

## Chapter 1

# U.S. Legal and Regulatory System

## Chapter Outline

Learning Objectives

Introduction

Role of Laws and Regulations

Role of Pharmacy Professional Practice Standards and Ethical Principles

Violations of Pharmacy Laws and Regulations

Summary

Self-Assessment Questions

Appendix 1-1. Code of Ethics: Pharmacy Associations

Appendix 1-2. Code of Ethics for Pharmacy Technicians: American Association of Pharmacy Technicians (AAPT)

## Learning Objectives

1. Explain key differences between laws/regulations or rules and pharmacy professional practice standards/ethical principles.
2. Identify the function of pharmacy laws and regulations or rules.
3. Discuss how professional standards and ethical principles impact your practice as a pharmacy technician.
4. Compare and contrast the processes required to establish laws, regulations, professional practice standards, and ethical principles.
5. Describe the different legal systems that could be involved for a legal dispute or a violation of a pharmacy law and/or regulation.

## Introduction

As part of your education and training to become a pharmacy technician, you will learn how extensively pharmacy is governed by laws and rules or regulations and other requirements, such as pharmacy professional practice standards and ethical principles. You may ask: “Why is there so much oversight?” Perhaps the most obvious reasons are the roles and responsibilities that pharmacists have in overseeing the provision of medications to nearly every member of society—whether by dispensing prescriptions; providing drug information to physicians, nurses, and other health care practitioners; counseling and assisting patients with understanding their drug therapy; or assisting patients with selecting the appropriate over-the-counter medications. Pharmacists are responsible for the delivery of medications and medication or drug therapy-related services in many settings, including community pharmacies, hospitals, long-term care facilities, and other health care sites where prescription medications are dispensed.

Legal requirements, ethical guidelines, and professional practice standards for pharmacy each serve a necessary purpose. They have been developed over many years in order to guide the safe and effective delivery of medications to patients. The oversight for pharmacy practice comes from a variety of sources (**Box 1-1**). Laws and regulations provide governmental oversight of pharmacy practice, including pharmacists and pharmacy technicians. For instance, in order to practice pharmacy, a pharmacist must have a current valid state pharmacy license for each state in which he or she practices. Similarly, many states now have laws or regulations that require pharmacy technicians to be licensed or registered and meet other requirements, such as specific training and education and criminal history background checks.

In contrast, professional practice standards and ethical principles come from different sources such as professional pharmacy organizations. These guidelines and principles provide pharmacists with guidance on delivering pharmacy services to patients so that they meet the expectations of their peers. For example, professional practice standards could assist pharmacists with dispensing medications to patients with particular diseases such as diabetes or high blood pressure.

### Box 1-1

#### Sources of Oversight and Standards for Pharmacy Practice

---

- Federal laws and regulations
- State laws and regulations
- Professional practice standards
- Ethical principles
- Case law

In dispensing such prescription medications, professional practice standards would guide pharmacists in consulting with the patient's prescriber about recommended medications and avoiding potential drug–drug interactions with other drugs that were prescribed for the patient. Practice standards also guide pharmacists when providing patients with information on how to take their medications properly—according to their doctor's prescription and avoiding drug interactions with over-the-counter drugs.

Ethical principles work in conjunction with the professional practice standards. In simple terms, ethical principles provide guidance for acting in an ethical manner. For example, ethical principles include important matters such as providing services with honesty and integrity, recognizing patient dignity, and obeying laws and regulations applicable to providing pharmacy services. Ethical principles provide a fundamental framework for interacting with the patient—showing care and compassion and maintaining the proper degree of patient privacy about the patient's medical conditions, drug treatment, and other private patient information.

Pharmacy technicians work in a health care field with one of the most highly regarded health care professionals. Nearly every year, health care providers—including pharmacists—are ranked near or at the top among professionals for honesty and integrity in public opinion polls. The polls also consistently rank pharmacists as one of the most trusted professionals.

Although pharmacy technicians may consider legal issues somewhat remote to their day-to-day responsibilities, the opposite is true. Legal requirements apply to nearly all of the pharmacists' professional actions as well as the duties and responsibilities performed by pharmacy technicians. Because pharmacy technicians must comply with the applicable laws and regulations, pharmacy technicians need to know and understand that they work in a field that is subject to numerous laws and regulations. The purpose of this book is to guide you through understanding the legal and regulatory environment applicable to the practice of pharmacy.

