Formularies and Pharmacy Benefit Management

Recommendations of the American Society of Internal Medicine

November 1997
REINVENTING MANAGED CARE

Formularies and Pharmacy Benefit Management: Recommendations of the American Society of Internal Medicine

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CONTENTS

2 Executive Summary
2 ASIM Recommendations

Introduction
4

5 What Are Formularies?
5 Types of Formularies
5 Prevalence of Formularies

Formulary Development
6

7 Impact of Formularies on Physician-Patient Relationships
7 Generic and Therapeutic Substitution
7 Formulary Use Among HMOs
7 Formularies and Individual Patient Differences
7 Formulary Compliance and Incentives
8 Number of Formularies in Use

The Legal Implications of Formularies
9

10 The Efficacy of Formularies in Reducing Costs
10 TennCare MCO Medicaid Study
10 Managed Care Outcomes Project

PBM and Pharmacy Benefit Managers
11

A Controversial Growth Industry
11

PBM Services
12

13 Managed Care and PBM
13 PBM and Disease Management

Concerns About the PBM Industry
14

15 The Future of Formularies and PBM

ASIM Recommendations for Improving Formularies and PBM
16

18 References
Executive Summary

As managed care continues to influence the delivery of health care, physicians confront new policies and procedures that undermine the quality of patient care. Frequently, managed care procedures produce additional layers of administration that encumber rather than enhance efficient medical practice.

Formularies contain costs by restricting access to the more expensive, brand-name pharmaceuticals. The trend among managed care organizations (MCOs) indicates both an increased use of formularies and a preference for more restrictive formularies.

The establishment and use of a formulary presents physicians with such challenges as:

- Lack of opportunity to participate in formulary development;
- Pressures from MCOs to substitute drugs; and
- Pre-authorization rules for prescribing nonformulary drugs.

Pharmacy benefit management (PBM) uses formularies and other cost-cutting measures to control the drug benefit costs of health plans. MCOs contract with PBM companies to administer their carved-out pharmacy benefit. However, the companies’ marketing promise to design fully integrated, database systems for disease management has yet to be fulfilled and remains a major disappointment for consumers and providers. PBM companies also often have close ties to many of the large pharmaceutical manufacturers, raising concerns about vertical integration, antitrust, and other conflict of interest issues.

"Reinventing Managed Care—Formularies and Pharmacy Benefit Management. Recommendations of the American Society of Internal Medicine" explores many of the challenges physicians encounter as a result of managed care’s efforts to contain pharmacy benefit costs.

ASIM offers the following recommendations to assist public policy leaders in making decisions about formulary use and to guide physicians in dealing with MCOs on these issues.

ASIM Recommendations

1. Formularies

   1. Formularies as mechanisms for cost control
      ASIM opposes any formulary that may operate to the detriment of patient care, such as a formulary developed primarily to control costs.

   2. Physician financial arrangements and formulary compliance
      MCOs and PBM organizations should link incentives to cost-effective practice rather than to formulary compliance, which places the physician's financial interest in conflict with the patient’s well-being.

   3. Inclusion of drugs in the formulary
      MCOs and PBM organizations should base decisions about which drugs to include in a formulary on the drug’s effectiveness, safety and ease of administration, as well as its cost. Similarly, evaluations of physician prescribing patterns (i.e., by drug utilization review) should give priority to the effectiveness, safety and ease of administration of the drugs as well as the cost of the medications.

4. Formularies and Pharmacy & Therapeutics (P&T) Committees
   A professionally qualified body should approve formularies for use by physicians in caring for a defined group of patients. ASIM recommends that P&T committees include representatives—and have the support—of the medical staffs that use the formulary.

5. Formulary compliance and nonformulary prescriptions
   MCOs and PBM organizations should construct formularies so that physicians have the option of prescribing nonformulary drugs—based on objective data supporting a justifiable, medically indicated reason—without facing cumbersome requirements for prior authorization.

6. Patient information on formulary use and options
   Patients should receive information about how the formulary functions and how copayment and deductible requirements may affect their pharmacy benefit.

7. The need to develop user-friendly formularies
   ASIM supports the industry’s development of technology to make formularies more accessible and easier to use. ASIM recommends physician input in designing and pre-testing these technologies.
8. **Monitor the effect of formularies on patients in managed care**

ASIM supports government and industry studies of the impact of formularies on patient care. ASIM recommends that HCFA develop an annual report card on the impact of formularies on beneficiaries enrolled in Medicare MCOs.

9. **Patient and physician notification of formulary changes**

ASIM supports prompt, prior notification of patients and physicians when MCOs and PBM entities change or discontinue their formularies. ASIM recommends that MCOs and PBM entities provide this notification within a specified time, not less than ninety (90) days before implementing the change.

II. Drug Therapy Choices

1. **Drug substitution**

   A. ASIM opposes therapeutic substitution in an outpatient setting without the prescribing physician's consent.

   B. Physicians should prescribe generically when therapeutic equivalency, safety and bioavailability are established. Physicians should consider carefully the advice, knowledge and experience of the pharmacist regarding selection of drug product alternatives that could result in cost savings to the patient.

