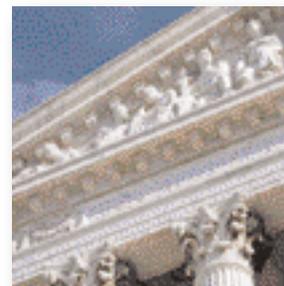


# Policies and Procedures

## Enhancing Pharmacy Practice and Limiting Risk

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### P&T COMMITTEES AND POLICY

Let's face it—health care settings, including pharmacies, can be legal land mines because patients and the public can and do get hurt. As a policy-recommending body to the medical and administrative staff in health care organizations, P&T committees have a primary role of maintaining a limited list (formulary) of medications approved for use that meet the needs of clinicians and their patients as well as those of the organization.<sup>1</sup> Because most members of P&T committees are not pharmacists, a primer on policies and procedures (P&Ps), including an emphasis on their importance for pharmacists, may be helpful for P&T committees in executing their duties.

Over the years, the increasing complexity of patient care has resulted in the need for P&T committee members to face increased responsibilities and challenges within their organizations. Trends in those responsibilities are reflected in guidelines published in 2008 by the American Society of Health-System Pharmacists (ASHP).<sup>2</sup> These trends have been

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more broadly described by Balu and colleagues to encompass Medicare, the use of pharmaco-economic data, and the value of information related to cost effectiveness.<sup>3</sup> Although clinicians and pharmacists alike recognize that sound P&Ps are needed to ensure safe and effective practice, forensic consultants on pharmacy practice issues view this need from a legal risk-management perspective.

Certainly, P&Ps are not foreign to P&T committees; indeed, they are ubiquitous in health care systems and managed care organizations, such as health plans and pharmacy benefit managers (PBMs). Policies exist to serve the needs of all members of an organization and to help the organization comply with various regulatory and accreditation demands. Policies can provide a course of action that guides and influences decisions. Thus, they are driven by laws and regulations, standards of practice or best practices, and institutional executive decisions governing a particular practice. To be effective, policies must be carried out in such a way that the people who are affected by them can understand their origins and rationale, can easily comprehend them, and can readily comply with them.<sup>1,2</sup>

Descriptions of procedures, practices, and guidelines are usually created by a service provider within the practice setting as tools to help individuals accomplish their work within the organization and to facilitate decision-making, with the aims of ensuring appropriate consistency. Having P&Ps in place—so that individuals don't have to "reinvent the wheel"—reduces the likelihood of causing harm to patients.

So, have you or your organization examined your pharmacy P&Ps lately? Were these P&Ps created in cooperation with the pharmacy staff and updated periodically, or were they "cut and pasted" from another source?

Accreditation bodies for health care organizations, such as the Joint Commission, expect an organization to create its processes and its process guidelines in consultation with those who use the

service. These bodies also expect organizations to achieve a procedure's purpose by selecting the most effective, appropriate means to serve users and by maintaining the accuracy and currency of information so that users are aware of changes. This can be accomplished with the use of a variety of marketing, communication, and educational approaches within or outside the organization.

### DEFINITIONS

Some important P&P concepts, as applied in pharmacy practice within health care institutions, are defined as follows:

*Policy statements* are agreements for the services to be provided. These statements are a result of a mandate by the P&T committee, which is responsible for pharmacy services within the institution, and they describe the services that will be provided. Policy statements should be developed in concert with the users (i.e., pharmacists, physicians, nurses, or other practitioners within the organization who are recipients of pharmacy services). The primary "client," of course, is the patient, who is not involved in the negotiation or development of policies but who is certainly at the center of all of the organization's activities.

*Procedures* are developed for internal use by health care providers to create a roadmap showing how a policy can be implemented or how a service can be delivered. Procedures refer to the various types of tasks performed by employees, resources that are necessary, boundaries of the service, and contingency plans for executing an alternative if the policy cannot be implemented (plan B). The formulation of procedures should receive input from the P&T committee, because resources (e.g., personnel, space, equipment, and training) might be needed. Moreover, other members of the institution who interact with the P&T committee or who are recipients of the service must be familiar with how the service is delivered.

*Policy* consists of governing laws and

regulations, and policy statements should reflect this fact. The Joint Commission, the American Society of Health-System Pharmacists, the American Society of Parenteral Nutrition, and the Society for Critical Care Medicine (the Clinical Pharmacy and Pharmacology Section) are examples of groups that adhere to best-practice policies. These policies go beyond the usual Board of Pharmacy rules for institutions or organizations located in the same states.

Institutions should be asking these questions:

- Has the P&T committee compared the level and breadth of services being offered with those provided by these accreditation and certification groups?
- Are the services offered consistent with the standard of practice for reasonable and prudent hospital pharmacists? If not, why not?
- If an incident could have been prevented or mitigated by a “standard” service that was not offered by the institution, that institution could be faulted for not providing that service.

