Chapter 2

OVERVIEW OF PRESCRIPTION DRUG BENEFITS IN MANAGED CARE

ROBERT P. NAVARRO AND
RUSTY HAILEY

INTRODUCTION

A prescription drug program is a vital component of comprehensive healthcare benefits offered by managed care organizations. Virtually all managed care organizations offer pharmacy benefits, and over 92% of commercial managed care customers purchase pharmacy benefits for their employees. In addition to commercial health plans, Medicaid programs include a pharmacy benefit, and as of 2006, Medicare Part D offers an outpatient prescription drug benefit to the 41 million Medicare beneficiaries. Therefore, other than the 46 million uninsured, the vast majority—approximately 85%—of the U.S. population may obtain prescription coverage through a private or public third-party managed pharmacy benefit program. Correspondingly, as a result of the Medicare Part D drug benefit, the Centers for Medicare and Medicare Services (CMS) projects that by 2008, 80% of prescription drug expenditures will be paid by a public or private third-party prescription program.[1] The 2004 to 2008 change in prescription drug expenditures by payer source is illustrated in **Figure 2-1**.

Prescription drug benefits are a highly coveted and a highly utilized benefit by plan sponsors as well as members. Plan sponsors should understand that offering all health plan members comprehensive pharmacy benefits makes clinical as well as economic sense. Clearly, prescription drugs are a management linchpin of many high-cost and high-prevalence medical conditions, including hypertension, outpatient infections, hyperlipidemia, congestive heart failure, diabetes, cancer, seizure disorders, migraine headache, asthma, allergic rhinitis, depression, psychosis, gastroesophogeal reflux disease (GERD), seizure disorders, and many others. Effective outpatient treatment with a pharmaceutical may obviate the need for more expensive and less benign medical resources, such as hospitalization and surgery.

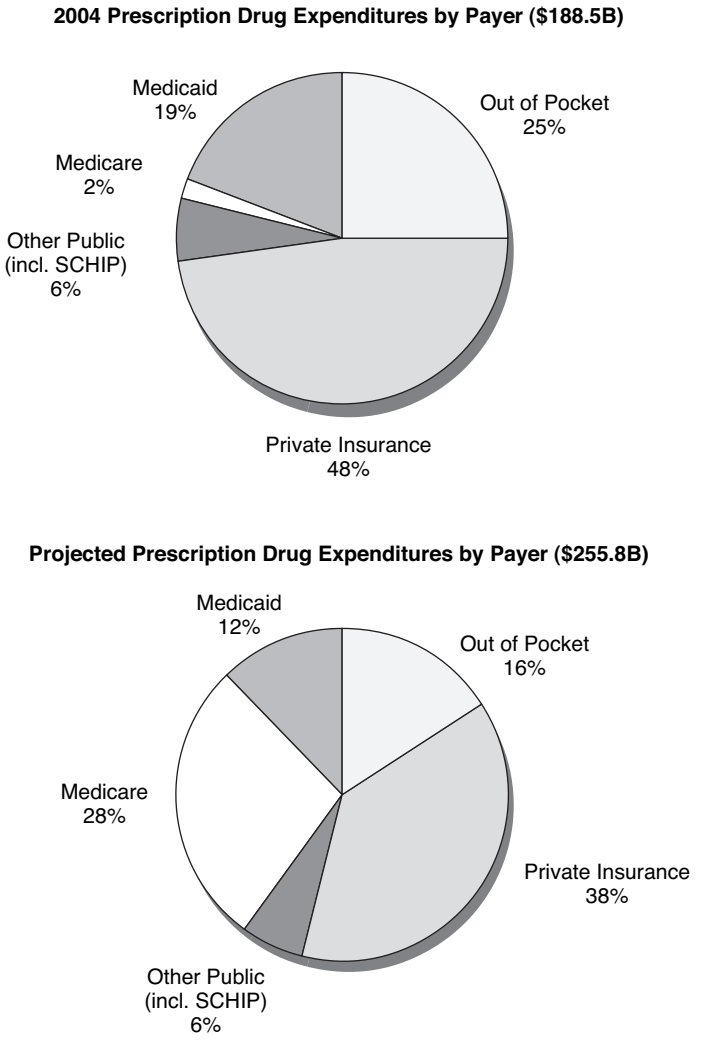

FIGURE 2-1 Change in Payer Source of Prescription Drug Expenditures (2004 and 2008). Data obtained from National Healthcare Expenditure Projections: 2005–2015. Prescription Drug Expenditures (Table 11). Available at: http://www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp. Accessed 30 May 2008.

GOALS OF PHARMACY BENEFIT MANAGEMENT

Health Care in the United States is a highly competitive market-driven business. Public (Medicaid and Medicare) and private (employer groups) plan sponsors have many competitive alternative sources for prescription drug benefits. As a result, providers of phar-

macy benefits must understand and anticipate the varied expectations and demands of purchasers, who are quite willing to switch to another pharmacy benefit provider on an annual basis if they are dissatisfied with their current provider. Generally, payers are interested in pharmacy benefit providers who are able to manage program costs, provide reasonable access to necessary medications, and provide excellent customer support programs. However, payers are different in their demands, and whereas one plan sponsor may place greater importance on cost containment and accept very limited benefits, another group, such as a union trust, may desire a broad range of drug coverage with very low copayments, and still another employer may be more interested in providing greater drug coverage supported by disease management programs. Pharmacy program providers counsel their clients on how they may achieve their desired outcomes by crafting their own customized pharmacy benefit management program.

Pharmacy directors attempt to manage the *supply cost* as well as the *utilization demand* of pharmaceuticals. This is accomplished by influencing the behavior of all individuals and entities that can control the supply and demand of pharmaceuticals by sharing with them the program financial risk. From a pharmacy benefit perspective, managed care implements supply side contracts with pharmaceutical manufacturers and dispensing pharmacies that essentially extract discounts on the drug ingredient cost (through manufacturer rebates and pharmacy reimbursement discounts) and a discounted pharmacy dispensing fee. Demand-side controls involve member prescription copayments or coinsurances paid by patient-members when they access and obtain pharmacy services. Member cost sharing is designed to encourage use of the most cost-effective products. Some managed care organizations (MCOs) also share a portion of the pharmacy benefit financial risk with prescribing physicians. The theory behind this strategy is that physicians will prescribe more cost-efficiently if they share in the cost of the drugs they prescribe. Despite the fact that this practice has been criticized for appearing to pay physicians for prescribing certain drugs, physicians with shared financial risk generally prefer generic or less expensive brand products, which also benefit patients through a lower copayment. In summary, pharmacy program managers attempt to obtain discounts on the drug ingredient cost as well as encourage the use of the least expensive yet therapeutically effective products to optimize pharmacy budget expenditures, which benefits plan sponsors as well as members.

As a result, pharmacy benefit managers (PBMs) must offer a broad range of program benefit design options to meet varied plan sponsor desires, while involving all stakeholders financially to achieve program objectives for each unique customer. The relationships and the flow of money among various stakeholders involved in medical and pharmacy benefits are shown in **Figure 2-2**. A general rule in identifying entities that may influence supply and demand is to "follow the money" trail. This model includes an MCO that contracts with a PBM for certain pharmacy benefit services (e.g., pharmacy distribution network and to contract with pharmaceutical manufacturers). However, large MCOs can provide complete pharmacy benefits directly without using a PBM. The relationships

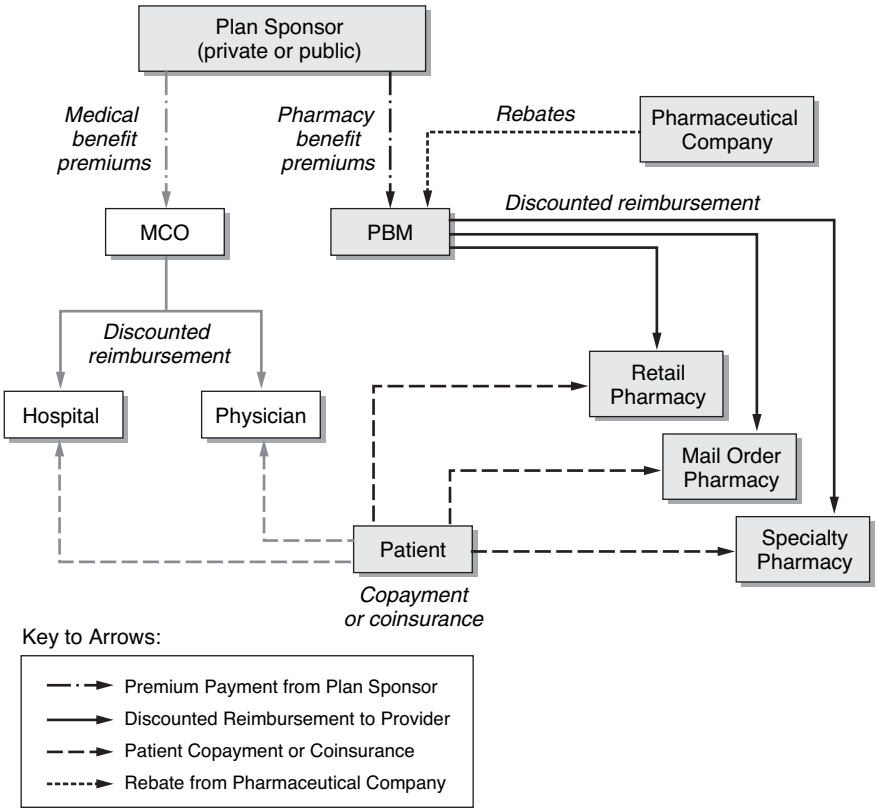

FIGURE 2-2 Relationships Among Stakeholders in Managed Prescription Drug Benefits (PBM model; medical benefit delivery de-emphasized).

involved in medical benefit delivery in Figure 2-2 are de-emphasized to highlight the pharmacy benefit delivery.