## **Role of Laws and Regulations**

Laws and regulations govern virtually all aspects of the practice of pharmacy. They establish permitted and prohibited conduct for pharmacists, pharmacies, and pharmacy technicians. They set the criteria that a pharmacy must satisfy to be licensed by a state and also the criteria that pharmacists must meet to be licensed in a state. They set the requirements that pharmacy technicians must meet to become registered or licensed in a state. The laws and regulations establish the pharmacist's responsibilities for operating a pharmacy, dispensing prescription medications, and providing other pharmacist services such as counseling patients about their medications. They establish the requirements for information that must be on the prescription label, such as the name and quantity of the prescribed

medication, directions for use, and other information. State laws and regulations applicable to pharmacy technicians may cover what they are permitted to do; prohibited conduct; and requirements to work as a pharmacy technician, such as registration or licensure and requirements to perform responsibilities under the supervision of a pharmacist.



## Key Point

---

Laws and regulations govern virtually all aspects of the practice of pharmacy.

Laws (also known as statutes) have primary authority over regulations. However, both have legal effect over the practice of pharmacy, pharmacists, pharmacy technicians, and pharmacies. In general terms, laws are enacted by the U.S. Congress or by a state legislature, and agencies adopt rules that interpret the laws in more details. State laws and regulations vary from state to state. Every U.S. state, territory, and the District of Columbia has its own laws and regulations governing pharmacy practice. While they may have similarities, they differ in many respects. One of these differences is how pharmacy technicians are regulated. These similarities and differences will be covered in greater detail in Chapter 6 (**Box 1-2**).

States have the authority to regulate the practice of pharmacy. However, federal laws and regulations also have an effect on various parts of pharmacy practice. Examples include laws that are applicable to all health care providers (e.g., the Medicare and Medicaid laws), laws directed at medications (e.g., the Federal Food, Drug, and Cosmetic Act), and laws directed at specific types of drugs (e.g., the federal Controlled Substances Act). As a special note, there are federal employers of pharmacists such as the U.S. Public Health Services and the armed services. Federal laws will be discussed in more detail in Chapter 3.

Although states have the primary authority to regulate pharmacy practice, one particular federal law significantly affects pharmacy practice. The federal Omnibus Budget Reconciliation Act of 1990 (commonly called “OBRA 90”) was the first federal law to address the standards of practice for pharmacists. OBRA ‘90 requires

### Box 1-2

#### Pharmacy Laws and Regulations or Rules

---

- Establish required, permitted, and prohibited conduct
- Provide for discipline and penalties for violations
- Vary from state to state
- Control pharmacy practice, licensure, and discipline

that pharmacists provide certain patient services as a condition of reimbursement when dispensing prescriptions to Medicaid patients. Because the states regulate the practice of pharmacy, the federal legislation takes an indirect approach by requiring that pharmacists perform certain patient care functions as a condition of reimbursement. OBRA '90 will be discussed in Chapter 3.

Laws and regulations are derived by different means. Enacting state or federal laws involves the state or federal legislature, respectively. State legislatures are comprised of two bodies, generally known as the House and Senate, although they may have other names depending on the state. State legislation must be passed by both the House and Senate and then become law through being signed by the Governor or otherwise allowed under the state law. However, laws passed by state legislatures may not become law through different actions. For instance, the state's Governor may veto legislation. If vetoed, the bill would not become law. If the bill is not signed by the Governor, it may become law if state laws allow it. Federal legislation must be approved by both the U.S. House of Representatives and the U.S. Senate to be eligible to become law; as with the states, the legislation then goes to the President for approval or veto. The state and federal processes for enacting legislation into laws are discussed in Chapter 2.

Regulations or rules, on the other hand, are issued by state administrative agencies or regulatory bodies pursuant to the authority granted to them by the laws or statutes. Most state Boards of Pharmacy are administrative agencies with authority to propose and adopt regulations to further implement pharmacy laws. For example, a state law that gives the Board of Pharmacy authority to regulate and license or register pharmacy technicians would also usually permit the Board of Pharmacy to adopt rules or regulations with more detailed requirements for pharmacy technician licensure or registration. These detailed regulatory requirements may include specific education and training, age requirements, and basic education level such as a high school degree.



