Objectives

After reading this chapter, you will be able to:

- Outline the origins of pharmacy
- Differentiate between the various kinds of pharmacy practices
- Identify the four stages of development of the pharmacy profession in the 20th century
- Summarize the functions of a pharmacist
- Discuss the education curriculum for today’s pharmacy student
- Explain the licensing requirements for pharmacists
- Explain the functions and work environments of the pharmacy technician
- Describe laws, regulations, professional standards, and ethics that affect the practice of pharmacy
- Outline the major pieces of statutory federal drug law in the 20th century
- Compare and contrast the roles of the Food and Drug Administration, the Drug Enforcement Administration, the Occupational Safety and Health Administration, and the national and state boards of pharmacy
- Review the functions that may legally be performed by pharmacy technicians in most states
- Discuss the potential for tort actions under the common law related to negligence and other forms of malpractice
- Understand the importance of drug and professional standards

Key Terms

Alchemy  Battery  Chain pharmacy
Apothecary  Brand name  Chemical name
Assault  Broken contract  Child-resistant container
Chapter Overview

Over the years, the practice of pharmacy has evolved into a scientific and knowledge-based profession. The role of the pharmacist has expanded from one who compounds and dispenses medications to one who also provides information and patient counseling regarding the safe use of medications.

Pharmacy in the United States is a heavily regulated profession, and knowledge of both federal and state law is necessary to practice pharmacy. Laws, regulations, and professional standards have been put in place to ensure public safety and the safe dispensing of medications. Regulatory bodies assist in the administration and enforcement of laws for the safe use of drugs. These agencies follow written rules or established guidelines to carry out federal or state laws.

The Origins of Pharmacy

Medicine has been practiced for thousands of years. Archeological discoveries have shown that early civilizations documented the use of animals, plants, and minerals to cure the sick. Over time, the practice of pharmacy has evolved into a more scientific approach to treating illness and disease. Learning about the history of pharmacy will help the pharmacy technician understand how the roles of a pharmacist and a pharmacy technician have evolved over time.

Pharmacy in Early Civilization

The history of pharmacy can be traced back thousands of years to early civilization, when disease was thought to be caused by evil forces, gods, or demons. Religious leaders, sorcerers, or medicinal healers would first identify the evil spirit before determining the medicinal remedy. These medicinal remedies were controlled primarily by religious leaders, who frequently mixed drug preparations with prayers, chants, rituals, and “magic.”
Archaeologists found the earliest documentation (18th century B.C.E., or before the common era) of medicinal preparations on clay tablets in ancient Mesopotamia. These tablets identify drugs or medicinal preparations from various sources, including animals, plants, spices, and minerals. The people of ancient Egypt made several major medical discoveries and began treating diseases in a more rational physical manner along with using the older spiritual techniques.

Although much of the advancement in medicine was a result of trial and error or spiritual ceremonies, the effect on the knowledge and development of medicine was large. The ancient Egyptians compiled drugs or medicinal recipes in lists known largely as formularies or pharmacopeias. The most notable collection of medicinal recipes from natural ingredients, written in about 1534 B.C.E. and used for centuries in Egypt, is a 110-page document called the *Ebers papyrus*. Knowledge of the healing properties of these natural substances slowly evolved into a scientific endeavor that involved the compounding and dispensing of medications.

The history of plant usage for medicinal purposes can also be traced back to China, where plants and other naturally occurring substances were used in a similar fashion. More than 2,000 years ago, a Chinese named Li Che Ten wrote a plant book entitled *Peng T’Sao* that listed more than 1,000 plants and nearly 8,000 recipes for their use. Still today, much of Asia relies heavily on natural herbs to treat common illnesses.

The foundations of much of modern Western medicine come from ancient Greece. From about 800 B.C.E. to about 200 C.E., Greek medicine moved from the divine and spiritual toward scientific observation and logical reasoning. The word *pharmacy* is derived from the ancient Greek word *pharmako*, meaning drug or poison. The Greek physician Hippocrates (c. 460–377 B.C.E.), also known as “the Father of Medicine” was the first to believe that illness was not the result of superstitions, evil spirits, or punishment from God, but instead had a natural cause or physical and rational explanation. He based his practice on medical and scientific observations and recording, and on the study of the human body. Hippocrates also believed that the body must be treated as a whole and not just a series of parts. Hippocrates is perhaps best known for the Hippocratic Oath, an oath by which physicians pledge to uphold a number of professional ethical standards and “to do no harm.”
Another Greek physician, Galen (130–200 C.E.), is often considered the most important contributor to modern-day medicine, apart from Hippocrates. Galen is credited with the discovery of blood in human arteries and for his dissection of the human cranial nerves, which supply key areas of the head, face, and upper chest. Galen dissected animals to further his knowledge of the human body and recorded his observations. The foundation of Galen’s treatment methods was his belief that disease resulted from an imbalance in one of the four “humors”—blood, yellow bile, black bile, and phlegm—and that the diseases were cured with compounds of opposing qualities—moist, dry, cold, or warm. Galen believed that a disease-causing imbalance could be located within an organ. Treatments devised by Galen were more precise because he believed that disease primarily affected one organ or region of the body. He also produced a systemic classification of drugs for the treatment of various illnesses and described the process of creating extracts from plants. Although Galen was a physician, he is considered the “Father of Pharmacy.”

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Dioscorides, a Greek physician, traveled extensively seeking medicinal substances. Between 50 and 70 C.E., he compiled a series of five books, collectively titled De Materia Medica, that included the properties, preparation, usage, dosages, storage, and testing of drugs. His text became the standard for pharmaceutical knowledge until the 16th century.

The De Materia Medica was the standard for pharmaceutical knowledge until the 16th century.

Pharmacy in the Middle Ages

Throughout Europe during the Middle Ages and Renaissance, physicians prescribed medications or herbal remedies to their patients, which were filled at apothecary shops. Along with the apothecary concept came the development of professional guilds, which controlled the training and length of apprenticeship for physicians (and other professionals).

The ancient pharmacy practices of the Greeks and Romans were questioned during the Renaissance. During this period, alchemy was prevalent. The goal of alchemy was to combine elements of chemistry, metallurgy, physics, and medicine with astrology and spiritualism to turn metals into gold. Exploration in the New World expanded the availability of medicinal agents in the form of new drugs and exotic spices. Pharmacies and hospitals run by religious orders also emerged during this period. These pharmacies and hospitals are the origin of pharmacies, healthcare clinics, and hospitals that we know today. It was also during this period that the works of Galen were challenged. Near the end of the Middle Ages, the Nuovo Receptario was published as the official pharmacopeia to be followed by all apothecaries.

The Nuovo Receptario was the first official pharmacopeia.

Pharmacy in the Modern Era

During the 17th and 18th centuries C.E., a more scientific approach to medicine emerged. Doctors began to question traditional ideas. More formal research and testing to determine the efficacy of natural ingredients was initiated, and several advances in pharmacy and medicine were made. Professional societies were formed in major
European cities. Scientists began to share their research by publishing their work in journals. During this time, William Harvey discovered how blood circulated through the body and Edward Jenner invented a vaccination for smallpox after discovering the relationship between cowpox and smallpox. Each major capital city in Europe published a list of commonly used drugs. The most notable of these is the one created in Great Britain, *Martindale’s Pharmacopoeia*. It was also during this time that pharmacists began to be recognized as healthcare providers.

