Chapter 2

Pharmacy Law

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Learning Outcomes

After completing this chapter, you will be able to

- Understand how the practice of pharmacy is regulated by federal and state laws and regulations and the role of state boards of pharmacy.
- Discuss state pharmacy laws and regulations that govern pharmacy technicians, including permitted functions and the requirements for pharmacy technician registration or licensure.
- Discuss the laws that regulate controlled substances, special requirements for pharmacy ordering and dispensing controlled substances, and the role of state prescription monitoring programs.
- Describe the restrictions on the sales of products containing pseudoephedrine and ephedrine.
- Describe the FDA approval process for drugs and the differences between brand name and generic drugs.
- Discuss generic drug substitution and the means for prescribers to indicate if substitution is not authorized.
- Discuss the difference between prescription drug inserts for prescribers and for patients.
- Discuss patient privacy in the pharmacy and the federal law that governs privacy of protected health information.

Key Terms

biennial inventory DEA-registered pharmacies are required by law to take an initial inventory of all controlled substances on hand upon commencing operations or upon change in ownership, with subsequent inventories conducted every two years thereafter.

child-resistant packaging Child-resistant packaging is special packaging used for hazardous products such as prescription and over-the-counter drugs and household products to reduce the risk of children ingesting dangerous items by adding caps that children will have difficulty opening. Child-resistant packaging must pass federal tests to assure that it meets the federal requirements.

controlled substances Drugs or chemical substances whose possession and use are regulated under the Federal Controlled Substances Act and by state controlled substance laws and regulations. Controlled substances are subject to stricter controls than other prescription and nonprescription drugs.

Drug Enforcement Administration (DEA) The federal agency that administers and enforces federal laws for controlled substances such as narcotics and other dangerous drugs and illegal substances. The DEA is part of the U.S. Department of Justice.

initial inventory The inventory a pharmacy takes of its stock of controlled substances upon beginning the dispensing or distribution of controlled substances.

legend drug A drug that is required by federal law to be dispensed by prescription only. It is the older term for drugs that are now identified as "Rx Only."

practice of pharmacy The practice of pharmacy is regulated by each state through its pharmacy laws and regulations. The state laws and regulations establish the scope of the practice of pharmacy in the particular state, meaning the responsibilities that pharmacists are permitted to perform in the state.

prescription monitoring programs State prescription drug monitoring programs are programs implemented by the states pursuant to state laws and regulations to collect, review, and analyze information received from pharmacies about controlled substance prescriptions dispensed in the state. The programs provide information that may be reviewed by state law enforcement and regulatory agencies to assist in identifying and investigating potential improper prescribing, dispensing, and use of prescription drugs.

regulations (or rules) Regulations (or rules) are issued by an administrative or governmental agency that establish the requirements that must be followed by the regulated persons or entities. For example, a state board of pharmacy issues regulations for pharmacy technicians to establish the qualifications that pharmacy technicians must meet in order to work as a pharmacy technician in a state.

The practice of pharmacy is extensively regulated by a number of laws and regulations. These laws and regulations cover essentially all aspects of pharmacy practice and establish permitted and prohibited conduct for pharmacies, pharmacists, and pharmacy technicians. States require pharmacies and pharmacists to be licensed. Many states have laws or regulations that require pharmacy technicians to be licensed or registered and meet other requirements, such as specific training and education, certification, and criminal history background checks. Pharmacy practice is also covered by ethical principles to provide a fundamental framework for interacting with patients. Examples of ethical principles are acting with honesty, integrity, compassion, and respect for patients.

Although states have the primary authority to regulate pharmacy practice, pharmacy is also subject to a number of federal laws. Examples of federal laws include the Food, Drug, and Cosmetics Act (FDCA) that regulates the safety of food, drugs, and cosmetics and the Controlled Substances Act that establishes requirements for the handling and dispensing of narcotics and other controlled substances. Another example is the Omnibus Budget Reconciliation Act of 1990 (commonly called "OBRA '90") that requires pharmacists to provide patient counseling as a condition of reimbursement when dispensing prescriptions to Medicaid patients. Table 2–1 provides a timeline of some of these and other important federal drug laws.

If state and federal laws or regulations differ, both must be followed, including the more stringent requirements, whether federal or state. For example, if a federal law has specific requirements for dispensing controlled substances, and a state pharmacy law has stricter requirements, the state law must be followed in addition to the federal requirements.

✔If the state and federal laws or regulations differ, both laws and regulations must be followed, including the more stringent requirements, whether federal or state.

Ethical Principles

Ethical principles exist in many areas of life. In health care, including pharmacy, they guide the performance of tasks and responsibilities so they fall within an ethical and moral framework. Pharmacy technicians' interactions with patients and other health care professionals should conform to societal values. In simple terms, this equates to "doing the right thing," such as being considerate of patients. Ethical principles include complying with laws and regulations, maintaining competency, and respecting patient privacy and confidentiality. Pharmacy technicians have their own set of ethical principles. The American Association of Pharmacy Technicians (AAPT) has developed a Code of Ethics for Pharmacy Technicians (See box 1–1 in Chapter 1 Introduction to Pharmacy).

