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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 drug
macy & Therapeutics Committees fashioned afte
ples of drug review are quite similar, although th
and utilization parameters (i.e., controlled in-pa
ronments), and organizational goals and objectiv

HMOs began developing P & T Committee
lary (formularies are discussed in depth in Chap
comprised largely of independent community-b
clinical credibility to the decisions. An HMO m
accused of selecting drugs based upon parsimo
MCO published *Drug Formularies: Myths and F*
process as follows[5]:

> **Myth #4:** Bean counters determine which dr
>
> The fact is, a formulary is established by a
> pharmacists. This committee compares each
> ness, and relative costs. Based on research an
> decides which ones are best for the formulary
> macists stay current on the newest nationw
> update our formulary based on the latest rese

To emphasize the focus on quality of care, many
cost or contract impact only after they make a f
clinical and safety data.

P & T Committees are now *de rigueur* with
public and private plan sponsors, physician provi
are two layers of P & T Committees in formular
(PBMs) (see Chapter 4) have their own P & T
tomers also have their own P & T Committee. La
sophisticated in managing its employee's health.
active part in taking care of their employees is by
macists. Large employer groups may form their
active participant in their MCO's P & T Com
MCOs use a PBM for some or most pharmacy be
2 and 4), approximately 80% of MCOs who use
decisions with their own P & T Committee.[6] Th
and may take advantage of PBM contracting bu
mittee for plan formulary decisions.

MCO and PBM P & T Committees are evol
tion Act (MMA) provided for the development
Participating Medicare Advantage–Prescription
drug plans (PDPs) were required to make drug fo

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)
administering the formulary system, which
the formulary and *establishing and implem*
ucts" (emphasis added).

Recommendations of the Working Group Coa
found in **Table 13-2.**

The Academy of Managed Care Pharma
concept paper that also emphasizes the broad re
tics Committee to include the following[8]:

"A formulary system is much more than a
for use by a managed healthcare organizati
procuring, dispensing, and administering
the system. Formularies often contain addi
ical information which assists healthcare p
affordable care for patients. Finally, for
healthcare systems that use formularies ha
and patients access to non-formulary drugs

Clearly, when a P & T Committee evaluates
members also must determine how the organiz
tively managed, accurately monitored, and opti

When a P & T Committee evaluates a dr
bers must determine how the physicians and
scribe, dispense, monitor, and ensure approp
review and evaluate clinical programs and utiliz

TABLE 13-2 Working Group Coalition Recomm

- Objectively appraises, evaluates, and selects drug
- Meets as frequently as is necessary to review and
system in light of new drugs and new indication
- Establishes policies and procedures to educate a
products, usage, and committee decisions.
- Oversees quality improvement programs that en
- Implements generic substitution and therapeutic
exchange of therapeutic alternatives based upon
formulary system. (Note: Therapeutic substituti
without the prescriber's approval, is illegal and s
- Develops protocols and procedures for the use o

Source: AMCP. *Principles of a Sound Drug Formulary*. Alexandria, VA: Acad
http://www.amcp.org/data/nav_content/drugformulary.pdf. Accessed 19 Au

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 com
business principles, the organization's pharmac
plan sponsor base. They also must appreciate
on participating physicians, pharmacists, case
most importantly, patients. Committee memb
or two year term, so that the committee contin

A typical mid-sized open-model health pl
following members, usually with equal voting

- Committee Chair (independent commu
plan medical director)
- Nine to fourteen additional independent c
- Health plan medical director (if not the C
- Health plan pharmacy director
- Geriatrician for Medicare Part D programs

In addition, the pharmacy department clinical
tract manager often attend Committee meetin
and discuss clinical and financial impact or con
health plans and PBMs may have broader Com
ethicist, quality assurance representatives, or a
tions may also use therapeutic category subc
review and render expert opinion recommenda
cific therapeutic categories. Multi-state MC
national P & T Committee that constructs
National Formulary for organizations with a n
state or regional plan level, for large self-insu
PBMs that have their own P & T Committee.
drug cost or pharmaceutical manufacturer co
only review the contracts or the financial impac
(e.g., a "may add" or a "must add" decision) fr
ications given "do not add" designation by the
to formularies irrespective of financial consider

Frequently, subcommittees are formed to
unique therapies generally limited to specialis
have oncology, neurology, rheumatology, or he
ing biotechnology agents often distributed thr
also are useful to perform emergency reviews
the release of a new break-through therapy, bla
of post-marketing drug research with importan

It is important to note that new drugs are
with other existing or soon-to-be-launched ph
therapeutic category. This is key difference be

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 through 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.

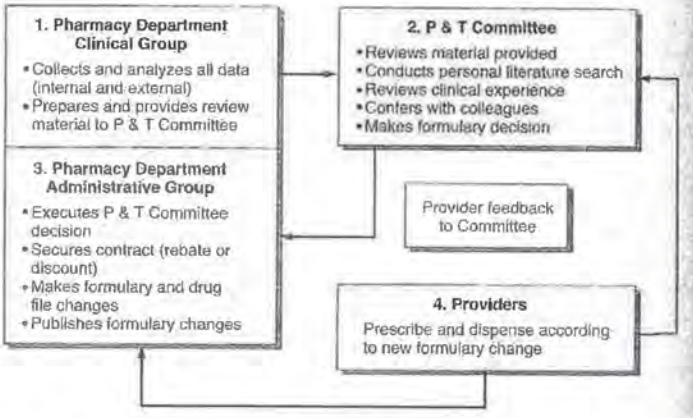

FIGURE 13-1 Information Flow among Pharmacy Departments, P & T Committee, and Providers.

There are three basic pharmacy department a
cuting the P & T Committee decisions:

1. *Clinical Pharmacy Activities.* The clinical pha
tion collection and analysis process, prepa
meeting materials, interface with Committe
nate the P & T Committee agenda.
2. *Pharmaceutical Relations and Contract Manag*
P & T Committee decisions and complete
pharmaceutical manufacturer discount or reb
3. *Pharmacy Benefit Program Management.* Form
file and claims adjudication processes, and
benefit design contracts; this includes coordi
formularies as well as developing a Web site

CLINICAL PHARMACY RESPONSIBILITIES

Clinical pharmacists play a central role in the di
ment processes, and are an important conduit thr
information reaches the members of the P & T C
drug product by the Committee, clinical pharm
and related clinical data. They will review, analyz
information into a cogent summary, usually terr
based information for further review by the P &
tion sources consulted by clinical pharmacists
analysis are discussed later in this chapter. Clinica
data of relevance within their own organization,
impact of potential formulary changes.

Physician and other healthcare professional
tional sources of information upon which the
including personal clinical and research experie
leaders, their own review of published peer-revi
abstracts, continuing education programs, and
marketing material.

PHARMACEUTICAL RELATIONS AND CONTRACT N

A pharmacist generally will lead the work group
and contract relationships between the MCO o
Discount and rebate contracts with pharmaceutic
benefit management, as the rebate income redu
(see Chapters 14 and 15). Although cost remains
erations in P & T Committee decisions, a lowe
positioning (see Chapter 9) when the therapeut

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