## Key Point

---

**Most state Boards of Pharmacy are administrative agencies with authority to propose and adopt regulations to further implement pharmacy laws.**

The regulatory process for a Board of Pharmacy to adopt regulations varies from state to state, but there are a number of basic similarities. In general, the Board is required to issue a formal public notice of the proposed regulation. Next, the Board is required in most instances to allow the public (e.g., pharmacists and other interested persons) to send comments to the Board if they have concerns or questions. In addition, the Board may be required to hold a public hearing to

receive comments in person. Thereafter, several options exist depending on the state laws. For example, the proposed regulation may be approved as initially proposed and adopted as a final regulation. Alternatively, the proposed regulation may be amended in response to comments received and reissued as a revised regulation. At the federal level, the process is generally similar. Regulations proposed by a federal regulatory agency are published for public comment. Once a regulation becomes effective by meeting the state or federal requirements for the approval process, it will be published in the state administrative code or Code of Federal Regulations as a final regulation.

Although the states have primary authority to license and regulate the practice of pharmacy, federal laws and regulations have authority over matters that affect pharmacy practice by governing how drugs are manufactured, distributed, and handled. For example, the federal Food and Drug Administration (FDA) regulates drugs that are available for use in the United States from manufacturing, distribution, labeling, and marketing to the determination of whether drugs are safe and effective for use in the United States. The federal Drug Enforcement Administration (DEA) regulates the subset of drugs called “controlled substances,” which includes drugs such as narcotics and sleeping medications.

Pharmacy practice is affected by both state and federal laws. As a general rule, when the state and federal laws have different requirements, the more stringent law must be followed. If federal law is less strict than state law, the stricter state law would be followed and vice versa. For example, if a federal law has specific requirements for dispensing controlled substances, and a state pharmacy law has added stricter requirements, the additional stricter state law requirement would be followed in addition to the federal requirements.

## **Role of Pharmacy Professional Practice Standards and Ethical Principles**

The practice of pharmacy is also affected by professional practice standards and ethical principles. Once a pharmacist is educated and licensed to practice pharmacy, the practice standards and ethical principles provide further guidance for pharmacists in the delivery of pharmacy services. Pharmacy is not unique in having professional practice standards and ethical principles. Other health care professionals, including physicians, dentists, and nurses, have practice standards and ethical guidelines.

### ***Professional Practice Standards***

Professional practice standards serve as guidelines for pharmacists to use with professional judgment in determining how to act in particular situations. Practice standards are not laws or regulations. They serve an important role in pharmacy

and the practice of other health care professionals by assisting providers with decision-making processes such as recommendations for treatment of a patient and provision of pharmacy services and other health care services.



## Key Point

---

**Professional practice standards serve as guidelines for pharmacists to use with professional judgment in determining how to act in particular situations.**

The definitions of the “practice of pharmacy” and “pharmacist care” are helpful in understanding professional practice standards because they describe the scope of pharmacy practice. These definitions show that the practice of pharmacy involves a number of different pharmacist responsibilities. Professional practice standards may relate to these areas of the practice of pharmacy. The Model Rules of the National Association of Boards of Pharmacy (NABP) define the practice of pharmacy and “pharmacist care” as shown below.

The “Practice of Pharmacy” means the interpretation, evaluation, and implementation of medical orders; the dispensing of prescription drug orders; participation in drug and device selection; drug administration; drug regimen reviews; the practice of telepharmacy within and across state lines; drug or drug-related research; the provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care in all areas of patient care, including primary care and collaborative pharmacy practice; and the responsibility for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices), proper and safe storage of drugs and devices, and maintenance of proper records for them. (See NABP Model Rules at <http://www.nabp.net>.)

“Pharmacist Care” is the provision by a Pharmacist of Medication Therapy Management Services, with or without the Dispensing of Drugs or Devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process, as defined in the Rules of the Board. (See NABP Model Rules at <http://www.nabp.net>.)

Pharmacy practice standards come from a variety of sources; however, they are usually developed by professional pharmacy organizations through a panel of

pharmacists with input from leaders of the profession. Pharmacy practice standards have been developed by a number of national pharmacy organizations. For example, two such organizations, the American Pharmacists Association (APhA) and the American Association of Colleges of Pharmacy (AACP), worked together to create the APhA/AACP Standards of Practice of the Profession of Pharmacy. The national professional association for health-system pharmacists, the American Society of Health-System Pharmacists (ASHP), also developed professional standards for pharmacists.



## Key Point

Pharmacy practice standards are usually developed by professional pharmacy organizations through a panel of pharmacists with input from leaders of the profession.