## LEGAL RISK: CASE SCENARIOS

The following scenario describes a policy-related case brought against a health care institution. This case was settled out of court under seal, which is typically done to avoid a costly public trial.

### Case A: Osteomyelitis

#### Following Knee Replacement

A 44-year-old woman was admitted to a hospital by her orthopedist for suspected osteomyelitis after knee-replacement surgery. The antibiotic vancomycin (Vancocin, ViroPharma) was selected for treatment. The patient had also been treated for a short period with ketorolac (Toradol, Roche) for analgesia.

A pharmacist calculated the vancomycin dosage (1 g every 12 hours) and recommended that blood levels be obtained at a specified time. Pretreatment serum creatinine concentrations were within normal limits. The patient’s vancomycin level was subtherapeutic (7.5 mcg/mL), and an internist was consulted. The internist increased the vancomycin dosage to 1 g every 8 hours. The pharmacist ordered another serum vancomycin analysis. The level came back at 41.5 mg/mL. The analysis was repeated,

and the result was confirmed. Serum creatinine levels were not measured to evaluate the patient’s renal status after the increased vancomycin dosage, even though the vancomycin level was substantially elevated and potentially toxic.

On the same day that the increased vancomycin concentration was detected, ketorolac 30 mg was administered. None of the physicians, pharmacists, or nurses had considered that a potentially nephrotoxic drug was being administered shortly after the patient was found to have a toxic level of vancomycin.

The patient was discharged home with orders to have her vancomycin level tested outside the hospital. Vancomycin was withheld, and the patient was instructed to return to the internist’s office for further follow-up. At her visit to the internist, her serum creatinine level was 5.3 mg/dL, in contrast to her levels of 0.7 to 1.3 mg/dL in the hospital. The patient was immediately flown to a tertiary-care hospital, where she was treated for acute renal failure and placed on hemodialysis.

What is the significance of the policies in this scenario? In this case, the pharmacy’s administrators had none in place for monitoring vancomycin. During the case investigation, they stated that “we did not, at the time of this patient’s care, monitor vancomycin patients.” However, a pharmacist was writing dosage recommendations, suggesting monitoring of blood levels and pharmacokinetics and evaluating those results during the patient’s hospitalization. Yet that pharmacist denied that there was a need to monitor the patient’s renal function, even in light of her toxic vancomycin level and the concomitant treatment with ketorolac, a potentially nephrotoxic drug.

Other pharmacists concurred, saying “we do not do vancomycin monitoring; our therapeutic drug monitoring is limited to aminoglycoside monitoring, which includes recommending and evaluating renal function tests.”

A pharmacist, acting as an expert witness, proposed these conclusions:

- The institution’s pharmacists were negligent and departed from the standard of care by not routinely providing a clinical monitoring service for any patient treated with intravenous (IV) vancomycin. A reasonable and pru-

dent hospital pharmacist would have monitored the dosage, kinetics, laboratory scheduling, and results in a patient treated with vancomycin in 2008 (the date of this case). One would not wait for the order “pharmacy to dose” to provide this essential clinical pharmacy service.

- Even if the pharmacists were not monitoring vancomycin, the review and approval (for dispensing through the Pyxis MedStation system) of a *stat* ketorolac 30 mg intramuscular (IM) order by the pharmacist in the face of a “hold vancomycin” order should have alerted the pharmacist to the risk of nephrotoxicity. Moreover, the pharmacist should have called the prescribing physician regarding this risk and should have pointed out that a check of the patient’s renal status was in order.
- None of this was done; therefore, the pharmacist was negligent and departed from the standard of care. A reasonable and prudent pharmacist would have investigated the reasons for the order to withhold vancomycin and the cause of the toxic vancomycin level.
- Because some physicians ordered “pharmacy-to-dose” vancomycin, a P&P should have been in place. Such a P&P would have had to be approved by the P&T committee, and all pharmacists would have provided the same level of service to this patient.
- A pharmacy management contractor provided pharmacy services to the hospital. This contractor was negligent and departed from the standard of care by not ensuring that a vancomycin-monitoring program was operational at the institution in 2008 (as it would later be in 2009). Such a monitoring policy was the standard of care in 2008.

The case was resolved before trial, and the hospital adopted a policy for monitoring vancomycin after the patient’s adverse event. In this case, the institution did not have a policy in place; as a result, pharmacists provided services that were not the standard of care. Even if these services were justified, each pharmacist failed to recognize a potentially toxic dose combination (vancomycin and ketorolac) and failed to advise the attending physician accordingly. Recognizing toxic doses is a basic responsibility of phar-

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macists. This responsibility is consistent with federal drug utilization review (DUR) guidelines and is considered the standard of professional care by many state boards of pharmacy.

The following case scenarios further demonstrate the importance of adopting and executing effective P&Ps.