Both public and private MCOs continue to aggressively manage pharmacy benefits in an attempt to promote the appropriate level of prescription utilization rate as well as optimize the drug expenditure spend. This focus on pharmacy benefit management may seem antithetical to the cost-effectiveness value of pharmaceuticals. However, health care in the United States is a market-driven business. Since the inception of managed healthcare concepts in the early part of the 20th century, purchasers of care have demanded cost-containment as well as a broad spectrum of healthcare benefits. Although managed care has aggressively managed all healthcare products and services, pharmaceutical benefits continue to be aggressively managed for three primary reasons:

1. Although pharmacy benefits are the third largest healthcare benefit expenditure of managed care plans (after hospital and outpatient medical benefits), the annual trend

rate of prescription drug benefits had been rising faster than the other two major benefits for the past several years. Today, pharmacy benefits consume approximately 20% of total managed care healthcare costs, compared with approximately 5% two decades ago. This trend seems to be slowing a bit since 2005, and may be reduced more by the loss of patent protection of a number of important high cost and high utilization drugs over the next three years.

2. Pharmacy benefits are highly visible to government and private plan sponsors and accessed more than hospital or outpatient medical benefits. The average commercial MCO members uses approximately 8 to 11 prescriptions per year, and the average Medicare Part D member uses approximately 17 to 23 prescriptions per year, whereas the average commercial member consults a physician 5 to 6 times per year, and many of these encounters are pediatric visits.
3. Pharmacy benefits *can* be easily managed. The recipe for managing prescription drug costs and utilization is well known and can be implemented within months with adequate resources, and if payers and members are willing to accept benefit limitations. The management strategies used today were initiated almost 25 years ago, and used by every pharmacy benefit manager to manage pharmacy benefits. However, while the strategies are well known, successful implementation is challenging.

Rather than severely restrict or eliminate pharmacy benefits, MCOs and PBMs attempt to counsel their customers to purchase a cost-effective benefit. That is, an intelligently managed pharmacy benefit will provide easy access to necessary drugs, even encourage the appropriate use of cost-effective pharmaceuticals, and guard against inappropriate use of unnecessary, ineffective, or overly expensive drugs.

Pharmacy benefit management has been successful in reducing pharmacy benefit costs by 25% to 45%, compared to unmanaged drug costs, depending upon the aggressiveness of the managed program. As pharmacy benefits evolve, and outcomes data demonstrate the comparative value of competitive pharmaceuticals, PBMs and purchasers of health care will be in a better position to develop and implement an intelligent pharmacy benefit that optimizes the appropriate use of the most cost-effective pharmaceuticals to achieve the best clinical, economic, and humanistic outcomes.

Pharmacists managing prescription drug benefits must provide high quality pharmacy benefits while managing program costs. The quest to *manage* costs, rather than merely *minimize* costs, remains the challenge. As pharmacy program costs continue to escalate at an annual trend rate of approximately 10% to 15%, it is tempting to merely restrict expensive drugs, require the use of only generic drugs, and to significantly increase the patent co-patient tier amounts. However, simply focusing on cost-minimization may be myopic and ultimately cost-ineffective in several therapeutic categories. High cost drugs *may* produce superior clinical and economic outcomes compared with less expensive alternatives. Also, very high member copayments may be a barrier to drug utilization and adherence, and may result in drug failure, which may require more expensive medical treatment. Thus,

pharmacy directors must consider the cost as well as outcomes associated with competing drug products when developing and managing their pharmacy benefit.

Health plan administrators as well as commercial and government payers often consider pharmacy benefits only as a cost center, and do not appreciate the value that a well-managed pharmacy benefit can bring to clinical, economic, and humanistic outcomes. In fact, a successfully managed pharmacy benefit should be considered an *investment* in cost-effective health care, rather than only a necessary expense. Health outcomes research in health plans, addressed below, provides the linkage between appropriate use of cost-effective drugs and positive outcomes, and helps administrators and payers migrate from cost-minimization to optimizing value. To achieve this goal, pharmacy benefit managers attempt to select the most cost-effective drugs for formulary inclusion, implement programs to promote the appropriate use and adherence, and document value by measuring outcomes. These goals are no different than those of hospital pharmacists, but are more difficult to control as the MCO pharmacy director is often managing prescription benefits for hundreds of thousands, or even millions of patients, from pediatric patients to Medicare beneficiaries, with literally every known disease for a prolonged period of time.

NOVEL CHALLENGES AND EFFECTIVE MANAGEMENT STRATEGIES

Pharmacy benefit management has evolved over the past 25 years to meet and—if possible—anticipate the clinical and financial market challenges threatening effective prescription drug benefit management. The events of the years leading up to 2010 and beyond provide some unique market trends not seen in the past two decades. The three most important concerns and challenges managed care pharmacy directors face include:

- Successful implementation of the Medicare Modernization Act Part D Medicare pharmacy benefit. Although some health plans have had experience in Medicare health benefits, very few have offered a comprehensive pharmacy benefit. Medicare Advantage plans (formerly Medicare + Choice) will hold financial risk for medical as well as pharmacy benefits in this population subgroup with 40 million elderly beneficiaries, which typically have more diseases, comorbidities, and consume more medications.
- Management of injectable biological medications, which are generally extremely expensive and often used in severe or life-threatening medical conditions (e.g., rheumatoid arthritis and other autoimmune disorders, HIV-AIDS, Crohn's disease, end-stage renal disease, and a variety of cancers). Many health plans and PBMs are using specialty pharmacies to provide and manage injectable biologicals, as these products require specialized distribution systems and patient management strategies. Injectable products may not be a component of the pharmacy budget, and are often part of the medical budget. However, even if injectables are not a financial responsibility of the pharmacy budget, often the pharmacy department is involved in managing injectable drug selection and utilization.

- Successfully implementing consumer-driven healthcare (CDH) initiatives that include health spending accounts (HSAs), and higher and more complicated copayments and coinsurance schemes. CDH initiatives should motivate and reward the consumer for self-management and include financial incentives and cost-sharing, without the unintended consequence of inadvertently building in financial disincentives to delay preventive care.

In addition to these novel challenges, health plans and PBMs continue to face the daily challenge of developing and implementing cost-effective pharmacy benefit programs customized for each of their customers. To meet the long-term and unique pharmacy benefit management challenges, pharmacy and medical directors routinely consider the following strategies as most effective (these strategies are discussed in depth later in this chapter)[2]:

1. Increasing the use of generic drugs. Health plans and PBMs frequently report that 50% to 60% of the prescriptions they reimburse are dispensed with lower priced generic alternatives. Some closed-model plans estimate they may be able to increase this rate to 70% or even 80%, especially in upcoming years when some important high-cost and highly utilized drugs lose patent protection (e.g., statins, calcium channel blockers, antidepressants, inhaled and nasal corticosteroids).
2. Raising patient prescriptions copayments and coinsurance amounts. Health plans and PBMs continue to increase copayments and coinsurance levels to encourage the use of lower cost preferred formulary products and to share the cost of medications with members who use them. The impact of copayments will be discussed below in the Drug Formulary Development and Management section.
3. Health plans and PBMs will more aggressively limit open access to the use of certain expensive drugs, or drugs with a misuse or abuse potential, through the use of prior authorization (physician and/or pharmacist must obtain approval to prescribe or dispense certain drugs), step-care edits (a lower priced drug must be used before a similar expensive drug is reimbursed), and other limits (e.g., quantity of units dispensed at one time, and the duration of use).
4. Health plans and PBMs may again promote more closed drug formularies. Closed formularies (a limited of drugs are reimbursed) were more common in the late 1980s and early 1990s, but formularies became more open (increased number of drugs reimbursed using expanded tiered copayments) by the late 1990s. However, with increasing drug program costs, and demands from plan sponsors for greater cost containment, pharmacy directors may again encourage the use of closed formularies. This reoccurring trend may be reinforced by the recent implementation of Medicare Part D formularies, which were generally more restrictive or closed.

Pharmacy directors will continue to use these and other strategies in the future, but will use them more aggressively and with more therapeutic categories. The following sections discuss important information systems, and commonly used prescription drug program management strategies in greater depth and detail.

