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Chapter 13

PHARMACY & THERAPEUTICS COMMITTEES IN MANAGED CARE ORGANIZATIONS

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INTRODUCTION

Drug product evaluations and selections have been made as long as drug choices have been available. In open and unmanaged systems, the prescriber makes the medication choice after considering pharmacological properties of alternative drugs, the unique patient care needs, and patient cost. Within organized healthcare delivery systems, such as hospitals or managed care organizations, Pharmacy & Therapeutics (P & T) Committees are authorized by the organization to conduct drug reviews and analyses, and make population-level drug formulary decisions. The formulary is then provided to participating physicians to select agents when making patient-level prescribing decisions. However, the responsibilities of the P & T Committee transcend simply compiling a list of recommended drugs. According to the American Society of Health-System Pharmacists (ASHP) *Statement on the Pharmacy and Therapeutics Committee*, the Committee ". . . evaluates the clinical use of drugs, develops policies for managing drug use and drug administration, and manages the formulary system . . . is a policy-recommending body to the medical staff and the administration of the organization on matters related to the therapeutic use of drugs."[1] The Committee must consider how drugs will be distributed, administered, monitored, and managed, as well as the cost impact to all stakeholders, and must also attempt to determine if outcomes suggested by clinical trial efficacy data will be borne out in real world practice, given the myriad of benefit design structures that may influence drug use and adherence.

The responsibilities of the P & T Committee have far-reaching implications for all healthcare professionals, plan sponsors, patient members, and indeed the health care organization itself. Appropriate selection and use of a pharmaceutical is often the most cost-effective form of prevention or therapy for many medical conditions. It is the responsibility of the P & T Committees, using a standardized drug evaluation process, to make pharmacotherapy recommendations for all healthcare professionals and members of the organization as well as consider and expeditiously process patient-specific exceptions.

This chapter describes the genesis of managed care Pharmacy & Therapeutics Committees, their role and structure, the drug evaluation and review process, and how Committee decisions become manifested in the organization's drug formulary.

GENESIS OF P & T COMMITTEES IN MANAGED CARE

Organized healthcare delivery systems, such as hospitals and managed care organizations (MCOs), have empowered a group of knowledgeable healthcare professionals, usually physicians and pharmacists, with the authority and responsibility to make pharmacotherapy evaluations and recommendations on behalf of the entire hospital or system. This group is now generally termed a *Pharmacy & Therapeutics Committee* or *Drug Formulary Committee*. The Committee's decisions are driven by organizational philosophy, goals, and objectives, and serve as the basis for drug therapy decisions made by all healthcare professionals within the system. The Committee communicates their decisions to professionals via the publication of a compendium of drugs approved by the Committee.

This compendium was initially termed a *pharmacopeia* in the United States in the late 18th century,[1] and today it is often called a *drug formulary*. In the 1920s, U.S. hospitals began creating drug formularies to eliminate therapeutic duplication.[2] By the 1960s, virtually every hospital in the United States had established a formulary system, largely influenced by the publication of the American Hospital Formulary Service by the American Society of Hospital Pharmacists (ASHP) in 1959.[3] In addition to the identification of a drug compendium or drug formulary for the health system or hospital, the P & T Committees became involved in drug storage, administration, monitoring, outcomes research, physician and patient drug use education, and other activities that would promote the appropriate use of formulary medications, guidelines for use of non-formulary medications, and procedures for procurement and use of investigational drugs.

The use of formularies has spread beyond the institutional setting. As described in Chapters 1 and 2, by the 1970s, health maintenance organizations (HMOs) began to flourish in several regions of the United States. As these HMOs expanded their benefits beyond medical and hospital, and added pharmacy benefits, they naturally hired pharmacists to manage the pharmacy benefit. Many early managed care pharmacy directors came out of hospital practice, and they logically applied the practices and principles of drug formulary development and management they learned in hospitals to the managed care practice environment. HMOs began developing drug formularies, and to provide the independent, critical evaluation of available drugs, they began forming their own Pharmacy & Therapeutics Committees fashioned after the hospital model. In fact, the principles of drug review are quite similar, although the type of drugs reviewed, administration and utilization parameters (i.e., controlled in-patient vs. uncontrolled out-patient environments), and organizational goals and objectives are quite different.