In North America, during the colonial period (from the 1600s to the 1700s), as new immigrants brought their families from other parts of the world, disease followed. Early colonists had few medical personnel and had to rely on home or natural remedies. The first pharmacists, known as druggists, were doctors until pharmacy became a specialty. As the colonies grew, more physicians came, bringing with them supplies from Britain. With the American Revolution and separation from Britain, colonists were forced to make their own preparations and chemical ingredients. It was during this time that the United States also developed its own pharmacopeia. After the Civil War, apothecaries began to emerge in towns across the country. Manufacturing plants were built, and people were trained to prepare medications accurately. As the physician’s role changed from dispensing medication to diagnosing disease, the role of the pharmacist emerged, and the separation of duties between the pharmacist and physician was established.

During the 20th century, many new categories of medicine such as antiseptics, antimicrobials, and antibiotics, including penicillin, were discovered. Over time, pharmacology has evolved into a science based on systematic research to determine the effects that drugs have on the body.

### Evolution of the Pharmacy Profession in the 20th Century

The evolution of the pharmacy profession in the 20th century can be categorized into four stages.

- **Traditional era (1920s)**—During this era, the pharmacy profession focused on preparing, compounding, and dispensing drugs from natural sources such as plants. A pharmacist in the traditional era not only sold drugs, but also often compounded and dispensed medicines made from botanicals. *Pharmacognosy*, the study of the medicinal properties of natural products from plant and animal sources and minerals, was emphasized during this period.

- **Scientific era (1940s and 1950s)**—During this era, the pharmacy profession focused on the development and testing of drugs and their effects on the human body. In the scientific era, pharmaceutical manufacturers developed ways to mass-produce new drugs consistently and economically. With the development of new drugs and dosage forms, *pharmacology*, the scientific study of drugs and their mechanisms of actions became important.

- **Clinical era (1960s)**—During this era, the pharmacy profession focused not only on the traditional roles of compounding and dispensing, but also provided drug information to patients and physicians. During the clinical area, pharmacy shifted from a product-focused profession to one that is patient focused.

- **Pharmaceutical care era (from the 1990s to the present)**—This era expanded the role of the pharmacist to include responsibility for appropriate medication use.
Pharmacy Practice Settings

The goal of the profession of pharmacy is to ensure the safe and effective use of medication. The scope of pharmacy practice includes traditional roles such as compounding and dispensing medications. It also includes modern roles related to patient care such as reviewing medications for safety and efficacy and providing drug information.

Pharmacists and pharmacy technicians can be employed in many different settings, including retail pharmacies (drug stores) and institutional pharmacies such as hospital pharmacies and pharmacies in assisted-living and long-term–care facilities, pharmaceutical manufacturing facilities, and insurance companies. They can also work in nuclear pharmacies, mail-order pharmacies, and home healthcare pharmacies. Pharmacy technicians are employed in most of the same settings as pharmacists. Pharmacists and pharmacy technicians work in clean, organized, well-lit, and well-ventilated areas, and spend much of their day on their feet. Pharmacy technicians typically work the same hours as a pharmacist. Depending on where they work, this may include evenings, weekends, and holidays, particularly in pharmacies that are open 24 hours.

The mission of pharmacy is to protect the public’s health and safety.

The U.S. Department of Labor’s Bureau of Labor and Statistics reports that in 2008, pharmacy technicians and aides held approximately 381,200 jobs. Of these, about 326,300 were pharmacy technicians and roughly 54,900 were pharmacy aides. Approximately 75 percent of these jobs were in a retail setting, while about 16 percent were in hospitals. Pharmacy technicians also work in numerous other pharmacy settings and specialty pharmacy practices.

Retail Pharmacies

A retail pharmacy, also called a community pharmacy or drug store, is usually divided into two areas. One area, the front area, typically offers over-the-counter drugs, dietary aids, medical supplies, nutritionals, and other miscellaneous merchandise. A second area, the back area, usually contains the pharmacy. Most prescriptions filled in the United States are filled in retail pharmacies, and approximately 65 percent of all pharmacists work in a retail pharmacy setting. Retail pharmacies include the following:

- Chain pharmacies—A chain pharmacy is a pharmacy that has multiple outlets located regionally or nationally, and is usually owned by a corporation. These pharmacies may be found in grocery stores, department stores, or drug stores. Most chain pharmacies are located in high-traffic areas to allow for large-volume dispensing. Chain pharmacies typically employ a large number of pharmacists and pharmacy technicians. Administrative decisions in chain pharmacies are usually made at the corporate level. In some cases, prescriptions can be filled at central locations and then shipped to the customer or store.

- Independent pharmacies—An independent pharmacy is a pharmacy that is owned and operated by a private owner or owners. The number of independent pharmacies has decreased in recent years because they have difficulty competing with high-volume chain pharmacies.

- Compounding pharmacies—A compounding pharmacy is a specialized pharmacy wherein the pharmacist and/or pharmacy technician compounds or prepares medication mixtures that are customized specifically for the unique healthcare needs of the patient.
Franchise pharmacies—A franchise pharmacy is a combination of a retail chain and an independent pharmacy. A franchise is a right granted to an individual or group (franchisee) to use the name of the company and market a company's goods or services within a certain territory or location.

Mail-order pharmacies—A mail-order pharmacy is a closed-door, centralized pharmacy operation that dispenses a large number of prescriptions, which are mailed directly to the patient.

Home infusion pharmacies—A home infusion pharmacy is one that specializes in parenteral mixtures (that is, mixtures administered by a needle or catheter into one or more layers of the skin), such as chemotherapy, antibiotics, nutrition and feeding supplies.

Institutional Pharmacies
An institutional pharmacy can broadly be defined as a facility that provides pharmaceutical-care services to patients in an institutional facility or organized healthcare system. Traditionally, this referred to a hospital pharmacy, but the definition has expanded to include long-term-care facilities, managed-care organizations, and nuclear pharmacies. As society's healthcare needs have changed, there has been an increased emphasis on providing care through organized healthcare settings. As a result, an increased number of pharmacists practice in institutional settings. As members of healthcare teams, pharmacists have an opportunity to be directly involved in patient care.

Hospital Pharmacies
A hospital pharmacy is an institutional pharmacy that provides services to patients and healthcare professionals in the hospital. Hospital pharmacies are responsible for maintaining patient records, and for ordering, stocking, compounding, and dispensing medications and other supplies.

Hospital pharmacy practice is composed of a number of highly specialized areas, including intravenous therapy, nuclear pharmacy, and drug information. In addition, a hospital may also provide clinical services in areas such as adult medicine, pediatrics, psychiatry, oncology, and infectious disease. The nature and size of the hospital helps determine the extent to which these services are needed. Hospitals provide services 24 hours per day, seven days a week. Pharmacists, pharmacy technicians,
and hospital administrators with advanced degrees may work in a hospital pharmacy.

**Long-Term-Care Facilities**

A long-term care facility provides a broad range of services for patients requiring a longer length of stay. These facilities may include nursing homes or assisted-living facilities. A long-term care pharmacy dispenses medications, sterile intravenous preparations, and nutritional products to patients in nursing homes, assisted-living facilities, and hospice programs. Long-term care pharmacies address the special needs of nursing homes, providing packaging for controlled administration (called unit of use or bubble packs), and special services that are more extensive than those provided by retail pharmacies. These special services include quality assurance checks, emergency drug kits and medication carts, regular and emergency (24-hours-a-day) delivery services, and in-service training programs for nursing assistants, nurses, and other professional nursing facility staff. Long-term care pharmacies employ consultant pharmacists who conduct monthly drug-regimen reviews for each resident to assess the safety, efficacy, and appropriateness of drug therapies.

