PART 1

Assisting the Pharmacist in Serving Patients

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Law and Ethics

Test Topics

After completing this chapter, you should be able to demonstrate knowledge of the following:

1. Federal, state, and/or practice site regulations, codes of ethics, and standards pertaining to the practice of pharmacy
2. Pharmaceutical, medical, and legal developments that impact the practice of pharmacy
3. State-specific prescription transfer regulations
4. Confidentiality requirements

Test Terms

- **civil laws** laws that govern wrongdoings against a person or property, and generally charges are brought forth by another individual
- **Controlled Substances Act (CSA)** 1970 act that was designed to help regulate drug use by creating rules and regulations for record keeping and dispensing, and requiring firms that handled controlled substances to register with the DEA; the act also organized controlled substances into a system of schedules based on the potential for abuse
- **Drug Listing Act** 1972 act established to create a list of marketed drugs for the Food and Drug Administration, which would assist with enforcing federal safety laws
- **Durham-Humphrey Amendment (DHA)** 1951 amendment that separated drugs into two categories: legend drugs (prescriptions drugs) and over-the-counter drugs (OTC); the amendment specified that news drugs can only be distributed through prescriptions (and should contain legends to that effect), but eventually may be changed to OTC status
- **ethics** system of values, principles, and duties that guide behavior
- **Food, Drug, and Cosmetic Act (FDCA)** 1938 act that helped ensure drugs being distributed were safe and fulfilled the reported claim of strength, purity, and quality
- **Health Insurance Portability and Accountability Act (HIPAA)** act established in 1996 that requires healthcare providers to provide a clear written explanation of how health information will be used and disclosed
- **Kefauver-Harris Amendment (KHA)** 1962 amendment that became part of the Food, Drug, and Cosmetic Act; the amendment was designed to institute higher safety measures for drugs approved by the Food and Drug Administration by requiring manufacturers to follow Good Manufacturing Processes (GMP)
- **Orphan Drug Act** 1983 act created by the Food and Drug Administration to speed up the approval process for new medications intended to help people with urgent needs
- **Poison Prevention Packaging Act (PPPA)** 1970 act created to reduce potential for accidental poisonings

The study and practice of pharmacology covers many legal and ethical issues. Regulations regarding the practice of pharmacy can change, so it's important to keep track of new developments. Current laws being debated include the right to die and the legal use of marijuana. Visit your state's Board of Pharmacy Web site for development that may impact you.

Laws are rules regarding conduct that are enforced by an authority, such as the government. Pharmacology is generally regulated by civil laws. **Civil laws** govern wrongdoings against a person or property, and generally charges are brought forth by another individual.

Whereas laws are enforced by the government, ethics are enforced by peers, professional organizations, and the community. **Ethics** are a system of values, principles, and duties that guide your behavior. Your ethical commitments to your patients include:

- nonmalfeasance—actions that avoid harm
- beneficence—actions that create benefits
- fidelity—adherence to laws and agreements; meeting patients' rights to receive care and respect
- veracity—truth
- justice—equal allocation of burdens and benefits

Confidentiality

Confidentiality is not only an ethical issue; it's also ethical legal one. The **Health Insurance Portability and Accountability Act of 1996** (**HIPAA**) was originally developed to make sure that people could not lose their medical coverage when they changed jobs, even if they had a pre-existing medical condition. Today, HIPAA affects almost all healthcare providers as well as anyone who is employed anywhere where patient information may be located, including pharmacies. Under HIPPA, the following information, which is also known as a patient's Protected Health Information (PHI) is considered confidential:

- names
- geographic location smaller than a state
- dates of birth, admission, discharge, or death
- telephone and fax numbers
- e-mail addresses
- Social Security numbers
- medical records or account numbers
- health plan beneficiary numbers
- certificate/license numbers
- vehicle or device numbers
- biometric indicators
- full face photos
- any other unique identifying number, characteristic, or code
- age older than 89

According to HIPAA, confidential information may only be released under one of the following circumstances:

- under written consent of the patient
- by subpoena
- in cases of mandatory reporting

RECALL TIP

Use the phrase "when to show medical records" to remember when confidential information can be released. "W" represents written consent of the patient, "s" represents subpoena, and "m" and "r" represent mandatory reporting.

