms built into the formulary would be greatly undermined.

Some plans require physicians to obtain prior authorization from the plan before prescribing some drugs. Plans explained that the prior authorization process is often used to encourage careful prescribing of drugs that carry elevated safety concerns, either when taken on their own or in association with other medications. Plans also noted that extremely expensive drugs are candidates for

prior authorization to assure judicious prescribing. Consumer advocates and some researchers counter that formulary tools that delay patients' access can jeopardize patients' health (NMHA 1998, Huskamp 2003b).

Research suggests that the availability of effective product alternatives is an important consideration when implementing formulary tools that restrict use (Soumerai 2004). A study that examined the effect of prior authorizations of an effective, high-cost drug, when few alternative choices were available, found that it almost eliminated the drug's use and probably reduced appropriate care (Bloom and Jacobs 1985). On the other hand, research has also confirmed that prior authorization of brand name drugs in a class with other generic alternatives greatly reduced drug spending, without increasing costs or use of physician or hospital services (Smalley et al. 1995).

What issues arise if plans change their formularies?

In current practice, formularies are frequently modified to reflect the introduction of new drugs in the market, updated clinical information, and changes in market competition (AAA 2000). The MMA prohibits plans from changing their therapeutic category definitions during the plan year, but allows plans to change the specific drugs listed on their formulary at any time.[5] Medicare beneficiaries may only switch plans during annual open enrollment periods. Thus, if plans change formularies midyear, enrollees will not be able to retain drug coverage for a particular drug simply by switching to a plan that covers it. Issues that occur when beneficiaries change plans are discussed later in the chapter.

If plans add or remove a drug, or change its tier status, the MMA requires that plans notify affected enrollees, physicians, pharmacies, and pharmacists prior to the change through a website posting. Adequately notifying enrollees about any formulary changes can reduce those instances in which beneficiaries first learn at the pharmacy that their drug is no longer covered or has higher cost sharing. If the plan uses no notification mechanism other than website postings, then affected people must consult a website regularly to learn of formulary changes. Consumer organizations comment that website-based communication with Medicare beneficiaries can be useful, but is not a sufficient mechanism for informing most beneficiaries of formulary changes, considering the limited numbers of elderly and disabled people who are able to access and use the Internet. A recent study found that only 22 percent of people age 65 and older use the Internet, up from 15 percent in 2000 (Fox 2004). The National Library of Medicine is involved with local library initiatives to increase seniors' internet use, particularly for accessing health-related information (Humphreys 2004).

Regardless of how beneficiaries learn about any formulary changes, balancing this information with their drug needs and their tiered cost-sharing structures can be confusing, particularly for some Medicare beneficiaries. In addition to available family members, pharmacists and physicians are likely to receive many formulary-related questions.

Our interviews revealed that periodic mailings and website postings were the most common methods for plans and PBMs to communicate formulary changes to enrollees and physicians. Physicians reported that it is difficult to keep track of formulary changes for their patients' plans, particularly when plans do not specifically highlight subtractions or additions. One physician reported that because she is unable to keep track of all the formularies and formulary changes in her patients' plans *prior* to writing prescriptions, she typically does not learn that she has prescribed a nonformulary drug until she gets a call from a pharmacist alerting her of the situation. This can be burdensome for the patient, the physician, and the pharmacist.

Another physician we interviewed said that he uses a hand-held computer loaded with drug information in conjunction with hard copies of plan formulary lists, but still unknowingly prescribes nonformulary drugs because of plan formulary changes. Physicians commented that limitations on the frequency of formulary changes could be helpful. For example, if changes, particularly subtractions, could occur only on a quarterly basis, physicians would know when to check for possible changes. The ability to access current formularies online may also be useful. As noted in Chapter 7, physicians' use of internet technologies in clinical practice is growing, but still not routine. Further, physicians pointed out that formulary changes not only affect future prescribing, but also affect all refillable prescriptions written in the past. Rewriting these previous prescriptions to reflect a formulary change can require substantial office time for physicians as well as pharmacists.

In the future, electronic prescribing is likely to become a tremendously useful tool in formulary adherence. However, current use is in its infancy. Although recent experiences suggest major financial and logistical obstacles, the MMA has offered some incentives to promote electronic prescribing.

The MMA does not require plans to alter their nonformulary exceptions process for enrollees taking a drug if it is removed from their formulary. Enrollees are most directly affected by a formulary change if the drug they have been accustomed to using is deleted from their plan's closed or tiered formulary. The change may have health and financial implications for beneficiaries because it requires that they either switch to a new drug that is on the formulary or continue to use the original drug and pay for it themselves, unless they are granted a nonformulary exception. Additionally, as noted earlier, expenditures on nonformulary drugs will not count toward the enrollee's total out-of-pocket spending for purposes of calculating deductibles and catastrophic spending thresholds.

Patient cost sharing can affect drug use. Recent studies show that tiered cost sharing can influence people to switch to preferred drugs (Motheral and Fairman 2001, Joyce et al. 2002). However, other recent research has found that when an employer-sponsored plan more than tripled copays for brand name drugs, some patients stopped taking the drugs rather than switch to less expensive medications (Huskamp et al. 2003a). Physicians we interviewed also commented that patients were less likely to take prescribed drugs with high cost sharing. CMS may wish to monitor the effects of cost sharing on beneficiary use of essential drugs.

A 1999 General Accounting Office study of Medicare managed care plans found that some plans made it difficult for physicians to obtain exceptions for patients to remain on existing medications at no additional cost if the drugs were dropped from the formulary (GAO 1999). Few plans in this study granted automatic nonformulary exceptions to beneficiaries who were in the plan and already taking the dropped drug—a policy referred to as "grandfathering." Under this policy, as long as the enrollee stays in the plan, the enrollee may purchase the drug under preferred status.

Consumer advocates and researchers have noted the importance of grandfathering coverage for drugs dropped from a formulary, particularly in the case of psychotropic drugs (NMHA 1998, Huskamp 2003b). Some plan representatives we interviewed noted that, for a limited number of drugs and illnesses, grace periods or grandfathered exceptions for a dropped drug may be granted automatically. However, in cases when a new (less expensive) generic drug becomes available, plans are much less likely to grant exceptions because there are generally no safety issues associated with switching. Plan representatives noted that, because the MMA only requires affected people to be notified of any formulary changes, beneficiaries on a grandfathered drug do not need notification, which can prevent unnecessary anxiety and action.