PHARMACY INFORMATION SYSTEMS AND HEALTH INFORMATICS

Similar to other healthcare delivery components, pharmacy benefit administration is critically dependent on efficient data and information systems. The basic information systems involved in pharmacy benefit management include the following:

- Internal health plan administrative data systems that include member eligibility files, group benefit claims adjudication files, provider files, and drug files that are used for accurate claims adjudication.
- In-pharmacy, point-of-service (POS) third party claims adjudication systems that dispensing pharmacists use to verify member, provider, and drug eligibility, and obtain copayment and reimbursement information in an online, real-time environment.
- Health plan or PBM pharmacy administrative claims file, used for drug utilization review, pharmacy program performance analysis, research, patient and physician intervention programs, and financial report generation. Drug files are often merged with medical files to generate an integrated claims database suitable for research.

The presence of a universally accepted electronic data interchange standard for pharmacy claims transmission and adjudication has accelerated the adoption of pharmacy e-commerce. This standard, maintained by the National Council for Prescription Drug Programs (NCPDP), "creates and promotes standards for the transfer of data to and from the pharmacy services sector of the healthcare industry."[3] This universal standard has allowed the pharmacy claims systems to be suitable for electronic commerce.

PHARMACY CLAIMS ADJUDICATION

Observation of the NCPDP data standards allows 99% percent of all managed care prescription claims to be processed electronically online and usually in real-time. Pharmacists rely on the third-party prescription drug program benefit design and coverage information provided to them through the in-pharmacy POS system. Pharmacy benefits programs, even within a single MCO or PBM, may be highly variable, may change frequently, and may have complex benefit design elements, so dispensing pharmacists simply must rely on electronic messaging to efficiently process prescriptions. When a pharmacist fills a managed care prescription, the required patient, drug, and prescriber data are input into the pharmacy POS system. Within seconds, the pharmacist is informed if the patient and drug are eligible for coverage, is informed of the copayment to be collected, and is provided any pertinent clinical information (e.g., drug interactions or clinical edits). If correct, the pharmacist completes the transaction and within seconds the claim is adjudicated online, informing the pharmacist of the reimbursement amount. The online pharmacy management systems provide patient-specific information at the point-of-dispensing that will identify adherence problems, drug interactions, dispensing errors, and print a patient information document. Pharmacy claims data are also used to identify members that may benefit from disease or case management, such as patients who appear to be misusing or

abusing redundant prescriptions from multiple providers, or displaying other inappropriate or excessive drug use patterns.

PHARMACY AND MEDICAL CLAIMS INTEGRATION AND CLINICAL PROGRAM SUPPORT

Over the past decade, healthcare information system standards have allowed easier integration of medical, administrative, and pharmacy claims datasets. Merging of these databases is accomplished through linking the common shared dimensions, such as identifiers for member, physician, and employer group benefit level. Health plans and PBMs compete on price as well as quality of care and services. Thus, health plans in particular are interested in measuring clinical and economic outcomes, and use comparative health plan data for marketing to potential customers. For example, a population of case-mix–adjusted patients with a specific medical condition can be stratified according to severity, age, comorbidities, and other characteristics, to compare the clinical and economic outcomes of each cohort. Similarly, physician drug prescribing patterns also may be evaluated and compared. A well-constructed merged database may be used to identify clinical "best practices" that are associated with the most cost-effective outcomes.

Most health plans participate in the National Commission for Quality Assurance (NCQA) accreditation process, and allow their performance metrics to be compared against competitive plans using the NCQA Health Plan Report Card.[4] The NCQA has also established many "effectiveness of care" indicators through its Health Plan Employer Data and Information Set (HEDIS®) program. The NCQA HEDIS are a list of almost 70 measures designed to collect data about the quality of care and services provided by the health plans.[5] Approximately one-half of these measures relate to appropriate pharmaceutical or immunization use, and can be used to measure pharmacy benefit contributions at a high level. Health plan quality initiatives are addressed elsewhere in this book.

ELECTRONIC PRESCRIBING

The rapid expansion of information technology applications in health care presents novel opportunities and challenges for pharmacists. Although electronic prescribing is not universal, many MCOs are experimenting with real-time electronic data transfer of prescription-related information among trading partners: the health plan, physician, and pharmacy. Electronic prescribing refers to the use of computing devices to enter, modify, review, and output or communicate drug prescriptions. For inpatient care, electronic medication ordering increases prescribing accuracy, dispensing efficiency, and reduces the number of adverse drug events and redundant medications. A number of outpatient pilot projects and initiatives in electronic prescribing are proliferating within managed care organizations to achieve the same goals, and also providing medication history, drug formulary options, drug hypersensitivities, and other clinically relevant data to the prescriber at the point of prescribing.

Electronic prescribing is an electronic data interchange application that provides electronic connectivity among all trading partners involved in prescription generation,

adjudication, and analysis.[6] E-prescribing links the health plan or PBM, with the physician and pharmacy. E-prescribing allows the physician, using a desktop or handheld device to access a patient's medication history, drug allergies, pharmacy benefits, and drug formulary drugs covered, and transmits a "clean" prescription to the patient's preferred pharmacy: all online and in real-time. **Figure 2-3** illustrates the electronic connectivity among trading partners.

There are several potential financial and patient care advantages to the physician, health plan, pharmacy, and patient. Point-of-prescribing medication information helps enforce drug formulary conformance, informs the physician of the member copayment impact of selected drugs, and prevents rejected prescriptions at the pharmacy. Prior authorization or step-care protocols may be enforced through e-prescribing, and the system can alert physicians of any drug interactions, history of adverse events, redundant prescriptions from other physicians, and incorrect dosages before the patient leaves the physician's office. The potential cost savings from e-prescribing result from reduced administrative costs and less physician and pharmacist time involved in the prescription process, reduction in drug interactions and adverse effects, improved safety and reduced medication errors, and improved medication compliance.

In the ambulatory environment, recent research shows that adverse events are common and can be serious. The Center for Information Technology Leadership reports that more than 8.8 million adverse drug events occur each year in ambulatory care, of which over 3 million are preventable, many resulting in deaths. In addition to reducing adverse

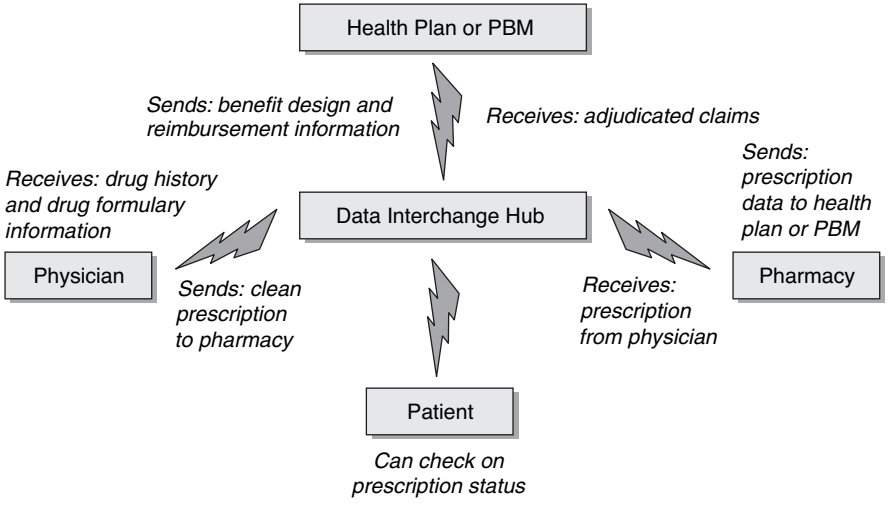

FIGURE 2-3 E-Prescribing Connectivity Among Managed Care Trading Partners.

drug effects, electronic prescribing can improve quality, efficiency, and reduce costs through other benefits, including[7]:

- Actively promoting appropriate prescription use and adherence.
- Providing information about formulary options and copay information.
- Improving dispensing efficiency and accuracy by providing instant electronic connectivity between the physician, pharmacy, health plans and PBMs.

More than 3 billion prescriptions are written annually.[6] Given this volume, even a small improvement in quality attributable to electronic prescribing would translate into significant healthcare cost and safety benefits if electronic prescribing is broadly adopted. Studies suggest that the national savings from universal adoption of electronic prescribing systems could be as high as $27 billion, including $4 per-member-per-year (PMPY) savings from reducing preventable adverse drug events, and $35 to $70 PMPY savings from more appropriate use of medications, for a total savings of $39 to $74 PMPY.[6] Electronic prescribing has significant benefits for pharmacists as well. The Institute for Safe Medication Practices estimates that pharmacists spend a significant amount of their time each day on clarifying prescription orders, and make 150 million phone calls to physicians annually on prescription accuracy related issues.[8]

RxHub® provides a universal portal that supports prescription electronic data interchange among trading partners.[9] Originally formed in 2001 by three PBMs, the enterprise now enjoys participation of PBMs, health plans, and numerous e-prescribing solution venders, for the purpose of:

> ". . . creating a single point of communication for all participants in the prescription creation and delivery process the founders formed a neutral organization, whose primary mission is to accelerate the adoption of electronic prescribing resulting in better medicine and lower administrative costs."[9]

All advantages of e-prescribing can lead to improved clinical, economic, and quality of life outcomes. E-prescribing will unquestionably increase, especially as it is an eventual requirement in the Medicare Modernization Act.