   C. When therapeutic equivalency, safety and bioavailability have been assured, ASIM recommends designating the privilege of drug product selection to the pharmacist.

   D. Any generic drug the pharmacist selects must be therapeutically equivalent and bioavailable and must result in cost savings to the patient.

III. Pharmacy Benefit Management

1. **Regulation of pharmacy benefit management and managers**

   A. ASIM supports government regulation of PBM entities. ASIM particularly supports government oversight of mergers between PBM entities and pharmaceutical manufacturers.

   B. ASIM supports the disclosure of the financial relationships between PBM companies, pharmacists and pharmaceutical manufacturers to patients, physicians and insurers.

2. **PBM organizations' requests to alter medication regimens**

   ASIM supports a requirement that PBM organizations request to alter medication regimens only when backed by objective data reported in peer-reviewed medical literature.

3. **Availability of PBM patient information to physicians**

   ASIM supports a requirement that PBM organizations provide—with the patient's consent—all available information about the patient's medication history to the treating physician.
Introduction

In recent years, formularies and pharmacy benefit management (PBM) have increased their influence on the practice of medicine. They affect the choice of prescription drug therapies in a variety of health care settings. From hospitals to various managed care entities, these cost-containment measures have caused much confusion and delivered only questionable benefits. Physicians and patients should be aware of formularies and PBM—what they are and how they influence the quality of health care.

Early formularies were lists of all the medications a hospital pharmacy carried. Later, formularies began to serve a regulatory function by limiting the availability of medications. The purpose of formularies has changed as the health care system evolves. Although hospital pharmacy and therapeutics (P&T) committees originally compiled formularies for clinical reasons, many managed care organizations (MCOs) have adopted them as a way to contain costs.

The effectiveness of formularies as a cost-containment measure is unclear. In some instances, formulary use has achieved both cost containment and behavioral changes in physician prescribing habits while still maintaining a high quality of care. These successes generally have occurred in hospital settings, where physicians are involved in designing and establishing the formulary. Physicians who work primarily in outpatient settings, however, have had a less positive experience with formularies.

There are two main philosophical approaches to the development of formularies: pharmacoeconomic and pharmacoepidemiologic.

- Pharmacoeconomic systems consider equally the cost of all intervention and therapeutic procedures in an episode of care. Visits to the physician, hospitalizations, blood tests, surgery, drugs and potential side effects are among the factors that a pharmacoeconomic evaluation assesses.

- Pharmacoepidemiology emphasizes data derived from clinical trials as the primary barometer (i.e., the "gold standard") of the effectiveness and value of drug therapy.

Pharmacoeconomics, treats clinical trials as one of many factors in determining the value and formulary placement of a drug. Pharmacoeconomic analysis can exclude newer, more effective, more costly drugs from a formulary on the basis of price alone.

Proponents of pharmacoepidemiology fear that the pharmacoeconomics approach marginalizes data on drug efficacy in favor of systems-based, economic evaluations.

As MCOs look for opportunities to control costs, PBM is gaining prominence, with its promises of reducing pharmacy costs and establishing more efficient accounting systems. The growth rate of companies offering PBM was virtually identical to that of health maintenance organizations (HMOS) during the 1980s. Early PBM programs primarily were claims processing services. PBM since has grown to include a host of services from pharmacy networking to developing integrated systems for disease management (DM).

PBM entities have become attractive partners for pharmaceutical manufacturers pursuing vertical integration of their drug products. Vertical integration allows manufacturers to control their products from development to distribution, gaining an advantage over competitors who rely on intermediaries. PBM companies provide a ready-made venue for both product marketing and distribution. The trend in mergers of PBM entities with pharmaceutical manufacturers has created great concern among government, consumer and health care provider groups. This concern includes the effect of such mergers on competition in the pharmaceutical industry and on the development of formularies and proprietary data systems.

Neither formularies nor PBM have been as effective as their proponents had promised. At best, these management strategies are part of an evolving system with little order and many players. Obtaining good data to demonstrate effectiveness is difficult, limiting any evaluation of these methods.

As PBM and its use of formularies grow and change, the health care industry should offer opportunities to assess their impact on health care, and patient advocates should seek this. The trend in managed care is to promote formularies and PBM as cost-cutting mechanisms. Physicians, patients and other consumers need to educate themselves in preparation for the changes these systems bring to health care.
What Are Formularies?

In general, a formulary is a compilation of drugs that professional health care staff in a certain setting consider to be the most useful in patient care. Hospitals originally developed formularies; however, formularies have made their greatest impact on HMOs, preferred provider organizations and other managed care entities. In recent years, federal and state health care programs also have adopted formularies.

Types of Formularies

Formulary design ranges from open or voluntary to closed or restricted; few formularies follow one strict model. (See below, "Types of Formularies.")