**Nuclear Pharmacies**

A nuclear pharmacy is a specialty practice of pharmacy that promotes health through the safe and effective use of radioactive drugs for diagnosis and therapy. Specialized equipment and training programs and certifications in radiotherapy are required to practice in a nuclear pharmacy.

**Managed-Care Organizations**

A managed-care organization is an organization that controls the financing and delivery of healthcare services for those who are involved in a specific healthcare plan. Managed-care plans deliver high-quality, medically necessary care while controlling cost. There are three types of managed-care plans:

There are three types of managed-care health plans: HMO, PPO, and POS.

- A health-maintenance organization (HMO) plan—A health-maintenance organization (HMO) provides care that is focused on keeping patients healthy or managing chronic diseases in an effort to decrease hospitalizations and emergency-room visits. HMOs encourage patients to take an active role in their healthcare by scheduling routine annual checkups, modifying risk factors, getting immunizations, and screening for diseases. HMOs have their own staff physicians. If patients would like to see a specialist, they need to get a referral from their primary care physician. A primary care physician is a “gatekeeper” who controls access to healthcare and costs. Some HMOs have an on-site pharmacy. An HMO has a formulary, which is a list of drugs that have been recommended for use by physicians and pharmacists. They may also have a tiered drug-pricing plan so that patients pay one price for a generic-name drug, a higher price for a “preferred” brand-name drug, and an even higher price for a “non-preferred” brand-name drug.
Preferred provider organization (PPO) plan—A preferred provider organization (PPO) is similar to an HMO in that it has a preferred provider network, but patients do not need to see a primary care physician for a referral to a specialist. PPOs generally offer financial incentives to use network providers.

Point-of-service (POS) plan—A point-of-service (POS) plan is a hybrid of an HMO and a PPO. It is called a point-of-service plan because each time a member seeks medical care, he or she must decide which option—HMO or PPO—to choose. This plan encourages the use of a primary care physician for referrals to specialists and offers financial incentives for using a primary care provider. It also allows the member to use out-of-network providers, but at a higher cost.

Role of a Pharmacist

The educational background, knowledge, and clinical skills that the contemporary pharmacist possesses make this individual a source of drug information for physicians, nurses, and patients. Pharmacists still compound and dispense prescription drugs to individual patients, but they also advise patients, physicians, and other healthcare professionals on the selection, dosages, interactions, and side effects of the medications. The specific role of a pharmacist will vary depending on the type of pharmacy. The pharmacist’s role may include the following:

- Obtaining a patient history, including a medical history, prescription and over-the-counter medication usage history, and allergy history
- Verifying dosage, strength, and formulation of the medication
- Counseling patients on the use of prescription and over-the-counter medications
- Monitoring and screening for drug interactions, duplications of therapy, response to therapy, and the safe usage of controlled substances
- Making recommendations and providing advice regarding usage of over-the-counter medications and devices
- Advising patients, physicians, and other healthcare professionals on the selection, dosages, interactions, side effects, and adverse reactions of the medications

The pharmacist possesses the education, knowledge, and clinical skills necessary to be a health and drug information expert.

Licensing Requirements for Today’s Pharmacist

A license to practice pharmacy is required in all 50 States and the District of Columbia, as well as in Guam, Puerto Rico, and the U.S. Virgin Islands. To obtain a license, a pharmacy student must obtain a Pharm.D. degree from a college of pharmacy that has been approved by the Accreditation Council for Pharmacy Education (ACPE). The pharmacist candidate must then pass the North American Pharma-
cist Licensure Exam (NAPLEX), which tests knowledge and pharmacy skills. Some states also require the Multistate Pharmacy Jurisprudence Exam (MPJE), which tests knowledge of pharmacy law. Both exams are administered by the National Association of Boards of Pharmacy (NABP). Some states and territories that do not require the MJPE have their own pharmacy law exam. All state boards of pharmacy also require a specified number of hours of training in a practice setting before a license is awarded. In most states, pharmacists must also meet continuing-education requirements to renew their licenses. State boards of pharmacies oversee licensing requirements.

A license to practice pharmacy is required in all 50 states.

To obtain a license to practice pharmacy, one must have a Pharm.D. degree, a passing grade on the NAPLEX, training, and in some states a passing grade on the MPJE.

The Role of a Pharmacy Technician

The primary role of a pharmacy technician, also called a pharmacy tech, is to receive and fill prescriptions. These prescriptions can come from hospitals, physicians, nurses, the patient, or the patient's caregiver. A pharmacy technician can assist in all daily activities that do not require the professional judgment of a pharmacist. The work of a pharmacy technician must be overseen by a licensed pharmacist. Many states limit the number of pharmacy technicians by specifying a ratio of technicians to pharmacists.

A pharmacy technician must work under the direct supervision of a licensed pharmacist. A pharmacy technician can assist in all activities that do not require the professional judgment of a pharmacist.

Without pharmacy technicians, pharmacists would not have enough time to perform the clinical tasks necessary to ensure the safe use of medications. Pharmacy technicians help reduce the risk of preventable and costly medication errors.

The duties of a pharmacy technician will vary depending on the pharmacy practice setting. In hospitals, nursing homes, and assisted-living facilities, technicians have added responsibilities, including preparing sterile solutions and delivering medications to nurses or physicians. Technicians may also record the information about the prescribed medication onto the patient's profile.

The duties of a pharmacy technician will vary depending on the work environment.

The scope of practice for a pharmacy technician is a list of responsibilities that a technician is legally qualified and approved to perform in the workplace. From a broad list of competencies included in the State Pharmacy Practice Act, each practice setting will specify those that are considered a technician's responsibilities. These responsibilities will be outlined in the departmental policy and procedure handbook and/or the technician's job description. It is the professional responsibility of each technician to know the scope of practice for his or her practice setting and abide by it in the performance of daily technician duties. Each technician must perform all responsibilities with the utmost professionalism and concern for care of the patient.
In pharmacy practice, there is a definite difference between the professional judgment of the pharmacist and that of a technician. The pharmacist has the knowledge to evaluate the medication regimen of a patient and assist in clinical decision-making to improve the health of the patient. The technician must obtain the knowledge to evaluate information on a written prescription, be alert for drug interactions and drug-disease contraindications with other prescriptions or over-the-counter medications, accurately fill prescriptions, and communicate effectively with the patient to ascertain when he or she may need pharmacist counseling. In a busy pharmacy, the technician often must be the eyes and ears of the pharmacist and use professional judgment to alert the pharmacist about situations that may require pharmacist intervention.

The ultimate responsibility for a pharmacy technician’s work rests with the supervising licensed pharmacist.

**Education and Licensing Requirements of a Pharmacy Technician**

Currently, there are no nationally standardized training requirements for pharmacy technicians. Some states require a high-school diploma or its equivalent. Other states require licensure or registration of pharmacy technicians with the state board of pharmacy. Still others require passing a certification exam. Several professional organizations offer a nationally recognized certification. The most common are the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA). Although most pharmacy technicians receive informal on-the-job training, programs have been developed to better train pharmacy technicians.

There are no nationally standardized training requirements for pharmacy technicians.

Formal technician training programs are available through a variety of organizations, including community colleges, vocational schools, hospitals, and the military. These programs range from six months to two years and include classroom and laboratory work. They cover a variety of subject areas, such as medical and pharmaceutical terminology, pharmaceutical calculations, pharmacy recordkeeping, pharmaceutical techniques, and pharmacy law and ethics. In addition, they are designed to prepare the student to pass a certification exam. Technicians also are required to learn the names, actions, uses, and doses of the medications they work with. Many training programs include internships or externships, in which students gain hands-on experience in actual pharmacies.