COMPONENTS OF A MANAGED PRESCRIPTION DRUG BENEFIT

Prescription drug benefits are provided through an internal pharmacy department within an MCO* or by a stand-alone pharmacy benefit manager (PBM; the role of PBMs will be addressed below and in Chapter 4). Regardless of the source (e.g., MCO or PBM), there is great consistency in the management strategies used to develop and manage a prescription drug program. Pharmacists operating health plan pharmacy benefits have borrowed many management strategies from hospital pharmacy programs, including the Pharmacy

* In this context, the term *managed care organization* refers to HMO, PPO, POS, and other health plans; Medicaid programs; Medicare Part D plans.

& Therapeutics (P & T) Committee, the drug formulary, pharmaceutical company contracting, physician academic counter detailing, utilization review, and health outcomes research. However, MCOs have had to include additional capabilities, such as development of a pharmacy distribution network, innovative pharmacy benefit design, member copayment schemes, member communication and education, and massive computer systems to process millions of claims in a real-time environment. This section will list and illustrate the components of a successful managed care prescription drug benefit program.

LEGAL BASIS FOR PHARMACY BENEFIT PROGRAMS

All states have regulatory bodies that control health-related benefit plans as well as licensing boards that control the practice of specific healthcare providers. The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals. The ERISA act has been supplemented by two important amendments. The Consolidated Omnibus Budget Reconciliation Act (COBRA) provides workers and their families the ability to continue their health coverage after loss of employment, and the Health Insurance Portability and Accountability Act (HIPAA) provides protection for patients from discrimination related to pre-existing medical conditions as well as enhanced confidentiality of medical information.[10]

MCOs and PBMs, as corporate entities, do not practice medicine or pharmacy, and do not claim to provide any and all desired pharmacy products and services. Rather, they arrange for defined medical and pharmacy benefits to be provided by licensed healthcare professionals within a defined structure and process. Healthcare professionals participating with an MCO or PBM provide pharmacy benefits that are specified and defined in a state regulated contract (e.g., Certificate of Coverage or other similar legal document) between the MCO or PBM and the purchaser of pharmacy benefits. Physicians and pharmacists agree to participate according to policies outlined in their respective provider manuals and contracts, which are generally filed with a state regulatory agency. The contract defines included and excluded benefits as well as the access rules through which members must obtain benefits. Drugs eligible for reimbursement are normally those included in the drug formulary (a list of reimbursed drugs) that is reviewed and updated from time to time. Drugs typically excluded from reimbursement include the following:

- Experimental or investigational drugs (drugs not approved by the U.S. Food and Drug Administration for commercial sale in the United States).
- FDA approved drugs when prescribed for unapproved indications ("off-label" indications). This is generally unenforceable through community pharmacies, as pharmacists are generally unaware of the prescribed indication or medical diagnosis for most prescriptions dispensed. The approved indication may be enforced if the pharmacist must obtain a prior authorization from the MCO or PBM prior to receiving reimbursement for the drug product.

- Drugs used for cosmetic purposes (e.g., Botox® for wrinkles) or possibly life enhancement drugs (e.g., PDE-5 inhibitors).
- A brand name drug for which there is an identical generic equivalent that is subject to mandatory generic substitution (e.g., drugs subject to a maximum allowable cost [MAC] reimbursement).
- Drug available without a prescription (or over-the-counter [OTC] drugs), including brand name drugs for which there is an identical OTC equivalent. Insulin is an exception, as it is a non-prescription drug in most states but remains covered by health plan pharmacy benefits.

It is important to note that all health plans and PBMs allow for medical exceptions to defined benefits. That is, a physician may appeal to a health plan or PBM for coverage and reimbursement for a non-covered benefit based upon an individual patient's medical needs. Additionally, patients have the ability to directly purchase any non-covered benefit outside of the pharmacy benefit, on a cash basis, with a physician's prescription. Pharmacy benefit design does not limit what a physician may prescribe; benefit design only limits what an MCO or PBM will reimburse.

CHANGES IN PHARMACY BENEFIT DESIGN

There are two principal changes occurring in benefit design. The first is greater use of formulary prescription copayment and coinsurance tiers as well as higher copayment tier dollar and coinsurance percent amounts, especially for non-preferred and injectable medications. The second major benefit design change is the growth of CDH and HSAs, which are encouraged by state and federal regulatory agencies as well as employer groups and health plans.[2,11] HSAs usually have lower monthly premiums and higher annual deductibles (often $2,500 for individuals and $5,000 for families), and give members more latitude and freedom in using HSA funds for health-related expenditures. A potential downside is that HSA members, used to near first-dollar coverage for medical and pharmacy benefits, will now have to spend $2,500 or more in out-of-pocket deductible expenses before benefits are covered 100% by the health plan. Early experiences of a few employer groups have found some members are reluctant to spend their own out-of-pocket money, and may delay preventive care, thus resulting in a need for delayed and more expensive acute medical treatment.[12] HSAs are most effectively used by informed members who are educated and motivated to optimize their health care, and are given appropriate information to make intelligent healthcare access decisions. HSA members are important targets for pharmaceutical companies with direct-to-consumer advertising for both prescription and over-the-counter medications.

DISTRIBUTION CHANNELS FOR OUTPATIENT PHARMACEUTICALS

Managed care organizations and PBMs must develop a pharmaceutical distribution system that meets member needs for easy access to prescription services as well as controlling drug ingredient and dispensing costs. Closed model health plans (e.g., staff or group

model MCOs) or large employer groups may have in-house, owned pharmacies for member convenience, supplemented with community pharmacies, often with mail service. Open model plans (e.g., independent practice associations [IPA] and network MCOs) will use a community-based pharmacy network including chain pharmacies, independent pharmacies, and often mail service pharmacy. Today, a pure MCO rarely exists, and most staff and group model plans now offer a hybrid distribution network consistent of in-house pharmacists supplemented by community and mail service pharmacies.

Generally 80% to 90% of third party outpatient prescriptions are dispensed through community pharmacies (pharmacy chains, independent pharmacies, supermarkets, or mass merchandise stores such as WalMart and Target). Most of the remaining prescriptions are dispensing through mail services pharmacies, often owned or associated with PBMs or chain pharmacies. A small percent of prescriptions, mostly generic drugs and often in rural areas, are dispensed in physician offices, which may not be reimbursed by MCOs or health plans. Of the $221 billion spent on outpatient prescription drugs in 2004, the National Association of Chain Drug Stores (NACDS) reports that 42.2% were dispensed through chain pharmacies, 18.7% through community independent pharmacies, 18.3% through mail service pharmacies, 12.2% through supermarkets, and 9.6% were dispensed through mass merchandise stores.[13] As a result, the basis of a managed care outpatient prescription network is often chain pharmacies, supplemented by other types of pharmacies. However, the NACDS reports that the largest annual growth in prescription sales from 2002 to 2003 occurred in mail service pharmacies, which grew by almost 18%, in contrast with all other pharmacy types, which grew between 5% and 8%.

Pharmacies participating in the pharmacy provider network agree, by contract, to dispense drugs prescribed by participating physicians to eligible members according to the drug formulary and other benefit design requirements. Open-access of POS plans may reimburse prescriptions from any licensed physician. Pharmacists participate in many different managed pharmacy programs, and by contract must use an online, real-time POS computer system to verify coverage information (eligible drug, member, and physician), learn any dispensing limitations or requirements (e.g., quantity limits, step-care protocols), obtain copayment information, and know the level of reimbursement from the health plan or PBM. Busy pharmacists dispensing 200 prescriptions per day simply must rely on an accurate and efficient online system to verify and adjudicate claims.

All participating pharmacies are bound by a provider agreement that stipulates they will provide approved prescriptions dispensed to their members in accordance with drug benefit and coverage policies, and for a specified discounted reimbursement. These policies are usually detailed in a Participating Pharmacy Policy and Procedure Manual that is updated from time to time by the MCO or PBM. Participating pharmacies agree to follow the drug formulary and dispensing requirements, use the POS system to adjudicate claims online and in real-time whenever possible, promote the use of generics, discourage the use of "dispense as written" prescriptions that encourage the use of brand drugs, and agree to participate in on-site audits of third party prescription records.

Pharmacists receive a discounted ingredient cost reimbursement based upon a discount off the drug average wholesale price (AWP) plus a discounted dispensing fee. The elements and calculations involved in determining pharmacy reimbursement of a brand drug in formulary copayment Tier II (brand preferred) is illustrated in **Table 2-1**. Wholesale acquisition cost (WAC) is the published drug list price, but is not used in determining pharmacy reimbursement from health plans or PBMs (WAC is de-emphasized in Table 2-1).

