QUESTIONS CH 3

PHARMACY LAW, REGULATIONS, AND STANDARDS

Learning Outcomes

After completing this chapter, you will be able to

- Understand how the practice of pharmacy is regulated by federal/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 U.S. Food and Drug Administration's 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.

MULTIPLE CHOICE

_____ 1. The federal agency that administers and enforces federal laws for controlled substances and illegal substances such as narcotics and other dangerous drugs is the:
   a. U.S. Food and Drug Administration (FDA)
   b. Drug Enforcement Administration (DEA)
   c. New Drug Application (NDA)
   d. National Association of Boards of Pharmacy (NABP)

_____ 2. The NABP:
   a. Enforces state laws in each state.
   b. Administers the national licensing exam for technicians.
   c. Is an organization whose members include State Boards of Pharmacy.
   d. Is part of the FDA.

_____ 3. Pharmacy technician registration or licensure in a state generally includes the following EXCEPT:
   a. Minimum age qualification
   b. High school graduation or graduate equivalency diploma (GED)
   c. Completion of formal or on-the-job training
   d. Requirement for liability insurance

_____ 4. The biennial inventory required by the DEA is the inventory of all controlled substances on hand to be conducted:
   a. Twice yearly
   b. Annually
   c. Every 2 years
   d. Every 3 years

_____ 5. The federal law that established health information privacy is called:
   a. Protected Health Information Act
   b. Health Insurance Portability and Accountability Act
   c. OBRA 90
   d. Prescription Drug Marketing Act

_____ 6. The federal law regulating controlled substances is:
   a. Drug Enforcement Administration (DEA) Act
   b. Combat Methamphetamine Epidemic Act
   c. Controlled Substances Act
   d. Food and Drug Act

_____ 7. Which of the following are NOT required to be registered with the DEA?
   a. Physicians who prescribe controlled substances.
   b. Nurse practitioners who prescribe controlled substances.
   c. Pharmacists who dispense controlled substances.
   d. Drug wholesalers that buy and sell controlled substances.

_____ 8. Prescription monitoring programs are programs that collect, review, and analyze:
   a. Information from pharmacies about controlled substance prescriptions dispensed in the state.
   b. Information from physicians about controlled substances prescribed in the state.