How can beneficiaries learn about a plan's formulary?

At the time of enrollment and annually thereafter, the MMA requires plans to inform their enrollees how their formulary functions and how to obtain more specific formulary information. For example, upon request, plans must provide information on cost-sharing levels applicable to each drug or class of drugs. Plans must be able to provide such information through a toll-free telephone number and in writing.

The MMA requires plans and the Secretary to provide more general plan information to prospective enrollees. Upon beneficiary request, plans must provide information on their coverage rules, utilization control mechanisms, and grievance procedures, as is required for Medicare Advantage plans. Plans do not, however, have to provide prospective enrollees with a list of covered drugs by name. The MMA requires the Secretary to disseminate plan information to the public, including comparisons of plan benefits, premiums, quality, cost sharing, and consumer satisfaction information, unless the information is unavailable. The Secretary is not required to disseminate formulary comparison information to the public.

The issue of whether plans should be required to provide their formulary to prospective enrollees is complex. Beneficiaries need formulary information if they want to select the plan that can give them the best value and the lowest out-of-pocket costs. Meanwhile, plans with the least restrictive formularies are likely to be attractive to beneficiaries with higher-than-average health care costs. In our interviews, some plans expressed the concern that, if they covered an expensive drug (and other plans did not), a disproportionate share of beneficiaries on those drugs in

their service area would enroll in their plan, particularly if plans were required to disseminate their formularies widely to prospective enrollees. Thus, competitive pressures could lead plans to offer less expansive formularies.

Two additional factors complicate beneficiaries' selection of plans based on their formularies. First, beneficiaries who take multiple drugs will need to determine which plan has the combination of formulary drugs that will yield the lowest out-of-pocket spending. Second, plans may change their formularies after beneficiaries enroll. Thus, beneficiaries who select a plan based on its formulary would likely be frustrated if, after they enroll, the plan drops specific drugs they use from its formulary.

What are the requirements for P&T committees?

The MMA requires that plans have or contract with a P&T committee to develop and review their formularies. The MMA does not specify the number of members that the P&T committee must have, but the law does stipulate that the majority must be practicing physicians and/or pharmacists. In fact, at least two members of the committee—a practicing pharmacist and a practicing physician—must be considered "independent experts." They cannot have a conflict of interest with the plan, and they must have expertise in the care of elderly or disabled persons.

In our interviews, plan representatives and physicians preferred practicing physicians and pharmacists over nonpracticing ones for P&T committee membership because of their familiarity with formularies.

Plan representatives disagreed on the importance of P&T committee member independence. Some stressed the importance of independence from the plan and from other intermediaries, such as drug manufacturers. Many of the P&T committees did not have a plan representative on the committee, but some did. A recent study cited in a managed care trade publication suggests a decline in the share of P&T committees with plan representatives; it fell from about 40 percent of the P&T committees in 1988 to about 20 percent in 2000 (Cross 2001). Other plan representatives stated that including plan-affiliated physicians and pharmacists on the P&T committees helps assure all physicians and pharmacists in the plan that they are represented in the formulary decision-making process, thus increasing formulary compliance. Some plans allowed members with conflicts of interest, such as relationships with drug manufacturers, to remain on the P&T committee, but required disclosure and possible abstention from voting on associated drug products. The MMA does not specifically address conflicts of interest between P&T committee members and drug manufacturers.

The MMA does not prescribe a set number of P&T meetings per year, but does require periodic evaluation and analysis of treatment protocols and procedures. The P&T committee may review any information it determines to be appropriate when making decisions regarding drug coverage status. Such information may include peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and information requested from drug manufacturers. The P&T committee must consider the strength of the scientific evidence and standards of practice when making clinical decisions. For example, the P&T committee may weigh randomized clinical trials and drug comparison studies more heavily than other types of studies it considers less definitive. The MMA also requires that P&T committees consider whether including a drug on the formulary or in a preferred tier has therapeutic advantages in terms of safety and efficacy. Consumer advocates state, however, that allowing P&T committees to examine "any information they deem appropriate" weakens the standards for coverage, allowing cost considerations to override effectiveness (NPAF 2003).

The MMA's requirement that at least two P&T committee members have expertise in treating elderly and disabled people may help to assure effective protocols for this population. Without clinical experience, P&T committees have limited information on drug effectiveness and adverse drug interactions in these populations, which are often excluded from studies due to their high rate of coexisting conditions (Hutchins et al. 1999).[6]

Need for drug comparison studies Currently, two drugs are rarely tested against each other for effectiveness in treating the same condition (Goldberg 1997). This lack of direct evidence has led health insurers, providers, consumers, and policymakers to advocate for independent head-to-head drug comparison studies. Such studies could provide improved evidence on which to base formulary and prescribing choices.

In the absence of head-to-head drug comparison studies, P&T committees and prescribing physicians use more indirect means to determine whether drugs are equally effective for the same conditions or if one is better. For example, they may consult or conduct a meta-analysis, which extrapolates findings from relevant single-drug placebo studies. Meta-analysis has many limitations, however, particularly when the research methods among available and selected studies are not parallel (Petitti 2000). In our interviews, plan pharmacy managers stated that single-drug studies do not often provide clear-cut comparisons among drugs that treat the same symptoms because of variance between study methods and protocols. They also raised concerns about the methodology of some studies conducted and submitted by drug manufacturers. In some drug classes, for example, randomized controlled trial studies—considered the gold standard among the research community—are minimal or unavailable.

Physicians and P&T committees are also faced with the question of which type of outcomes to weigh more heavily when choosing a preferred drug. For example, is evidence of a drug's ability to reduce heart attacks more important than a drug's ability to reduce cholesterol levels? How much weight should P&T committees place on side effects of effective drugs? These questions are being debated by researchers and stakeholders alike.