#### **Case B: Osteomyelitis After Traumatic Knee Injury**

A 56-year-old woman was admitted to a hospital for the treatment of osteomyelitis following a traumatic knee injury. She received the aminoglycoside antibiotic gentamicin (Garamycin, Schering-Plough) in accordance with the hospital's aminoglycoside "protocol" (another term for "policy"). Kinetics, blood drug levels, and renal function were monitored, and dosage recommendations were made. A permanent vestibulopathy (balance disorder) resulted from the gentamicin.

During the case investigation, the patient testified that she experienced "roaring" in her ears while hospitalized. (The roaring is a form of tinnitus, a manifestation of gentamicin toxicity.) She further testified that she was not ambulatory; she was restricted to bed rest. No staff member inquired about unusual ear symptoms or told her to report such symptoms.

A lawsuit was brought against the hospital, specifically against the pharmacists. The institution's P&Ps were examined by the plaintiff's attorney and by his pharmacist standard-of-care expert. The policy clearly described clinical examination and education of the patient to detect aminoglycoside toxicity, but this was not performed. At the deposition, when asked about the policy that required clinical monitoring, the pharmacist who monitored the drug's pharmacokinetics replied, "We don't do that."

This case was resolved in the plaintiff's favor. The institution's P&Ps were adequate, but they were not followed. This shortcoming created a difficult legal scenario for the hospital, which was responsible for defending the pharmacist, its agent.

#### **Case C: Postoperative Treatment of Knee Inflammation**

A middle-aged man with a history of gout was hospitalized for a surgical procedure. While in postoperative care, he experienced severe pain and swelling in his

left knee. An orthopedic surgeon was consulted, and he prescribed colchicine (Colcrys, URL Pharma) and the nonsteroidal anti-inflammatory drug indomethacin (Indocin, Ovation) to treat the acute gouty inflammation.

The pharmacist who reviewed the order and approved dispensing IV colchicine overrode a high-dose alert, which indicated that the patient should be treated with a maximum dose of 4.8 mg. Instead, the patient received more than 10 mg of colchicine before he started to show signs of pancytopenia and renal failure. The colchicine was stopped, but the patient died.

In this instance, a policy concerning high drug doses was in place, but the pharmacist overrode it. The policy stated that the pharmacist was to consult with the prescribing physician for alerts; however, this did not occur, nor did the pharmacist (1 year out of training) consult with a senior pharmacist. There was no substantive defense for the pharmacist or the hospital in this matter. The plaintiff's lawyer and the lawyer's pharmacist standard-of-care expert used the hospital's own policy as evidence of what should have been done, but was not, resulting in the death of the patient.

A final scenario involves a health care institution's basic responsibility for handling recalls of pharmaceutical products.

#### **Case D: Recalled Heparin Products**

Following the "Chinese heparin" adulteration fiasco a few years ago, the primary manufacturer of heparin, at the urging of the FDA, instructed hospital pharmacists to recall and quarantine certain lots of the product that had been associated with severe immunotoxicity. A hospital's managing pharmacist, concerned about the short supply created by the recall, decided not to quarantine or return the recalled heparin products. The number of products recalled escalated, and eventually all lots of heparin were recalled. The hospital's chief purchasing officer dispatched dozens of pharmacy technicians to remove any heparin products in their assigned stations throughout the large institution.

Two or three months after the recall, a cardiac surgery patient received 50,000 units of heparin and subsequently developed heparin-induced thrombocytopenia, which was probably related to the adulterated heparin. A lawsuit was brought

against the hospital. A subsequent investigation revealed that the recalled heparin was found in and returned from the hospital for several months after the product's recall and after the patient's exposure.

Specific pharmacy standard-of-care violations against the pharmacist claimed that he violated the state's Board of Pharmacy requirements for recalled or adulterated pharmaceutical products, violated the institution's own P&P recalls, and failed to adequately conduct the recall within the institution. Further, after the managing pharmacist had decided not to quarantine certain heparin products, cardiac surgery patients who received heparin were not notified of that decision.

This case was resolved in the plaintiff's favor without a trial. The take-home lesson: it is not enough to have good policies; they must also be followed and not dismissed by the staff.

## **CONCLUSION**

Many examples can be given to illustrate the need for P&Ps in organized health care settings. As pharmacy practice, medication use, and the community's requisite standard-of-care have advanced, so has the potential legal risk of causing patient harm. As a result, properly written, executed, disseminated, and audited P&Ps provide a safer and more effective drug-therapy environment within an institution. They should encompass managing the risk of litigation against both the organization and its staff, including licensed professionals. Pharmacists as well as physicians and others involved in the medication-use system need to remain engaged with P&Ps to ensure that they are properly executed. P&Ps also need to be constantly updated by P&T committees or through administrative channels within the institution.

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