State Pharmacy Laws and Regulations

State pharmacy laws and **regulations** set the requirements for pharmacies, pharmacists, pharmacy technicians, and the **practice of pharmacy**. Both laws and regulations are necessary to regulate the practice of pharmacy, including

Table 2–1. A History of the FDA and Drug Regulation in the United States

Year	Act	Purpose
1906	Food and Drug Act	Outlaws states from buying and selling food, drinks, and drugs that have been mislabeled and tainted
1912	Sherley Amendment	Outlaws labeling drugs with fake medical claims meant to trick the buyer
1930	FDA	Food and Drug Administration is named
1938	Federal Food, Drug, and Cosmetic (FDC) Act of 1938	Requires new drugs to be proven safe prior to marketing; starts a new system of drug regulation; requires safe limits for unavoidable poisonous substances; and allows for factory inspections
1951	Durham-Humphrey Amendment	Defines the type of drugs that cannot be used safely without medical supervision and limits the sale to prescription only by medical professionals
1962	Kefauver-Harris Drug Amendments	Requires manufacturers to prove that their drugs are effective prior to marketing
1972	Over-the-Counter Drug Review	Nonprescription medications must be safe, effective, and appropriately labeled
1982	Tamper-Resistant Packaging Regulations	Makes it a crime to tamper with packaged products and requires tamper-proof packaging
1984	Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)	Allowed FDA to approve generic versions of brand-name drugs without repeating research to prove safety and efficacy; allowed brand-name drugs to apply for up to 5 years of additional patent protection for new drugs to make up for time lost while their products were going through the FDA approval process
1988	Prescription Drug Marketing Act	Designed to eliminate diversion of products from legitimate channels of distribution and requires wholesalers to be licensed
1997	Food and Drug Administration Modernization Act	Expands scope of agency activities and moves agency to the Department of Health and Human Services (DHHS)
2003	Medicare Prescription Drug Improvement and Modernization Act of 2003	Includes Medicare Part D which increases access to medications through private insurers

Adapted from U.S. Food and Drug Administration, Center for Drug Evaluation and Research.

pharmacy technicians. State pharmacy laws establish the legal requirements, restrictions, and prohibitions for the practice of pharmacy. State laws are enacted by state legislatures through the legislative process; however, because laws are usually more general, regulations or rules are needed to provide the details to implement the law. While laws are enacted through the state legislative process, regulations or rules are issued and adopted by state regulatory agencies through the regulatory or rule-making process. For pharmacy practice, the pharmacy laws are enacted by the state legislature and regulations are usually adopted through the state board of pharmacy.

Because each state enacts legislation and adopts regulations for pharmacy, the particular requirements may vary from state to state. For example, the requirements for pharmacy technicians vary by state. Nonetheless, an important and universal distinction for pharmacy technicians to understand is that they work under the supervision and direction of pharmacists and may perform only the tasks permitted under state law.

State pharmacy laws and regulations distinguish between the tasks and responsibilities that pharmacists perform and those that pharmacy technicians are permitted to perform. State pharmacy laws do not permit pharmacy technicians to perform pharmacy tasks and responsibilities that are limited to pharmacists and require the professional judgment, education, and training of a pharmacist.

✔State pharmacy laws do not permit pharmacy technicians to perform pharmacy tasks and responsibilities that are limited to pharmacists and require the professional judgment, education, and training of a pharmacist.

State Boards of Pharmacy

State boards of pharmacy are responsible for regulating the practice of pharmacy including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The state boards of pharmacy have regulatory authority over a number of areas, such as licensing pharmacies and pharmacists; registering or licensing pharmacy technicians; inspecting pharmacies; issuing rules and regulations; investigating complaints; and disciplinary actions against pharmacies, pharmacists, and pharmacy technicians for violations of pharmacy laws and regulations. Information on the various state boards of pharmacy is available through the National Association of Boards of Pharmacy (NABP) Web site at www.nabp.net.

Pharmacy Licensure

Every state requires pharmacies to have a valid current pharmacy license or permit in order to operate the pharmacy. State pharmacy laws and regulations set the requirements for pharmacy licensure. Pharmacies must satisfy many requirements which include record keeping requirements, security, a pharmacist-in-charge, and a licensed pharmacist on duty while the pharmacy is open. State requirements vary as to whether the pharmacy technicians may or may not remain in the pharmacy during a pharmacist's break period. State boards of pharmacy conduct pharmacy inspections to verify that the pharmacy meets the licensure requirements and also perform periodic pharmacy inspections at other times.

Many states have more than one category of pharmacy license. The different licensure categories that states may identify include retail, community, institutional, hospital, nuclear, mail-order, and long-term care. Some states also use categories for special or limited-use pharmacies and sterile-compounding pharmacies. Another category used by states is for nonresident pharmacies. Most states require pharmacies that are located in another state (i.e., nonresident pharmacies) to be licensed in the state if they mail, ship, dispense, or deliver prescription drugs to residents of the state.

Pharmacy Technicians

Many states have enacted laws and adopted regulations establishing requirements that pharmacy technicians must meet to be able to assist pharmacists. However, the requirements for pharmacy technicians vary from state to state. The state board of pharmacy in each state is the best resource for obtaining the current requirements. Nonetheless, although they are variable, there are several common requirements. These include a requirement for pharmacy technician registration or licensure (and the accompanying qualifications), permitted tasks, and prohibited conduct. Some states require criminal background checks. Regardless of whether licensure or registration is required, these requirements allow states to assure that pharmacy technicians meet certain requirements, to regulate the tasks that pharmacy technicians may perform, and to allow for disciplinary actions against pharmacy technicians for violations of state pharmacy laws and regulations including loss of licensure or registration if appropriate. The qualifications for pharmacy technician registration or licensure generally include a minimum age, high school graduation or the equivalent, completion of a training program including pharmacy employer training programs, and an examination. Some states allow pharmacy technician certification to satisfy the education or training requirements (see Chapter 1 Introduction to Pharmacy for more information on licensure, registration, and certification).

✔The qualifications for pharmacy technician registration or licensure generally include a minimum age, high school graduation or the equivalent, completion of a training program, including pharmacy employer training programs, and an examination.