Drug Regulations

A drug is defined as an agent intended for use in the diagnosis, mitigation, treatment, cure, or prevention of disease in humans or in other animals. The following sections describe drug regulations that have been implemented for public safety.

Food, Drug, and Cosmetic Act of 1938

RECALL TIP

To help remember what the Food, Drug, and Cosmetic Act is all about, remember the act's acronym, FDCA. "F" represents fulfilled, "d" represents description of, "c" represents claim, and "a" represents act. This way FDCA stands for Food, Drug, and Cosmetic Act, but it also stands for "fulfilled description of claim act."

The **Food, Drug, and Cosmetic Act (FDCA)**, which was created largely in response to the Sulfanilamide Disaster, helped ensure drugs being distributed were safe and fulfilled the reported claim of strength, purity, and quality. The act prohibited the distribution of any drug that was not considered safe by the Food and Drug Administration (FDA). However, the FDCA did not require substances to be effective. Through this act, the FDA was given the power to allow or deny a company to distribute a drug.

Durham-Humphrey Amendment of 1952

RECALL TIP

To help remember what the Durham-Humphrey Amendment did, remember its acronym DHA. "D" represents distinguished, "h" represents harmful, and "a" represents application. Now when you think about DHA, you remember Durham-Humphrey Amendment and "distinguished harmful application."

The **Durham-Humphrey Amendment (DHA)**, which is also known as the prescription drug amendment, separated drugs into two categories: legend drugs (prescription drugs) and over-the-counter drugs (OTC). The act specified that all drugs new to the market can only be distributed to patients through prescriptions, but eventually may be changed to OTC status. In addition, prescription medication bottles must carry a legend (or label) stating that the medication can only be dispensed with a prescription. The DHA also prohibited prescription drugs from being refilled without the consent of the doctor or prescriber.

Kefauver-Harris Amendment of 1962

The **Kefauver-Harris Amendment (KHA)** became part of the FDCA to institute higher safety measures for drugs approved by the FDA. Manufactures became responsible for Good Manufacturing Processes (GMP), which required them to prove both the safety and effectiveness of drugs in clinical trials before the FDA would grant permission for marketing and distribution. If a drug is approved by the FDA for sale in the United States, the drug is considered safe and effective when taken properly. In addition, KHA established definitive procedures for new drug applications (NDA) as well as investigational drugs.

Controlled Substances Act of 1970

The **Controlled Substances Act (CSA)** is part of the Comprehensive Drug Abuse Prevention and Control Act. The CSA was designed to help regulate drug use by creating rules and regulations for record keeping and dispensing, and requiring firms that handle controlled substances to register with the DEA. The CSA also organized controlled substances into a system of schedules based on the potential for abuse.

- Schedule I: Drugs with no medical use and a high potential for abuse, such as heroin and LSD.

RECALL TIP

To help you remember how drug schedules are organized, think about how you create your own daily schedule. All you need to do is prioritize. Generally, you put the most important task, or in this case the most potential for abuse, first. This item is number one in your priority list. As you go down the priority list, the potential for abuse decreases.

- Schedule II: Drugs with a medical use and a high potential for abuse, such as morphine and methamphetamine. If this type of drug is abused, it may lead to severe dependence. No refills are allowed.
- Schedule III: Drugs with a medical use and a potential for abuse, such as codeine and hydrocodone. If this type of drug is abused, it may lead to moderate dependence. Patient may receive up to 5 refills in 6 months.
- Schedule IV: Drugs with medical use and a low potential for abuse, such as diphenoxylate and oxazepam. If this type of drug is abused, it may lead to limited dependence. Patient may receive up to 5 refills in 6 months.
- Schedule V: Drugs with a medical use and a low potential for abuse, such as OTC cough syrups that contain codeine (Phenergan). If this type of drug is abused, it may lead to limited dependence. Patient may receive as many refills as their physician deems appropriate.