As shown in the example, the drug AWP is generally used to determine drug ingredient reimbursement. In Table 2-1, the AWP is discounted by 15%. This level of discount is used to approximate the actual acquisition price (AAC) by the pharmacy. It is actually quite difficult to positively identify the AAC for a particular prescription, as the pharmacy inventory is based upon volume discounts, special offers, and early payment discounts. Thus, rather than burden pharmacies with the requirement to identify the exact AAC of a prescription, MCOs and PBMs approximate this amount using a discounted AWP. Brand drug AWP discounts may be 15% to 18%, and generic drug discounts are often in the AWP less 40% to 60% range. Other payments may exist, such as for special incentives for generic substitution or member clinical consultation, and medication therapy management (MTM) program activities, as mandated by the Medicare Part D regulations.

SPECIALTY PHARMACY DISTRIBUTION

The increasing use of high-cost injectable biological products is identified as the greatest threat to pharmacy benefit management. However, despite the challenge in managing cost and utilization of expensive products, injectable biologicals present unique, advanced therapy for many severely debilitating and life-threatening illnesses. Thus, as much as health plans welcome the launch of life-saving drugs, they are faced with the reality that uncontrolled

TABLE 2-1 Calculations Involved in Determining Pharmacy Reimbursement from a Managed Care Plan

	Preferred Brand Drug Tier II
Wholesale Acquisition Cost (WAC)*	$80.00
Average Wholesale Price (AWP)	$100.00
Drug Reimbursement (AWP—15% Discount)	$85.00
Dispensing Fee (+)	$2.50
Subtotal	$87.50
Member Tier II Copayment (–)	$25.00
MCO Reimbursement to Pharmacy	$62.50

*WAC is not used in pharmacy reimbursement.

Source: RP Navarro, 2006.

utilization may place a plan in financial peril. Health plans support the use of evidence-based treatment guidelines and protocols, and usually implement prior authorization edits on expensive biological injectables to encourage appropriate use for Food and Drug Administration (FDA)-approved indications. A large Blue Cross and Blue Shield plan found that 37% of injectable expenses were for oncology and related products, 11% were for inflammatory diseases of the colon, 9% of injectables were for leucocyte stimulants, and 2% was spent on anti-inflammatory and anti-arthritis injectable products.[14]

The unique distribution, storage, and utilization consideration of injectables has caused the development of carve-out specialty pharmacy distributors (SPDs). Specialty pharmacy services may also be offered internally through PBMs and health plans. Specialty pharmacies manage the distribution and use of self- and physician-administered injectable products. SPDs may send injectables directly to a physician's office or infusion center specifically for a patient appointment, or self-injectable drugs may be mailed directly to a member's home. Volume purchasing by SPDs introduces cost efficiencies into the system that are passed on to payers and members. SPDs also use rebates, formulary-style product steerage, copayments and coinsurance, and provider discounts as other methods of controlling injectable drug costs. Chapter 6 contains further discussions about specialty pharmacy distribution.

Health plans also may use SPDs to buy and store inventory on behalf of physicians, which prevents physicians from stocking and storing expensive mediations, and removes them from the flow of dollars. In this scheme, the SPD bills the health plan and/or member directly, and the physician is paid an infusion and/or administration fee by the health plan. The growing availability to biotechnology pharmaceuticals will likely increase the role and importance of SPDs in the future. Traditional discounted reimbursement of injectable products as a Part B Medicare Benefit will be altered through the use of a CMS average selling price (ASP) plus 6% method. Many plans are adopting this Medicare-style cost-plus reimbursement for injectables in their commercial plans as well. The implementation of the CMS competitive acquisition program (CAP) for injectable has been delayed, and the impact of the CAP is unknown at this time.

INTERNET PHARMACY ACCESS

Internet pharmacies developed in the late 1900s, and were thought to be a future threat to community and mail service pharmacies. However, this has not occurred, and although some Internet pharmacies remain in existence (e.g., http://www.drugstore.com), others have ceased business. In reality, Internet pharmacies were simply an online method to access traditional pharmacy services with mail delivery. Internet pharmacy access allows patients to refill prescriptions and purchase non-prescription drugs, vitamins, and other health products online. However, rather than Internet pharmacies threatening mail service pharmacies, we have seen chain and mail service pharmacies develop patient-friendly Internet portals, and have developed their own Internet pharmacy capabilities. Managed care supports Internet access to pharmacy services of U.S. licensed participating pharma-

cies because Internet access increases the use of the mail service pharmacy component, which is considered a growing source of pharmacy budget savings.

While Internet access to licensed U.S. chain and mail service pharmacies is a patient convenience, there remains a safety concern about unregulated Internet pharmacies outside of the United States. Counterfeit and inert drugs from international sources have been distributed through Internet pharmacies, and international commerce through the Internet is impossible to control.

In response, the National Association of Boards of Pharmacy® (NABP) developed the Verified Internet Pharmacy Practice Sites(tm) (VIPPS) program in 1999.[15] To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria. According to the NABP Web site, twelve Internet pharmacies have satisfied VIPPS criteria,[15] including the mails service pharmacies of PBMs (e.g., Caremark, Medco Health Solutions, Prescription Solutions), health plans (e.g., CIGNA, Coventry), pharmacy chains (e.g., CVS, Walgreens), and Internet pharmacies (e.g., http://www.Familymeds.com, http://www.Drugstore.com).

PHYSICIAN DISPENSING

Some health plans may reimburse physicians for dispensing drugs directly from their office, but this is an uncommon practice and most often occurs only in rural areas without adequate coverage of community pharmacies. Health plans will often not reimburse physicians for dispensing drugs unless the physician's office agrees to accept the same level of reimbursement as is paid to pharmacies and if the physician's office submits pharmacy claims through a POS terminal. Physician dispensing units often contain a limited amount of acute care drugs and generally promote the use of generics. Some applications link in-office physician dispensing units for acute care drugs with mail order for chronic care medications. The American Academy of Family Practice supports the right of physicians to dispense,[16] but thus far most medical groups have not focused on developing in-house dispensing activities, other than through a co-located and usually independent community pharmacy (state law may allow the medical group to own the pharmacy space, and obtain rent, but may prevent the medical group from owning the licensed pharmacy practice itself).

PHARMACY AND THERAPEUTICS COMMITTEE MANAGEMENT

Managed care has borrowed the P & T Committee concept from hospitals as a source for formulary development and drug coverage decisions. In addition to the clinical drug review, the Committee must make recommendations on drug formulary coverage and copayment tier, and other dispensing limitations or restrictions. A managed care P & T Committee typically consist of 10 to 15 physicians and pharmacists who meet quarterly.

Clinical pharmacists with the health plan or PBM conduct a review of available data and information, and prepare a drug monograph for distribution to members of the P & T Committee that contains a recommendation for formulary inclusion or exclusion. Chapter 13 provides an in-depth discussion on P & T Committees.

The data and information reviewed by clinical pharmacists includes the following:

- Peer-reviewed published clinical efficacy and effectiveness studies
- Safety and toxicity data
- Published health outcomes and economic data
- Data on file and economic models submitted by the pharmaceutical manufacturer that is usually organized according to the Academy of Managed Care Pharmacy *Format for Formulary Submissions*[17] (see also Chapter 11)
- Plan-specific expected utilization patterns
- The positioning and impact on other formulary drugs
- Manufacturer contracts

Due to concerns about drug safety and utilization patterns, a new drug is usually not formally reviewed for formulary consideration for at least three to six months after its launch. During that time, the drug may be available for reimbursement as a non-formulary or non-preferred drug, usually on the copayment Tier III. The Medicare Part D regulations require that a drug be reviewed within 90 days, and a formulary decision must be made within 180 days. Medicare Part D regulations also require a separate Medicare P & T Committee and members appropriate to evaluate drugs for the elderly. Many health plans share members between commercial and Part D P & T Committees, and often hold their meetings sequentially.

Clinical data (efficacy, effectiveness, and safety) are the two primary formulary decision criteria, but net cost ranks quite high as a decision consideration as well. Increasingly, credible health outcomes and economic data are available and considered by managed care P & T Committees, and formulary decisions are becoming more based upon clinical, and economic outcomes, rather than solely on pharmacy budget cost minimization. Humanistic or quality of life outcomes remain less important for most drugs, but quality of life data are used subjectively when appropriate and convincing. The Academy of Managed Care Pharmacy *Format for Formulary Submissions*[17] has made a significant and positive impact on improving the quality and quantity of data available for reviews, as well as the ability of clinical pharmacists to review the body of existing data.

DRUG FORMULARY DEVELOPMENT AND MANAGEMENT

Health plans and PBMs have used drug formularies for the same reasons they are used in hospitals: to identify and promote the most cost-effective pharmaceuticals in the most appropriate manner. A drug formulary is a preferred list of medications developed by the health plan or PBM P & T Committee to guide physician prescribing and pharmacy dis-

pensing. Formularies are not novel but have been used for decades by hospitals, health plans, and other healthcare institutions as a method of inventory control and to promote the use of the most cost-effective products.[19] Early formularies in the United States were primarily compilations of formulas and recipes used to prepare medicines. The first hospital formulary, the Lititz Pharmacopoeia (1778), attempted to standardize compounding and dispensing of medicines in military hospitals that were set up during the Revolutionary War.[19] A formulary system is the method and process used that continually updates the formulary's content of prescription medications. The formulary system is a uniquely dynamic system that represents the current body of pharmaceutical knowledge and medical community practice standards resident in the healthcare setting it serves (see also Chapter 9).