HMOs began developing P & T Committees and publishing their own drug formulary (formularies are discussed in depth in Chapter 9). The use of a P & T Committee, comprised largely of independent community-based physicians and pharmacists lends clinical credibility to the decisions. An HMO making its own drug decisions would be accused of selecting drugs based upon parsimony rather than outcomes. One current MCO published *Drug Formularies: Myths and Facts*, and defends its formulary decision process as follows[5]:

> **Myth #4:** Bean counters determine which drug appears on any formulary.
>
> The fact is, a formulary is established by a clinical committee of doctors and pharmacists. This committee compares each drug's safety, side effects, effectiveness, and relative costs. Based on research and discussion, the clinical committee decides which ones are best for the formulary. In addition, our doctors and pharmacists stay current on the newest nationwide developments in medicine, and update our formulary based on the latest research.

To emphasize the focus on quality of care, many P & T Committees will consider a drug's cost or contract impact only after they make a favorable formulary decision based upon clinical and safety data.

P & T Committees are now *de rigueur* within MCOs, and are largely accepted by public and private plan sponsors, physician providers, or individual members. Often there are two layers of P & T Committees in formulary decisions. Pharmacy benefit managers (PBMs) (see Chapter 4) have their own P & T Committee, and often their MCO customers also have their own P & T Committee. Large employer groups are becoming more sophisticated in managing its employee's health. One way that employers are taking an active part in taking care of their employees is by employing physicians, nurses, and pharmacists. Large employer groups may form their own P & T Committee or become an active participant in their MCO's P & T Committee. Although the vast majority of MCOs use a PBM for some or most pharmacy benefit management services (see Chapters 2 and 4), approximately 80% of MCOs who use a PBM also make their own formulary decisions with their own P & T Committee.[6] They evaluate the PBM recommendations and may take advantage of PBM contracting but ultimately use their own P & T Committee for plan formulary decisions.

MCO and PBM P & T Committees are evolving. In 2003, the Medicare Modernization Act (MMA) provided for the development of Medicare Part D pharmacy benefit. Participating Medicare Advantage–Prescription Drug (MA-PDs) plans and prescription drug plans (PDPs) were required to make drug formulary decisions for members through

a P & T Committee. MMA legislation required that the Committee include at least one pharmacist and physician member with expertise in the care of geriatric patients, and those members be free of conflicts of interest. Additional language specified the frequency of P & T Committee meetings, the types of formulary management and utilization management activities for which the committee was responsible, and also specified that drugs and drug classes should be reviewed in a regular and timely manner. The increasing use of specialty pharmaceuticals will require the P & T Committees to include or regularly consult with specialists who commonly use such injectable biologicals and other specialty medications to make certain this class of medications is fairly and appropriately evaluated. Due to the extremely high cost of specialty pharmaceuticals, which in many cases will extend the life of a patient only by a few months, P & T Committees are increasingly adding or consulting with ethicists to consider the ethical issues involved on these drug selection additions.

ROLE OF THE MANAGED CARE P & T COMMITTEE

Members of any organization's P & T Committee have the opportunity and responsibility to offer what their experience and analysis shows to be the best drugs available to patient members of their organization. Their decisions will affect patient care and clinical outcomes, have a significant financial impact on the MCOs and customers, and may even influence the lives of many individuals with medication therapy needs. However, the Committee's first responsibility is to the patient, and to select the safest and most cost-effective drugs available for formulary inclusion.

In 1999, a coalition of several organizations convened to discuss the principles of a sound drug formulary system. The Coalition Working Group participants met to identify the principles of a sound drug formulary system (**Table 13-1**). The Working Group succinctly emphasized that the responsibilities of the P & T Committee go beyond creating the formulary, and include promoting the *effective use* of formulary products through the following statement[7]:

TABLE 13-1 Principles of a Sound Drug Formulary System Coalition Working Group Members

- Academy of Managed Care Pharmacy (AAMC)
- American Medical Association (AMA)
- American Society of Health-System Pharmacists (ASHP)
- Department of Veterans Affairs (VA)
- National Business Coalition on Health (NBCH)
- U. S. Pharmacopoeia (USP)
- American Association of Retired Persons (AARP; observer)

Source: AMCP. *Principles of a Sound Drug Formulary.* Alexandria, VA: Academy of Managed Care Pharmacy, October 2000. Available at http://www.amcp.org/data/nav_content/drugformulary.pdf. Accessed 19 Aug 2008.