The Poison Prevention Packaging Act of 1970

RECALL TIP

To help remember what the Controlled Substances Act is all about, remember the act's acronym, CSA. "C" represents created, "S" represents schedules for, and "a" represents abuse. Now, CSA stands for Controlled Substances Act, but it also stands for "created schedules for abuse."

The **Poison Prevention Packaging Act** (**PPPA**) was created to reduce accidental poisonings. Included in this act are requirements for child-resistant closures on prescription and OTC drugs intended for oral use, as well as a provision requiring manufacturers to include package inserts with certain drugs. The few exemptions to the act include cardiac medications and single dose sizes. The PPPA was originally enforced by the FDA but was later transferred to the Consumer Product Safety Commission when the agency was created in 1973.

The Drug Listing Act of 1972

The **Drug Listing Act** was established to create a list of marketed drugs for the FDA, which would assist with enforcing federal safety laws. All manufacturers or firms that repackage drugs, including foreign firms, are required to register with the FDA. Registered firms are assigned registration numbers that are formatted using the National Drug Code numbering system.

The National Drug Code (NDC) numbering system is a coded system created to identify a drug by simply looking at the code on the label. The code is made up of 10 characters and numbers which are broken up into three segments, either 4:3:3 or 4:4:2.

- Segment 1: identifies the product manufacturer or distributer
- Segment 2: identifies the product code, strength, and dosage form
- Segment 3: identifies package sizes and types

The Orphan Drug Act of 1983

The **Orphan Drug Act** is a special program created by the FDA to speed up the approval process for new medications intended to help people with urgent needs. The FDA created the program to help develop and market treatments for rare diseases (diseases with fewer than 200,000 cases), such as AIDS and Tourette syndrome. To encourage researchers to participate, incentives include grants, protocol assistance by the FDA, and special tax credits. If a drug is approved under the act, the manufacturer gets exclusive marketing rights for seven years.

Prescription Drug Marketing Act of 1987

The Prescription Drug Marketing Act implemented new safety measures for prescription drugs in the United States. The goal of the act is to reduce the risk of repackaged, mislabeled, and adulterated substances entering the marketplace. This was done through:

- prohibiting reimportation of drugs by anyone except manufacturers
- enforcing sales restrictions
- regulating sample distribution

Pharmacy Standards

Specific pharmacy standards are created by your state's Board of Pharmacy. These rules, along with applicable federal laws, create the basis of pharmacy practice. State standards may be stricter than federal laws. In this case, pharmacies are required to practice under the more rigid regulations. To find out what your state requires, go online and search for your state's State Board of Pharmacy.

The Omnibus Budget Reconciliation Act of 1990

The Omnibus Budget Reconciliation Act (OBRA 90) required states to develop programs to improve the quality of pharmaceutical care. OBRA also requires pharmacists to perform Drug Utilization Review (DUR). As a result of these programs, patients receive:

- counseling about prescribed and OTC medications
- warnings about potential allergy interactions
- techniques for self-monitoring drug therapy

Patient Self-Determination Act of 1990

RECALL TIP

Use the phrase "ahead decisions" to remember the idea behind advance directives. Advance directives are decisions you make about your care ahead of time. You can have your decision in writing with a living will or entrust someone to carry out your wishes with a durable power of attorney.

The Patient Self-Determination Act requires hospitals to inform patients about their rights and their ability to create an advance directive. There are two types of advance directives:

- *Living will.* This document provides very specific instructions about the type of care a patient chooses in particular circumstances. Wishes regarding life-sustaining treatment, artificial nutrition and hydration, and comfort care can all be decided before a person becomes ill.
- *Durable power of attorney.* This allows a patient to choose a representative to make decisions on the patient's behalf should the patient become incapacitated.

Blanket Consent

Blanket consent is a form that allows a physician to do what he or she thinks is necessary for a patient. It is generally signed at the first meeting between a healthcare provider and a patient, and contains language about how the physician has discussed treatment with the patient and the patient has had the opportunity to ask questions.