The benefit design is enforced through the formulary, which is the basis for the drug and reimbursement information used by the pharmacist to process eligible claims using the POS system. Formulary booklets are mailed to participating physicians and often abridged formulary documents are provided to members. However, paper documents are often discarded, and many plans and PBMs provide pharmacy benefit and formulary information for physicians and members online. This allows for more frequent changes, and efficiency in communicating formulary matters to providers and members.

Some formularies are "open," signifying that most drugs are eligible for reimbursement although the level of member copayment varies with formulary position. Some drugs are "on formulary" but available only if the patient satisfies certain prior authorization (PA) criteria. Drugs may be subject to a PA based upon cost or safety issues, to attempt to control use for labeled indications only, or to limit use for certain types of patients.

Other formularies may be "closed," indicating a select number of drugs are eligible for reimbursement, while others are not. Closed formularies do not allow for reimbursement of non-formulary products, and if one is prescribed, the pharmacist must contact the prescribing physician to request a change to a formulary product, or the patient must pay cash for a non-formulary product. The open and closed nature of formularies is cyclical. Since the mid-1990s, formularies were often more open and inclusive, with non-preferred or even non-formulary products covered on Tier III. However, due to rising costs and the recent development of Medicare formularies, many MCOs are returning to more restrictive, closed formularies as well as including higher and tiered copayments.

Physician and member formulary conformance may be enforced using different mechanisms depending upon if the formulary is inclusive or exclusive. Closed and open formularies both use a tiered copayment structure, described below, to encourage physician prescribing and member use of generic or preferred formulary products. Some health plans and PBMs use pharmacists to "academically detail" directly to physicians who continuously disregard the formulary. Many health plans and PBMs provide physicians "formulary conformance report cards" and indicate opportunities for prescribing changes that favor formulary products. Some plans and PBMs offer financial incentives to physicians for high levels of formulary conformance.

FORMULARY COPAYMENT TIERS

MCOs and PBMs often use tiered formulary copayments as an integral component of their pharmacy benefit design. Two copayment tier plans have been in existence for over 20 years, but in the last decade more plans are adopting three or more copayment tier benefit plans. The purposes of tiered copayments are to:

1. Share some of the prescription costs with the utilizing member, and help reduce some of the pharmacy program costs to the plan sponsor, and,
2. Encourage physicians to prescribe, and patients to accept, lower cost drugs, which usually have a lower patient copayment.

Through a copayment system, members pay a flat dollar payment per prescription (i.e., $12.00, or $30.00), while with a coinsurance, a patient pays a percent of the total prescription cost (e.g., 50%), sometimes up to a maximum cap amount.

Drugs are placed into copayment tiers generally based upon their value to the plan and payer. A drug's value is based upon its clinical benefits as well as the net cost. Generic drugs are generally less expensive than brand name alternatives, and as a result, generic drugs are found on the lowest copayment tier, Tier I. Preferred formulary brand drugs are placed into copayment Tier II, and non-preferred or non-formulary drugs are found in Tier III. Three-tier formularies are the most common tiered formulary structure, although some programs, notably union trust groups, may still have two tier formulary copayments (generics in Tier I and all brands in Tier II).

We are seeing some large MCOs and PBMs offer greater copayment tier options for their customers, and may include four and five tiered formularies. Tier IV may include unessential, lifestyle, or cosmetic drugs, and Tier V may contain self-injectable drugs. Copayments are more common today, but coinsurance payments are becoming more popular with self-injectable biologicals and expensive non-essential drugs in higher copayments tiers. An example of a common three tier open formulary copayment structure is found in **Table 2-2**.

Copayments continue to increase in dollar amount, especially for Tier III non-preferred products. Many large health plans and PBMs have announced options for Tier III copayments over $60.00 for clients who desire such cost containment measures. A summary of average copayment amounts from a number of large health plans over the past five years is shown in **Figure 2-4**.

TABLE 2-2 Example of Three-Tier Drug Formulary Copayment Structure

Three Tier Formulary Example

Tier I Generic Drugs	Tier II Preferred Formulary Brand Drugs	Tier III Non-Preferred or Non-Formulary Brand Drugs
Copayment $13.00	Copayment $31.00	Copayment $53.00

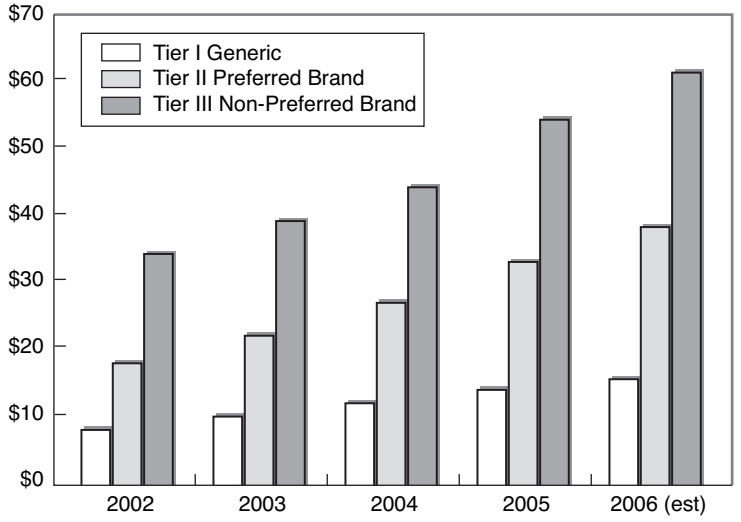

FIGURE 2-4 Examples of Average Copayment Amounts for Various Tiers 2002–2006.
Source: Average health plan copayments were compiled from a variety of research projects and personal communications with pharmacy and medical directors, 2002–2006.

Examples of formularies and copayment tiers used to encourage the use of lower priced medications are found in **Table 2-3**. This table shows possible entries for the hydroxymethylglutaryl-coenzyme A (HMG Co-A) reductase inhibitor therapeutic category (e.g., statins), a high cost and high utilization category, for 2006 and for 2008 (before and after simvastatin and pravastatin lose patent protection). The number of dollar signs ($) is a graphic indication of the relative price of the products within the therapeutic category.

The 2006 statin formulary category includes one generic statin in Tier I, two preferred formulary brand drugs in Tier II, and two non-preferred brand drugs in Tier III. The 2008 formulary includes three generic statins in Tier I, one high potency statin in Tier II, and the two remaining non-preferred brand statins in Tier III. This copayment structure will encourage physicians to prescribe, and members to prefer, generic statins first, and, if necessary, Lipitor® on Tier II, before the non-preferred Tier III statins.

The formulary position of a drug, and the resulting prescription copayment, can have a significant impact on the cost of the drug to a health plan and the member. **Table 2-4** illustrates the impact of a Tier II and Tier III copayment on the health plan payment to a pharmacy as well as to the member. The WAC is a realistic price that approximates the actual acquisition cost of a drug. The AWP is an artificial calculated number, somewhat archaic, which often remains used in pharmacy reimbursement calculations.

TABLE 2-3 Examples of potential HMG Co-A Reductase Inhibitor Therapeutic Category Drugs (Statins) in a Commercial Formulary in 2006 and 2008

HMG Co-Reductase Inhibitor Formulary (single entity statins)—2006

	Tier I	Tier II	Tier III
Type of Drugs	Generic	Preferred Formulary Brand	Non-Preferred or Non-Formulary Brand
Drugs Included	$ lovastatin	$$$ Pravachol (pravastatin) $$$ Lipitor (atorvastaton)	$$$$$ Crestor (resuvastaton) $$$$$ Zocor (simvastatin)
Copayment Amount	$12.00	$25.00	$45.00

HMG Co-Reductase Inhibitor Formulary (single entity statins)—2008

	Tier I	Tier II	Tier III
Type of Drugs	Generic	Preferred Formulary Brand	Non-Preferred Non-Formulary Brand

Drugs Included	$ lovastatin
	$ simvastatin
	$ pravastatin
		$$$ Lipitor (atorvastaton)	$$$$$ Crestor (resuvastaton)

Copayment Amount	$18.00	$35.00	$65.00

Non-reimbursed drugs: Pravachol (brand of pravastatin) and Zocor (brand of simvastatin)

TABLE 2-4 Impact of a Tier II and Tier III Copayments on the Cost of a Drug to a Health Plan and Member

	Preferred Brand Tier II	Non-Preferred Brand Tier III
Wholesale Acquisition Cost (WAC)	$80.00	$80.00
Average Wholesale Price (AWP)	$100.00	$100.00
Drug Reimbursement (AWP—15%)	$85.00	$85.00
Dispensing Fee (+)	$2.50	$2.50
Subtotal	$87.50	$87.50
Member Tier II Copayment (–)	$25.00	$45.00
MCO Reimbursement to Pharmacy	$62.50	$42.50

In this example, drugs with identical AWPs ($100.00) are put in Tier II and Tier III. In Tier II, the patient pays a $25.00 prescription copayment, and the MCO payment to the pharmacy is $62.50. In the Tier III example, the patient pays a greater portion of the drug cost ($45.00 copayment), and as a result, the payment from the MCO to the pharmacy is less ($42.50). This illustrates how a health plan or PBM can reduce costs, which are passed on to the plan sponsor, by increasing the member copayment cost. When on Tier II, the MCO pays approximately 60% of the AWP to the pharmacy, whereas when on Tier III, the MCO pays approximately 40% of the AWP to the pharmacy, over a 30% savings, although the patient must pay a copayment that is 180% of the Tier II copayment.