The pharmaceutical industry contends that current research methods are sufficient for physicians and plans to make informed choices. Manufacturers already spend considerable resources demonstrating the safety and effectiveness of their drugs through the FDA approval process, which includes research on drugs even after they are available to the public. In response to growing demand from the medical community for more data, the pharmaceutical research and development process has become increasingly lengthy and complex (PhRMA 2003). In fact, manufacturers have recently funded some head-to-head studies on brand name cholesterol lowering drugs, but these kinds of studies are uncommon.

The plan managers we interviewed identified a need for unbiased information on drug-to-drug comparisons of clinical outcomes. With independent, evidence-based outcomes research, plans could have a better opportunity to select formulary drugs based on clinical effectiveness. Further, studies designed to test drugs for certain subpopulations can inform formulary protocols for patients with specified characteristics, such as coexisting medical conditions and drug regimens. Without sufficient clinical evidence for selecting one drug over another in a therapeutic class, P&T committees may select drugs based on price factors (AAHP 2002).

Physicians and beneficiaries would also benefit from having an independent resource for drug-to-drug comparisons. Physicians would have greater access to unbiased effectiveness research, which would assist them in selecting drugs to prescribe. Physicians mentioned to us that they currently consult a variety of sources—some considered more trustworthy than others—to select a drug of choice to prescribe. Also, if independent drug-to-drug results were available to the public, beneficiaries would have an objective resource for understanding which drugs work better than others for specified medical conditions. This information could help beneficiaries sort through consumer advertising.

Provisions in the MMA recognize that providers, patients, and health insurers need improved evidence to make informed health care choices. The MMA authorizes the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research studying the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs). The law calls for this research to evaluate and synthesize available scientific evidence and identify areas for which existing evidence is insufficient.

Under its Evidence-based Practice Program, AHRQ already supports the systematic review and analysis of scientific literature on a variety of health-related topics and disseminates the findings. However, this program does not currently focus on pharmaceutical care.

The MMA directs the Secretary to collaborate with public and private sector entities to help develop new scientific knowledge regarding health care items and services, including prescription drugs. Such research could include testing drugs' effectiveness against other drugs used to treat the same condition. Results from this research are to be disseminated to plans and beneficiaries. However, CMS may not use data obtained from such outcomes studies to withhold coverage of a prescription drug.

To carry out these research, evaluation, and communication efforts, the MMA authorizes $50 million in 2004 and additional funds as needed in later years. As yet, these funds have not been appropriated by Congress. Further, no amount was authorized specifically for research on prescription drugs over other types of health care items and services.

In addition to authorizing AHRQ to conduct or sponsor comparative research, the MMA also notes its support of public-private partnerships to do the same. Funding research through a government agency would subject studies to the annual congressional appropriations process, which could leave the research vulnerable to unstable funding. As an alternative to Congressional appropriations, a specified percentage of sales from drug manufacturers, health plans, and PBMs may be an appropriate and available mechanism for funding needed outcomes research.

Uwe Reinhardt, a noted health economist, suggests that independent research institutes, which would function like not-for-profit foundations, conduct cost-benefit analyses on drug therapies. These institutes could attract distinguished researchers and could disseminate findings in scholarly literature and public venues for consumers and physicians (Reinhardt 2001, Reinhardt 2004). Reinhardt notes that drug-to-drug research should be transparent and subject to peer review to garner stakeholder respect.

The independence of the comparative outcomes research is essential to its success. If drug manufacturers were to conduct the research, health insurers and consumer organizations might not trust the findings; if health insurers conducted the research, consumer organizations and drug manufacturers might be distrustful.

Conducting head-to-head studies and other evidence-based outcomes research would be very expensive, and interpretations of the results could vary. At issue, therefore, is who would conduct these tests and who would pay for them. Funding could be provided by the public sector, the private sector, or a collaboration between the two.

In sum, Medicare and the Congress will face numerous formulary implementation issues as details for the drug benefit unfold. Formulary issues could also arise when beneficiaries move from one drug plan to another, when drug plans enter and leave the program, or when drug plans switch PBMs. Such issues are discussed in the following section.

Plan transition issues

To encourage efficiency, quality, and cost control, the Medicare drug benefit depends upon competition among private plans. The challenge for the Medicare program is to provide opportunities for continued competition among plans while minimizing instability and disruption for beneficiaries. Plans must have the flexibility to make business decisions about their continuing participation in the program, and Medicare must have the ability to reject plan bids that do not meet cost and quality standards. Finally, beneficiaries must be able at periodic open seasons to change enrollment from one prescription drug plan or Medicare Advantage (MA) plan to another that better meets their needs.

As prescription drug plans enroll beneficiaries, as plans enter and exit markets, and as beneficiaries change plans, plan sponsors and the Medicare program will have to ensure that the transition from enrollment in one plan to another is as seamless as possible. Plans must have the infrastructure in place to make sure that enrollees can switch between plans, taking their patient information and benefit history with them. Crucial tasks will include educating beneficiaries, communicating with relevant physicians and pharmacists, distributing new drug benefit cards, transfering data on eligibility and enrollment, and implementing additional processes to minimize problems for beneficiaries arising from disruption of pharmacy networks and formulary systems.

Some health plans and large public and private employers have recently gone through the experience of changing the PBM that manages their drug benefit. PBMs are likely to offer private drug plans under Medicare Part D. MedPAC, with the help of researchers at NORC/Georgetown University, conducted a series of structured interviews with experts and conducted site visits and focus groups with active and retired employees of some of these companies to understand the experiences of stakeholders when these transitions occur. Our goal was to examine the issues that arise when health plan sponsors switch from one pharmacy benefit manager to another to see if there were any policy lessons that could be applied to

implementation of the Medicare drug benefit. We focused on both best practices and the problems that plan sponsors and participants have experienced following a change.