- In an open formulary, prescribed products are reimbursable whether or not the plan's formulary lists or recommends them.
- A closed formulary limits reimbursement to a select number of drugs in each therapeutic class; physician compliance with these limits is mandatory.

A selective or partially closed formulary limits reimbursement to prescribed formulary drugs, plus select nonformulary drugs, subject to prior authorization or approval.

Other formulary schemes specify upper limits—or maximum allowable costs—for payment of prescription costs.

Prevalence of Formularies

Formularies are becoming more prevalent and more restrictive in managed care health plans. In 1994, more than 70 percent of managed care plans used formularies. By 1995, nearly 80 percent had established formularies. The trend in HMOs is for smaller, more restrictive formularies. (See chart below.)

![Percentage of Managed Care Plans Using Formularies, 1994](chart)

Source: SMG Marketing Group, Inc., Chicago
Formulary Development

In a typical formulary system, the medical staff of a health care organization evaluate, appraise and choose drugs they consider most useful for patient care and place these in the organization’s formulary for prescribing. Generally, the staff review the formulary on a quarterly basis.

The group responsible for the development and implementation of a formulary usually is called the pharmacy and therapeutics (P&T) committee. The institution, MCO or PBM entity appoints a P&T committee to review drugs for the formulary. Ideally, committee members represent the interests of the plan participants and act independently of plan influences. Satisfied that the drugs under consideration do not differ significantly in therapeutic benefit, the P&T committee submits the drugs to bidding by pharmaceutical manufacturers.

P&T committees then evaluate presentations from drug company representatives—including information from clinical trials and outcomes analysis—and examine the medications’ cost-effectiveness. Among the major determinants of drug selection for formularies are the financial terms the pharmaceutical company offers. However, by basing a decision primarily on cost, a P&T committee might overlook important therapeutic advantages of a nonformulary drug.

The P&T committee also may indicate a preferred dosing method to reduce drug cost while maintaining quality. For example, the formulary might specify administering a drug by pulse dosing—delivering high concentrations over short time intervals—rather than by continual dosing—delivering a constant concentration of the medication over a continuous time period.

Ideally, in hospitals and staff-model HMOs, physicians and medical staff play an essential role on the P&T committees, establishing and maintaining the formulary system. They provide the requisite clinical knowledge, making sure that the patient’s welfare remains the principal objective. They also can advocate for patient access to any drug not on the formulary, when necessary. Physicians involved in P&T activities also have the opportunity to continue their education in clinical pharmacology and therapeutics.

The American Medical Association, however, has found that physicians often play only a limited role in the development and maintenance of formularies in ambulatory settings. Without physician involvement in the development and review of formulary systems, the primary objective of decision makers may shift from patient care to cost containment.

Physicians nonetheless can request additions to formularies. In exceptional cases, MCOs accommodate the provision of nonformulary drugs. The percentage of HMOs that allows physicians to override the formulary is increasing (currently, about 80 percent allow it); however, there are no records of the actual approval rate of requests for additions or exceptions to formularies. (See chart above: “Formulary Development.”)
Impact of Formularies on Physician-Patient Relationships

Generic and Therapeutic Substitution

Formulary systems and third-party payers encourage the prescribing of generic drugs. As a result, patients can receive preparations that often are different—either by chemical composition or brand name—from the medication prescribed. The effect of substitution on any given patient can range from none to harmful.

- **Generic substitution** allows the interchange of nonproprietary and proprietary drugs with the same chemical composition.
- **Therapeutic substitution** selects a chemically different drug that has a comparable therapeutic effect.

Even though generics are chemically equivalent to name-brand drugs, differences in packaging (coated vs. uncoated formulations) or in flavor, concentrations of inert ingredients, or a given patient's physiology may contraindicate therapeutically equivalent drugs.

The Food and Drug Administration (FDA) began testing generic drugs in 1990, to establish industry standards for the therapeutic equivalence of generic and name-brand drugs. Generic drug candidates undergo rigorous testing for therapeutic and bioequivalence, labeling and manufacturing procedures before approval by the FDA Office of Generic Drugs. FDA publishes a monthly list—called the “Orange Book”—of approved generic medications and their therapeutic ratings; physicians and pharmacists should consult this publication when considering alternatives to brand-name drugs.

Formulary Use Among HMOs

The majority of HMOs and an increasing number of employer-sponsored prescription plans use formularies. This trend has a direct impact on the quality of care physicians can provide their patients. In 1995, HMOs filled 88 percent of prescriptions using formularies; they filled more than 42 percent of these with generic products. More than 70 percent of all HMOs required generic substitution. Choosing a brand-name drug over a generic often required higher copayments for the patient. While the majority of HMOs (89 percent) allowed choice of brand-name drugs, only 12.5 percent did so without additional copayments.

In a recent survey of self insured employers, almost 70 percent participating in managed care health plans are seeking to initiate or increase formulary use. Currently, few employer-sponsored prescription plans use restricted formularies; however, the trend among prescription plan sponsors is for increased restriction of formularies. (See chart, this page: “Likelihood of Employers Using Formularies.”