Many states have established laws and regulations that set a limit on the number of pharmacy technicians who may assist a pharmacist at one time. Other states have no limits on the number of pharmacy technicians who may assist a pharmacist. These limits are known as pharmacy technician ratios. If the ratio is three to one (3:1), one pharmacist may supervise up to three pharmacy technicians at one time. Some states allow a higher pharmacy technician ratio if one or more of the pharmacy technicians meets additional requirements, such as passing a pharmacy technician certification exam. In a few states, all pharmacy technicians are or will eventually be

required to be certified by passing a certification examination in addition to meeting the other training and education requirements.

Patient Counseling

State pharmacy laws and regulations set the requirements for patient counseling by pharmacists regarding their prescription medications. Pharmacist counseling involves the pharmacist discussing the patient's medication treatment with the patient or the patient's caregiver. Counseling includes providing the patient with information about his or her medications such as what they are for, when and how much to take, whether to take with food, how to store the medication, and possible side effects. Patient counseling is very important to ensure that patients take their medications correctly.

Nearly every state requires pharmacists to *offer to counsel* patients on new prescriptions. The offer to counsel differs from patient counseling. The offer to counsel occurs when the patient is asked if he or she would like to receive information from the pharmacist about their prescription medication, whereas counseling is providing information to the patient. States vary on whether an offer to counsel is required on refill prescriptions.

An important point for pharmacy technicians is that patient counseling must be provided by the pharmacist. Pharmacy technicians are *not* authorized to counsel patients on their medications. Nevertheless, pharmacy technicians may assist the pharmacist with language translation if they are fluent in the patient's language and such services are needed during the patient counseling process. In some states, pharmacy technicians are permitted to ask patients if they want to receive counseling from the pharmacist (the "offer to counsel"). Many states permit pharmacy interns to provide patient counseling under the supervision of a pharmacist.

✔Patient counseling must be provided by the pharmacist. Pharmacy technicians are not authorized to counsel patients on their medications.

Controlled Substances

Controlled substances are subject to stricter controls through federal and state laws and regulations than other drugs because of their potential for misuse, abuse, diversion, and addiction. Pharmacies, pharmacists, pharmacy technicians, as well as drug manufacturers, drug distributors, physicians, and other health care providers must comply with these additional requirements to avoid penalties and maintain their authorization to handle controlled substances.

The federal law regulating controlled substances is the Controlled Substances Act. The law and its regulations establish comprehensive requirements and controls over the manufacture, import, export, distribution, ordering, dispensing, and prescribing of controlled substances. The definition of controlled substances in the federal law includes drugs and other substances and their immediate precursor chemicals. A precursor is a substance that may be turned into a controlled substance through a chemical reaction.

The federal Controlled Substances Act regulates the distribution and handling of controlled substances including manufacturing, distribution, dispensing, storage and recordkeeping, and other actions involved with the distribution of controlled substances. The federal law includes a number of requirements. Pharmacies, prescribers, wholesale distributors, drug manufacturers, and others must be registered with the **Drug Enforcement Administration (DEA)**. Once registered, a DEA number is assigned. For a physician, the number starts with either the letter A or the letter B followed by the first letter of the physician's last name. An example of the format of a DEA number is AS1234567. On occasion, the pharmacist may instruct the pharmacy technician on how to verify whether the prescriber's DEA number is valid. Some of the requirements for pharmacies include special order forms for ordering Schedule II controlled substances, called DEA Form 222 (see Chapter 19 Purchasing and Inventory). Pharmacists must complete a DEA Form 222 and it must be signed by the pharmacy's authorized pharmacist. Other pharmacy requirements for controlled substances include reporting significant losses, records of dispensing controlled substances, and inventory records. These strict controls for controlled substances guard against abuse, misuse, and diversion of controlled substances throughout their distribution.

States' controlled substance laws and regulations may have stricter controls than federal laws. Pharmacies must comply with both state and federal controlled substance laws. If the state-controlled substance law or regulation has stricter requirements, pharmacies along with

others handling controlled substances must comply with the stricter requirements.

✔If a state controlled substance law or regulation has stricter requirements, pharmacies along with others handling controlled substances must comply with the stricter requirements.

Pharmacies are required to keep complete, accurate, and up-to-date records for controlled substances that they purchase, receive, distribute, dispense, or discard. Schedule II records must be kept separately from CIII, IV, and V records. Pharmacies are required to immediately report any theft or significant loss of controlled substances to the DEA using DEA Form 106, "Report of Theft or Loss of Controlled Substances."

Schedules of Controlled Substances

The federal controlled substances law created five schedules (i.e., classifications) for controlled substances numbered I, II, III, IV, and V. A drug is placed into a controlled substance schedule based on certain criteria, such as its potential for abuse or addiction and its medical use. The schedule a drug or substance is placed in determines its level of control. Schedule I is the most restrictive schedule and Schedule V is the least restrictive schedule of controlled substances (table 2–2). Because they have no legally approved medical uses, Schedule I drugs are not available in the pharmacy. Federal regulations allow certain controlled substances to be dispensed *by a pharmacist* without a prescription if specific requirements are met. These requirements include: the substance is not a prescription drug, a pharmacist must approve the sale, the purchaser is at least eighteen years of age, and the pharmacy maintains a record book with information on the sale. The record book should include the purchaser's name and address, the name and quantity of the product purchased, the date of purchase, and the name or initials of the dispensing pharmacist. An example of a controlled substance that may be dispensed by a pharmacist in some states is a Schedule V over-the-counter cough syrup containing a limited amount of codeine. Some states; however, have stricter controlled substances laws and require that all controlled substances be dispensed by prescription only.