Key findings include:

- Organizations need advance preparation to ensure a smooth change in PBMs. Transition planning requires several months of effort, ideally at least six months in advance of the transition date. Although this time frame may be unrealistic in the Medicare context, CMS should work to ensure that Medicare Part D plans have the longest possible lead time.
- Effective communication of plan changes requires repeated notifications. Beneficiaries need frequent messages through multiple channels to prepare them for coming changes.
- Physicians and pharmacists must be informed about plan changes. In our study, providers reported that they had received little advance notice of changes although they were frequently required to explain the changes to their patients.
- Most transition problems take place in the first few months and then are resolved. However they can be quite disruptive when they occur. Interviewees reported that most problems were handled by staff both in the sponsoring company and the new PBM. CMS and participating drug plans should ensure adequate numbers of trained personnel are available to handle post-transition issues.
- Data transfers are generally well managed. Although interviewees reported that most transfers of enrollment and claims data were handled efficiently, more individualized services such as renewals of open prescriptions and prior authorizations were frequent sources of problems during the transition.

In this section, we will describe our study and present the findings. Next we will explore the implications of this work for implementation of the Medicare drug benefit. In the cases we examined in the study, the decision to change PBMs was made on a company wide basis. Managers from the company made the initial decision and oversaw the transition process for all affected employees. In the case of Medicare, once plans decide to enter or exit markets, individuals will make decisions on whether or not to enroll in a Part D plan and which plan to choose. The law requires the Secretary to contract with a fallback plan to provide drug benefits in a region if no private plan offers a stand-alone drug plan. If one or more private drug plans enters a region served by a fallback plan, all enrollees in the fallback plan will have to enroll in one of the new plans. Conversely, if all private plans in a region leave and are replaced by a fallback plan, enrollment will have to be transferred to the fallback plan.

In general, it is difficult to predict the number of people who will make plan changes in any one area during any open season. Some of the issues with private plan transitions will not be relevant for Medicare, and some of the solutions will not be practical. Nevertheless, the study suggests a number of lessons that can be applied in the Medicare context.

The role of the pharmacy benefit manager

Medicare drug plans are likely to be managed by pharmacy benefit managers, either alone or in partnership with other entities like health plans, insurers, pharmacies, or pharmaceutical manufacturers. Currently, most drug coverage in the commercial market is managed for health plans or other purchasers by PBMs. They manage drug benefits for about 200 million Americans, processing about 70 percent of the more than 3 billion prescriptions dispensed annually and accounting for nearly 80 percent of all expenditures for prescription drugs (PCMA 2003, HPA 2003). PBMs began as claims processors, organizers of pharmacy networks, and mail-order pharmacies. They now perform a range of functions, including negotiating price discounts and rebates with pharmacies and pharmaceutical companies, conducting drug utilization reviews, and customizing formularies and drug benefit designs for their customers. Thus they play a major role in managing the cost and utilization of prescription drugs nationally.

Recent survey findings indicate that large employers are generally satisfied with the service and performance they receive from their PBMs (Drug Benefit Trends 2003). In results that parallel findings from 2002, 468 large employers (those with more than 2,500 employees) gave their PBMs an average rating of 7.7 out of 10 on their performance.[7] Satisfaction was highest for administrative functions such as claim processing and maintaining pharmacy networks. It was lowest for services related to

managing cost and utilization of the drug benefit, including disease management programs, formulary management, and rebates.

Survey results also indicate that 66 percent of large employers were very likely to retain their current PBM at the end of the contract period, while 29 percent were unsure, and 5 percent were very unlikely to renew their contracts (Pharmacy Benefit Management Institute 2004). In part, the high likelihood of renewal may reflect the resources required in making a contracting change and the initial disruption that these changes may entail. A third party administrator noted that his company experienced significant increases in labor costs when one PBM they contracted with was acquired by another company (Princeton Consultants 2002). The company had to conduct biweekly meetings with its clients and the PBM to monitor the conversion process. Implementation problems (for example, the failure of maintenance drug prescription refills to transfer from the old plan to the new one) continued to tax the company's resources after the conversion was completed. The fact that PBMs receive their lowest ratings in the first year of a contract indicates that implementing a new drug plan is likely to result in some disruption of services.

Study design

In the absence of detailed information on the dynamics of PBM transitions, MedPAC contracted with researchers at NORC at the University of Chicago and Georgetown University to conduct a series of structured interviews with experts and make site visits with large employers who had recently experienced a change in the PBM that managed their prescription drug benefit (see text box). The visits included focus groups with active and retired employees and interviews with stakeholders. The purpose of the study was to examine their experiences to understand how Medicare may provide opportunities for continued competition among PBMs while minimizing disruption for its beneficiaries. Our findings are based on transitions at about eight different organizations that clearly cannot represent the full range of situations that have arisen across the country. Similarly, focus group participants at the organizations we visited may not reflect all attitudes present at each site. Sample size limits our ability to generalize from our results, but our findings do allow us to pinpoint some of the areas of vulnerability in the transition process as well as some of the most successful ways that companies have handled these issues.

What steps are involved in the transition process?

An organization may decide to change PBMs for several reasons including cost, service problems, restructuring of a health benefit plan, or implementation of a new clinical care management program. In our interviews, cost concerns were the most significant factor. In addition, organizations often made changes because they had service problems, including lack of responsiveness by the current vendor and errors in data management. Some changes were made by large organizations in concert with a reorganization of their health benefit program that included creation of a uniform drug benefit across the organization. By carving out the drug benefit, they sought to simplify management of drug spending and utilization.

Transition processes occur in three phases: planning the change; implementing the change, including communicating it to affected parties; and monitoring post transition problems. Early activities include designing the new benefit, selecting the vendor, working with the vendor on transition issues, and developing the communications strategy. Later activities focus on communicating with employees and retirees and ensuring that the data transfers occur and new benefit cards are issued. Finally, activities after the transition focus on problem solving for people who have service disruptions or do not understand the new benefits.

In this section, we describe how transitions are managed based on findings from both the site visits and the expert interviews. Key questions addressed include:

- What were the steps taken to initiate and implement a transition from one PBM to another?
- Were any criteria used in the selection process for a new PBM to anticipate or limit disruptions?
- What time frame was involved in implementing the change?
- What educational efforts were conducted and how did they vary between active employees and retirees?
- What processes were most likely to be problematic? How were they handled?