Health care experts cautiously acknowledge the cost savings of prescription drug substitution and restricted formularies. They warn, however, that certain strategies—such as therapeutic substitution—are potentially harmful, denying patients access to necessary treatment and possibly causing long-term health care costs to increase.

Formularies and Individual Patient Differences

In a report, titled “Ethnic & Racial Differences in Response to Medicines,” the National Pharmaceutical Council (NPC)—a research-oriented pharmaceutical association in Reston, VA—summarized research conducted over the past 15 years, showing significant differences in drug metabolism rates, clinical drug responses and side effects among ethnic and racial minorities. The report concluded that prescription management programs that use restricted formularies may be inappropriate for these populations. The NPC report recommended that:

- formularies need to be flexible, so that reasonable alternative drugs and dosages are available to all patients, without regard to race or ethnicity; and
- health care policy makers should encourage the development of formularies that customize drug therapy for special sub-populations.

Formulary Compliance and Incentives

MCOs use a variety of incentive and disciplinary mechanisms, directed at physicians and patients, to encourage or enforce compliance with a formulary. Physicians might receive a reprimand...
from an oversight committee or even face deselection (i.e., termination) from the plan. Physicians who occasionally prescribe outside the formulary might receive educational phone calls or letters from the health plan administrators. Frequent noncompliance with the formulary might incur a financial penalty—often part of the risk arrangement between the physician and the health plan. Salaried physicians might see the incentive tied to their raises. In a survey of physicians participating in MCOs, the overwhelming majority of network and group model physicians rejected the use of financial incentives to affect physician decision making. Clinicians expressed concern about MCOs tying reimbursement to cost-saving clinical decision making and about the adverse effect this has on patient care. Although financial incentives have become more prevalent as a means of changing physician behavior, they are an unpopular way to win clinician support for a formulary.

Physicians who do not comply also may expose their patients to financial liability. Patients who choose to go outside a formulary face financial disincentives ranging from higher copayments to responsibility for the full cost of the nonformulary prescription. An emerging trend in patient incentives for pharmacy benefits is the use of variable copayments. Generally, MCOs apply a higher copayment to brand-name prescription drugs than to their generic counterparts. Under the variable copayment system, the amount of the copayments also would depend on whether the dispensing pharmacy was in the MCO's network. Increases in copayments are not uncommon. Today, patients with prescription drug insurance coverage can expect to pay, on average, $5.10 for a generic prescription and $8.39 for a brand-name prescription. MCOs believe that patients will steer physicians to prescribe cheaper medications if the alternative drug results in cost savings to the patient.

For physicians, whose priority is quality care, there is little incentive to prescribe a medication solely on the basis of cost. Most physicians would not disregard a medication’s proven clinical efficacy and the patient's profile just to achieve cost savings. Patients’ uneasiness about switching to an alternative medication may increase when they understand that cost rather than their well-being prompted the change.

### Number of Formularies in Use

Currently, physicians who participate in several managed care plans often find themselves trying to keep track of three or more formularies. Many physicians resolve the problem of multiple formularies by using the most restrictive version for all prescribing decisions. MCO formularies, therefore, must become more user friendly. Making formularies available on computer disks or via online services will help physicians keep track; many policy analysts advocate the establishment of a single national formulary to resolve confusion.

Physicians and patients also must keep up to date on changes in formularies. These changes often occur with little or no warning from the MCO and do not come to the patient’s or physician's attention until the plan refuses to authorize a prescription. A change in the discount for a particular drug could lead to its inclusion or exclusion from a formulary. Similarly, changes in utilization have an impact on sales volume, overall market share, and manufacturer stability; this can affect which medications will become part of the formulary. Physicians and patients should receive advance notice from the MCO about formulary changes to be able to make appropriate decisions about drug therapy.

Formularies are components of the overall benefits packages that company managers negotiate. As they attempt to supply the most cost-effective benefits to employees, benefits managers are mindful of economic forces. Consequently, there is no guarantee to the patient that the company's benefits plan—and formulary—will remain the same from year to year. This further complicates appropriate formulary use and creates anxiety for the patient.
The Legal Implications of Formularies

As health systems merge, hospitals and health plans attempt to cut costs by further restricting drug formularies. Legal experts suggest that all involved in the drug-dispensing process (physicians, pharmacists, hospitals, drug companies, insurers and employers) increasingly are vulnerable to lawsuits from patients claiming that a formulary drug either didn't help them or caused them harm. Typically, a physician writes a prescription for a patient, who takes it to his pharmacist to be filled. If the drug is not on the health plan's formulary, the pharmacist calls the physician, explains the situation and suggests a therapeutically equivalent drug that has the plan's approval. The physician can agree to the substitution or request a waiver from the health plan for the initially-prescribed drug. If the plan denies the waiver, the physician has no option except to approve the substitute drug.