Table 2–2. Schedules for Controlled Substances

Schedule	Classification characteristics	Examples of controlled substances
Schedule I (CI)	No accepted medical use High potential for abuse Not available by prescription	Heroin and marijuana
Schedule II (CII)	High potential for abuse or misuse High risk of dependence FDA-approved medical uses	Meperidine (Demerol), methadone, morphine, oxycodone (OxyIR, OxyContin), methylphenidate (Ritalin)
Schedule III (CIII)	Moderate potential for abuse, misuse, and dependence	Includes drug products that contain small quantities of controlled substances combined with other noncontrolled drugs such as acetaminophen and codeine (Tylenol #3) and acetaminophen with hydrocodone (Vicodin)
Schedule IV (CIV)	Low potential for abuse and limited risk of dependence	Diazepam (Valium), lorazepam (Ativan), phenobarbital, and other sedatives and hypnotics
Schedule V (CV)	Lower potential for abuse, misuse, or dependence	Cough medications that contain a limited amount of codeine, anti-diarrheal medications containing a limited amount of an opiate, such as diphenoxylate/atropine (Lomotil)

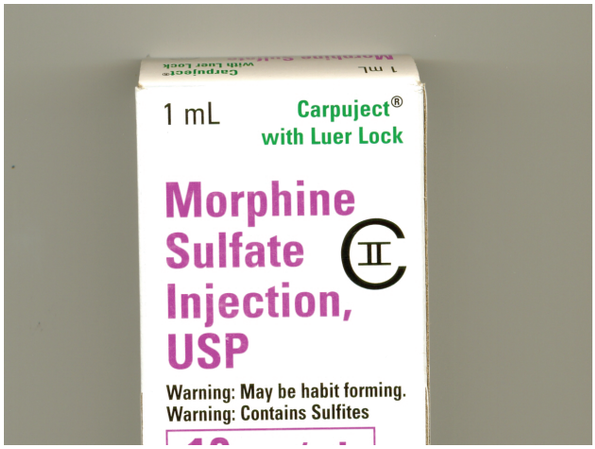

Figure 2–1. CII label for a Schedule II controlled substance.

Labeling of Controlled Substances

Federal law requires that the drug manufacturer's packaging for controlled substances be labeled with a specific symbol to indicate that they are controlled substances. The symbol to indicate a controlled substance is the letter *C* with the appropriate Roman numeral placed inside the *C* symbol. A Schedule II controlled substance is denoted "CII" (figure 2–1). The prescription container labels for dispensing controlled substance prescriptions are not required to contain this symbol; however, federal law requires that pharmacies place a specific caution message on the patient container advising the patient that they may not give the controlled substance to any other person. The required statement is "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Dispensing Controlled Substances

Prescribers and pharmacists both have responsibilities to ensure that only legitimate controlled-substance prescriptions are issued and dispensed. For a controlled-substance prescription to be valid, it must be prescribed by a licensed prescriber for a legitimate medical purpose in the normal course of the prescriber's professional practice. The prescribing practitioner must be registered with Drug Enforcement Administration (unless exempt from registration, such as Public Health Service physicians) and be licensed to prescribe controlled substances by the state. Pharmacists have a corresponding responsibility to dispense controlled substances pursuant to a valid prescription issued for a legitimate medical purpose in the course of the prescriber's practice. Prescribing a controlled substance or knowingly filling a controlled-substance prescription in violation of the laws and regulations may result in criminal or civil penalties for violation of the controlled substance laws.

Federal and state laws require specific information for controlled-substance prescriptions. Controlled-substance prescriptions must contain the date issued; the patient's full name and address; the practitioner's name, address, and DEA registration number; the drug name, strength, dosage form, and quantity prescribed; directions for use; the number of authorized refills (if any); and the signature of the prescriber (unless a verbal prescription is permitted). Pharmacists may dispense Schedule II controlled substances only pursuant to a written prescription signed by the practitioner unless an exception applies. For example, in an emergency, the practitioner may telephone or fax the prescription to the pharmacist. The prescriber must still provide the original written signed prescription to the pharmacist within seven days and indicate that it was authorized for emergency dispensing. Some states require specific tamper-resistant or multi-part forms for Schedule II prescriptions (figure 2–2). Federal regulations allow facsimile Schedule II prescriptions in some instances, such as for a patient residing in a long-term care facility or for a hospice patient.

Federal and state laws set specific requirements for refilling and transferring controlled-substance prescriptions. Federal law allows Schedule III and IV prescriptions to be refilled up to five times within six months after the date that the prescription was issued by the prescriber. Schedule V prescriptions may be refilled more than five times, but have a six-month time limit on refills. Schedule II prescriptions may not be refilled and are not transferable between pharmacies. Federal law allows Schedule III, IV, and V prescriptions to be transferred from one pharmacy to another for one refill (if the state law permits). Pharmacies using a real-time online computer system connecting their pharmacies may transfer Schedule III, IV, and V prescriptions up to the maximum number of authorized refills. Pharmacies are required to maintain complete and accurate records for all controlled substances that they purchase, receive, distribute, or dispense. Federal law requires the pharmacy to keep controlled-substance records for two years and have them readily available for DEA inspection if