Components of the transition study design

Expert interviews

We conducted 10 phone interviews with experts with a wide variety of experiences in drug benefit management and pharmacy issues. Experts included representatives from large pharmacy benefit managers (PBMs), consultants with experience on PBM transitions, representatives from pharmacy trade associations, representatives from health plans and other large organizations that had recently changed PBMs. Individuals were chosen for both their expertise and varying perspectives. We asked them to comment on strategies for planning and managing a PBM transition. Additional questions focused on methods for communicating the transition to members and other key stakeholders. We also asked interviewees to identify best practices and lessons learned.

Site visits

The study targeted two large organizations that had recently undergone PBM transitions. The first site was a large private company. This organization made a transition from one large PBM to another large PBM about two months prior to the site visit. Nearly 25,000 employees and retirees (about three-fourths of its population) were affected. Concurrent with the transition, the organization made significant changes to the plan design, including increased copays, mandatory generic substitution, and mandatory mail-order use for maintenance drugs. The second site was a large public organization. This organization insures approximately 75,000 employees in 5 separate health plans. Approximately one year prior to the site visit, the organization carved out the drug benefits from its five health plans to form one PBM contract. The leadership of this organization also made significant plan design changes simultaneously with the PBM transition.

Focus groups

Each one-day site visit included a series of in-person interviews with key stakeholders in the transition process, a focus group with active employees, and a focus group with retirees. Interviewees were identified in consultation with each organization's benefits office and through background research on each site. The interviews were conducted by three-person teams using structured protocols tailored to each interviewee's perspective as either an employer or group purchaser, a union or employee representative, or a pharmacist or physician.

Each of the focus groups included 8 to15 participants. A convenience sample of participants was used for both the active and retiree focus groups at each site. Participants responded to advertisements for the focus groups posted in employee areas and newsletters or announcements that were distributed at retiree meetings. Topics discussed at the focus groups included participants' level of satisfaction with both the current and previous drug plan, experiences during the transition, and opinions on the way the organization handled the benefits transition. We recognize the potential bias of using a nonrepresentative sample of focus group respondents, and we understand that our findings may not represent the full range of attitudes present within each site's affected population. Those with negative experiences may have been more motivated to attend the sessions. However, personal experiences discussed during the focus groups provide constructive examples of the potential effects PBM transitions can have on beneficiaries. Furthermore, many participants shared neutral or positive feelings and experiences regarding the transitions. ■

Transition planning

Transition planning and implementation requires several months of effort. Interviewees agreed that the planning should start at least six months before the transition date, though eight to nine months was considered preferable.

One health plan reported that circumstances forced it to implement a new drug plan within 90 days. Although the transition was accomplished, the process was exceedingly difficult for all parties. Following the change, the plan experienced an upsurge in complaints from participants,

with call volume in the first month following the change equaling nearly 60 percent of total calls for the previous year.

Changing vendors to manage a pharmacy benefit is a time consuming process. Internal meetings are required to determine the goals of the change and the relative priority accorded to each goal. These meetings will culminate in the preparation of a request for proposal from potential vendors and a review of the submitted proposals. After a new vendor is chosen, the transition process begins. This process includes developing and testing a system to transfer enrollment and drug data from the old vendor to the new one. Procedures must be developed to communicate changes to affected individuals. Employees will have to receive enrollment cards from the new PBM before the start of the contract to avoid disruption in service. Systems must also be in place at pharmacies to accept the cards and access up-to-date enrollment, formulary, and copay information.

One factor complicating analysis of the transition process is that organizations often change their drug benefit design at the same time as they change PBMs. Interviewees were divided on whether it is preferable to make benefit design changes simultaneously with the switch to a new PBM. Some benefits managers and consultants said making many changes at once avoided having several periods of disruption. Employees and retirees would already be aware of changes, and personnel would be in place to respond to questions and problems. Moreover, because controlling health care costs often motivated the decision to switch, organizations wanted the savings from design changes in addition to those from changing PBMs. Others suggested that making too many changes at once was far too disruptive, and adjustments should be made over the course of several years. One consultant estimated that, in about half of the cases, plans also change benefits.

Data transfers

A core transition activity is the transfer of enrollment and prescription data from one PBM to another. Consultants assisting in transitions, benefits personnel, and PBM staff all said that systems-level data transfers are much more streamlined than they were several years ago, primarily because the large PBMs have standardized their data codes. However, a consultant who works with a pharmacy trade association said that many disruptions with data transfers still occur, along with "lots of surprises that require pharmacist involvement." All respondents agreed that data transfers should occur as early as possible to allow time for error checking and testing of the data transfer. Timeliness is particularly important for the transfer of eligibility information and of mail-order prescriptions that still have refills available. The failure to transfer eligibility information correctly will mean that coverage for an individual's prescription will be rejected, while an error in transferring an open refill makes it illegal for the mail-order pharmacy to dispense the needed drug without a new prescription from the doctor. Once testing of the data transfer has been completed, the final data transfer must occur as close to the actual transition date as possible to minimize errors. The failure of a data transfer to occur for one organization we interviewed caused major difficulties. Enrollees were unable to get prescriptions filled until the eligibility files for the new PBM were updated.

An additional advantage to early transfer is that, given time, the incoming PBM can target mailings to people who will be affected by changes to formularies, copay amounts, or prior authorization requirements; the employer cannot do targeted mailings for privacy reasons.

Pharmacy benefit managers' relationships

Good relationships with old and new vendors are critical. Generally, interviewees said that the old PBMs had been helpful and the new PBMs had been responsive to both the organization and the employees and retirees. They were also well prepared for the increased volume of inquiries immediately following the transition. Benefits managers from two organizations said one reason for their smooth transition was that the account manager from the incoming PBM was very effective. However, in one organization the incoming PBM was concurrently managing several other transitions, which resulted in greater disruption and less responsiveness. Representatives from two organizations expressed dissatisfaction with their outgoing PBMs because they were not helpful. In one case, the PBM did not transfer any data or provide any assistance.

Post-transition issues

Typically, the post-transition adjustment period lasted two to four months depending on the extent of changes in key procedures, particularly those related to prior authorization. After that time, most transition problems were resolved, although some problems persisted beyond

that period. Those first several months could be very difficult. Several organizations reported extremely high call volumes initially. After three to six months, any remaining issues tended to be associated with benefits design. One consultant said that some organizations "grandfathered" the formularies and prior authorization requirements of the outgoing PBM for the first two to three months of the transition. This practice could minimize the disruption but also reduce the expected savings.