> "The Pharmacy and Therapeutics (P & T) Committee . . . is the mechanism for administering the formulary system, which includes developing and maintaining the formulary and *establishing and implementing policies on the use* of drug products" (emphasis added).

Recommendations of the Working Group Coalition for P & T Committee activities are found in **Table 13-2.**

The Academy of Managed Care Pharmacy published the *Formulary Management* concept paper that also emphasizes the broad responsibility of the Pharmacy & Therapeutics Committee to include the following[8]:

> "A formulary system is much more than a list of medications that are approved for use by a managed healthcare organization . . . Policies and procedures for the procuring, dispensing, and administering of the medications are also included in the system. Formularies often contain additional prescribing guidelines and clinical information which assists healthcare professionals to promote high quality, affordable care for patients. Finally, for quality assurance purposes, managed healthcare systems that use formularies have policies in place to give physicians and patients access to non-formulary drugs where medically necessary."

Clearly, when a P & T Committee evaluates a drug for formulary consideration, the members also must determine how the organization can ensure that the product is effectively managed, accurately monitored, and optimally used.

When a P & T Committee evaluates a drug for formulary consideration, the members must determine how the physicians and pharmacists of the organization will prescribe, dispense, monitor, and ensure appropriate utilization. P&T Committees also review and evaluate clinical programs and utilization management strategies. These P & T

TABLE 13-2 Working Group Coalition Recommendations for P & T Committee Activities

- Objectively appraises, evaluates, and selects drugs for the formulary.
- Meets as frequently as is necessary to review and update the appropriateness of the formulary system in light of new drugs and new indications, uses, or warnings affecting existing drugs.
- Establishes policies and procedures to educate and inform healthcare providers about drug products, usage, and committee decisions.
- Oversees quality improvement programs that employ drug use evaluation.
- Implements generic substitution and therapeutic interchange programs that authorize exchange of therapeutic alternatives based upon written guidelines or protocols within a formulary system. (Note: Therapeutic substitution, the dispensing of therapeutic alternates without the prescriber's approval, is illegal and should not be allowed.)
- Develops protocols and procedures for the use of and access to non-formulary drug products.

Source: AMCP. *Principles of a Sound Drug Formulary.* Alexandria, VA: Academy of Managed Care Pharmacy, October 2000. Available at http://www.amcp.org/data/nav_content/drugformulary.pdf. Accessed 19 Aug 2008.

Committee decisions touch all participating providers and members, and have far-reaching implications on health and economic outcomes. Decisions made by the P & T Committee may be challenged or appealed. In some situations, a Committee may reconsider and/or reverse a decision. For this reason, many Committees have a consumer member whose role is to represent the interests of patients. However, the Committee operates independently and decisively in the best interest of the patient, and ideally is uninfluenced by any other internal or external special interest person or group.

AN ILLUSTRATIVE EXAMPLE OF A P & T COMMITTEE STRUCTURE

Pharmacy and Therapeutics Committees are generally similar in their structure, size, authority, and the process they observe, allowing for differences in model type (e.g., open or closed, and product line: HMO, PPO, POS), and membership (e.g., commercial, Medicaid, Medicare). The reader is advised that while we discuss the P & T Committee of a typical mid-size health plan to illustrate an example, organizations are different. Organizational by-laws as well as the state-filed Certificate of Coverage provide the authority and responsibility for the formation and function of a "formulary decision entity," (e.g., a P & T Committee) to make drug product selection decisions for the organization. The Committee consists of healthcare professionals, usually physicians and pharmacists, although nurses, quality assurance directors, ethicists, or economists may be committee members of some larger organizations. In very select instances, MCOs have begun including plan members in the role of patient advocates as members of P&T Committees. At the time of this writing, it is unclear as to whether this practice will become more widespread. The Committee members are predominantly independent practitioners not employed by the sponsoring MCO or PBM, but generally are participating plan providers. Staff or group model plans may use physicians employed by the health system or the exclusively contracted medical group. Some organizations may include faculty members from medical and/or pharmacy schools.