Although professional practice standards are not laws or regulations developed by legislatures or regulatory agencies, they have a significant impact on pharmacy practice. They may guide the pharmacist's consultation with the patient's physician. For example, if a pharmacist is concerned about a potential drug–drug interaction with the patient's prescribed medication, professional standards may provide guidance to the pharmacist for evaluating the potential drug interaction and contacting the prescriber to recommend an alternate medication for the patient.

## ***Ethical Principles***

Ethical principles, on the other hand, guide the performance of professional responsibilities within an ethical and moral framework. They guide pharmacists' and pharmacy technicians' interactions and relationships with patients and other health care professionals to conform to society's ethical values. In simple terms, acting according to ethical principles means doing the “right thing” and acting in consideration of the patient. Following ethical principles also includes a number of other considerations such as complying with the applicable laws and regulations, promoting high professional standards in providing care to patients, maintaining professional competency, and respecting patient privacy and confidentiality. Pharmacy technicians also need to adhere to ethical principles. For example, pharmacy technicians become aware of confidential patient information. Ethical principles (as well as privacy laws and regulations) require respect for the patient's privacy and preventing inappropriate disclosure of a patient's private information. ASHP and APhA have both developed their own Code of Ethics for Pharmacists (see **Appendix 1-1**). The American Association of Pharmacy Technicians (AAPT) has developed a Code of Ethics for Pharmacy Technicians (see **Appendix 1-2**).





## Key Point

---

Ethical principles guide the performance of professional responsibilities within an ethical and moral framework.

### **Violations of Pharmacy Laws and Regulations**

There are different legal systems where violations of pharmacy laws and regulations may be addressed: a disciplinary action with an administrative hearing before the state Board of Pharmacy, a civil court proceeding, and a criminal court proceeding. Of these, violations of pharmacy laws and regulations are normally considered and determined by the state Board of Pharmacy as disciplinary actions. However, violations of pharmacy laws and regulations may be a part of other legal proceedings.

These are the general steps involved with a Board of Pharmacy disciplinary matter; however, the process may vary from state to state. A disciplinary action against a pharmacist, pharmacy technician, or pharmacy usually starts with a complaint being received by the Board of Pharmacy or where a violation is found during a Board of Pharmacy inspection. The Board of Pharmacy will conduct an investigation to determine the circumstances, appropriate Board action, and will notify the pharmacy, pharmacy technician, and/or pharmacist of the violation. Depending on the Board's determination, the Board may dismiss the matter without a Board hearing, or may recommend that the person or pharmacy agree to take corrective actions. If the disciplinary action comes before the Board of Pharmacy for a hearing, the Board will consider the violation and circumstances to determine the type of penalties to be applied, if any. Possible penalties include monetary fines and temporary or permanent loss of the license or registration. For instance, a law or regulation may not permit a pharmacy technician to perform certain responsibilities or duties or only allow the technician to perform them if the individual is a Certified Pharmacy Technician. A pharmacy technician that violates the law or regulation would receive a notice of a violation, and a Board hearing would usually be held. At the hearing, the facts would be discussed and the pharmacy technician would be permitted to provide information regarding the matter to the Board such as explaining the circumstances. A technician may decide to have legal representation (i.e., an attorney) at the disciplinary hearing. The hearing is a legal process to resolve the violation and decide whether a penalty is appropriate. The same general process would apply to violations issued by a Board of Pharmacy against a pharmacist or pharmacy. This is a general discussion of the process as the particular process may vary considerably depending on the state.

Violations of pharmacy laws and regulations may also be a part of a civil lawsuit. This is a general discussion because these lawsuits are complicated in many instances. An example is a lawsuit for professional negligence (also called a medical malpractice case). These types of lawsuits generally involve a patient claiming injury as a result of medical treatment. For instance, a patient could claim that he or she was injured as a result of a prescription being filled incorrectly and may use the violation of the pharmacy law or regulation as part of the professional negligence case. When such disputes arise, the civil court system operates to resolve them through lawsuits with juries to determine if the defendant was or was not negligent. In some instances, the parties to the cases may decide to resolve the matter through an alternative dispute resolution process such as arbitration or mediation. If the case goes to trial, the facts and circumstances will be considered by the jury to determine if the defendant or defendants were at fault in causing the patient's injuries.