Generic drugs are one of the most important cost containment components of an effective drug formulary. Members are well accepting of generics, and most often ask for a generic drug. Generic drugs generally cost a fraction of the brand costs, and AB-rated products (considered to be bioequivalent and generically substitutable), are increasing in importance, as several high cost and high utilization drugs will soon lose their patent protection. In addition to encouraging the use of generics through lower copayments, health plans and PBMs also have a mandatory generic reimbursement program, often referred to as a MAC program.

Through a mandatory generic program, the generic form of drug is assigned a MAC, which is the upper level of pharmacy reimbursement by the MCO or PBM. This means that if a pharmacist dispenses a brand name equivalent to a drug with a MAC, the pharmacist will only be reimbursed at the MAC level, which approximates the acquisition cost of the generic. This almost guarantees a generic drug will be dispensed if the drug is subject to a MAC, unless the patient is willing to pay cash for the brand drug, or the physician demands the brand drug through a "dispense as written" order. Pharmacists are advised of drugs subject to a MAC as well as the MAC level of reimbursement through the POS pharmacy claims adjudication system.

Health plans and PBMs often develop their own proprietary MAC programs and list of drugs subject to a MAC, and the mechanism they use to establish a MAC level may vary. However, in general, a product is assigned a MAC if there are three or more generic products available from reputable generic manufacturers, and the AAC is significantly lower than the AAC or WAC of brand drugs. The level of significance varies with different health plans and PBMs, but generally if the AAC of a generic product if more than 50% less than the AAC or WAC of a brand drug, and the generic AAC has stabilized, a MAC will be assigned.

The use and impact of high tiered copayments on pharmacy program costs and prescription adherence are controversial topics. Certainly copayments can reduce the cost of drugs by 20% to 40% or more, depending upon the copayment amount. However, critics of high dollar copayments claim the high copayment amounts are financial deterrents to members obtaining, and remaining on, prescribed drugs, and high copayments results in poor adherence and failed outcomes. Such negative outcomes may occur, but critics must

also realize that lack of adherence is caused by a number of other factors, such as lack of member understanding, forgetfulness, belief that mediations are unnecessary, adverse effects or fear of adverse effects, and cultural barriers to medication use.[20–23] Some employer groups have adopted novel copayment structures, and have reduced the copayment for chronic medications for several high cost and high prevalence medical conditions, such as diabetes, asthma, hypercholesterolemia.[24,25]

PHARMACEUTICAL MANUFACTURERS' REBATE CONTRACTS

Borrowed from hospitals and other industries, health plans sought—and received—a financial incentive (rebate) to more favorably position contracted drug products. It is important to note that the price or rebate are not the most important drivers in formulary positioning; clinical efficacy and safety appropriately remain the most important decision criteria. However, in the absence of statistically and clinically significant differentiation among similar drugs, the net cost (which may be reduced by a rebate) can have an important impact on ultimate formulary positioning. This is especially true in crowded, relatively undifferentiated therapeutic categories, such as angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), and proton pump inhibitors as well as expensive, competitive categories with clinical product differentiation, such as antidepressants, statins, and inhaled corticosteroids. Rebates are also discussed in Chapter 15.

However, a rebate may make a drug more attractive by making it less expensive than competitors, and a rebate may result in a preferred formulary position *if* the clinical features and benefits of the rebated drug are somewhat similar to non-rebated, more expensive alternatives. The rebate savings obtained reduce the net price of contracted drugs, which in turn reduces the overall prescription drug program expenses. A reduced net price will result in a more favorable cost-effectiveness ratio, and may result in more positive economic outcomes. These savings are passed on to plan sponsors through lower premiums (or, lower than would be without rebates) and to patients through a lower prescription copayment (rebated products are usually in Tier II, which has a lower prescription copayment than Tier III).

The effect of rebates is similar to discounts. Health plans and PBMs that contract with community pharmacies, and do not take possession of drug products, are usually offered rebates. In contrast, health plans with in-house, owned pharmacies that take possession of drug products may qualify for a discount (often a wholesale chargeback). The net result is similar, although the administration and flow of money of rebates and discounts are dissimilar.

Rebates' contract terms are varied and somewhat complex. However, in simplest terms, rebates provide health plans with incentives to position contracted products in a favorable position because rebates reduce the net cost of the product. The favorable formulary position helps pharmaceutical manufacturers, because physicians and members generally prefer drugs with lower copayments, such as those found in Tier II. Rebate con-

tracts often contain two components, an access rebate and a performance component. The flat, access rebate (the smaller of the two contract components) is offered for a Tier II preferred formulary status. The value of the access rebate may vary based upon the number of competitive products sharing Tier II. For example, if a product has an exclusive Tier II position, the access rebate may be higher, but if the product shares Tier II with one or more other products, the access rebate may be lower. Traditionally with three-tier open formularies, rebates were not offered for Tier III positioning. However, with closed formularies, commonly seen in Medicare Part D, rebates are offered for Tier III status, because if a product is not covered on Tier I, II, or III, it is not reimbursed in a closed formulary. Thus, manufacturers pay for access to Tier III, which is preferable than their product not being reimbursed at all.

The performance rebate component, greater than the access component, may be based upon market share (in plan or national), volume growth, or other similar metric. Although a rebate contract may allow a health plan or PBM to include more than one product on a formulary tier, there is a better chance of achieving performance tiers if there are a limited number of products in a tier. There is a trend away from two component contracts (access and performance) to only a flat access rebate.

Rebates are additive, and highly variable based on the therapeutic category, number of similar products, competitive nature of the category, and the clinical and safety differentiation among products. Frequently, the ceiling on total rebate income for a specific drug will be capped at 15.1%, the "best price" limit required in Medicaid statutes (discussed below). If this amount is exceeded in commercial plans, the pharmaceutical companies must provide the same amount to all Medicaid plans under contract. Products in crowded and undifferentiated therapeutic categories may be associated with total rebate potential of 20% to 30% or more. Conversely, unique, highly differentiated products may have no rebate offered or a very low rebate (e.g., 5% total rebate). Products and categories associated with no, or very low rebates include many unique injectable biological products, HIV/AIDS drugs, and atypical antipsychotics.

Health plans and PBMs are relatively transparent regarding sharing rebates with their clients, although the exact terms of rebate contracts remains confidential. However, rebates are generally passed on to clients, or used to reduce pharmacy program cost. An example of how a rebate may reduce the net cost of a contracted drug is shown in **Table 2-5**. In the illustration, the drugs of the same WAC have significantly different net costs based upon formulary tier, member copayment, and rebate (paid for Tier II positioning). As stated above, WAC is a realistic price that approximates the actual acquisition cost of a drug. AWP is an artificial, calculated number that is often approximately 20% higher than the WAC, is somewhat archaic, but often remains used in pharmacy reimbursement calculations. Rebate calculations are usually based on the WAC.

In this example, the net cost of two drugs with identical WACs is shown. The drug on the preferred Tier II position is associated with a 20% rebate off the WAC. The rebate value is $32.00, which results in a net cost $12.00 less than the Tier III product, despite

TABLE 2-5 Impact of Copayment and Rebate on Drug Net Cost to an MCO or PBM

	Preferred Brand Tier II	Non-Preferred Brand Tier III
WAC	$128.00	$128.00
AWP	$160.00	$160.00
Drug Reimbursement (AWP – 15%)	$108.80	$108.80
Dispensing Fee (+)	$2.50	$2.50
Subtotal	$111.30	$111.30
Member Copayment (–)	$25.00	$45.00
MCO Reimbursement to Pharmacy	$86.30	$66.30
Rebate (15% of WAC)	20%	0%
Rebate Amount (–)	$32.00	$ 0.00
Net MCO Cost	$54.30	$66.30

the higher member copayment associated with the Tier III drug. Rebates will remain an important cost containment strategy to manage the net cost of brand drugs.

Although the regulation is somewhat more complex, the primary impact of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) required pharmaceutical manufacturers to extend commercial drug rebates 15.1% or greater to State Medicaid programs. As a result, the rebate on many drugs would not exceed this percentage, although in competitive therapeutic categories, rebates could reach the 20% to 45% range, which is extended to Medicaid programs. Additionally, some state Medicaid programs mandate payment of a "supplementary rebate" to assist in reducing program costs. Other novel rebate contracts, including outcomes-based rebates, adherence-based rebates, and drug expense guarantees are interesting, but often difficult to administer.

