Keywords: controlled substance, medication errors, naloxone, prescription drug monitoring programs, regulations, risk management, duty to warn, Patient Protection and Affordable Care Act, OBRA 1990, pharmacists, physicians

Abbreviations: board of pharmacy (BOP), Centers for Disease Control and Prevention (CDC), continuing education (CE), health care professionals (HCP), National Association of Boards of Pharmacy (NABP), Omnibus Budget Reconciliation Act of 1990 (OBRA 90), prescription drug monitoring programs (PDMPs), quality improvement program (QIP)

INTRODUCTION

Implementation of the Patient Protection and Affordable Care Act has resulted in many changes involving patient care delivery, access to insurance, and the roles and responsibilities of health care professionals (HCPs) such as physicians, nurses, and pharmacists. Some effects on HCPs have been driven by marketplace economics; others have been driven by changes in professional practice brought about either internally, by the professions themselves, or by regulatory bodies, such as licensure boards and health departments. Examples have included physicians’ scope of practice and oversight; independent practice by physician assistants and nurse practitioners; and pharmacists administering vaccinations or performing mid-level services in physician-dependent arrangements or collaborative agreements.

Continuing a process set in motion by the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), patients’ expectations of their pharmacists continue to broaden—along with the pharmacy profession’s desire to expand its scope of practice. In response to patient expectations as well as societal challenges, state boards of pharmacy (BOPs) continue to pass regulations to address standards of care and regulatory issues. To maintain the skills of the profession, BOPs in all 50 states and the District of Columbia have passed regulations requiring continuing education (CE). Annually, pharmacists must obtain 15 hours of approved CE to meet requirements in 45 states; the remaining states require fewer hours. Medication-error reporting, medication safety, and pain management have been identified as common areas needing CE, analogous to physicians’ continuing medical education requirements dedicated to risk management. However, pharmacy law continues to be the most frequently dictated CE requirement.

This article will focus on opioid-use monitoring, medication-error prevention, and counseling/duty-to-warn issues to illustrate new or emerging legal risks resulting from professional practice expansion in pharmacy.

OPIOID USE

The Centers for Disease Control and Prevention (CDC) estimates that in 2010, the volume of prescribed opioids reached the level at which every American could be medicated around the clock for a month. Addressing the epidemic of opioid overdoses is a priority of the Drug Enforcement Administration, the CDC, and BOPs. The Controlled Substances Act (CSA) states that a prescription for a controlled substance must be issued only for a legitimate medical purpose by a registered practitioner. The prescribing practitioner has the responsibility for prescribing and dispensing controlled substances for a legitimate medical purpose. The pharmacist has a corresponding responsibility to ensure that the prescription is valid. A pharmacist who knowingly fills a prescription that does not meet the definition of a legitimate medical purpose is subject to penalties. Pharmacists have often struggled in determining whether a prescription that appears valid on its face is in fact valid.

In 1939, California launched a prescription drug monitoring program (PDMP) that collected data on controlled-substance prescriptions to assist the state’s practitioners in prescribing such medications. Currently, 49 states and the District of Columbia have a functional PDMP, with 34 of these jurisdictions mandating submission of prescription data for controlled substances on Schedules II through V and 15 states requiring such data for Schedules II through IV. Pennsylvania requires submission only of Schedule II data, and Missouri does not have a program. Some states have expanded their monitoring to include prescription data on noncontrolled or nonscheduled products containing ingredients such as butalbital, acetaminophen, caffeine, and tramadol. New Jersey’s PDMP data requirement includes human growth hormone, while Connecticut requires submission of marijuana data daily. In addition, 46 states now require that data be submitted within seven days of dispensing, and 16 of these states require data reporting in less than 24 hours.

Access to this data offers practitioners a view of patients’ history with controlled substances. Forty-five states and the District of Columbia send unsolicited reports. Of these states, 34 send reports to physicians and pharmacists about patients they are managing. Massachusetts’ PDMP emails messages monthly to prescribers whose patients have met the criteria for triggering such an alert. By mid-2015, 24 states were requiring
physicians and/or dispensers to view the PDMP under certain circumstances before prescribing or dispensing prescriptions. For example, Tennessee requires that practitioners check the PDMP before prescribing an opioid or benzodiazepine for more than seven days unless the patient meets exception criteria. Ohio requires that practitioners review the PDMP before initiating an opioid or benzodiazepine; the practitioners must request periodic PDMP reports if the treatment will exceed 90 days unless the patient meets exception criteria.

The National Association of Boards of Pharmacy (NABP) is supporting states’ efforts with its Interconnect software, which enables certain participating states to share data. Interconnect ensures that state data-access rules are enforced by its program; data are not stored at the NABP. The NABP has a memorandum of understanding with 33 states to use Interconnect. In 2014, the NABP's Interconnect logged 7 million requests for data.10 State PDMPs and Interconnect enable the pharmacist to access data to help ensure the validity of a prescription presented at the pharmacy.

