

Chapter 1 Consumer Safety and Drug Regulations

1. A client calls her primary care provider requesting a prescription for an antidepressant medication. She tells the nurse that she is severely depressed and would like the prescription called in to her local pharmacy. How should the nurse respond?

- a. The nurse encourages the client to see a psychiatric professional for an evaluation to obtain the prescription.
- b. The nurse tells the client to ask the pharmacist to recommend an over-the-counter antidepressant.
- c. The nurse can offer to write the client a prescription if it is a refill.
- d. The nurse offers to give the client a few samples to use until her next appointment.

ANSWER:

a

2. A client visits her health care provider for her annual physical. She questions the nurse regarding the use of an herbal supplement that she saw advertised on television for weight loss. What information can the nurse share with her client?

- a. The production of herbal medicines is not regulated by the FDA.
- b. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the FDA is responsible for ensuring that a dietary supplement is safe before it is marketed.
- c. Herbal medicines are tested by the FDA to determine if they have interactions with prescribed medications.
- d. Herbal medicines, while not approved by the FDA, are considered harmless.

ANSWER:

a

3. Upon leaving the exam room, a client tells the nurse that she is confused regarding her prescription. She asks the nurse if a cheaper, generic drug will be weaker than her current prescription. How should the nurse respond?

- a. Drug standards assure consumers that the same drug must be of uniform strength, quality, and purity.
- b. The prescribed medication is of better quality but will cost more.
- c. The insurance companies mandate there are different strengths between generic and brand name prescriptions.
- d. Every drug has a different chemical composition that cannot be duplicated.

ANSWER:

a

4. The FDA, under the direction of the Department of Health and Human Services, mandates which of the following?

- a. Prescription and nonprescription drugs must be shown to be effective as well as safe.
- b. All labels must include a listing of active ingredients; some labels require a listing of inactive ingredients as well.
- c. All new products must be tested by the FDA before **being** released to the public.
- d. All drugs must have "warning" labels.

ANSWER:

a

5. An older adult client is reluctant to take any prescribed medications and questions the nurse about the production process and safety of her medications. How should the nurse respond?

Chapter 1 Consumer Safety and Drug Regulations

- a. Federal laws require all drugs marketed in the United States to meet the minimal standards of strength, purity, and quality.
- b. Most medications are made outside the United States.
- c. Pharmaceutical companies follow their own guidelines.
- d. Insurance carriers set the parameters for drug manufacturing.

ANSWER:

a

6. The nurse in the local drug prevention clinic is asked by a client about the relative danger of various drugs. She explains that the Drug Enforcement Administration (DEA) classifies drugs that can be abused or have addictive properties into categories or schedules. Which of the following are factors that are considered when classifying the schedule of a particular drug? (SELECT ALL THAT APPLY.)

- a. the potential cost to produce the drug
- b. the medical value of the drug
- c. the harmfulness of the drug
- d. the potential for abuse or addiction
- e. the popularity of the medication

ANSWER:

b, c, d

7. The Federal Food, Drug and Cosmetic Act was amended three times. Which of the following are true about the amendments? (SELECT ALL THAT APPLY.)

- a. The amendments occurred in 1951, 1962, and 1972.
- b. The amendments lessened regulations to prevent tampering with drugs, food, and cosmetics.
- c. It is stated that prescription and nonprescription drugs must be shown to be effective and safe.
- d. The 1972 amendment established the National Drug Code (NDC) Directory.
- e. The NDC Directory provides the FDA with a number made up of five parts.

ANSWER:

a, c, d

8. A nurse is giving a presentation at a local community college about drug regulation. What act should she state as the first federal regulation established for consumer protection in the manufacturing of drugs and food?

- a. the Pure Food and Drug Act
- b. the Controlled Substance Act
- c. the Federal Food, Drug and Cosmetic Act
- d. the Foods and Drug Administration

ANSWER:

a

9. A nurse looks in a reference book to determine whether a particular drug is a controlled substance. What is the MOST authoritative standard for officially approved drugs in the United States?