After completion of a training program, students receive a diploma, a certificate, or an associate’s degree, depending on the curriculum. In many states, pharmacy technicians are required to keep their knowledge current by attending educational seminars necessary for continued certification. In some states, pharmacy technicians are also required to obtain a certain number of continuing-education credits to maintain such certification.
Depending on the area of practice, additional training and certifications may be required. To receive certification as a nuclear pharmacy technician, for example, students must complete an online self-study course and supervised instruction in addition to an internship under a nuclear pharmacist. Additional training may also be required by hospitals for pharmacy technicians who will perform sterile and non-sterile compounding.

**Hospital**

In addition to direct patient-care involvement, pharmacy technicians in hospitals are responsible for systems that control drug distribution. These systems are designed to ensure that each patient receives the appropriate medication, in the correct form and dosage, at the correct time. Hospital pharmacy technicians fill medications for stock on hospital units, fill orders for checking by the pharmacist, interpret medication orders, and, depending on state law, may enter them in the computer system pending a pharmacist’s verification. These specialty pharmacy technicians also work in the IV room making sterile preparations. In addition, they work closely with other hospital personnel, including nurses and nurse’s aides. They also fill medication carts, inventory medications, and compound various prescriptions. Hospital pharmacists maintain records on each patient, using them not only to fill medication orders but also to screen for drug allergies and adverse drug effects. The hospital pharmacist also prepares or supervises the distribution of a 24–72 hour supply of medication for each patient (unit dosage system). Pharmacists also advise the medical staff on the selection and side effects of drugs. They may make sterile solutions to be administered intravenously. They may counsel hospitalized patients on the use of drugs before the patients are discharged. In larger academic hospitals, pharmacists may accompany physicians on rounds. Hospital pharmacists may also be responsible for formulary development, managing drug product recalls, managing floor stock, dispensing investigational or hazardous drugs, and managing medication storage areas, drug delivery systems, and automated dispensing machines.

The hospital pharmacist ensures that each patient receives the right drug at the right time.

A pharmacy technician in the hospital setting, under the supervision of a licensed pharmacist, may also perform some of the aforementioned duties. In addition, they may also do the following:

- Package and label medications.
- Fill a 24–72-hour unit-dose cart.
- Maintain records and gather information for the pharmacist’s use.
- Check the work of another pharmacy technician in the preparation of medication carts.
- Prepare IV medications.
- Deliver medications.
- Stock medications in the pharmacy and satellite locations.
- Inspect nursing stations for expired medications.
Obtain laboratory results for pharmacists.
Fill drug boxes or trays for emergency use.
Operate manual or computerized robotic dispensing machines.

Retail
Pharmacists serve patients and the community by providing information and advice on health, providing medications and associated services, and by referring patients to other sources of help and care, such as physicians, when necessary. Pharmacists in retail pharmacies dispense medications, counsel patients on the use of prescription and over-the-counter medications, and advise physicians about medication therapy. Those who own or manage community pharmacies may sell non–health-related merchandise, hire and supervise personnel, and oversee the general operation of the pharmacy. Some retail pharmacists provide specialized services to help patients with conditions such as diabetes, asthma, smoking cessation, or high blood pressure. Some pharmacists are also trained to administer vaccinations.

In the retail setting, the duties that can be carried out by a technician (depending on state law) may include the following:

- Retrieving written prescription orders
- Accepting requests for prescription refills
- Retrieving medications from the shelf
- Verifying the information on the prescription for completeness
- Entering prescription orders into the computer
- Counting, pouring, weighing, and measuring medications
- Reconstituting medications
- Prepackaging bulk medications
- Filling and recording the prescription
- Selecting the appropriate prescription container
- Creating prescription labels
- Entering patient and prescription information
- Transferring prescriptions

Advances in the use of computers in pharmacy practice now allow pharmacists to spend more time educating patients and maintaining and monitoring patient records. As a result, patients have come to depend on the pharmacist as a healthcare and information resource. Pharmacists must be knowledgeable about the composition of drugs, their chemical and physical properties, and their manufacture.
and uses, as well as how products are tested for purity and strength. Additionally, a pharmacist needs to understand the activity of a drug and how it will work within the body. More and more prescribers rely on pharmacists for information about various drugs, their availability, and their activity, just as consumers do when they ask about nonprescription medications.

**Managed Care**

Pharmacists and technicians are employed in various capacities within managed-care organizations (MCOs). Managed care is a system designed to optimize patient care and outcomes and foster quality through greater coordination of medical services. MCOs strive to improve access to primary and preventive care, and ensure the most appropriate and effective use of medical services in the most cost-effective manner. Besides dispensing medications and making sure that patients receive the right therapy conveniently and cost effectively, pharmacists may be involved in monitoring drugs used in chronic diseases.

**Home Healthcare Pharmacies**

The pharmacist or technician who works in a home healthcare setting may prepare IV medications such as IV nutritionals, antibiotics, chemotherapy, and fluids for use at home. Pharmacists are also responsible for maintaining patient records, counseling patients and their caregivers, and monitoring the safe use of these medications at home.

**Long-Term–Care Pharmacies**

Long-term–care pharmacies employ consultant pharmacists to review the medication profiles of each resident monthly to assess the appropriateness and efficacy of drug therapies. They monitor the distribution and administration of medications and ensure that the medications administered have not expired. They also educate medical staff and family members regarding drug therapies. They may also provide medications to residents who are planning a leave from the facility. These pharmacies also prepare unit-dose packaging and specialized dispensing systems, which are patient-specific medication packages that are easy to administer. They also design their dispensing systems with multiple checkpoints to prevent potentially adverse drug interactions or patient reactions, and maintain customized medication-administration records for their client facilities.

In addition to the duties performed by a technician in a hospital or retail setting, a pharmacy technician working in a long-
term–care facility, under the supervision of a licensed pharmacist, may also perform the following tasks:

- Fill and maintain drug boxes or emergency kits.
- Deliver medications to a nursing home.
- Prepare unit doses of medications.
- Conduct inspections in nursing homes to remove expired or recalled medications.

**Nuclear Pharmacies**

Nuclear pharmacy is a specialized area of pharmacy practice. A pharmacist practicing in a nuclear pharmacy specializes in the procurement, compounding, quality assurance, dispensing, packaging, distribution, and development of radiopharmaceuticals. In addition, the nuclear pharmacist monitors patient outcomes and provides information and consultation regarding health and safety issues.

**Other Duties**

In addition to the duties mentioned thus far, a pharmacy technician's role in various pharmacy practice settings may also involve the following:

- Preparing insurance claim forms
- Maintaining medication profiles
- Answering phones
- Stocking shelves and maintaining inventory
- Ordering medications
- Cleaning equipment
- Pricing prescriptions
- Operating the pharmacy cash register

**Pharmacy Laws, Regulations, Professional Standards, and Ethics**

Pharmacy is a highly regulated profession. A complex set of laws, regulations, and standards have been put in place to ensure public safety and the safe dispensing of medications. An understanding of these laws is necessary for pharmacists to pass the North American Pharmacist Licensure Exam (NAPLEX) and for pharmacy technicians to pass a certification examination, and more importantly to know the responsibilities of a pharmacist and pharmacy technician when working in a pharmacy.

Pharmacy laws, regulations, and standards have been designed to ensure public safety.