How did organizations communicate changes to plan participants?

Study participants agreed that extensive communication is essential to a smooth transition. People stressed that different modes of communication should be used, including mail, e-mail, internet materials, personal meetings, and, if necessary, one-on-one assistance to answer specific questions. In particular, organizations cannot rely on e-mail and internet access alone for retirees and for employees who do not work in office settings. Moreover, the messages communicated should be clear and concise. Interviewees who were responsible for the communication believed that they did a good job with this. However, some focus group attendees were less positive and did not really understand the changes until they tried to fill a prescription. Study participants consistently stressed the need for frequent and varied communication because of the complexity of the issues and the fact that people do not always read their mail or e-mail. Even with multiple mailings, e-mails, meetings, and notices, many employees and retirees did not actually assimilate the changes until they were filling a prescription. One physician whom we interviewed for our formulary study also noted that it was hard to keep track of all of the communications she received from all of the health plans with whom she participated.

Interviewees stressed that planning the communications strategy should begin early in the transition planning. One organization held meetings about five months prior to the transition to make the business case for the change. In these meetings and in subsequent mailings, senior management and benefits personnel explained that increasing pharmaceutical costs were difficult for the company to absorb and were unsustainable over time. Employees and retirees were told that, in order to continue to provide jobs and benefits in the long term, the organization would have to make some changes. Although this early communication was unusual, benefits personnel at that company believed that this was an effective strategy for them. A representative of an organization of retired public employees emphasized that communication should begin much earlier for retirees.

There was no consensus on when to start informing employees about specific changes regarding formularies, copays, and the new mail-order systems. Most organizations held meetings and sent out written materials three to four months before the transition date. Some waited until open enrollment, usually two months before the transition, because they believed that it was only then that employees really began focusing on their health benefit options.

The incoming PBM also corresponded with employees and retirees before the transition. The PBM usually mailed materials several months before the transition, often at the time of the normal open season for benefit changes. In addition, incoming PBMs sometimes made their website and 800-number accessible several weeks early. In one instance, some employees did not receive any information until several weeks after the transition, creating many problems for people trying to figure out new formularies and prior authorization requirements.

When possible, targeted mailings were sent to people who would be affected by specific changes, such as those using drugs that would require prior authorization or that would be on a different tier for cost-sharing purposes. However, this kind of individualized communication was sometimes problematic because privacy rules precluded the employer from having this information. The incoming PBM in these cases had to receive the data from the old PBM in time to prepare mailings.

More often, we were told that mailings were sent to everyone, highlighting specific areas of attention such as a listing of all drugs that would require prior authorization. Such a mailing would include general instructions and a number to call for assistance. We were told by one health plan representative that such general mailings can cause confusion and distress to some enrollees who would not actually be affected by the changes. For example, an individual who had already received prior authorization for a particular medication might receive a general mailing indicating that the drug would not be on the formulary.

Interviewees reported that they made some adjustments when communicating with retirees. Several people reported that they used a larger font for retiree mailings. They did not rely too heavily on the Internet because retirees were less likely to be online than current employees, although this was changing as more seniors were becoming familiar with the Internet.

Generally, interviewees said that messages should be simple, focusing on what would change and what people should expect. The information should provide details about what really matters to people, for example, copay changes and new prior authorization requirements.

Communicating with physicians and pharmacists

Interviewees said it was rare for organizations or PBMs to communicate transitions and benefit changes to pharmacists and physicians. On the other hand, both physicians and pharmacists reported that it is not unusual for employees and retirees to first learn of changes to their drug benefits when they were obtaining a prescription or filling it. Lack of notification put the providers in the position of trying to resolve their patients' problems without adequate information. When they had advance knowledge, they acted as a trusted source of information to employees and retirees.

Study participants emphasized the importance of communicating with the pharmacists who play an important role in these transitions. Pharmacists stressed that information should be sent directly to local pharmacies as well as to the corporate headquarters of the major pharmacy chains. One representative from a drugstore trade association noted that pharmacists spend much more time counseling people following a transition or change to benefits because, despite having received information, people do not always understand the changes. These lengthy consultations can be burdensome to pharmacists. Pharmacies are also busier prior to a switch because people often get refills in advance to avoid increased copays and formulary changes. With advance notice—at least 30 days in advance—pharmacies might be able to schedule additional pharmacists or assistants. Interviewees added that information provided to them should include a description of the new benefits structure, formularies, and copay tiers and amounts. Pharmacists should also receive a copy of the new identification card.

Similarly, if doctors are aware of a change, they can schedule longer appointments if they anticipate that patients will need help understanding the changes. Some physicians reported that they first received notice of changes to their patients' formulary or benefit design following a phone call from a pharmacist. In these instances, a patient is likely to be waiting at the pharmacy while the pharmacist attempts to contact the physician and explain that the prescription cannot be filled. This situation creates disruptions for the physician, pharmacist, and the enrollee. Interviewees recommended that information for physicians be sent to office staff.

What problems arise during transitions?

Most transition problems can be classified into two types: those related to the transition and those related to changes in benefits design. Examples of transition disruptions included improper loading of copay information, which led to inaccurate charges at the retail counter; lack of awareness of which drugs were on the formulary on the part of physicians, pharmacists, and employees, which caused confusion or delays when a prescription was rejected; and refill data not transferring, which required the individual to obtain a new prescription from the doctor. The majority of transition problems were resolved within the first several months. However, these disruptions were stressful and time consuming to resolve for both the enrollee, the new PBM, and organization management.

Transfer of prior authorizations was one of the most problematic areas described in our study. Drug plans may require prior authorizations for drugs that are not on the plan formulary but are medically necessary for a particular enrollee, drugs that are particularly expensive, or drugs that are subject to overuse or abuse. The drugs requiring prior authorization may vary from plan to plan. In addition, plans often have different prior authorization requirements, making it administratively difficult for pharmacists to keep track of these procedures. However, even when both plans required prior authorization for the same drug, most plans had a difficult time transferring the information from the old PBM to the new one. A number of interviewees reported that this problem resulted in multiple physician visits simply to rewrite prescriptions.