Everyone in the sequence of events must follow accepted professional standards. Constraints of time (making an appeal for the physician's first choice) or information (lack of or incomplete data about substitute drugs) must be handled effectively to avoid negative patient outcomes and possible litigation. Should an unfavorable event occur as a result of the substitution, the patient only has to prove negligence somewhere along this chain of responsibility. Ultimately, however, litigation may focus on those who assemble the formularies (e.g., a PBM organization). The litigation would focus on the method of compiling the formulary, contending that the methodology violated an obligation to the insurer or to the patient. If a case turns on a plan's decision not to pay for nonformulary drugs or to pressure physicians into prescribing a substitute drug, the court will examine critically the entire formulary development process.

Much of the lawsuit's outcome depends on how restrictive the formulary is. If the physician can go outside the pre-selected formulary relatively easily, and if the plan grants frequent waivers, the responsibility for misprescribing lies with the physician. However, habitual prescribing outside the restricted formulary runs counter to the fundamental purpose of having a formulary—that is, cost control.
The Efficacy of Formularies in Reducing Costs

TennCare MCO Medicaid Study

A study released in 1996 reported that 98 percent of the physicians working with a restricted formulary in Tennessee's TennCare MCO (the state's Medicaid program) were unable at one time or another to prescribe their first choice of drug because it was not on the MCO's formulary. The MCO advised most of these physicians (95 percent) to make generic or therapeutic substitutions for their first-choice drug. Two-thirds of physicians who had to switch to substitutes reported adverse experiences for their patients. (See chart below: "Consequences of Switching Drugs").

This study also highlighted some of the classic complaints about the user friendliness of formularies. Physicians who sought approval for a non-formulary drug of choice gained it only 23 percent of the time. The requirement to demonstrate "medical necessity" led to an overly burdensome experience for almost two-thirds of physicians in the study. Slow response rates, unresponsive "hotlines," and lack of information about the health plan's implementation of a new payment system were among other problems that a majority of study physicians encountered.

Managed Care Outcomes Project

The Managed Care Outcomes Project study, conducted in 1994, found an unexpected correlation between restrictive formularies and higher long-term costs of illness. (The pharmaceutical industry, however, has questioned the study's methods.) According to the survey's findings, patients under restricted formularies incurred higher costs in other, more expensive areas of health care. Patients with similar severity of illness showed a common pattern: they had increases in visits to physicians, emergency room visits and hospitalizations—all of which produced higher medical costs. Other studies, observing a broad spectrum of health care delivery organizations, also have found a consistent correlation between prescription drug restriction and increased medical costs.

A well-managed formulary can increase the prudent use of generic drugs. However, industry experts suggest that managed care would do better clinically and save more money by considering drug costs in light of lower overall medical expenditures. There is a limited perspective when plans examine the cost of drugs in isolation. MCOs should consider formularies as one element in an overall economic strategy, and not as a panacea for cost containment.

While proponents claim that formularies are becoming more acceptable to physicians, much remains to be done to broaden their appeal and utility. ASIM encourages physicians to exercise due diligence in knowing their formularies and advocating on behalf of their professional interest and their patients' interest. Formularies provide great opportunity for misuse and abuse. This potential has increased with the advent of pharmacy benefit management.

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**Consequences of Switching Drugs**

Two-thirds of the physicians forced to switch their patients' prescriptions report the patients had problems afterwards.

Have any of your patients had problems after a prescription had to be switched?

| Base: Physicians forced to switch patient's prescriptions |
|-------------------|-------------------|-------------------|
| Yes               | No                | Not sure          |
| 66%               | 32%               | 2%                |

Formularies and Pharmacy Benefit Management  ■  page 10
PBM and Pharmacy Benefit Managers

PBM continues to unfold as an MCO cost-containment strategy. Much of the evolution of PBM is a result of the influence of the pharmaceutical industry, its position in the market and the scrutiny of consumers, providers and government. Three of the largest companies that offer PBM—PCS Health Systems, Inc. (formerly known as Pharmaceutical Card System, Inc.), Medco and Diversified Pharmaceutical Services (DPS)—illustrate the diverse ways PBM has emerged. PCS began as a pharmacy claims processor; Medco as a small mail order pharmacy; and DPS as a subsidiary of an HMO.

All three recently have merged with leading pharmaceutical companies. Companies that offer PBM, then, do not approach the service from the same background and are continually adapting their services to the changing health care marketplace.

PBM companies “carve out” the provision of prescription drugs from other medical services, contracting with third-party payers to provide cost-effective, accessible and high-quality pharmaceutical benefits. These third-party payers include employers, insurers, or public or private plan sponsors. Acting as intermediaries among pharmaceutical companies, physicians, third-party payers and pharmacies, PBM companies become the hub of drug therapy activities. (See chart above: “Pharmacy Benefit Management: Relationships.”)

