Ambulatory Care Formularies and Pharmacy Benefit Management by Managed Care Organizations

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Executive Summary

The trend in health care 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 to substitute drugs; and
- Pre-authorization rules for prescribing non-formulary drugs.

Pharmacy benefit management (PBM) uses formularies and other cost-cutting measures to control the drug benefit costs of health plans. Managed care organizations (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.

“Ambulatory Care Formularies and Pharmacy Benefit Management by Managed Care Organizations” explores many of the challenges physicians encounter as a result of managed care’s efforts to contain pharmacy benefit costs. ACP–ASIM offers the following recommendations to assist public policy leaders in making decisions about formulary use and to guide physicians on these issues.

ACP–ASIM Recommendations

I. Formularies

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

b. Decisions about which drugs are chosen for formulary inclusion should be based upon the drug’s effectiveness, safety, and ease of administration rather than solely based on cost.

c. Evaluation of physician prescribing patterns (i.e., drug utilization review) should give priority to the effectiveness, safety, and ease of administration of the drugs prescribed rather than solely based on costs.

d. ACP–ASIM recommends that financial incentive arrangements should be linked to cost-effective practices rather than formulary compliance.

e. ACP–ASIM opposes financial arrangements that place the physician’s financial interest in conflict with his or her patient’s well-being.

f. ACP–ASIM recommends that formularies should be constructed so that physicians have the option of prescribing drugs that are not on the formulary (based on objective data to support a justifiable, medically indicated cause) without cumbersome prior authorization requirements.

g. ACP–ASIM recommends that a patient information program be instituted by MCOs to make patients aware of formulary utilization and any associated costs such as co-pays.

h. Patient formulary education should include how the formulary functions, and a discussion of how co-payment and/or deductible requirements may affect their pharmacy benefit.
i. ACP–ASIM supports prompt prior notification to patients and physicians when formularies are changed or discontinued.

j. ACP–ASIM recommends such notification be given within a specified time period, not fewer than 90 days prior to change implementation.

k. Formularies should be approved on a regional basis by a professionally qualified body that includes practicing physicians using that formulary.

l. ACP–ASIM recommends that Pharmacy & Therapeutic (P&T) committees be representative of, and have the support of, the medical staffs that will utilize the formulary.

m. ACP–ASIM supports industry moves to develop technology to make formularies more accessible and easier to utilize. ACP–ASIM recommends physician input in designing, and pre-testing of, these technologies.

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

o. Prescribing patterns should be influenced primarily through educating physicians on safety and efficacy. Cost should be a determinant only when safety and efficacy are equal among specific drug choices.

II. Pharmacy Benefit Management

a. ACP–ASIM supports government regulation and industry self-regulation of Pharmacy Benefit Managers (PBMs). ACP–ASIM particularly supports close government oversight of mergers between PBMs and pharmaceutical manufacturers.

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

c. ACP–ASIM supports requiring that PBM organizations’ requests to alter medication regimes should occur only when such requests are based on objective data supported by peer reviewed medical literature and which undergo review and approval of associated MCOs’/MBHOs’ P & T committees.

d. ACP–ASIM supports requiring that, with a patient’s consent, PBM organizations be required to provide treating physicians with all available information about the patient’s medication history.
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. (1)

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 interventions 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. (2)

- 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 and 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. (3)

PBMs are gaining prominence with their promises of reducing pharmacy costs and establishing more efficient accounting systems. PBMs select participating pharmacists, pharmaceutical manufacturers, and suppliers and negotiate quantity discounts with manufacturers and pharmacists. Some MCOs own PBMs while others contract with PBMs. PBMs also are involved in formulary establishment, with 20% of HMO formularies PBM controlled in 1998, according to the SMG Market Letter dated March 1999. (4)

According to the SMG Market Letter dated August 2000 (5), 90% of HMOs had a contract with a PBM, up from 58% in 1994, while 83.6% of PPOs had a contract with a PBM, up from 37% in 1994. At this point in time, there were a total of 76 PBMs that held steady from 1999. A January 2000 Kaiser Family Foundation Report stated: “PBMs currently manage an estimated 71 percent of the volume of prescription drugs dispensed through retail pharmacies that are covered by third-party payers.” (6)
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.

- 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 non-formulary drugs, subject to prior authorization or approval. (7)
- 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. According to the *Hoechst Marion Roussel Managed Care Digest Series* for 1999 (8), 92.2% of HMOs used drug formularies in 1998, of which 48.4% were closed, up from 38.1% in 1997.