**Laws**

A **law** is a rule that represents the minimum level of acceptable standards. Laws are passed and enforced to protect the public. Laws are developed from a multitude of sources. In the United States, laws can be divided into four categories:

- Constitutional law—Constitutional law is derived from the Constitution and the Bill of Rights.
Legislative law—Legislative law is drawn from the U.S. Congress and state legislatures.

Administrative law—Administrative law is derived from the president or state governor.

Common law—Common law is drawn from the judicial branch of the government.

All these together govern the practice of pharmacy. Violations in laws may result in fines, probation, disciplinary action, suspension or loss of licensure, and even incarceration.

Violation of a law may result in a fine, probation, disciplinary action, or incarceration.

Regulations

A regulation is a written rule or established guideline that exists to carry out a federal or state law. Regulatory bodies assist in the administration and enforcement of laws. For example, each state has its own board of pharmacy. These boards establish state-specific regulations for practicing pharmacy that must be followed within that state. They are also responsible for the licensing and/or certification of pharmacy personnel. The board is also responsible for disciplinary action against personnel who work in pharmacies.

The National Association of the Boards of Pharmacy (NABP) assists the boards of pharmacy in each state by implementing standards that reduce the likelihood of mistakes. The Drug Enforcement Administration (DEA) is a federal regulatory body that, in addition to its many other functions, has published regulations for enforcing the acquisition, storage, dispensing, and documentation of controlled substances. The DEA works with local and state agencies to ensure compliance of these regulations. The Food and Drug Administration (FDA) was established to protect public health by regulating the safety and efficacy of food, dietary supplements, drugs, medical devices, and biologics. It is also the governing body responsible for ensuring that only safe and effective drugs reach the consumer. The FDA also has regulations for generic drug substitution and patient counseling, and a system called MedWatch for reporting adverse events or product problems.

MedWatch is a system utilized by the FDA to receive information about adverse events or product problems.

Professional Standards

A professional standard is a code of conduct or practice that professionals in a discipline would follow or carry out in a given circumstance. It can measure the quality of a product or the performance of a professional, comparing it against the norm. The Joint Commission is an agency that accredits and certifies healthcare organizations. It maintains higher standards for accreditation and works to improve the safety and quality of healthcare.

Ethics

Ethics are a system of moral standards of conduct and behavior for a person, group, or a profession. Ethics are the basis for reflection and analysis when a course of action is unclear. Codes of ethics regarding professional behavior provide language to aid in the decision-making process. Professional employees are held to high standards of
conduct. Paraprofessionals such as pharmacy technicians are also held to high standards of conduct. The American Association of Pharmacy Technicians (AAPT) has a code of ethics that guides technicians in their associations with patients and other healthcare professionals.

### History of United States Federal Pharmacy Law

Federal laws set the standards for the practice of pharmacy. These laws were established to protect the public from the unregulated manufacturing, distribution, and dispensing of unsafe drugs.

**Pure Food and Drug Act (1906)**

The Pure Food and Drug Act was the first federal law regulating drugs. It prevented the manufacture, sale, or distribution of inaccurately labeled food and drugs across state lines. It also required that labels not contain false information of a drug's strength and purity.

**Food, Drug, and Cosmetic Act (1938)**

The Federal Food, Drug, and Cosmetic Act (FD&C) was passed after a legally marketed elixir containing antifreeze killed 107 patients. This act called for the creation of the Food and Drug Administration (FDA) and required all drug manufacturers to file a New Drug Application (NDA) to provide evidence of a drug's safety before any drug could be approved for the market. Manufacturers had to ensure the purity, safety, packaging, and strength of the medication. It also gave the FDA the authority to approve or deny NDAs and conduct inspections of manufacturing facilities to ensure compliance with regulations. Pharmaceutical manufacturers were also required to conduct animal studies and human clinical trials and submit the results of these studies before approval of a new drug would be granted.

This act also clarified and extended the definitions of adulterated and misbranded drugs and defined the United States Pharmacopeia (USP) and the National Formulary (NP) as official compendia.

The FD&C Act defined the USP and the NF as the official compendia.

**Durham-Humphrey Amendment (1951)**

This amendment to the Food, Drug, and Cosmetic Act established clear criteria for the classification of prescription or nonprescription over-the-counter medications. It prohibited the dispensing of legend “prescription” drugs without a prescription. Legend drugs are drugs that are not considered safe for use without medical supervision. Over-the-counter (OTC) drugs can be legally obtained without a prescription and are generally safe for use without medical supervision. Each prescription medication would be required to bear the legend “Caution: Federal Law Prohibits Dispensing Without a Prescription.” It also authorized the taking of verbal prescriptions and the refilling of prescriptions.

A legend drug cannot be dispensed without a prescription. Over-the-counter drugs can be obtained without a prescription.
Kefauver-Harris Amendment (1963)
This amendment required that all medications be pure, safe, and effective for use in humans. It also required all drug manufacturers to file an investigation new drug application (INDA) before starting a clinical trial in humans. After the drug has been proven safe and effective in clinical trials, the manufacturer can submit a new drug application to request approval for marketing. This amendment was enacted in response to the thalidomide tragedy, in which the use of thalidomide by pregnant women caused severe birth defects.

This act, also known as the Controlled Substances Act (CSA), required the pharmaceutical industry to keep records and implement security measures for certain medications. It was created to prevent and control drug abuse. This act divided controlled substances into five schedules, or classes, based on their potential for abuse (see Table 1.1). Schedule I drugs have the highest abuse potential, while Schedule V drugs have the least. A controlled substance is defined as a drug with a potential for abuse or addiction. This act set limits on the number of refills allowed for each schedule. Schedule II drugs are not allowed any refills. Schedule III–IV drugs are allowed five refills, and

<table>
<thead>
<tr>
<th>Schedule of Drug</th>
<th>Manufacturer’s Label</th>
<th>About These Drugs</th>
<th>Examples of Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>C-I</td>
<td>Drugs have no accepted medical use in the U.S.; highest abuse potential.</td>
<td>LSD, heroin</td>
</tr>
<tr>
<td>II</td>
<td>C-II</td>
<td>Drugs have an accepted medical use; high abuse potential, with severe psychological or physical dependence liability; no refill allowed.</td>
<td>Amphetamines, methadone, opium, codeine, morphine, oxycodone</td>
</tr>
<tr>
<td>III</td>
<td>C-III</td>
<td>Drugs have an accepted medical use; moderate abuse potential (less than those in Schedules I and II); five refills allowed.</td>
<td>Combination narcotics such as codeine/acetaminophen, hydrocodone/acetaminophen and anabolic steroids</td>
</tr>
<tr>
<td>IV</td>
<td>C-IV</td>
<td>Drugs have an accepted medical use; low abuse potential (less than those in Schedule III); five refills allowed.</td>
<td>Benzodiazepines, barbiturates</td>
</tr>
<tr>
<td>V</td>
<td>C-V</td>
<td>Drugs have an accepted medical use; lowest abuse potential (less than those in Schedule IV); some drugs may be dispensed OTC if over 18 years of age in some states.</td>
<td>Liquid cough preparations with codeine</td>
</tr>
</tbody>
</table>

Kilo K one thousand times Base unit \( \times 10^3 \)
the prescription is valid for six months after the date of issue. The Drug Enforcement Agency (DEA) regulates all matters relating to controlled substances.

The DEA is responsible for all regulations pertaining to the acquisition, storage, dispensing, and documentation of controlled substances.

The CSA placed legal limits on the number of refills allowed for controlled substances. Schedule II drugs are not refillable. Schedule III–IV drugs are allowed five refills and the prescription is valid for six months from the date of issue.

There are five schedules for controlled substances.