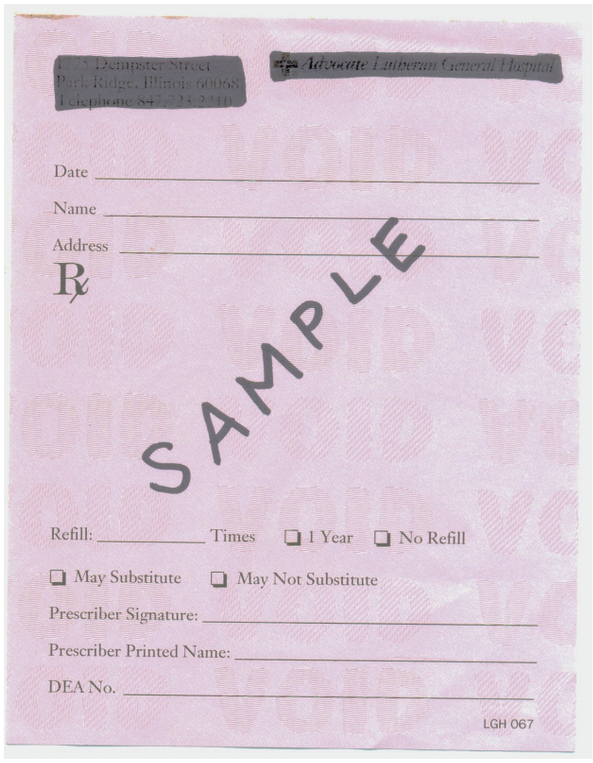

Figure 2–2. Example of a tamper-resistant prescription for a Schedule II drug.

requested. State laws may require pharmacies to keep records for a longer time period. Examples of records that must be kept are invoices or receipts for purchases of controlled substances, inventory records including **initial** and **biennial inventories,** and records of any transfers of controlled substances between pharmacies. Each controlled-substance inventory must be a complete and accurate record of all controlled substances in the pharmacy on the inventory date. A separate inventory is required for each pharmacy location.

State Prescription Monitoring Programs. Many states have enacted laws and regulations to institute **prescription monitoring programs** to monitor prescribing and dispensing of controlled substances. Most state prescription monitoring programs require pharmacies to report information on controlled-substance prescriptions dispensed for drugs in Schedules II, III, IV, and V; however, some programs require reporting for dispensing of Schedules II, III, and IV drugs. These programs require pharmacies to submit information on the controlled-substance prescriptions that they dispense to the designated state authority electronically on a periodic basis (e.g., once or twice a month, or in some states, more frequently). More than thirty-five states have implemented these programs. The information that pharmacies provide to these programs includes patient information, prescriber information, pharmacy identification, and prescription information including the name and quantity of the controlled substance and the date the prescription was dispensed. These programs are used by states to identify potential diversion and abuse of prescription controlled substances by the patient, pharmacy, or prescriber, and to identify potential patients that would benefit from drug abuse treatment programs.

✔Prescription monitoring programs require pharmacies to submit information on controlled-substance prescriptions to help states identify potential diversion and abuse.

Restrictions on Sales of Products Containing Ephedrine or Pseudoephedrine. The sales of over-the-counter drug products containing ephedrine and pseudoephedrine are subject to restrictions on their sales under federal law and laws enacted in many states. The federal law restricting sales of these products is called the Combat Methamphetamine Epidemic Act of 2005 (CMEA). It was enacted due to continuing concerns about the use of over-the-counter (OTC) products to illegally manufacture methamphetamine or amphetamine. Ephedrine and pseudoephedrine, which are the active ingredients in common cough, cold, and allergy products, are precursor chemicals to methamphetamine and amphetamine. The laws limit the amount of these products that a customer may purchase in a single transaction, in a day, or over a 30-day period, and require that the products be locked up or otherwise not available for public access. They also require customers to sign a logbook with details on the drug product and amount purchased. Federal law limits sales of these products to 3.6 grams daily and limits purchasers to 9 grams of these products in a 30-day period. The federal 3.6 gram daily limit for pseudoephedrine hydrochloride 30 mg tablets would be about 146 tablets or about 73 tablets of 60 mg pseudoephedrine hydrochloride. Further information is available from the DEA at http://www.deadiversion.usdoj.gov/meth/trg_retail_081106.pdf.

Purchasers must provide their valid photo identification and sign a logbook with their name, address, and date

and time of purchase. The logbooks may be used by law enforcement to identify violations of the law. Many states have also enacted laws restricting the sale and purchase of these OTC products, and some have different requirements and restrictions. The federal law must be followed in all states, and if the state law is stricter, it must also be followed.

Brand Name Drugs and Generic Drugs

The FDA approves all drugs that are available for distribution in the United States to assure that they are safe and effective. Before a new drug is approved, the drug manufacturer must submit a new drug application (NDA) to the FDA. The NDA includes information about the drug, including results from clinical trials in humans, results of animal studies, how the drug acts in the body, and how it is manufactured, processed, and packaged. The FDA reviews the NDA to assess whether the drug is safe and effective for its proposed use(s), if the benefits of the drug outweigh the potential risks, if the proposed labeling is appropriate, and whether the methods used in manufacturing the drug are adequate to ensure the quality of the drug. If the FDA's review of the NDA is favorable and the drug is determined to be safe and effective, the FDA approves the drug for use in the United States.

Most companies market new drugs with a trade or brand name. Lipitor is an example of a brand name for a drug that is manufactured and distributed by the drug manufacturer Pfizer. The generic name for Lipitor is atorvastatin. Pfizer is the company that developed atorvastatin and submitted the NDA to FDA for approval. The FDA approved the drug as safe and effective for use in the United States. Manufacturers that develop new drugs, such as Pfizer in this example, are granted patents for the drug, which give them exclusive rights to market the drug until the patent expires. Typically, patent protection for a drug lasts an average of 11 years. Once the patent expires, other drug manufacturers may seek approval from FDA to market generic equivalents, or copies, of the drug.