Interviewees cited problems with mail-order procedures. One common problem occured when individuals mailed in refill requests to their old PBM just before the transition date and the prescriptions were never transferred to the new PBM.

Many other challenges were related to the new benefits design. People often did not understand the new formularies, prior authorization requirements, or mandatory mail-order, and they disliked the higher copays that often accompanied these changes. These problems likely would have arisen even if an organization did not change PBMs.

What do we know about the factors that ensure a smooth transition from one drug plan to another?

Although disruptions will occur even with the best planned, well-managed transition, interviewees mentioned several activities that could ease the change. All agreed that good communication is essential, that people need to be told in clear and concise language what to expect and what they need to do to minimize disruptions. They also need to be informed multiple times and via different methods, such as mail, meetings, and websites. Organizations should not rely too much on information provided by any one mode of communication.

The presence of a few key people to manage the transition and oversee the technical aspects and communication strategies is essential. These people are also extremely important in the initial months post-transition because they frequently help resolve disruptions. Interviewees emphasized the central roles of the benefits staff as well as a strong implementation team from the incoming PBM. Moreover, knowledgeable staff are more likely to anticipate problems and develop solutions to address them. For example, one organization anticipated that prior authorization requirements could be a difficult adjustment for people. In order to minimize the problems associated with this change, they included the list of drugs that would require prior authorization in several newsletters and mailings. As a result, they had few questions and problems with this aspect of the benefit change.

Several benefits personnel stressed the importance of maintaining good relationships with the outgoing vendors. Good relationships make data transfers go much more smoothly. A representative from one large organization noted that its outgoing PBM refused to transfer any patient files to the new vendor. As a result, the new PBM could not target any communication to enrollees in advance. He suggested that contracts should include language stating the obligations of the outgoing PBM in the event it loses the contract in the future.

What are the implications of this study for implementation of the Medicare prescription drug benefit?

In this final section, we draw some conclusions from the experiences we examined that should be taken into account as CMS develops regulations for the drug benefit. Our findings are based on situations in which employers or health plans decided to use a new PBM to manage drug benefits. In these situations, the organizations took responsibility for managing the transition to the new PBM. In contrast, private drug plans will compete for individual members under the Medicare drug benefit. Most changes will be made on an individual level without needing large data transfers of the type studied here.[8] Nevertheless, we believe that certain strategies could encourage smooth transitions for beneficiaries enrolled in Part D who switch between private drug plans, whether these switches result from plans' decisions to withdraw from a particular market, fallback plans entering or exiting markets, or beneficiaries selecting a different plan among a set of competitors.

Regulations that help ensure a smooth transition for beneficiaries between drug plans are important to promote continuing competition between plans. Plans may be unwilling to enter new markets if they find establishing plans and handling post-transition problems to be too costly. Similarly, if beneficiaries find the transition process too burdensome, they may be unwilling to change plans even in the face of higher premiums or lower quality in their current plan. Under these conditions, the benefits of competition might not be realized.

- CMS should ensure that drug plans have sufficient time to implement transition strategies. When transitions ran smoothly for the organizations we studied, a careful planning process over at least six months, extensive communication, and attention to special issues were important factors. The careful oversight by the staff of a corporate benefits office, together with attention to operational details by the incoming PBM, was critical to minimizing problems. Even then, employees and retirees could point to an

array of transition problems. In the Medicare context, less transition time will be available to the new plans. Some drug plans will be required to submit bids to CMS by June 2005, and the agency should try to maximize the available time for plan implementation by responding quickly to plan proposals and providing information to beneficiaries in a timely manner.

- Because of the abbreviated time frame, coordination of data between the old and the new drug plans will be of critical importance. In private sector transitions, new PBMs rarely obtain a complete medication history from the old PBM. This may be even less likely under Part D, unless Medicare requires it. The result may be unnecessary or duplicated efforts to address special situations that had been resolved with the old PBM and diminished ability for the incoming PBM to detect dangerous drug interactions. Plans providing drug benefits to Medicare beneficiaries should report how they will handle enrollment and data transfers for new beneficiaries and how they will transfer data for beneficiaries who leave their plans. These processes should be specified in contracts with CMS.

- Drug plans should ensure that they have sufficient staff available to handle the post-transition problems of beneficiaries. In the private sector, trained staff guide the affected individuals through the transition process. These people take care of the bulk transfer of records and the overall communications, and provide a process for dealing with individual problems. In Medicare transitions, all the shifts will be at the individual level. If their medical records do not transfer to the new drug plan, beneficiaries will have to obtain new mail-order prescriptions or new prior authorizations for maintenance drugs. All Medicare drug plans should have the capacity to provide information on these processes in advance of the transition date. But since it will be difficult, if not impossible to target messages based on individual needs, plans also should be well prepared with effective call-in resources (and dedicated staff) to address individual problems in the days, weeks, and even months immediately following the transition.

- Medicare and participating plans must develop a detailed communication strategy to inform beneficiaries about their options. All of our study participants emphasized the importance of frequent, simple messages repeated through different modes of communication. Messages must be easily understood because the Medicare population is older, frailer, and more likely to have cognitive impairments than the people affected by the transitions we examined.

  Transition issues will be far more individualized for Medicare, since each individual, rather than a single employer, will have to choose his or her own plan. In addition, Medicare will provide information to compare plans; choice among plans was not a feature of private sector transitions. Communication will be resource intensive if the withdrawal of a large plan requires many beneficiaries to select new plans or if large numbers of beneficiaries choose new drug plans in a particular open season. CMS should consider providing information to family members or other designated individuals for those beneficiaries who request additional assistance.

- Plans should also develop strategies to ensure that pharmacists and physicians are prepared for benefit changes for their patients following open seasons. Even more so than in private sector transitions, pharmacists and physicians may bear a significant part of the education burden as beneficiaries transition among Medicare plans. They are at the front line when beneficiaries do not understand the differences between plans. And they will have additional demands for medication changes to comply with formulary, prior authorization, and other requirements. Pharmacists will also need to know all of the sources of coverage that a beneficiary may have in order to bill properly. Although the new drug plan will be the first source of information in these situations, many beneficiaries are likely to depend upon help supplied by their physician or pharmacist. ■

Glossary of formulary terms

Drug utilization review (DUR)—a program, implemented by payers, for assessing data on drug use and prescribing patterns against explicit criteria (Cook et al. 2000).