Poison Prevention Packaging Act (PPPA) (1970)
This act established standards for child-resistant packaging to prevent accidental childhood poisonings. It required that some OTC medications and almost all legend drugs be packaged in child-resistant containers. A child-resistant container cannot be opened by 80 percent of children younger than five years old, but can be opened by 90 percent of adults. A patient or prescriber can request that a drug be dispensed in a non–child-resistant container.

Common examples of medications that do not need to be dispensed in a child-resistant container include the following:

- Sublingual nitroglycerin tablets
- Inhalation aerosols
- Oral contraceptives (available in blister packs)
- Potassium supplements in unit-dosage form
- Some corticosteroid tablets

Drug Listing Act (1972)
This act assigns a unique drug code to each medication known as the National Drug Code (NDC). This code consists of 11 characters that identify the manufacturer, medication and dosage form, and size and type of packaging. The first five digits identify the manufacturer or distributor of the drug. The next four digits identify the product, strength, and dosage form of the medication. The last two digits identify the packaging size and type. This act also allows the FDA to compile a list of currently marketed drugs (see Chapter 2 for more information).

Each medication is assigned a unique code known as the National Drug Code.

Orphan Drug Act (1983)
This was enacted to stimulate the development of drugs for rare diseases. A rare disease is a disease that affects fewer than 200,000 people in the United States. Prior to this act, pharmaceutical companies had little incentive to invest money for the development of treatments for a small number of people because they were often not cost effective to develop and market. This law provides seven-year marketing exclusivity on the drug's patent, a tax credit of 50 percent of the cost of clinical trials in humans, and research grants for clinical testing of new therapies to treat orphan diseases. Many economists who focus on the pharmaceutical industry believe that these drugs will replace the “blockbuster” drugs of the 1990s in terms of drug manufacturer profits, as these medications are usually inordinately expensive.
The Orphan Drug Act deals with drugs used to treat rare diseases.

**Waxman-Hatch Act (1984)**

Also known as the Drug Price Competition and Patent-Term Restoration Act, this act ensured that brand-name drug manufacturers would have patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs, as well as provide an incentive for new drugs to reach the marketplace. The act ensured that when the patent protection and marketing exclusivity for these new drugs expired, however, consumers would benefit from the rapid availability of lower-priced generic versions of brand-name drugs. It also created a generic drug-approval process and established the abbreviated new drug application (ANDA) approval process, which permits generic versions of previously approved innovator drugs to be approved without submitting a full new drug application (NDA).

One drug can have several names, including a brand, generic, and chemical name. A **brand name** is a name given by the manufacturer. A **generic name** is the non-proprietary name. The **chemical name** describes a drug’s chemical composition and is the official name of a drug that describes the exact chemical formula of the drug. Generic drugs are equivalent to their brand-name counterparts in safety, efficacy, strength, dosage, route of administration, and intended use. A generic drug can be substituted for the brand-name drug if the drug is A/B rated by the FDA and the prescription does not state “dispense as written.” (See Chapter 2.)

A brand name is the name the drug manufacturer gives the drug. A generic drug is equivalent to the brand-name drug in safety and efficacy.

**Prescription Drug Marketing Act (PDMA) (1987)**

This act was designed to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. supply chain. It also states that prescription drugs manufactured in the United States and exported can no longer be reimported, except by the product’s manufacturer. Finally, it prohibits the sale or trading of drug samples to others than for whom they were intended or the distribution to persons other than licensed physicians.

**Anabolic Steroid Control Act (1990)**

Anabolic steroids are synthetic substances that promote human muscle growth and are often used illegally by athletes. Use of these medications have serious health consequences and can permanently damage the body when they are abused. Many of these drugs are manufactured illegally and sold on the black market. This act classified anabolic steroids as Schedule III controlled substances, increasing the penalty for the illegal distribution of these...
drugs. Prescriptions for Schedule III drugs can be refilled for up to six months or no more than five times, whichever comes first.

**Omnibus Budget Reconciliation Act (OBRA) (1990)**

This act requires that pharmacies that fill prescriptions for Medicaid obtain, record, and maintain basic patient information. It also says that each state must require its pharmacists to offer counseling on all aspects of drug therapy to patients, as well as perform a drug-utilization review (DUR). A drug-utilization review (DUR) is a review of a patient profile to ensure that medications dispensed to a patient in the past were correct. It also requires that the patient profile be reviewed prior to the filling of each prescription. Patients may refuse counseling; documentation of this refusal, either a patient signature or a notation in the computer, should be maintained.

**Health Insurance Portability and Accountability Act (HIPAA) (1996)**

This act was implemented to improve continuity and portability when transferring health-insurance coverage from one employer to another. It also sought to improve the effectiveness of Medicare and Medicaid by placing safeguards to protect patient confidentiality, including medical and prescription records. Privacy regulations established patients’ rights, including rights to access their records, disclosures, and communication of health information. It also set standards for protection of identity and health information and ensured privacy while transmitting claims. Pharmacy staff must acknowledge and agree to abide by HIPAA standards for each patient. This can be maintained electronically or in a records book. Pharmacists and pharmacy technicians must not reveal any information about a patient outside the pharmacy, except to other healthcare providers with a “need to know” to provide care.

> Pharmacists and pharmacy technicians must respect a patient’s right to privacy.

**Food and Drug Administration Modernization Act (1997)**

This act focused on reforming the regulation of food, medical products, and cosmetics. It modified the process for getting approval for clinical studies, testing subjects, and having new drugs approved for human use. It also changed the labeling requirements of all legend or prescription medication from “Caution: Federal Law Prohibits Dispensing Without a Prescription” to an “Rx only” symbol. It also required further testing of all products containing mercury in the United States. This law also authorized pharmacy manufacturers submitting new drug applications (NDAs) to provide additional resources to help the FDA speed up the approval process.

**Medicare Prescription Drug, Improvement, and Modernization Act (2003)**

This act gives all people who receive Medicare benefits the option for prescription-drug coverage under the Medicare Part D plan. Participation in this program is voluntary. In order to receive benefits, patients are required to enroll with a third-party vendor and pay an

![A group of prescription bottles containing pills with Rx on the labels.](image)
additional premium. The act was designed to help alleviate the pressures of medical costs. It also allowed for the reimbursement of medication management therapy services (MMTS) in those patients with certain health conditions or those on high-cost medications. MMTS provides a yearly review of a patient's profile to ensure that patients on expensive medications or with certain health conditions are not experiencing adverse reactions, drugs interactions, or paying high costs for unnecessary therapies.

This act also created health savings accounts (HSAs) as a health insurance option for patients under the age of 65. A health savings account is a medical savings account for those patients who have a high-deductible health plan (HDHP). Individuals pay high deductibles in return for lower negotiated medical expenses and tax-deductible premiums. Funds deposited into this account are not subject to federal tax and can be withdrawn for medical expenses. The funds that are not used in one calendar year can be rolled over to the next year without a penalty.

**Combat Methamphetamine Epidemic Act (2005)**

This was enacted to reduce the availability of drugs used to illegally produce methamphetamine and to stop the use of methamphetamine. It reclassified all products containing pseudoephedrine, phenylpropanolamine, and ephedrine, and set a limit on the quantity that can be purchased during a 30-day period (3.6g in one day, or 7.5g per 30 days). Both phenylpropanolamine and ephedrine have since been taken off the market, meaning that this act now pertains only to pseudoephedrine. It also requires that the product be placed behind the counter or in a locked cabinet not accessible to the consumer. The purchaser must provide identification, and the seller must maintain a written bound book or electronic log book of all pseudoephedrine sales.