Generic equivalents contain the same active ingredients and have the same dosage form, strength, and formulations as their brand name counterparts. Whereas the manufacturer that developed the original version of a drug must submit an NDA to the FDA, generic drug companies must submit abbreviated new drug applications (ANDAs). Generic manufacturers must meet the same standards for manufacturing, quality, and labeling as brand drugs; however, they do not need to repeat the original research. They must show bioequivalence to the brand name drug, which means that the drug will deliver the same amount of the drug to the body in the same amount of time as the brand name drug. Generic drugs have a different appearance than the brand name drug because laws do not allow a generic drug to copy the appearance of the brand name drug. Generic drug companies distribute the drug under the generic name, not the brand name drug.

Rx for Success

Manufacturers of generic drugs can market their drugs at lower prices than their brand name counterparts because they don't have new drug development and research costs that brand name companies have.

Generic Drug Substitution

For drugs that have an FDA-approved generic equivalent, pharmacists are permitted to substitute the generic equivalent drug for the brand name drug unless the prescriber prohibits generic substitution. Generic substitution by pharmacists is regulated by the state generic substitution drug laws and regulations. These laws and regulations set the requirements for when pharmacists may or may not substitute therapeutically equivalent generic drugs for prescribed brand name drugs. State laws and regulations establish different means for prescribers to advise pharmacists that they do not want generic substitution for their patients. Depending on the state, the laws may instruct prescribers to indicate no substitution through various phrases including "dispense as written," "DAW," "no substitution," "do not substitute," "DNS," or words of similar effect. Conversely, if the prescriber wants to permit substitution, state laws may instruct the prescriber to use terms such as "substitution permitted" or words of similar effect. Patients may also ask to have the brand name drug dispensed in place of the generic drug. In some states, pharmacists are required to do generic substitution for certain types of patients, such as all patients with prescription drug coverage paid for by the state medical assistance (Medicaid) program.

The FDA provides a list of generic drugs that the agency has found to be therapeutically equivalent to the brand name drugs in its publication, *"Approved Drug Products with Therapeutic Equivalence Evaluations,"* commonly called the "Orange Book." Pharmacists use the "Orange Book" to find the FDA's determination that a particular manufacturer's generic drug is therapeutically equivalent to the brand name drug. Not all drugs have a generic equivalent. If the drug company still has a patent on the drug, the brand name drug is the only one available.

✔Pharmacists use the "Orange Book" to find the FDA's determination that a particular manufacturer's generic drug is therapeutically equivalent to the brand name

Prescription Drug Labeling and Package Inserts

Prescription drug products are labeled by the drug manufacturer. The prescription drug container label includes standard information such as the name and address of the drug manufacturer, drug name, strength and dosage form, manufacturer's expiration date for the drug, lot number, package size or quantity, DEA schedule (if appropriate), and "Rx Only" to indicate that the drug is for prescription use only (figure 2–3). Prescription drugs are also called **"legend drugs"** due to a federal law enacted in 1951 (the Durham-Humphrey Amendment) that required certain drugs to require a prescription and be labeled with the statement, "Caution: Federal law prohibits dispensing without a prescription." Each product label must include a lot number and expiration date. The lot number is the number used by the drug manufacturer to identify each particular batch of the drug during the manufacturing process and is used to identify drug products that may need to be pulled from distribution in the event of a drug recall. The expiration date is derived from studies conducted by the drug manufacturer on the stability of the drug in the manufacturer's container. The date is used to determine how long the drug product may be used or dispensed to patients. Drugs that have reached their expiration date may not be used or dispensed to patients.

Figure 2–3. Comparison of a brand name (R) and generic (L) equivalent label for the same drug.

Prescription drug products also include a *package insert*. The package insert provides physicians, pharmacists, and other health care professionals with medical and scientific information about the prescription drug. Information in the package insert includes important information about the drug, such as the indications for use, dosage and administration, adverse reactions, warnings, precautions, and contraindications for the drug. The package insert also provides details about how to prepare the drug, proper storage, and the available package sizes with NDC numbers. The prescription drug package insert is not intended for patients.

Prescription Drug Information for Patients. Pharmacists provide patients with different types of written information for their dispensed prescription drugs. Patients are provided with printed information about their dispensed medication called *consumer medicine information* or CMI. In addition, the FDA requires pharmacists to provide patients with a *patient package insert* ("PPI") with the dispensing of *certain* prescription drugs such as estrogens and oral contraceptives. PPIs are written specifically for patient use, whereas, package inserts are developed for use by physicians and pharmacists.

Another type of patient written information used for certain prescription drugs is the *Medication Guide* or *Medguide.* Medication Guides contain FDA-approved information to assist patients with avoiding serious adverse events, to inform patients about known serious side effects, or to promote patient adherence with their treatment. The FDA requires that Medication Guides be provided to patients when certain medications are dispensed. An example of a drug requiring a Medication Guide is zolpidem (Ambien). Medication Guides may be for an individual drug or for a class of drugs. A link to

FDA Medication Guides can be found in the Resources section at the end of this chapter.

Over-the-Counter Drug Labeling. Over-the-counter (OTC) drugs are drugs that the FDA has approved to be safe for use by consumers without a prescription. Because they do not require a prescription, OTC drugs are labeled with information designed to assist consumers in using the medications correctly. The labeling for OTC drug products is intended to sufficiently inform the consumer of the uses for the drug, the recommended dosage, how often to use the drug, who should or should not take the medication, and to provide information on side effects and precautions for using the drug. For example, the container labeling for OTC drugs used for sleep aids would advise the consumer not to drive a car after taking the medication due to the risk of drowsiness. The product labeling also contains the drug name and the total quantity of drugs in the container. OTC products have a specific *Drug Facts* section that lists the active ingredients, uses, warnings, and directions for use (see figure 2–4). OTC drug products, like prescription drug products, are required to be labeled with an expiration date as determined by the drug manufacturer.