In some matters, although very rare, the violations of pharmacy laws or regulations may be criminal in nature; criminal penalties would be handled in the criminal courts. Although rare, this could occur when the charges involve violations of criminal laws and the state or federal prosecutor or district attorney decides to bring criminal charges. In general, criminal violations involve wrongful conduct that was intentional.

## Summary

The pharmacy profession is extensively regulated by laws and regulations that govern virtually every aspect of the practice of pharmacy such as pharmacist and pharmacy licensure requirements, scope of pharmacist practice, prescription dispensing requirements, use of pharmacy technicians, prohibited conduct, and disciplinary actions. Although pharmacy laws and regulations have general similarities, the specific requirements vary from state to state. Violations of pharmacy laws and regulations, including violations by pharmacy technicians, are generally handled by the state Board of Pharmacy.

Laws and regulations are derived by different means. State legislatures enact laws, whereas state administrative agencies such as state Boards of Pharmacy adopt regulations. Many states have laws specifically applicable to pharmacy technicians, including requirements for registration or licensure and permitted duties. Because laws and regulations vary from state to state, pharmacy technicians should be knowledgeable about the ones operating in their specific state. The pharmacy profession is also subject to pharmacy professional practice standards and ethical principles. Practice standards provide guidelines for the delivery of pharmacy services. Ethical principles guide the performance of pharmacy care within an ethical and moral framework.

## Self-Assessment Questions

1. What are three sources of oversight and standards for pharmacy practice?
2. What federal agency regulates the subset of drugs called “controlled substances,” which includes drugs such as narcotics and sleeping medications?
3. What is a federal law that affects pharmacy practice for pharmacists?
4. What organizations have developed professional practice standards for pharmacy?
5. What regulatory body issues a notice of violation if there is a violation of a pharmacy law or regulation?

## **Appendix 1-1. Code of Ethics: Pharmacy Associations**

### ***American Pharmaceutical Association Code of Ethics for Pharmacists (APhA)***

(Endorsed by the American Society for Health-System Pharmacists)

#### **Preamble**

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

#### **I. A pharmacist respects the covenantal relationship between the patient and pharmacist.**

Considering the patient–pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.

#### **II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.**

A pharmacist places concern for the well-being of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.

#### **III. A pharmacist respects the autonomy and dignity of each patient.**

A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.

**IV. A pharmacist acts with honesty and integrity in professional relationships.**

A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior, or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.

**V. A pharmacist maintains professional competence.**

A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

**VI. A pharmacist respects the values and abilities of colleagues and other health professionals.**

When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.

**VII. A pharmacist serves individual, community, and societal needs.**

The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.

**VIII. A pharmacist seeks justice in the distribution of health resources.**

When health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society.

## **Appendix 1-2. Code of Ethics for Pharmacy Technicians: American Association of Pharmacy Technicians (AAPT)**

### ***Code of Ethics for Pharmacy Technicians***

#### **Preamble**

Pharmacy Technicians are healthcare professionals who assist pharmacists in providing the best possible care for patients. The principles of this code, which apply to pharmacy technicians working in any and all settings, are based on the application and support of the moral obligations that guide the pharmacy profession in relationships with patients, healthcare professionals and society.

#### **Principles**

- ▶ A pharmacy technician's first consideration is to ensure the health and safety of the patient, and to use knowledge and skills to the best of his/her ability in serving patients.
- ▶ A pharmacy technician supports and promotes honesty and integrity in the profession, which includes a duty to observe the law, maintain the highest moral and ethical conduct at all times and uphold the ethical principles of the profession.
- ▶ A pharmacy technician assists and supports the pharmacists in the safe and efficacious and cost effective distribution of health services and healthcare resources.
- ▶ A pharmacy technician respects and values the abilities of pharmacists, colleagues and other healthcare professionals.
- ▶ A pharmacy technician maintains competency in his/her practice and continually enhances his/her professional knowledge and expertise.
- ▶ A pharmacy technician respects and supports the patient's individuality, dignity, and confidentiality.
- ▶ A pharmacy technician respects the confidentiality of a patient's records and discloses pertinent information only with proper authorization.
- ▶ A pharmacy technician never assists in dispensing, promoting or distribution of medication or medical devices that are not of good quality or do not meet the standards required by law.
- ▶ A pharmacy technician does not engage in any activity that will discredit the profession, and will expose, without fear or favor, illegal or unethical conduct of the profession.
- ▶ A pharmacy technician associates with and engages in the support of organizations, which promote the profession of pharmacy through the utilization and enhancement of pharmacy technicians.