### Regulatory Agencies

Regulatory agencies assist in the administration and enforcement of laws for the safe use of drugs. These agencies follow written rules or established guidelines to carry out federal or state laws.

**Food and Drug Administration (FDA)**

The Food and Drug Administration (FDA) is a federal agency that was established to protect public health by regulating the safety and efficacy of food, dietary supplements, drugs, medical devices, biologics, tobacco products, and cosmetics. It is responsible for ensuring that any drug or food approved for marketing is safe when used as directed. The FDA does not develop new therapies or conduct clinical trials to demonstrate safety and effectiveness. FDA members evaluate data and perform inspections of clinical-trial study sites to protect the rights of participants and verify the quality and integrity of the data. The FDA does not regulate the practice of pharmacy within each state.
state. The FDA is under the Department of Health and Human Services (HHS) and is divided into six product centers, one research center, and two offices.

The FDA requires that all manufacturers submit applications for investigational studies and approval for new drugs. A drug will not be approved for marketing by the FDA unless it has been deemed safe and effective for human use. The FDA also oversees all aspects of drug development and distribution, including packaging and marketing. A manufacturer may not make or advertise a false claim, and must fully disclose all side effects, adverse reactions, and contraindications.

The FDA also publishes a reference that identifies all drugs approved by the FDA and is used to make sure that generic drugs can be safely substituted for the brand-name product. The Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the FDA Orange Book, is published annually.

The FDA Orange Book contains information on which generic drugs can safely be substituted for the brand-name drug.

**Drug Enforcement Administration (DEA)**

The Drug Enforcement Administration (DEA) is a federal regulatory body that operates under the judicial branch of government. It is responsible for enforcing laws relating to the acquisition, storage, dispensing, and documentation of controlled substances. The DEA works closely with local and state agencies to ensure compliance of these regulations. The DEA inspects all medical facilities, including pharmacies, where suspicious or illegal activity has been detected, and monitors prescribers who prescribe controlled substances. The Controlled Substances Act requires that all institutions, pharmacies, or individuals involved in any activity relating to controlled substances be registered with the DEA. The DEA also issues a license to individual pharmacies so they can order scheduled drugs from wholesalers, and a license to physicians so they can write prescriptions for controlled substances.

**Occupational Safety and Health Administration (OSHA)**

The Occupational Safety and Health Administration is the main federal agency responsible for the enforcement of regulations relating to the safety and health of workers. It is under the Department of Labor. It provides training and education, and encourages continual improvement in workplace safety and health.

**National Association of the Boards of Pharmacy**

The National Association of the Boards of Pharmacy (NABP) is a professional pharmacy organization that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, eight Canadian provinces, and New Zealand. It assists its member boards of pharmacy by developing, implementing, and enforcing uniform standards that protect public health by reducing the likelihood of mistakes. Although it has no regulatory authority, it is responsible for developing a national pharmacist licensure examination (NAPLEX), which is administered by local state boards of pharmacy. It also coordinates the administrative process of licensure reciprocation of pharmacists practicing in different states. In addition to working with each state board of pharmacy to meet the needs of their state, they provide several accreditation programs. The Verified Internet Pharmacy Practice Sites (VIPPS) provide an ongoing evaluation of an Internet pharmacy’s practice. In order to be VIPPS-accredited, a pharmacy must comply with the licensing requirements of each state to which it dispenses medications.
Because many states have differing laws regarding the practice of pharmacy, the NABP developed the Model State Pharmacy Practice Act (MSPPA). It gives individual states a model on which to base their regulations and individualize them according to their state's needs.

State Boards of Pharmacy

Each state has its own board of pharmacy. These state boards of pharmacy establish state-specific regulations for practicing pharmacy that must be followed within that state. They are also responsible for the licensing and/or certification of pharmacy personnel, and for disciplinary action of personnel who work in a pharmacy. Each state board is also responsible for developing and administering a law exam necessary for licensure or reciprocity from another state.

The state board of pharmacy has the authority to seek disciplinary action against a pharmacist or pharmacy technician.

Each state board may also provide regulations on the filling and refilling of prescription medications and controlled substances. Typically, most nonscheduled prescriptions are refillable for one year from the date of issuance. Controlled substances that are Schedule III, IV, or V can be refilled a maximum of five times or six months from the date of issuance, whichever comes first. The board may also regulate the sale of over-the-counter medications.

Each state board may also have specific requirements for the ratio of pharmacy technicians to pharmacists in various practice settings. They also regulate the activities of a technician and may have minimum educational and training requirements necessary to practice as a pharmacy technician.

Licensing and professional oversight of pharmacists and pharmacy technicians is carried out by the state boards of pharmacy.

Violations of Laws

Violations of laws can occur at the local, state, or federal level, and the legal action taken as a result will depend upon the law that was violated. Civil law is a type of law that covers acts committed against individuals rather than against the local, state, or federal government, and suits are brought about by private citizens. Occasionally, the crimes committed may involve a violation of a state or federal law, in which case the responsible party can be prosecuted.

Torts

A tort is defined as causing personal injury intentionally or because of negligence. It is a civil case that one citizen brings against another. In a tort, the injured party sues the party they believe caused the injury. In a tort action, the person or party filing the case (plaintiff) must establish that the party being sued (defendant) was under a legal duty to act in a particular way. They must also demonstrate that the party being sued failed to act accordingly. Third, they must prove that the filing party, the plaintiff, suffered an injury or loss as a direct result of the party being sued. The law of torts seeks to compensate victims for injuries suffered by action or inaction of others. It also seeks to shift the cost of such injuries to the person or persons who are legally
responsible for inflicting them. Third, it seeks to discourage injurious, careless, and risky behavior in the future.

Examples of torts include the following:

- **Broken contracts**—Broken contracts are the simplest form of torts. A broken contract is a broken promise to do or not do an act.
- **Negligence**—Negligence is conduct that falls below the standards of behavior established by law.
- **Slander**—Slander is verbal communication of false statements against another individual.
- **Libel**—Libel is written communication of false statements against another individual.
- **Malpractice**—Malpractice is negligence in meeting the standard of care.
- **Assault**—Assault is an unlawful threat to do bodily harm.
- **Battery**—Battery is causing physical harm to another person.

The most common tort against healthcare practitioners is negligence. Negligence is when a person unintentionally performs or fails to perform an act that a reasonable person would or would not have done in a similar situation. To prove negligence, you must prove that a person's conduct falls below the normal standard of care established by law. **Standard of care** is the level of performance that is expected of a healthcare worker in carrying out his or her professional duties. The standard of care takes into account the educational background and training of the healthcare provider, the normal practices within the geographic area of the healthcare provider's workplace, and compliance of local, state, and federal laws and regulations.

**A pharmacist can be sued for negligence if he or she fails to meet a minimum standard of care.**

In the case of a negligence or malpractice suit, the prosecutor or plaintiff must provide evidence that the party committed the four Ds of negligence: duty, derelict, direct cause, and damages. The plaintiff must prove that the defendant had a duty and that the provider of care breached this duty, resulting directly in injury to the patient. The plaintiff must prove his or her case by what is termed “preponderance of the evidence.” Preponderance of the evidence is the level of proof that must be shown in a civil case to sway the judge or jury one way or another in a lawsuit.

**Law and Professional Standards**

Laws and regulations from local, state, and federal agencies govern the practice of pharmacy. In addition to these laws, national standards for drugs and professional guidelines for behavior and performance have been established by professional organizations.