While this committee often is named the Pharmacy & Therapeutics Committee, it may be termed the Drug Formulary Committee or a similarly named group. The Committee size varies among organizations, and some large MCOs or PBMs may have therapeutic subcommittees of the National P & T Committee. In general, a typical medium size MCO has a P & T Committee consisting of 10 to 15 members, although some have up to 20 members. The largest group represented is comprised of physician members who generally represent the specialties who are experts in the most commonly used therapeutic categories, including family practice, general internal medicine, oncology, pulmonology, cardiology, obstetrics and gynecology, or pediatrics. Committees often invite additional specialists to attend a specific meeting to discuss certain therapeutic categories if the Committee does not believe the members have adequate expertise or experience (e.g., endocrinology, infectious diseases, neurology, psychiatry, gastroenterology, or other specialties). Due to the growing number of elderly and individuals with special needs with drug benefits covered under Medicare Part D, many P&T Committees include physicians and pharmacists who specialize in geriatrics in order to consider the unique needs of these subgroups.

In addition to clinical expertise, ideal committee members understand managed care business principles, the organization's pharmacy benefit management philosophy, and the plan sponsor base. They also must appreciate and consider the impact of their decisions on participating physicians, pharmacists, case managers, quality assurance directors, and most importantly, patients. Committee members agree to serve often for a staggered one or two year term, so that the committee continuously evolves yet maintains continuity.

A typical mid-sized open-model health plan P & T Committee may consist of the following members, usually with equal voting authority:

- Committee Chair (independent community-based participating physician or the plan medical director)
- Nine to fourteen additional independent community-based participating physicians
- Health plan medical director (if not the Committee chair)
- Health plan pharmacy director
- Geriatrician for Medicare Part D programs

In addition, the pharmacy department clinical pharmacists and the pharmaceutical contract manager often attend Committee meetings as non-voting staff members to present and discuss clinical and financial impact or contract information. Plans may differ. Larger health plans and PBMs may have broader Committees that may include an economist, an ethicist, quality assurance representatives, or a non-clinical lay plan member. Organizations may also use therapeutic category subcommittees that have the responsibility to review and render expert opinion recommendations to the full P & T Committee on specific therapeutic categories. Multi-state MCOs and PBMs may have a corporate or national P & T Committee that constructs a primary organizational formulary (or National Formulary for organizations with a national presence) that is "customized" at a state or regional plan level, for large self-insured plan sponsors, or by MCO clients of PBMs that have their own P & T Committee. Some organizations separate discussions of drug cost or pharmaceutical manufacturer contract terms from clinical discussions, and only review the contracts or the financial impact after a drug has received a positive review (e.g., a "may add" or a "must add" decision) from the P & T Committee. Typically, medications given "do not add" designation by the P & T Committee are not listed or added to formularies irrespective of financial considerations.

Frequently, subcommittees are formed to conduct reviews of highly sophisticated or unique therapies generally limited to specialists. For example, large organizations may have oncology, neurology, rheumatology, or hemophilia subcommittees to review emerging biotechnology agents often distributed through specialty pharmacies. Subcommittees also are useful to perform emergency reviews between full committee meetings, such as the release of a new break-through therapy, black box safety warnings, or the publication of post-marketing drug research with important results.

It is important to note that new drugs are not reviewed in isolation, but are compared with other existing or soon-to-be-launched pharmacotherapy options, regardless of their therapeutic category. This is key difference between the functions of the Committee and

the role of the FDA. The FDA only evaluates one entity at a time in terms of effectiveness and safety. Whereas the P & T committee will consider all viable alternative treatments, including those treatments that may not be pharmacological, or the off-label use of existing medications.