- a. USP/NF
- b. FDA
- c. DEA
- d. OBRA

Chapter 1 Consumer Safety and Drug Regulations

ANSWER:

a

10. What does the 1983 Orphan Drug Act give pharmaceutical companies the financial incentive to do?

- a. develop medications for diseases that affect only a small number of people
- b. give samples to health clinics
- c. develop medication for orphaned children
- d. develop medications requested by the local community

ANSWER:

a

11. The nurse discusses the use of a newly marketed orthopedic device to a client. Which of the following is an accurate statement regarding the safety of the device?

- a. The FDA ensures basic standards prior to allowing any drug or new product to be marketed.
- b. The device is safe to use because a number of clients have used it.
- c. The manufacturing company is responsible for ensuring the safety of a device before distributing it to the public.
- d. The Drug Enforcement Administration handles all the safety requirements of new products.

ANSWER:

a

12. The nurse is explaining the use of prescription pads to a new employee. What is a good guideline to follow regarding prescription pads?

- a. Prescription pads should be kept in a locked or secure area when not being used.
- b. Prescription pads should be easily accessible to health care providers for distribution to clients.
- c. Prescription pads are distributed in limited numbers to each provider.
- d. There are no established guidelines regarding prescription pads.

ANSWER:

a

13. A client asks why pharmacists must offer counseling before dispensing medication. The nurse explains that this is required by which act?

- a. Omnibus Budget Reconciliation Act
- b. the Pure Food and Drug Act
- c. the Controlled Substances Act
- d. the Federal Food, Drug, and Cosmetic Act

ANSWER:

a

14. A client calls her health care provider's office to ask the nurse about a label on a new prescription bottle that has a warning about drowsiness. What does the nurse know about prescription labels?

- a. The FDA regulations mandate that all prescriptions must include a listing of all active and inactive ingredients and that certain medications must include warning labels.
- b. The label is a recommendation provided by the pharmacy.
- c. The DEA enforces the use of warning labels for all medications.
- d. Providers are required to give the pharmacy appropriate warnings.

ANSWER:

a

Chapter 1 Consumer Safety and Drug Regulations

15. A nursing instructor is explaining the roles of the FDA and DEA in setting standards for drug control. What area does the FDA control?

- a. the approval and removal of medical products on the market
- b. Only controlled substances (narcotics)
- c. enforces laws against drug activities, including illegal drug use, dealing, and manufacturing
- d. monitors the need for changing the schedules of abused drugs

ANSWER: a

16. A nurse is a long-term employee in a medical office and understands the importance of keeping accurate medical records of all dispensed controlled substances. For how long should the office maintain the records?

- a. two years
- b. one year
- c. four years
- d. six years

ANSWER: a

17. A client asks her primary care provider if there are any regulations concerning nonprescription medicines. The provider explains that nonprescription medicines are governed by which act?

- a. the Federal Food, Drug, and Cosmetic Act
- b. the Pure Food and Drug Act
- c. the Controlled Substance Act
- d. the Omnibus Budget Reconciliation Act

ANSWER: a

18. An athlete requests a prescription for an anabolic steroid (C-III) from her physician. How often can a prescription for a C-III drug be refilled?

- a. C-III may be refilled up to five times in six months.
- b. C-III drugs may be refilled at the discretion of the physician and state regulations.
- c. C-III drugs are not approved for medical use in the United States.
- d. C-III can only be refilled with a new written prescription.

ANSWER: a

19. The nurse knows that Ritalin is a C-II controlled substance. She explains to her client that C-II medications have what level of potential for abuse?

- a. C-II medications have a high abuse potential and may lead to severe dependence.
- b. C-II medications are safe to take as the client sees fit.
- c. C-II medications may lead to limited dependence.
- d. C-II medications have the lowest abuse potential of all controlled substances.

ANSWER: a

20. A nurse is discussing the prescription policy to her client for some possible medications. Which drug,

Name _____ Class _____ Date _____
: _____ : _____ e: _____

Chapter 1 Consumer Safety and Drug Regulations

according to its classification, requires a new written prescription for a refill?

- a. codeine (C-II)
- b. Valium (C-IV)
- c. codeine with Tylenol (C-III)
- d. promethazine with codeine (C-V)

ANSWER:

a