A growing trend is the merger of pharmaceutical manufacturers with PBM entities. Drug manufacturers view PBM entities as a means of vertical integration—that is, the control of their products from development to distribution. By merging with large PBM entities, major pharmaceutical manufacturers can provide pharmacy benefits to large populations of MCO enrollees. The Federal Trade Commission has allowed these mergers under stringent guidelines, despite the potential for conflict of interest and the protests of consumer groups. Opponents of these mergers maintain that the pharmaceutical companies use their PBM partners to market their products to the disadvantage of competitors. The Washington Post recently reported that “drug makers are taking advantage of their ownership of companies that manage prescription drug benefits for health insurance plans.” Citing the relationship between Eli Lilly and PCS, the article alleged that Lilly intended to use PCS to market two of its products, Prozac (an anti-depressant medication) and Axid (an anti-ulcer medication), over competitor brands. Although pharmaceutical companies deny such schemes, they remain an issue because of the mergers.

PBM Services

A full-service PBM offers the following services (see page 12, “Pharmacy Benefit Management: Services”):

- **Claim Processing**—Electronically provides the pharmacy with information about member eligibility, benefit coverage and prescription reimbursement; maintains a database to serve as a source of information for both the PBM company and the payer about cost, utilization and overall benefits management.
- **Pharmacy networks**—Negotiates agreements with retail pharmacies (usually on the basis of volume discounts or rebates) to offer payers a pharmacy network geographically accessible to members.
- **Formulary management**—Manages drug formularies developed by plans, customizes a formulary to meet a health plan’s particular needs, or develops a nationwide drug formulary.

Formularies and Pharmacy Benefit Management
- **Report generation**—Provides routine or custom reports to assist the payer in evaluating cost and utilization.

- **Generic use programs**—Develops programs to influence members to choose generic drugs, whether through increased copayments for nongeneric drugs or by offering better discounts for generics than for brand-name drugs.

- **Manufacturer rebates**—Negotiates rebates from pharmaceutical manufacturers for delivering a certain volume of products or for achieving a certain market share of a product.

- **Academic detailing**—Enforces formulary guidelines to move market share from high-cost products to cheaper, bioequivalent formulary products, using educational interventions such as letters or telephone calls to specific prescribers, general newsletters, site visits for staff presentations and personal appointments.

- **Maintenance drug programs**—Offers programs to supply maintenance medications, usually to treat chronic diseases, by filling and refilling prescriptions in large quantities.

- **Drug utilization review (DUR)**—Supplies concurrent and retrospective DUR, including the capacity to generate comparative profiles of physician prescribing or pharmacy dispensing.

- **Disease management**—Uses integrated database computer systems to combine the application of clinical practice guidelines with cost controls.

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<td>Claims processing</td>
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<td>Formulary management</td>
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<td>Drug utilization review</td>
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<td>Pharmacy networks</td>
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<td>Reports</td>
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<td>Drug-management programs</td>
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Managed Care and PBM

A 1996 annual survey of employers and HMOs indicated that more than half of respondents were less than satisfied with the performance of the company providing PBM (measured on a scale from 1 to 10). The PBM service that received highest ratings was pharmacy claims processing. The survey revealed decreases in ratings for overall service and performance from 1995 to 1996 (a 7.2 rating in 1995 vs. 6.3 in 1996). More than half were disappointed in their expectations for high-quality performance. (See chart below: "HMOs Rate PBM Functions.")

Dissatisfaction also was evident in the ratings for disease management, management reports, cost-effectiveness, promised services, eligibility management, mail order pharmacy, and value for administrative costs. The highest-rated PBM services were less complex in design and implementation than services that received lower ratings. Ironically, services that received the lowest ratings often were those that PBM companies use to distinguish themselves from market rivals.

PBM and Disease Management

Experts indicate that one of the largest disappointments of PBM is its failure to develop an integrated database and methodology for disease management—highly touted as the ultimate goal of PBM. Industry fervor for DM seems to have died down, if not disappeared, as the complications of such programs have surfaced.

One expert has suggested that the lack of advances in this area may be due to poor definition of DM goals: 

"While no one was completely sure what it was, we were all certain it was the key to the future of pharmaceutical care management and the end to the age-old debate on the value of pharmaceutical products in the cost-effective treatment of disease."

Several companies offer some well-designed disease management programs; programs for managing asthma, diabetes, kidney and heart disease are available. The effectiveness of these programs, however, awaits measurement. Despite these problems, PBM and its cost-saving components, such as DM, remain attractive to MCOs and employers as ways to reduce pharmacy benefit costs. In some cases, they have demonstrated flexibility to meet payer needs without compromising patient access. However, if PBM is to garner support from other entities whose primary interest is not cost containment or vertical product integration, there are concerns its advocates must address.
Concerns About the PBM Industry

The recent mergers and alliances between PBM companies and pharmaceutical manufacturers have raised concerns about their effect on the relative market shares of generic and brand-name products. Some believe that formulary management by PBM-industry entities acting in their own self-interest will compromise patient care. Additionally, many payers have called for legislative oversight of drug manufacturer-owned PBM companies, citing issues of anti-competitive trade.