Access to data and receipt of reports on patients are raising questions about practitioners’ level of accountability. However, the intent of PDMPs is not to obstruct the dispensing of legally prescribed medications: Patients must be allowed access to necessary therapies.

Another regulatory response to the opioid epidemic involves naloxone regulations. On July 3, 2014, U.S. Attorney General Eric Holder released a memorandum urging federal law-enforcement agencies to identify, train, and equip their employees with the tools necessary to combat the opioid epidemic. Naloxone was identified as a vital tool.11 This national effort is strengthened by state regulations that give individuals access to naloxone. According to the Network for Public Health Law, 32 states and the District of Columbia have amended their laws to allow medical professionals to prescribe and dispense naloxone for opioid overdose emergencies; individuals may use naloxone for this purpose without fear of legal repercussions. In addition, 24 states have expanded Good Samaritan laws to cover individuals who request assistance for an overdose victim.12

Patients are asking practitioners to provide naloxone, a lifesaving product, as part of a modern public safety system. State regulations expanding the use of naloxone—by allowing practitioners to prescribe it for overdose prevention and pharmacists to dispense it without a prescription—have taken place under broad collaborative agreements or state initiatives. Pharmacists can determine naloxone’s appropriateness by protocol, but potential naloxone users need education on overdose symptoms and training in assembling naloxone kits—untrained naloxone users may lose the opportunity to save a loved one’s life.

The naloxone initiative is moving practitioners in all health care settings to the front line of overdose prevention. All practitioners must clearly understand state and federal regulations on naloxone, since a risk of regulatory and legal exposure is associated with this broadening area of practice.

MEDICATION-ERROR PREVENTION

To Err Is Human, the landmark 1999 Institute of Medicine (IOM) report, mobilized efforts to address medication errors. The IOM estimate of 7,000 deaths annually from preventable medication errors has fueled federal and state government spending, accreditation organization requirements, and BOP regulations that focus practitioners’ attention on error prevention.13 BOPs recommend that practitioners review workflows to address the causes of medication errors. While technology has been stressed as a key to reducing the estimated $21 billion in wasteful spending attributable to preventable medication errors, BOPs play a role by educating and engaging pharmacists on medication safety.14 Florida, Iowa, Maryland, New Mexico, New York, Oregon, Pennsylvania, and the District of Columbia include medication error or safety requirements in their annual CE hours.1 More than 20 states have regulatory language requiring pharmacies to maintain a form of quality improvement program (QIP), also known as continuous quality improvement (CQI) in some cases, to monitor and prevent errors. In 1999, Texas became the first state to pass legislation aimed at establishing a peer review committee for QIPs in pharmacies.15 The Texas program remains voluntary, but the BOP has mandated that pharmacies implement a QIP to help resolve hearings on medication errors.

Providing notification of a serious injury from a medication error is a relatively new practice in pharmacy but not in health care. Most states require that the patient be notified of an error. The physician must be notified if the patient has taken the erroneous medication. Pharmacists must document the error, investigate what occurred, and implement changes to prevent reoccurrence. Employee training and updated policies are essential for prevention. Most states’ regulations prevent the release of QIP information for civil or administrative actions other than those initiated by the BOP. QIP records and peer-review committee minutes must be kept from one to four years, depending on the state. Many BOPs require a specific number of committee reviews per year. The pharmacy’s QIP process and records are generally audited as part of a BOP inspection. Beginning in 2010, Massachusetts requires that the BOP be notified within 15 days of a serious injury or death from improper dispensing of a medication.16 Medication errors resulting in serious personal injury or death must be reported to Colorado’s BOP immediately.17 This is an important issue for the risk-management programs of hospitals, health care systems, and retail organizations.

State BOPs have identified the QIP process as essential to public safety. HCPs should review their established QIPs to ensure that the pharmacy process meets regulatory language. Risk-management personnel’s assessment of needs and training in the pharmacy will ensure that the staff has the tools to manage the error review process effectively and to update policies and procedures routinely. Documentation is essential to minimize risk; personnel should be trained and evaluated to ensure compliance. Employees’ commitment to the QIP is vital to achieve regulatory compliance and improve patient safety.