Pharmacy Best Practices

According to the American Pharmacists Association, the goal of the pharmacy is to responsibly assist society in the use of medication, devices, and services in an effort

to achieve an optimum outcome. To do this, pharmacists need to follow specific guidelines and practices when handling and storing controlled substances.

Checking for Prescription Errors

Prescription errors can have deadly consequences. When filling a prescription, it's a good idea to take the following precautions.

- Check the original order against the label, against the bottle of medication before filling, and before filling the vial and labeling.
- Verify the route and dose that the physician ordered with what you prepared.
- Check when and how the patient should take the medication.
- Document the procedure in the patient's medical records: note the date, time, drug, dose, route, site, result/tolerance, and patient education.
- Verify the name on the physician's order.

Ordering and Dispensing Controlled Substances

Since controlled substances have the potential to be abused, pharmacies must abide by requirements regarding the ordering and dispensing of these drugs. For a pharmacist to order, receive, handle, or dispense a controlled substance, the pharmacy must be registered with the DEA and have a DEA registration number. You'll learn more about DEA registrations numbers in Chapter 10: *Dispensing Medications*. Prescription orders also have requirements that must be met before the prescription can be filled. The following prescription requirements pertain to orders for controlled substances in all schedule categories:

- date of issue
- full name and address of the patient
- the drug name, strength, dosage form, and quantity prescribed
- directions for use
- full name, address, and DEA number for the prescriber
- the signature of the prescriber, for written orders
- For Schedule II substances, a written or typed order with the prescriber's signature is required. In an emergency, a physician may also phone in a prescription, but he or she must provide a hard copy of the prescription within 7 days.

Transferring Prescriptions of Non-Controlled Substances

In order to transfer non-controlled substances between pharmacies, pharmacies must follow these specific rules:

1. The prescription transfer can only take place between licensed pharmacies, and the transferring pharmacist must record the following information in the patient medication record system:
   - a copy of the prescription has been issued
   - the name and address of the pharmacy and pharmacist that the prescription was transferred to
2. The pharmacist receiving the prescription must do the following:
   - write "transfer" on the patient's prescription
   - include all required information on the prescription, such as the patient's information and the prescriber's information, along with the name of the transferor pharmacist

3. Once a prescription is transferred, the original pharmacy can no longer refill the prescription.
4. If pharmacies use a common electronic database for prescription recordkeeping, a patient can refill a prescription at any participating pharmacy.

Record Keeping

Pharmacies must follow specific record-keeping requirements for maintaining controlled substances.

- Pharmacies must keep track of the receipt and delivery of all controlled substances, no matter their schedule.
- Controlled substances must be inventoried every 2 years.
- Schedule II drugs must be singled out due to the potential for abuse. For a prescriber to obtain a controlled substance from a pharmacy for office use, the prescriber or pharmacist must order the drug using DEA Form 222. Copies 1 and 2 of the form need to be forwarded to the drug wholesaler, with the carbon paper intact.
- For drugs in other schedules, pharmacies only need to keep the invoice to document receipt.

Storing Controlled Substances

Since controlled substances have the potential for addiction and harm, federal regulations require that controlled substances must be stored in a secure location with strictly limited access. In addition, controlled substances can never be left unattended, and inventory should be limited.

Generally, Schedule II drugs should be stored separately from other Scheduled drugs. However, if the drugs are stored in a community setting, Schedule II can be dispersed throughout the other inventory. Here are other approved and prohibited storage methods:

Approved storage methods include:

- Safes and steels cabinets that are bolted to the floor or wall
- Locking storage drawers that are inaccessible from other drawers

Prohibited storage methods include:

- Portable storage containers
- Corridor storage areas

Legal Implications

When controlled substances are abused, they have the potential to be fatal. Because of this, there are consequences for violating regulations or willfully altering records.

If a pharmacy violates the CSA or DEA regulations, the DEA has the right to seek criminal charges, monetary fines, and/or revoke, suspend, or deny the pharmacy's controlled substance registration or a pharmacist's license.