With the entrance of Medicare and Medicaid into managed care, the federal government has increased its scrutiny of PBM structures. The Office of the Inspector General (OIG) issued a report in spring 1997 on the Medicare and Medicaid experience with PBM. Acknowledging the function and role of PBM in managed care's efforts to control costs, the government agencies charged with the oversight of these programs nonetheless are concerned about the propriety of the close links between many PBM organizations and the pharmaceutical industry.

A major concern is the potential for bias in the PBM company's decision making. If PBM is not independent of drug manufacturers, biases can affect the development and management of formularies. Standards for DUR, the quality of the information disseminated to physicians, educational interventions, marketing on the basis of outcomes studies, and claims of cost-effectiveness all come into question.

The report also raises issues of confidentiality. The close links between manufacturers and PBM companies could lead to illegal disclosure of patient information. Additionally, many patients are not aware of the relationships between MCOs, PBM companies and drug manufacturers. (Because many PBM organizations also employ the pharmacist who dispenses the drug, some states now require pharmacists to disclose to customers any financial relationships they share with the PBM entity.).

Finally, there is no satisfactory accrediting process for PBM. This was the OIG report's second greatest concern. It is not clear who oversees PBM, leaving each organization to establish whatever controls it can over its PBM partner. The current state of the PBM industry, therefore, provides no objective source of information that consumers need to assess a PBM company's performance. The extent of peer review of PBM is also questionable.
The Future of Formularies and PBM

Many expect a major shake-up in the PBM industry within the next 10 years. Formularies will remain an important PBM tool to control pharmacy costs. The trend is toward more—rather than less—restriction in drug therapy. Physicians should be prepared to insist on waivers and to advocate for additions to restrictive formularies when they believe it is warranted, based on objective scientific data.

As database development becomes more important in creating integrated health care systems, the PBM industry will shift its emphasis from drug services to information technology. Companies will promote the use of practice guidelines derived from these systems. The goal will be to improve patient health using standardized tools that match treatments to patient needs. This system also should allow physicians to monitor patient status methodically.

Electronically accessible patient information is the biggest challenge for PBM in the future if it is to realize the potential of disease management. ASIM applauds efforts to enhance and make more efficient use of technology and encourages the industry to work with physicians in developing systems to accomplish the goal of a DM-integrated data system while maintaining patient confidentiality.

ASIM advocates the oversight of PBM-pharmaceutical manufacturer relationships. These relationships undermine the credibility of the clinical data presented to support drug efficacy. Similarly, claims of improved outcomes and cost-effectiveness have little credence if pharmacy benefit managers are suspected of favoring their drug manufacturing partners in developing and maintaining formularies and DM programs.
ASIM Recommendations for Improving Formularies and PBM

The use of formularies and PBM in managed care has increased in recent years, and this trend will continue. Physicians and patients should be aware of the implications of PBM and formularies in determining quality of care and access to care. ASIM has developed the following policies and recommendations in response to the issues of PBM and the development and implementation of formularies. These recommendations can assist health care providers and public policy leaders in formulating policies and guidelines for practice and advocacy.

I. Formularies

1. Formularies as mechanisms for cost control

ASIM opposes any formulary that may operate to the detriment of patient care, such as a formulary developed primarily to control costs.

Formularies operating primarily to contain costs are detrimental to the interests and well-being of patients. Studies of the cost-effectiveness of formularies have been inconclusive. According to anecdotal observations, long-term health care costs increase when MCOs restrict their formularies. Effective formulary development should incorporate and give high priority to pharmacoeconomic data as well as to economic considerations.

2. Physician financial arrangements and formulary compliance

MCOs and PBM organizations should link incentives to cost-effective practice rather than to formulary compliance, which places the physician's financial interest in conflict with the patient's well-being.

Cost effective rather than cost-control practices recognize the patient's well-being as primary and promote quality patient care. Patients should have access to effective treatment rather than the least expensive therapy. In formulary utilization review, MCOs and PBM organizations should give priority to the effectiveness, safety and ease of administration of the drugs as well as their cost. Similarly, evaluations of physician prescribing patterns (i.e., by drug utilization review) should give priority to the effectiveness, safety and ease of administration of the drugs as well as the cost of the medications.

MCOs and PBM organizations should base drug selection and inclusion in a formulary on the pharmacoeconomics as well as the pharmacoeconomics of the drug. Peer-reviewed medical journals should be the source of this data. Physician efficiency in prescribing medications should not be linked primarily to short-term cost-savings but also to patient outcomes. Allowing the physician to tailor medications to a specific patient's needs improves overall outcomes, offering more long-term cost savings.

3. Inclusion of drugs in the formulary

MCOs and PBM organizations should base decisions about which drugs to include in a formulary on the drug's effectiveness, safety and ease of administration, as well as its cost. Similarly, evaluations of physician prescribing patterns (i.e., by drug utilization review) should give priority to the effectiveness, safety and ease of administration of the drugs as well as the cost of the medications.