DUTY TO WARN: MANDATORY COUNSELING

As the pharmacist’s traditional role of dispenser broadens to that of health care practitioner, the definition of a reasonable and prudent pharmacist continues to change. The Omnibus Budget Reconciliation Act of 1990 included provisions that have had an enormous impact on
pharmacy practice. Responsibilities for patient counseling, medication adherence, and side-effect management began to evolve with the passage of OBRA 90. States continue to pass pharmacy regulations addressing the need to counsel patients about medications. Pharmacists are required to offer counseling in 29 states, while the pharmacist is required to provide oral counseling under certain conditions in 19 states. Most state regulations are directed at new prescriptions or modifications to existing prescriptions but allow pharmacists judgment with regard to refills. State regulations vary in governing who may actually counsel the patient (such as the pharmacist versus other licensed pharmacy employees).18 BOPs’ increased counseling requirements align with the profession’s campaigns to recognize pharmacists as providers as well as medication-management experts. These national campaigns highlight the pharmacist’s expertise and the availability of dispensing systems to ensure accurate and appropriate use of medications. Pharmacists have long been held to a virtually error-free standard with regard to dispensing medications, but the expanding view of pharmacists’ professional capabilities has begun to increase their liability in duty-to-warn cases.

Historically, the courts had consistently ruled that the responsibility to warn patients about potential adverse drug reactions remained with the physician. Courts have often used judicial doctrine to exclude pharmacists from the duty to warn. Initially in Happel v WalMart, the case against a pharmacist who dispensed Toradol (ketorolac) to a patient with a documented allergy to aspirin was dismissed.19 Upon appeal, the Supreme Court of Illinois found that the pharmacist had specific knowledge of the potential danger and therefore had a duty to notify the physician or warn the patient of the potential danger. In Keffer v Lorenz, the pharmacy computer system warned the pharmacist of a potential serious drug interaction.20 The court denied a motion to dismiss, once again stating that a pharmacist with specific knowledge had a duty to warn the patient or advise the physician of the potential danger. The case of Baker v Arbor Drugs Inc. illustrates the additional responsibilities the profession is assuming when it draws attention to its enhanced knowledge and technical capabilities. In this case, Arbor Drugs advertised that its pharmacy system was designed to assist the pharmacist in monitoring patient profiles and detecting serious drug interactions. The pharmacist filled new prescriptions for a patient; one of these drugs had a significant interaction with the patient’s current medications. The pharmacist did not warn the patient about the possible interaction. The Michigan Court of Appeals reversed a lower courts’ dismissal of the case, stating that Arbor had voluntarily taken on the duty to warn patients by advertising that its system would detect interactions.21

In each of these cases, the pharmacist had specific knowledge that may have changed the outcome had the pharmacist notified the physician or warned the patient. The pharmacist’s role as the medication expert of the health care team is evolving. Previously, meeting expectations for an error-free dispensing environment generally eliminated a pharmacy from litigation. Today, patients and the courts are shifting some of the duty to warn from prescriber to pharmacist. The National Association of Chain Drug Stores (NACDS) has compiled a state list of duty-to-warn cases in which courts recognized a pharmacist’s duty to warn when specific information was known.22 The duty to warn is being associated with now-basic pharmacy practices such as monitoring for drug interactions and known drug allergies. Health care sites with pharmacies must include non-dispensing activities in their policies and procedures that address quality and safety to minimize practice risk.

**IMPLICATIONS FOR P&T COMMITTEES**

This article has highlighted contemporary case-law, regulatory, and legal trends that affect pharmacists’ professional scope of care. Opioid-use monitoring, medication-error prevention, and counseling/duty to warn illustrate new or emerging legal risks resulting from the expansion of professional practice.

Evolution in practice results in a corresponding change in standards that affect physicians and pharmacists, such as the duty to warn. P&T committees must consider updating review standards for practice related to the safe and effective use of medications in their organizations. That includes, but is not limited to, standard operating procedures, formularies, policies, protocols, and multidisciplinary practice agreements across the organization that touch on medication use.

The following represent a few of the potential considerations for P&T committees as they address organizational or patient-safety exposures, with guidance on addressing key issues raised in this article:

1. Assess changing case law and regulations that affect the scope of practice in all areas of an organization (inpatient, outpatient, home care). This includes the expanding ambulatory and home-based services that health care systems are providing or contracting to receive, and it can also be important for narrow-network provider groups or hospitals collaborating with a health plan.

2. Review policies and procedures based on the most recent state or federal laws and regulations, taking into account case law from state and federal courts.

3. Work with the information technology staff to evaluate the electronic health record’s use in monitoring, identifying, and reporting drug-use practices across the organization. Ensure primary data security to prevent “hacking” in addition to compliance with the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act.

4. Anticipate emerging access to drugs by persons other than licensed clinicians as telemedicine, robotics, and other technological advances expand traditional methods of drug distribution.

To manage the impact of changes effectively, coordinate with the risk-management personnel of the health plan, hospital, health system, or retail organization. Work with the education department to make sure that proper certifications are in hand and that continuing education incorporates content related to drug use or management. And remember that any organization that has a P&T committee or employs an HCP should be practicing risk management every day.
REFERENCES