**United States Pharmacopeia**

United States Pharmacopeia (USP) is a non-governmental, independent scientific organization that sets standards for all over-the-counter and prescription medications and other healthcare products manufactured or sold in the United States. USP sets scientifically developed standards that help ensure the identity, quality, purity, strength, and consistency of medicines. The mission of the USP is to set standards and create programs that improve the health of people around the world by ensuring quality,
safety, and benefits of food. The USP also publishes an unbiased reference, the USP-NF that contains standards for specific drugs and ingredients, dosage forms, medical devices, and dietary supplements. Pharmaceutical manufacturers must comply with these standards for their drugs to be approved by the FDA. The USP-NF also includes other standards designed for pharmacists covering key topics such as maintaining a physical environment in their pharmacies that promotes safe medication use, quality assurance in compounding, and sterile compounding practices.

**Professional Organizations**

Many national professional pharmacy organizations have set standards that are higher than the established guidelines for practice. Some examples of professional organizations include the following:

- The American Pharmacists Association (APhA)
- The American Society of Health-System Pharmacists (ASHP)
- The American Society of Consultant Pharmacists (ASCP)

The mission of each of these organizations varies, but all provide for a standard of care that is above those required by federal and state laws.

Professional organizations also exist for pharmacy technicians. The National Pharmacy Technician Association (NPTA) (http://www.pharmacytechnician.org/) is an organization created to meet the needs of all pharmacy technicians working in various practice settings. Another organization, The American Association of Pharmacy Technicians (AAPT) (http://www.pharmacytechnician.com), promotes the safe, efficacious, and cost-effective dispensing, distribution, and use of medications. It also provides continuing-education programs and services to help technicians update and maintain their skills.

The Pharmacy Technician Certification Board (PTCB) is one organization that develops, maintains, and administers certification and recertification programs for pharmacy technicians. Five organizations (the American Pharmacists Association, the American Society of Health-System Pharmacists, the Illinois Council of Health-System Pharmacists, the Michigan Pharmacists Association, and the National Association Boards of Pharmacy) joined in 1995 to oversee the PTCB and to maintain a national certification program. The PTCB develops standards and acts as the credentialing board. Pharmacy technicians must be recertified every two years.

**PTCB is a national organization that develops standards for pharmacy technicians.**
The history of pharmacy can be traced back thousands of years to early civilization, when medicinal remedies were largely controlled by religious leaders who frequently combined drug preparations with prayers, chants, rituals, and “magic.”

Today's pharmacist has a broader scope of practice. A pharmacist not only compounds and dispenses medication, but is also responsible for ensuring positive outcomes for drug therapy.

Pharmacists are highly educated and trained professionals who can practice in a variety of settings.

Pharmacists serve as resources for patients and healthcare professionals on all matters relating to drug therapy.

The pharmacy technician is a paraprofessional who can assist in all daily activities that do not require the professional judgment of a pharmacist. The work of a pharmacy technician must be overseen by a licensed pharmacist.

Pharmacy is a heavily regulated profession. Laws, regulations, and standards have been put in place to ensure public safety and the safe dispensing of medications.

Statutory federal drug laws and amendments have shaped the practice of pharmacy by ensuring the safety and efficacy of drugs brought to the market.

State boards of pharmacy have regulations to license pharmacists and technicians. They also have the authority to take disciplinary action for violations against their laws and regulations.

The most common tort against healthcare practitioners is negligence.

Standards for the practice of pharmacy are set by professional organizations, regulatory bodies, and state boards of pharmacy.

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Learning Assessment Questions

1. The prescription label of a legend drug container will usually have two names on it: the generic and the trade or brand name. What is the trade or brand name?
   A. The chemical name of the drug
   B. The proprietary name of the drug given by the manufacturer
   C. The abbreviated generic name of the drug
   D. The common name

2. A technician takes a phone call from a patient who wants to know what the side effects are for her new medication. What should the technician do?
   A. Tell the patient what the side effects are.
   B. Tell the patient to hold on while he or she looks up the answer in a reference book.
   C. Put the patient on hold and notify the pharmacist.
   D. Tell the patient to stop taking her medication.

3. What do the last two digits in the NDC number identify?
   A. Product
   B. Strength
   C. Package size
   D. Formulation

4. The practice of pharmacy is regulated by federal and state law. Which of the following federal laws mandates the use of safety caps?
   A. OSHA
   B. HIPAA
   C. PPPA
   D. CSA

5. The Omnibus Budget Reconciliation Act (OBRA) required pharmacists to do which of the following?
   A. Use pharmacy technicians.
   B. Counsel patients.
   C. Limit the use of controlled substances.
   D. Bill third-party payers.
6. To what did the Health Insurance Portability and Accountability Act establish a patient's right?
   A. Protection of identity and health information
   B. Mortality
   C. Free health insurance
   D. Free prescription medications

7. A patient would like information concerning a good pain reliever that is available over the counter. What should you do?
   A. Show the patient where the pain relievers are in the pharmacy.
   B. Recommend a pain reliever.
   C. Inform the patient that he or she should speak with the pharmacist.
   D. Recommend several options and let the patient choose.

8. What is the system utilized by the FDA to receive information about adverse events or product problems?
   A. OSHA
   B. MedWatch
   C. Product recall
   D. DEA

9. Which act reclassified all products containing pseudoephedrine, and set a limit on the quantity that can be purchased during a 30-day period?
   A. DEA
   B. FD&C
   C. Food and Drug Administration Modernization Act
   D. Combat Methamphetamine Epidemic Act

10. According to CSA, a Schedule II drug is allowed how many refills?
    A. One refill
    B. Five refills, as long as they are within six months from the date of issue
    C. No refills are allowed
    D. eleven refills in one year

11. Questions involving controlled substances should be directed to which regulatory agency?
    A. The FDA
    B. The state board of pharmacy
    C. The DEA
    D. The National Association of the Boards of Pharmacy

12. Which regulatory agency is responsible for the licensure or registration of pharmacy personnel?
    A. The state board of pharmacy
    B. The FDA
    C. OSHA
    D. The National Association of Boards of Pharmacy

13. The Orphan Drug Act deals with drugs that are __________.
    A. Expired
    B. Controlled substances
    C. Used to treat rare diseases
    D. No longer marketed

14. Another name for a retail pharmacy is a __________.
    A. Hospital pharmacy
    B. Long-term–care facility
    C. Community pharmacy
    D. Nuclear pharmacy

15. A pharmacy technician can do all of the following except __________.
    A. Counsel patients
    B. Aid the pharmacist in filling prescriptions
    C. Maintain computerized patient records
    D. Maintain drug boxes or trays for emergencies

16. Which amendment established clear criteria for the classification of prescription and non-prescription over-the-counter medications?
    A. FD&C
    B. The Durham-Humphrey Amendment
    C. The Kefauver-Harris Amendment
    D. Food and Drug Administration Modernization Act
17. If a pharmacist fails to meet the minimum standard of care, he or she may be sued for _________.
   A. Slander
   B. Negligence
   C. Malpractice
   D. Libel

18. Which source would you use to determine whether a generic drug is interchangeable with a brand name drug?
   A. USP-NF
   B. The FDA Orange Book
   C. Martindale's Pharmacopeia
   D. USP

19. Which agency is responsible for ensuring the safety and efficacy of all marketed drugs?
   A. DEA
   B. FDA
   C. OSHA
   D. Joint Commission

20. The Comprehensive Drug Abuse Prevention and Control Act of 1970 designated how many schedules of controlled substances?
   A. Four
   B. Five
   C. None
   D. Six