Poison Prevention Packaging Act. The federal Poison Prevention Packaging Act requires that hazardous products such as prescription drugs, many OTC drug products, and other products such as household cleaners and furniture polish be sold in **child-resistant packaging**. The packaging must meet a test to show that it will prevent 80% of children from opening the package but allow 90% of adults to open the containers without difficulty. Many OTC products require child-resistant packaging such as products containing aspirin, iron, and ibuprofen.

The law allows consumers or the patient's prescriber to ask the pharmacist to dispense the medication in non-child-resistant packaging. Some prescription drugs are exempt from child-resistant packaging because it is not appropriate, feasible, or practical. Examples of exempt products include sublingual nitroglycerin tablets and oral contraceptives (birth control pills), which are packaged in numbered tablet dispenser packs.

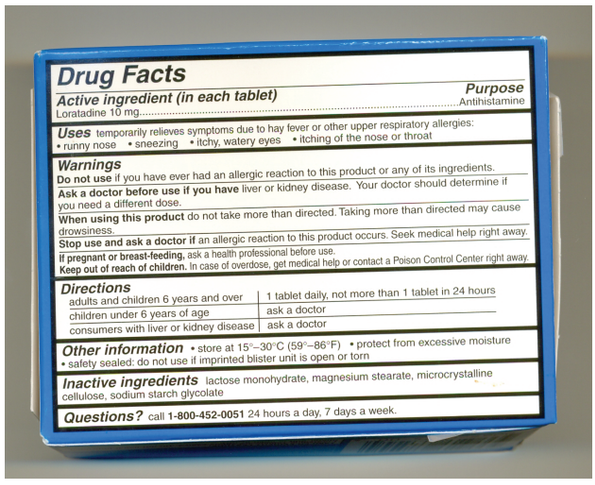

Figure 2–4. Drug Facts section of an OTC label.

Patient Privacy

Pharmacies, including pharmacists and pharmacy technicians, are required by federal and state laws to maintain the required privacy and confidentiality of patient health information. It is important to maintain privacy and confidentiality of patient health information and health records, as failure to comply with the law may subject violators to penalties.

Virtually all pharmacy records contain private patient health information. Examples include prescriptions, computer records, patient profiles, patient prescription containers, written patient information that identifies the patient, patient billing records, and oral conversations regarding patients. Maintaining the privacy and confidentiality of patient health information requires appropriate safeguards for pharmacy patient records. This includes taking care to discard patient information in a secure manner and taking reasonable precautions to maintain privacy of pharmacy conversations about patients.

Both state and federal laws establish requirements for maintaining privacy of patient health information. The primary federal law establishing health information privacy is the Health Insurance Portability and Accountability Act (HIPAA). States also have laws protecting the privacy and confidentiality of patient health and medical information. Due to the complexity of the topic, it is outside of the scope of this section to discuss the various state laws and regulations governing patient privacy.

HIPAA sets national standards for the privacy of medical records. HIPAA is a complex law and the following is a general overview. The law applies to health care providers including pharmacies, physicians, hospitals, nursing homes, and many other entities that handle

health information, such as health plans and billing services. HIPAA protects patient's individually identifiable health information, which is known as "*protected health information,*" or *"PHI."* PHI is any health information that identifies the patient or could reasonably be used to identify the person. Examples of pharmacy PHI include pharmacy prescription records, computer records, prescription container labels, and other pharmacy health information records that identify the patient, and oral communications about patients' prescriptions and health care treatment. However, health information that is de-identified, so as not to disclose the identity of the patient, is not PHI. For example, pharmacists and pharmacy technicians discussing a particular drug therapy in general and not in relation to a patient would not be considered PHI.

Pharmacies are permitted to use and disclose patient health information as necessary to provide patient health care services. HIPAA permits certain uses and disclosure of patient health information. HIPAA allows the use and disclosure of PHI for patient care, treatment, and health care operations. Such disclosures are necessary for providing pharmacy services. Examples include dispensing prescriptions, patient treatment, billing for pharmacy services, and managing patient care.

Rx for Success

Pharmacy technicians must maintain the privacy and confidentiality of patients' personal health information. This requires appropriate safeguards for pharmacy patient records, discarding patient information in a secure manner, and taking reasonable precautions to maintain privacy of pharmacy conversations about patients.

Summary

This chapter provides an overview of laws and regulations affecting the practice of pharmacy. It is designed to provide pharmacy technicians with a foundation of the laws that affect the pharmacy profession. Pharmacy technicians who are interested in additional information about the laws and regulations for a particular state and the specific requirements for pharmacy technicians should refer to the resources section and contact their state board of pharmacy.

Disclaimer

This chapter has been prepared by the author for general information purposes only and is not intended to contain all laws and regulations that relate or may relate to the practice of pharmacy, including but not limited to pharmacy technicians. This publication and the information within are not provided in the course of an attorney-client relationship and are not intended to provide legal or other advice. Such advice should be rendered only in reference to the particular facts and circumstances appropriate to each situation by the appropriate legal professionals and/or consultants selected by the person. Any references or links to information or to particular organizations or references are provided as a courtesy and convenience, and are not intended to constitute any endorsement of the linked materials or the referenced organizations or materials by the author or publisher. The content and views on such links and of such organizations are solely their own and do not necessarily reflect those of the author or publisher. The author, Diane L. Darvey, prepared this publication on her own behalf, not as a representative of the National Association of Chain Drug Stores (NACDS). NACDS did not review or approve this publication, and its contents do not necessarily represent the views of NACDS.