CLINICAL PHARMACY AND DISEASE MANAGEMENT SERVICES

Health plans and PBMs offer an array of clinical pharmacy services, many of which are online and real-time edits provided to the dispensing pharmacist. Others include prospective or retrospective utilization monitoring, adherence intervention, and disease management program support.

Online, real-time point-of-dispensing edits provide commonly used guidance regarding drug interactions, early refill prevention, duplicate medications, age and gender edits, and step-care edits. Health plans and PBMs also provide computerized drug use review (DUR), screening for drug misuse and abuse, polypharmacy, and non-adherence, and other dangerous or inappropriate drug use patterns. Interventions may include patient and or physician communications requesting clarification of the potential dangerous pattern.

Health plans may offer disease-specific management programs to augment healthcare services provided by plan physicians that may include general disease education, diagnostic screening events, and case management. Most common diseases included in clinical programs include diabetes, asthma, cardiovascular disease (hypertension and lipid disorders), chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and behavioral health. Disease management programs in managed care are addressed elsewhere in this book.

MCO pharmacy departments and PBMs often play a supportive role in health plan and employer disease management programs. Pharmacy program drug utilization data are often used to identify patients with poorly controlled medical conditions (identified by the number and type of medications used) or have drug adherence problems (through inconsistent prescription refills records). Pharmacy departments may obtain resource support from pharmaceutical manufacturers that often provide unbranded disease management resources (e.g., physician or patient education materials or educational grants) to supplement health plan efforts. Disease management offering from pharmaceutical manufacturers will not influence formulary decisions, and in fact the reverse influence exists. That is, health plans and MCOs may seek clinical program support from manufacturers whose drugs have been previously selected for preferred formulary positions.

Clinical pharmacy programs are important in supporting health plan quality of care initiatives, such as NCQA accreditation and improvement of NCQA HEDIS measures. This was previously discussed in the Pharmacy and Medical Claims Integration and Clinical Program Support section.

PHARMACY BENEFIT MANAGERS

Pharmacy benefit managers, such as Medco Health Solutions, CVS Caremark, Express Scripts, Inc., Prime Therapeutics, MedImpact, WellPoint Pharmacy Management, and many others, are stand-alone companies that specialize in all aspects of pharmacy benefit management. They sell their services to private or public purchasers, including MCOs, self-insured employers, Medicaid programs, and Medicare Advantage Part D plans, as well as directly to Medicare members, and other purchasers of pharmacy benefits. **Table 2-6** provides a list of the largest PBMs.

Pharmacy benefit managers have evolved as specialized experts in pharmacy benefit management. Many large health plans, such as Aetna, Humana, CIGNA, and Coventry, manage their pharmacy benefit programs through an internal "captive" PBM. Although many large MCOs manage their pharmacy benefit through an internal pharmacy department, they may use a PBM for claims processing, pharmaceutical manufacturer contracting, and other "back end" commodity services. Other small MCOs, large self-insured employers, and state Medicaid agencies may use a PBM for full-service, turn-key prescription drug benefits.

Although PBMs do not offer any services a health plan could not develop through an internal pharmacy department, they manage many millions of lives, and offer economies

TABLE 2-6 Membership of Largest U.S. PBMs

Approximate Membership of the Largest U.S. PBMs	
CVS Caremark	82 million
Medco Health Solutions	71
Express Scripts, Inc.	51
WellPoint Pharmacy Management	36
MedImpact	21
Prime Therapeutics	13

Source: Compiled by RP Navarro from PBM Web sites and marketing material, 2006–2007.

of scale to MCOs regarding computer services, patient call centers, contracting with pharmacies and with pharmaceutical manufacturers, and other services. The PBM may offer such services less expensively than could be developed by an MCO.

The amount of PBM services purchased by MCOs, Medicaid plans, and self-insured employers depends entirely on the needs of the PBMs' customer. Some of the offered services include the following:

- Pharmacy distribution network (community, mail, and possibly specialty products)
- Drug formulary development and management
- P & T Committee support services
- Pharmaceutical manufacturer contracting
- Physician and member communications
- Member service help line support
- Health plan pharmacy benefit Web site development and maintenance
- Clinical pharmacy services (utilization review, adherence monitoring, clinical edit development) and disease management program support
- Claims processing and report generation

The PBM market is very competitive, and most large PBMs offer similar services. Decisions on PBM selection usually come down to aligned interests (e.g., cost containment, member services, and clinical programs), transparency, quality of service, and cost.

MEASURING PHARMACY BENEFIT MANAGEMENT PROGRAM PERFORMANCE

The competitive managed care environment requires that health plan and PBM pharmacy programs are effectively managed to achieve desired clinical, economic, and quality of life objectives. Health plans have been criticized for managing pharmacy costs separate from medical costs, when the use of resources—and outcomes—of both may be inextricably linked for many medical conditions. As discussed earlier, appropriate use of cost-effective pharmaceuticals may result in higher pharmacy program costs, but may prevent use of more expensive medical resources, such as hospitalizations and emergency department visits.

However, despite the awareness that the pharmacy program must be managed to optimize the drug spend, the pharmacy director must focus on pharmacy program performance metrics as well. The pharmacy program director will monitor specific performance metrics on a monthly basis and attempt to modify controllable factors if performance measures suggest costs are rising more than forecast, member satisfaction is declining, drug-related clinical outcomes are being achieved, or other markers of poor pharmacy program performance are indicated.

Some of the basic performance benchmarks monitored (monthly, quarterly, or annually) will include the following financial and quality of care metrics:

- Total prescription program costs as well as costs and trends of selected therapeutic categories and specific high cost and/or highly utilized drugs
- Monthly per-member-per-month (PMPM) and annual per-member-per-year (PMPY) program costs, PMPM and PMPY or high cost therapeutic categories, and cost trends
- Prescription utilization (PMPM and PMPY) overall and for selected highly utilized therapeutic categories
- Administrative and claims processing fees (overall and per prescription)
- Prescription discount or rebate (total amount, per prescription, PMPM, and PMPY)
- Generic dispensing rate (overall, by pharmacy, by group, by therapeutic class, and by physician), and missed generic substitution opportunities
- Drug formulary conformance rate (overall, by physician, and by pharmacy)
- Patient satisfaction and member complaints related to the pharmacy program
- Number of drug formulary prior authorization exception requests and approvals, and review of authorization trend
- NCQA HEDIS measure scores related to pharmacy (e.g., percent of post-myocardial infarction patients receiving a beta blocker)
- Trend of all the preceding performance measurements measured monthly, quarterly, or annually.

There are many more performance measurements that pharmacy directors routinely monitor, especially with more sophisticated programs that may include drug formulary conversion, compliance, and persistence activities. However, with the preceding basic performance measurements, a pharmacy director can evaluate the effectiveness of his or her prescription drug management program.

CONCLUSION

Pharmacy benefits are an important component in comprehensive healthcare benefits and, when optimized, can contribute to clinical, economic, and quality-of-life outcomes of benefit to plan sponsors as well as members. Purchasers of pharmacy benefits have many options for obtaining a customized pharmacy program, and must identify their objectives clearly to their pharmacy benefit provider to make certain the benefit is appropriately designed. Primary

future challenges will be control of expensive biologicals, and implementing a successful consumer-driver healthcare benefit, such as through a health savings account.

Pharmacy directors see increased use of generics and higher member copayments as two important methods to help contain costs. However, the pharmacy benefit must be integrated in the broad medical benefit to demonstrate the contribution of appropriately used, cost-effective pharmaceuticals.

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Appendix 2-1 ACRONYMS

AAC	actual acquisition price
ACE	angiotensin converting enzyme
ARB	angiotensin receptor blocker
ASP	average selling price
AWP	average wholesale price (drug)
CAP	competitive acquisition program
CDH	consumer-driver healthcare
CHF	congestive heart failure
CMS	Centers for Medicare and Medicare Services
COBRA	Consolidated Omnibus Budget Reconciliation Act
COPD	chronic obstructive pulmonary disease
DUR	drug use review
ERISA	Employee Retirement Income Security Act of 1974
FDA	Food and Drug Administration
GERD	gastroesophageal disease
HEDIS	Health Plan Employer Data and Information Set
HIPAA	Health Insurance Portability and Accountability Act
HSAs	health spending accounts
MAC	maximum allowable cost
MCOs	managed care organizations

MTM	medication therapy management
NACDS	National Association of Chain Drug Stores
NABP	National Association of Boards of Pharmacy
NCPDP	National Council for Prescription Drug Programs
NCQA	National Commission for Quality Assurance
OBRA '90	Omnibus Budget Reconciliation Act of 1990
OTC	over-the-counter (drugs)
PA	prior authorization
PBMs	pharmacy benefit managers
PMPM	per-member-per-month
PMPY	per-member-per-year
POS	point-of-service (pharmacy)
P & T	Pharmacy & Therapeutics (Committee)
SPD	specialty pharmacy distributor
VIPPS	Verified Internet Pharmacy Practice Sites™
WAC	wholesale acquisition cost