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4. Formularies and Pharmacy & Therapeutics (P&T) Committees

A professionally qualified body should approve formularies for use by physicians in caring for a defined group of patients. ASIM recommends that P&T committees include representatives—and have the support of—the medical staffs that use the formulary.

Physician participation in the development of formularies will help ensure that the welfare of the patient will be paramount. Qualified, practicing physicians who serve on P&T committees also will have an impact on formulary utilization review, ensuring that effectiveness, ease of administration, safety and efficacy are considered with equal or greater weight than cost alone.

5. Formulary compliance and nonformulary prescriptions

MCOs and PBM organizations should construct formularies so that physicians have the option of prescribing nonformulary drugs—based on objective data supporting a justifiable, medically indicated reason—without facing cumbersome requirements for prior authorization.

Prior authorization requirements may hinder timely drug therapy and lead to excessive long-term health care costs. MCOs can minimize the effects of these requirements by basing formularies on current medical evidence and relevant pharmacoeconomic information and by regular reviews and updates. These reviews and updates should take into account new medical evidence and newly-approved drugs. Formularies also should include an exceptions process, directed by a clinician with appropriate expertise, by which a patient or participating physician may introduce science-based medical evidence to support
reimbursement for a prescription drug not routinely included in the plan's formulary.  

6. **Patient information on formulary use and options**  
A. Patients should receive information about how the formulary functions and how copayment and deductible requirements may affect their pharmacy benefit.  
Switching drugs, the existence or availability of copayments, and changes in formularies can have an impact on the quality of care a patient receives. An integrated patient information system that communicates with and educates MCO enrollees about drug use, formulary choices and any differences that may arise when a drug is changed will allow the patient to make informed choices with the physician's assistance.

7. **The need to develop user-friendly formularies**  
A. ASIM supports the industry's development of technology to make formularies more accessible and easier to use. ASIM recommends physician input in designing and pre-testing these technologies.  
Among the chief concerns of physicians are the number of formularies and the variety of means for disseminating them. To make formularies more accessible and user-friendly to physicians, MCOs should develop a more convenient format. Physicians who participate in several managed care plans often find themselves trying to track three or more formularies. Patients suffer when physicians manage this problem by prescribing only from the most restrictive formulary.

8. **Monitor the effect of formularies on patients in managed care**  
A. ASIM supports government and industry studies of the impact of formularies on patient care. ASIM recommends that HCFA develop an annual report card on the impact of formularies on beneficiaries enrolled in Medicare MCOs.  
Studies and continued research should focus on the impact of drug formulary constraints on patient outcomes. A report card could help to correct deficiencies in formulary design and enhance formulary utilization.

9. **Patient and physician notification of formulary changes**  
A. ASIM supports prompt, prior notification of patients and physicians when MCOs change or discontinue their formularies. ASIM recommends that MCOs provide this notification within a specified time, not less than ninety (90) days before implementing the change.  
Advance notification provides physicians and patients with the opportunity to find alternative therapies if needed. It also prevents the hassle of having a prescription rejected.

II. **Drug Therapy Choices**  
1. **Drug substitution**  
   A. ASIM opposes therapeutic substitution in an outpatient setting without the prescribing physician's consent.  
   B. Physicians should prescribe generically when therapeutic equivalency, safety and bioavailability are established. Physicians should consider carefully the advice, knowledge and experience of the pharmacist regarding selection of drug product alternatives that could result in cost savings to the patient.  
   C. When therapeutic equivalency, safety and bioavailability have been assured, ASIM recommends designating the privilege of drug product selection to the pharmacist.  
   D. Any generic drug the pharmacist selects must be therapeutically equivalent and bioavailable and must result in cost savings to the patient.

III. **Pharmacy Benefit Management**  
1. **Regulation of pharmacy benefit management and managers**  
   A. ASIM supports government regulation of PBM entities. ASIM particularly supports government oversight of mergers between PBM entities and pharmaceutical manufacturers.  
   B. ASIM supports the disclosure of the financial relationships between PBM companies, pharmacists and pharmaceutical manufacturers to patients, physicians and insurers.  
The federal government should scrutinize and regulate the various forms of PBM entities and their relationships with pharmaceutical manufacturers to prevent conflicts of interest. These arrangements can undermine patient access to appropriate therapy.

2. **PBM organizations' requests to alter medication regimens**  
   A. ASIM supports a requirement that PBM organizations request to alter medication regimens only when backed by objective data reported in peer-reviewed medical literature.  
When there is conflict between a physician's prescription and a PBM formulary, MCOs should avoid putting patients at risk to cut costs.

3. **Availability of PBM patient information to physicians**  
   A. ASIM supports a requirement that PBM organizations provide—with the patient's consent—all available information about the patient's medication history to the treating physician.  
PBM organizations should provide physicians with appropriate and necessary information for timely and effective care. PBM organizations should respond to physician requests in a timely manner and with proper precautions for patient confidentiality.
References