Drug Efficacy Study Implementation (DESI) drugs—a group of drugs of insufficient efficacy based on decisions resulting from a review by the National Academy of Sciences and the Food and Drug Administration (FDA) pursuant to federal law. These drugs are not reimbursable by U.S. government programs (IOM 2000).

Formulary—a continually revised list of preferred drugs that are considered by a health care organization to be the most useful in caring for the patients it serves (IOM 2000).

> ***Open or unrestricted formulary***—a comprehensive listing of medications typically including almost every commercially available product in each therapeutic class. Payers provide coverage for these medications since there are no restrictions (IOM 2000).
>
> ***Closed formulary***—an exclusive list of specific drugs limited to only some of the commercially available products in each therapeutic class. Drugs that do not appear on the list of approved products (nonformulary drugs) are not covered by the health plan, pharmacy benefit manager, or employer, and patients are liable for the drugs' full retail prices, unless they obtain prior approvals or nonformulary exceptions (IOM 2000).
>
> ***Partially/selectively closed formulary***—a formulary hybrid that limits drug choices within certain therapeutic classes and offers unlimited choices within other drug classes. Such formularies direct prescribers to preferred agents within therapeutic classes, which may be included in treatment protocols or clinical guidelines. In some cases, entire categories, such as drugs used solely for cosmetic purposes, may be closed to prevent payment for those drugs that are excluded from coverage (IOM 2000).

Formulary system—the policies and procedures by which a health care organization maintains and updates its formulary for coverage. It includes policies and procedures for implementing the formulary, such as a nonformulary exceptions process, if applicable (AMCP 2000a).

Generic drug—a drug containing the same amount of active ingredient in the same dosage form as its brand-name counterpart. A generic drug has similar bioavailability (i.e., the same amount of medication is delivered to the body over the same time period) but may differ in characteristics such as color and shape (AAA 2000).

Generic substitution—substitution of a generically equivalent drug for a multi-source brand drug. In many cases, this can be done without the prescribing physician's approval (AAA 2000).

Incentive-based formulary—a formulary that contains different cost sharing for preferred and nonpreferred brand name drugs, and generic drugs, thereby giving patients an financial incentive to request preferred or generic medications (AAA 2003).

Medicaid preferred drug list—list of medications that Medicaid enrollees may receive without first obtaining prior authorization from the state (Bernasek et al. 2004).

Nonformulary exceptions process—process by which a drug not listed on a formulary may be covered or a nonpreferred drug may be obtained at a lower level of enrollee cost sharing. Nonformulary exceptions can require the physician to establish medical necessity for the drug's use (Cook et al. 2000).

Off-label use—the use of prescription drugs for conditions not approved by the FDA (IOM 2000).

Pharmacy and therapeutics (P&T) committee—an advisory committee, usually with substantial representation by physicians and pharmacists, that is responsible for developing, managing, updating, and administering the drug formulary system (Goldberg 1997).

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Glossary of formulary terms *(continued)*

Pharmacy benefit managers (PBMs)—companies that, on behalf of health plans, process pharmaceutical claims, negotiate prices with retail pharmacies and drug manufacturers, and manage enrollee drug use (CBO 2002).

Prior authorization or approval—a procedure that requires physicians to obtain permission to prescribe a specified drug before the drug is covered (Cook et al. 2000).

Step therapy protocol—a treatment design that recommends beginning a trial of drug therapy for a medical condition with one particular drug or class of drugs before proceeding to other drugs or drug classes (IOM 2000).

Tiered cost sharing—a pharmacy benefit design that financially rewards beneficiaries for using generic and formulary drugs by requiring progressively higher levels of cost sharing (fixed-dollar copays or coinsurance levels) for brand name and nonformulary drugs (AMCP 2000a).

Therapeutic classification system—a grouping of drug products based on various criteria, which may include similarity of chemical structure, clinical indications, pharmacology, and therapeutic activity (IOM 2000).

Therapeutic or drug class—a group of drugs that have similar chemical, pharmacological, and/or therapeutic properties (IOM 2000).

> ***Open class***—a drug class that contains numerous drug products, all of which are covered whether listed or not (IOM 2000).
>
> ***Closed class—***a drug class that limits coverage to only listed drugs (IOM 2000).

Therapeutic equivalence—property of drugs differing in composition or in their basic drug entity, but of the same pharmacological and/or therapeutic class, that are considered to have very similar pharmacological and therapeutic activities and adverse reaction profiles when administered to patients in clinically equivalent doses (IOM 2000).

Therapeutic interchange—authorized exchange of various therapeutically equivalent drugs by pharmacists through: a) previously established written guidelines or protocols within a formulary system, or b) prescriber permission at the time of exchange (IOM 2000). ■

Endnotes

1 If an open formulary has tiered cost sharing, enrollees have financial incentives to use preferred-tier drugs.

2 Beta-blockers are formally known as beta-andrenergic blocking agents and work by affecting the response to nerve impulses in certain parts of the body, decreasing the heart's need for blood and oxygen, and therefore its workload.

3 USP sets and publishes standards and other information for prescription drugs, dietary supplements, and other health care products. USP assisted the VHA with developing its formulary's classification system.

4 Medicare Part D excludes drugs for which payment is available under Parts A and B and those in therapeutic categories that may be excluded under Medicaid, except for smoking-cessation agents.

5 Plans can change their formulary classification system midyear if the Secretary makes an exception to account for new therapeutic uses and newly approved covered drugs.

6 To address this concern, Medicare has recently begun reimbursing for the medical costs incurred by elderly Medicare patients in clinical trial research.

7 This survey does not reflect the experiences of companies that have chosen to manage drug benefits internally and have replaced PBMs with claims processors.

8 If a fallback plan is offered in a geographic region and then replaced by a single private drug plan, or if a private drug plan exits a market and is replaced by a fallback plan, the process will be similar to the replacement of one PBM by another in the private market.

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