Similarly, if a pharmacy is caught altering records, it is considered fraud, and the consequences may be the same as violating federal regulations. Check you state's Board of Pharmacy for any additional laws and consequences.

Chapter Summary

- Pharmacology is enforced legally by laws and ethically by peers, professional organizations, and the community.
- Personal information and account numbers are confidential.
- Confidential information can only be released under written consent of the patient, by subpoena, and in cases of mandatory reporting.
- The Food, Drug, and Cosmetic Act ensured drugs were safe and claims made about ingredients were accurate.
- The Durham-Humphrey's Amendment established prescription and over-the-counter drugs.
- The Kefauver-Harris Amendment required manufacturers to prove the safety and effectiveness of drugs.
- The Controlled Substance Act categorized drugs based on potential for abuse and regulated the record keeping and dispensing of controlled substances.
- The Poison Prevention Packaging Act implemented safety closures on drugs to reduce accidental poisonings.
- The Drug Listing Act created a list of marketed drugs for the FDA.
- The National Drug Code numbering system is used to identify drugs by simply looking at the code on the label.
- The Orphan Drug Act was created by the FDA to speed up the approval process for medications for people suffering from rare diseases who have urgent needs.
- The Prescription Drug Marketing Act helped reduce the risk of prepackaged, mislabeled, and adulterated substances from entering the marketplace.
- State pharmacy standards may be stricter than federal laws; pharmacists must follow the more rigid standards.
- OBRA 90 improved the quality of pharmaceutical care through patient education and appropriate practice.
- The Patient Self-Determination Act requires hospitals to inform patients about their healthcare rights and ability to create an advance directive.
- Blanket consent allows a physician to do what he or she thinks is necessary when treating a patient.
- To help prevent prescription errors, check the prescription order, label, and medication storage container for accuracy.
- Pharmacies must be registered with the DEA to order, receive, handle, or dispense a controlled substance.
- Pharmacies must follow specific rules in order to transfer a prescription. Participating pharmacies must be licensed and keep track of all necessary information.
- Controlled substances must be inventoried every two years.
- Controlled substances must be locked in a secure cabinet. In addition, controlled substances can never be left unattended, and inventory for controlled substances should be limited.
- If a pharmacy violates the CSA or DEA regulations, the DEA has the right to seek criminal charges, monetary fines, and/or revoke, suspend, or deny the pharmacy's controlled substance registration or a pharmacist's license.
- If a pharmacy is caught altering records, it is considered fraud, and the consequences may be the same as violating federal regulations.

PRACTICE TEST QUESTIONS

Law and Ethics

1. Which amendment or act is also known as the prescription drug amendment?
   a. Kefauver-Harris Amendment
   b. Omnibus Budget Reconciliation Act
   c. Durham-Humphrey Amendment
   d. Poison Prevention Packaging Act

2. Which of the following is considered "confidential" information?
   a. Directory information
   b. License number
   c. Country of origin
   d. Marital status

3. Which organization enforces the Poison Prevention Packaging Act?
   a. The Council of Health-System Pharmacists
   b. Food and Drug Administration
   c. Drug Enforcement Administration
   d. Consumer Product Safety Commission

4. What is a safe and effective drug?
   a. A medication classified as a Schedule V controlled substance
   b. A drug approved by the FDA for sale in the United States
   c. A medication that prevents pregnancy
   d. A drug that has no side effects

5. The Kefauver-Harris Amendment of 1962 requires drug manufacturers prove to the FDA:
   a. the effectiveness of their products before marketing them.
   b. that household substances packaged for consumers use child-resistant packaging.
   c. that drugs which cannot be used safely without medical supervision, be labeled for sale and be dispensed by a prescription of an authorized prescriber.
   d. All of the above

6. When completing DEA form 222 to obtain Schedule II medications, which requirement must be met?
   a. Copies one and two must be forwarded to the wholesaler, with the carbon paper intact.
   b. The form must be handwritten in pencil.
   c. More than one item must be ordered per line.
   d. Suppliers must accept and fill an order even if it has errors and erasures.