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 appoints a P&T com-
mittee 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 non-formulary 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, 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. (10)

Physicians nonetheless can request additions to formularies. In exceptional cases, MCOs accommodate the provision of non-formulary 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. (11) (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. (12)

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 bio-equivalence, 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 1998, HMOs filled 92.2 percent of prescriptions using formularies; they filled 45.2 percent of these with generic products. Choosing a brand name drug over a generic often required higher co-payments for the patient while the majority of HMOs (94.7 percent) allowed choice of brand name drugs. (8)

### HMO Pharmacy Utilization

<table>
<thead>
<tr>
<th>Model Type</th>
<th>Use of Formulary</th>
<th>Closed Formulary</th>
<th>Proprietary Formulary</th>
<th>In-house Pharmacy</th>
<th>Prior Authorization</th>
<th>Practice Guidelines</th>
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<tbody>
<tr>
<td>IPA</td>
<td>92.9%</td>
<td>47.8%</td>
<td>84.5%</td>
<td>27.4%</td>
<td>87.2%</td>
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<td>59.7%</td>
<td>76.1%</td>
<td>60.0%</td>
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<tr>
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<td>48.3%</td>
<td>73.9%</td>
<td>85.7%</td>
<td>50.0%</td>
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</tr>
<tr>
<td>Overall</td>
<td>92.2%</td>
<td>48.4%</td>
<td>82.5%</td>
<td>34.8%</td>
<td>82.7%</td>
<td>76.4%</td>
</tr>
</tbody>
</table>

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In a 1996 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. (13)

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. (14)

**Formularies and Individual Patient Differences**

In a report, titled “Ethnic and Racial Differences in Response to Medicines,” the National Pharmaceutical Council (NPC)—a research-oriented pharmaceutical association in Reston, VA—summarized research showing significant differences in drug metabolism rates, clinical drug responses, and side effects among ethnic and racial minorities. (15). 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 subpopulations.

**Formulary Compliance and Incentives**

A variety of incentive and disciplinary mechanisms, directed at physicians and patients, are used 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. (16)
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. (17)

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 co-payments to responsibility for the full cost of the non-formulary prescription. An emerging trend in patient incentives for pharmacy benefits is the use of variable co-payments. Generally, a higher co-payment is applied to brand-name prescription drugs than to their generic counterparts. Under the variable co-payment system, the amount of the co-payments also would depend on whether the dispensing pharmacy was in the insurer’s network.

Increases in co-payments are not uncommon. In 1998, the average co-payment per prescription on non-formulary brand name drugs was $16.77, covering 39.9% of the prescription cost. By comparison, the average co-payment per prescription on formulary brand name drugs was $8.93, which covered 24.7% of the prescription cost. (8) The underlying theory is that patients will steer physicians to prescribe cheaper medications if the alternative drug results in cost savings to the patient. (7)

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**

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 non-formulary 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. (18)

**PBM and Pharmacy Benefit Managers**

PBM continues to unfold a 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 ultimately 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. (19)

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 below: “Pharmacy Benefit Management: Relationships.”)
PBM companies also can be subsidiaries of direct providers of health care; for example, Medco also owns mail order pharmacies. Generally, however, PBM companies subcontract with other providers to fill specific niches. These arrangements can take many forms and can become a permanent part of the basic service package, adding to the difficulty of clearly defining what PBM is.

**A Controversial Growth Industry**

The PBM industry continues to exhibit strong growth, with new companies and partnerships continually emerging. The Pharmaceutical Research and Manufacturing Association (PhRMA) now estimates that MCOs account for 50 percent of the U.S. drug market; the MCOs handle much of those transactions through PBM entities.

Overall enrollment in PBM programs is expected to reach more than 175 million in the next few years. This growth has motivated many new entries into the market while long-time leaders expand through acquisitions and mergers. There are now more than 100 companies claiming to offer PBM services, though the majority offer only claims processing or mail order prescription services. A smaller proportion offer a full range of pharmacy benefit services, including mail order pharmacy, comprehensive reporting capabilities, a retail network, and integrated claims processing. (20)

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 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 reported in 1997 that “drug makers are taking advantage of their ownership of companies that manage prescription drug benefits for health insurance plans.” (21) 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:

- 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.

- 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 co-payments for non-generic 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—Coordinated system of preventive, diagnostic, and therapeutic measures intended to provide cost-effective quality health care for a population who have or are at risk for a specific chronic illness or medical condition. (22)

Managed Care and PBM

A 1998 annual survey (23) of employers and HMOs indicated that 60 percent of employers and 54 percent of HMOs responding were satisfied with the performance of the company providing PBM (measured on a scale from 1 to 10, with 10 being the highest level of satisfaction). This annual PBM satisfaction rating showed improvement over the previous two years. The PBM service that received highest ratings was “pharmacy network.” (See chart: “HMOs, employers happier with their PBMs.”)
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.” (26) Several companies offer some well-designed disease management programs; programs for managing asthma, diabetes, and 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.
HMOs, employers happier with their PBMs

HMOs and, to a lesser extent, employers that contract with pharmacy benefit management companies were happier last year than they were the year before with the PBMs’ performance, the Pharmacy Benefit Management Institute found in a poll. PBMI received responses from 330 large employers (more than 2,500 employees each) covering more than 10.5 million people, and 69 HMOs with a collective enrollment of more than 15 million.

Overall, and for most individual functions too, ratings were higher than 1997, but there’s still a lot of room for improvement. About 40 percent of employer and 46 percent of HMO respondents gave their PBMs a rating of 7 or less on a scale of 1 to 10.

These and other findings are in PBMI’s 1998 Pharmacy Benefit Manager Customer Satisfaction Survey Report.
With the entry 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 (24) 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.) (25)

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

A major shake-up in the PBM industry is already underway. 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. ACP–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.

ACP–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.
References

23. “HMOs, Employers Happier with Their PBMs.” Managed Care February 1999.