PHARMACY DEPARTMENT ROLE IN NEW DRUG EVALUATION

As discussed in previous chapters, MCO or PBM pharmacy departments have the responsibility to design and administer an effective pharmacy benefit for organization clients. A dynamic drug formulary, developed by the P & T Committee and executed by the pharmacy department, is a seminal requirement for an effective pharmacy benefit designed to optimize clinical and economic outcomes.

Connection between the P & T Committee and the MCO or PBM is maintained to the sponsoring organization through the medical director of pharmacy staff members on the P & T Committee. The organization's pharmacy department generally coordinates and supports the P & T Committee meetings and activities by orchestrating and scheduling meetings, providing drug review material and summaries to Committee members, recording and distributing Committee meeting minutes, and putting Committee decisions into action (e.g., changing claim adjudication drug file, publishing formulary changes to providers and members). **Figure 13-1** illustrates the flow of information among the pharmacy department groups, the P & T Committee, and health plan providers.

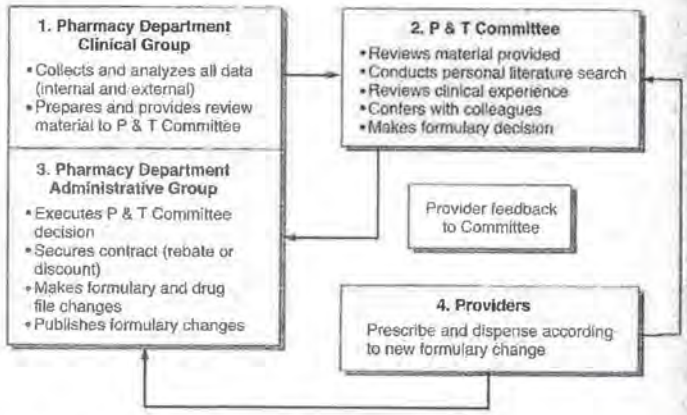

FIGURE 13-1 Information Flow among Pharmacy Departments, P & T Committee, and Providers.

There are three basic pharmacy department activities involved in supporting and executing the P & T Committee decisions:

1. *Clinical Pharmacy Activities.* The clinical pharmacists manage the data and information collection and analysis process, prepare and disseminate P & T Committee meeting materials, interface with Committee members and consultants, and coordinate the P & T Committee agenda.
2. *Pharmaceutical Relations and Contract Management.* The contract manager will review P & T Committee decisions and complete negotiations as appropriate related to pharmaceutical manufacturer discount or rebate contracts.
3. *Pharmacy Benefit Program Management.* Formulary changes must be reflected in drug file and claims adjudication processes, and executed in accordance with pharmacy benefit design contracts; this includes coordination of printing member and provider formularies as well as developing a Web site application.

CLINICAL PHARMACY RESPONSIBILITIES

Clinical pharmacists play a central role in the drug review and drug formulary management processes, and are an important conduit through which critically analyzed new drug information reaches the members of the P & T Committee. For each evaluation of a new drug product by the Committee, clinical pharmacists gather a broad array of new drug and related clinical data. They will review, analyze, and organize, and then transform the information into a cogent summary, usually termed a *new drug monograph*, of evidence-based information for further review by the P & T Committee members. The information sources consulted by clinical pharmacists when conducting a drug review and analysis are discussed later in this chapter. Clinical pharmacists review cost and utilization data of relevance within their own organization, and often model the utilization and cost impact of potential formulary changes.

Physician and other healthcare professional P & T Committee members have additional sources of information upon which they will make their formulary decision, including personal clinical and research experience, recommendations of key opinion leaders, their own review of published peer-reviewed literature, scientific meetings and abstracts, continuing education programs, and pharmaceutical company scientific and marketing material.

PHARMACEUTICAL RELATIONS AND CONTRACT MANAGEMENT

A pharmacist generally will lead the work group responsible for managing the business and contract relationships between the MCO or PBM and pharmaceutical companies. Discount and rebate contracts with pharmaceutical companies are important to pharmacy benefit management, as the rebate income reduces the net cost of contracted products (see Chapters 14 and 15). Although cost remains secondary to clinical and safety considerations in P & T Committee decisions, a lower net cost may influence drug formulary positioning (see Chapter 9) when the therapeutic outcomes expected from comparable

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