7. Which federal law ensured that drugs being distributed were safe and fulfilled reported claims?
   a. Controlled Substances Act
   b. Omnibus Budget Reconciliation Act
   c. Food, Drug, and Cosmetic Act
   d. Durham-Humphrey Act

8. Which law requires pharmacists to counsel patients on new medications?
   a. Durham-Humphrey's Amendment
   b. Comprehensive Drug Abuse Prevention and Control Act
   c. Prescription Drug Marketing Act
   d. Omnibus Budget Reconciliation Act

9. What is the purpose of the Orphan Drug Act?
   a. Stops the use of drugs without a prescription in animals
   b. Allows drug companies to bypass lengthy testing to treat persons who have a rare disease
   c. Ensures safety and effectiveness of manufacturing practices
   d. Applies stricter rules concerning controlled substances sales and distribution

10. The best time to check for errors on a prescription while filling is:
    a. when the order is first received, during filling, and after filling.
    b. while filling the order, after filling, and when handing the medication to the patient.
    c. when checking the original order against the label, against the stock bottle before filling, and before filling the vial and labeling.
    d. before applying the label, before applying the auxiliary labels, and before giving the final product to the pharmacist to check.

11. Which of the following statements identifies "blanket consent"?
    a. A separate consent form must be signed for each individual procedure.
    b. The consent outlines many items of routine care and/or information and is signed on the first encounter with a healthcare provider.
    c. The physician regarding risks, side effects and benefits must give detailed information.
    d. It is used in case of emergency.

12. The middle segment of a national drug code represents which of the following product elements?
    a. Product code, strength, and dosage form
    b. Package size, manufacturer, and strength
    c. Dosage form and manufacturer
    d. Package size and product strength

13. In a court of law, the intentional altering of records will result in a charge of:
    a. felony.
    b. misdemeanor.
    c. forgery.
    d. fraud.

14. The Patient Self-Determination Act, a federal law relating to end-of-life decisions for patients with terminal illnesses, requires two different documents under federal law. The two documents are called:
    a. Emergency Consent and Durable Power of Attorney.
    b. Advance Directive and Specific Consent.
    c. Durable Power of Attorney and Living Will
    d. General Consent and Guardian Directive.

15. Which of the following statements about transfer requirements is TRUE regarding refillable non-controlled substances?
    a. Prescriptions can be refilled three times between non-related, non-networked pharmacies.
    b. Prescriptions can be refilled as many times as the prescription is refillable if the pharmacies share an electronic real-time database.
    c. Prescriptions can be refilled as often as the patient and prescriber agree.
    d. Prescription refills are up to the discretion of the pharmacist.

16. Controlled substances for office use can be obtained by a prescriber:
    a. through DEA order form 222.
    b. with a prescription marked "For Office Use Only."
    c. per a phone order.
    d. by visiting a pharmacy and showing proper identification.

17. A controlled substance inventory must be conducted by a pharmacy:
    a. every year.
    b. every two years.
    c. every three years.
    d. every four years.

18. What action can be taken by the DEA if it feels a pharmacy has violated CSA or DEA regulations?
    a. It may seek criminal penalties.
    b. It may seek civil monetary fines.
    c. It may revoke, suspend, or deny the pharmacy's controlled substances registration.
    d. All of the above

19. Which statement below is TRUE regarding the Controlled Substances Act?
    a. The Act establishes a system of schedules classifying drugs by their potential for abuse.
    b. The Act requires the registration of individuals and organizations that handle controlled substances.
    c. The Act requires strict recordkeeping of controlled substances inventories.
    d. All of the above

21. A physician prescribes Percocet for a patient going home after abdominal surgery. The patient eventually runs out of the drug and calls the pharmacy for a refill. The technician explains to the patient that:
    a. This medication can only be filled twice.
    b. This medication has an unlimited amount of refills.
    c. This medication will need another prescription from the physician, because it does not allow refills.
    d. This medication must be refilled within 30 days of the first prescription.

22. Schedule IV controlled substances can be refilled:
    a. As many times as the provider allows.
    b. 5 times in 6 months.
    c. Twice.
    d. Zero times; refills are not allowed.