Self-Assessment Questions

1. Pharmacy technicians are permitted to do the following
   a. All tasks that pharmacists are permitted to do
   b. Any task that the pharmacist asks them to do
   c. Any tasks that they are permitted to do by the pharmacy laws
   d. Any task that they determine they can safely do
2. Counseling patients about their prescription medications
   a. May be done by the pharmacy technician if he or she believes he or she understands the medication
   b. May be done only by the pharmacist
   c. May be done by the pharmacy technician when the pharmacist is on the telephone or speaking with another patient
   d. May be done by the pharmacy technician if it is only for one drug
3. What is meant by a legend drug?
   a. A drug that is famous
   b. An herbal drug
   c. A drug that can be bought over-the-counter
   d. A drug that can be dispensed only pursuant to a valid prescription
4. Controlled substances are subject to
   a. The same controls as any prescription drug
   b. Stricter controls that other prescription drugs
   c. Stricter controls only in hospital pharmacies
   d. Lesser controls than other prescription drugs
5. Which of the following Schedules of Controlled Substances have the highest abuse potential and an accepted medical use?
   a. Schedule I
   b. Schedule II
   c. Schedule III
   d. Schedule V
6. Products containing ephedrine or pseudoephedrine
   a. May not be sold in pharmacies due to federal restrictions
   b. May be kept in the front of the pharmacy for public access
   c. May only be kept behind the counter and sold in limited amounts
   d. Require a prescription
7. All of the following drugs must be dispensed in a child-resistant container *except*
   a. Sublingual nitroglycerin tablets
   b. Controlled substances
   c. Celecoxib (Celebrex)
   d. Iron-containing multivitamins
8. Which of the following statements is most correct?
   a. The patent holder of a brand name drug is the only company that has the rights to market the drug
   b. Brand name drugs and generic drugs both require an NDA
   c. According to the FDA, generic drugs must look like their brand counterparts
   d. The drug manufacturer determines whether a generic drug can be substituted for its brand name counterpart
9. Who has the authority to sign a DEA Form 222 when ordering Schedule II controlled substances?
   a. Only the owner of the pharmacy
   b. Only the person who signed the application for pharmacy registration with the DEA
   c. Only a pharmacist
   d. The prescribing physician
10. What is the name of the law that requires pharmacists to provide patient counseling as a condition of reimbursement when dispensing prescriptions to Medicaid patients?
    a. Food, Drug, and Cosmetics Act (FDCA)
    b. Omnibus Budget Reconciliation Act of 1990
    c. Durham Humphrey Amendment
    d. The Controlled Substances Act

Self-Assessment Answers

1. c. Pharmacy technicians are allowed to perform only tasks that are permitted by pharmacy laws.
2. b. Patient counseling may be performed only by a pharmacist or a pharmacy intern under the supervision of a pharmacist. In some states, pharmacy technicians are permitted to ask patients if they want to receive counseling from the pharmacist ("offer to counsel").
3. d. A drug is considered "legend" if it has the statement on its label, "Caution: Federal Law Prohibits Dispensing Without a Prescription." Therefore, the drug can't be dispensed without a prescription from an authorized prescriber.
4. b. Controlled substances are subject to stricter controls than other prescription drugs because of their potential for misuse, abuse, diversion, and addiction.
5. b. Schedule I drugs have no accepted medical use. Schedules II-V all have accepted medical uses and have decreasing abuse potential as the numbers increase.
6. c. OTC cough, cold, and allergy products containing ephedrine and pseudoephedrine may be kept only behind the counter and sold in limited amounts. The Combat Methamphetamine Epidemic Act of 2005 (CMEA) is the federal law that restricts sales of these products. It was enacted due to continuing concerns about the use of over-the-counter (OTC) products to illegally manufacture methamphetamine or amphetamine.
7. a. Some drugs, such as sublingual nitroglycerin, oral contraceptives, and other drugs packaged for patient use by the manufacturer, do not require the child-resistant packaging.
8. a. Holding a patent on a drug means no one else can produce or market that drug for the life of the patent. Generic drugs may be bioequivalent to brand name drugs, but may look different. The FDA approves generic drugs and determines whether they are bioequivalent to the branded reference drug. Generic substitutions by pharmacists are regulated by state generic substitution drug laws and regulations.
9. c. The person who signed the application for the pharmacy's registration with the DEA has the authority to sign DEA Form 222. He or she may delegate that authority to another by issuing a power of attorney. You do not have to be a pharmacist to sign a DEA Form 222 as long as you have a valid power of attorney from the registrant.
10. b. Commonly called OBRA '90, the Omnibus Budget Reconciliation Act of 1990 required pharmacists to provide patient counseling as a condition of reimbursement when dispensing prescriptions to Medicaid patients. The Food, Drug, and Cosmetics Act (FDCA) regulates the safety of food, drugs and cosmetics. The Durham-Humphrey Amendment defined the types of drugs that require a prescription and required that prescription drugs be labeled with the statement "Caution: Federal law prohibits dispensing without a prescription." The Controlled Substances Act establishes requirements for handling and dispensing of narcotics and other controlled substances.

Resources

Darvey DL. *Legal Handbook for Pharmacy Technicians*. Bethesda, MD: American Society of Health-System Pharmacists, 2008.

National Association of Boards of Pharmacy (NABP): www.nabp.net

Drug Enforcement Administration (DEA): Office of Diversion Control: www.deadiversion.usdoj.gov/index.html

Food and Drug Administration (FDA) Center for Drug Evaluation and Research: www.fda.gov/drugs/default.htm

Orange Book: *Approved Drug Products with Therapeutic Equivalence Evaluations*: www.accessdata.fda.gov/scripts/cder/ob/default.cfm

Medication Guides: http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm