

**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

**FEEDBACK:**

- a. The client should be encouraged to seek a psychiatric professional evaluation to obtain the prescription.
- b. Antidepressants are not sold as over-the-counter medications; a prescription is required. Try again.
- c. The nurse cannot write a prescription without evaluating the client. Try again.
- d. Samples are not given out to a client who has not been evaluated by a practitioner. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 8:16 PM

**DATE MODIFIED:** 11/26/2017 8:32 PM

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

**FEEDBACK:**

- 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 dietary manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. Try again.
- c. The FDA does not test supplements. Try again.
- d. There are documented interactions with specific herbal supplements and prescribed medications. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 8:22 PM

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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

FEEDBACK:

- a. Drug standards assure consumers that the same drug must be of uniform strength, quality, and purity.
- b. Generic and trade drugs are the same medication. Generic is the name that is assigned to a new drug. The trade name is the name the pharmaceutical company assigns to that drug to have exclusive rights to market it. Try again.
- c. Insurance companies have no control over the production of medication. Try again.
- d. The laws regulating drugs state that consumers can be assured that all preparations with the same name have the same uniform strength, quality, and purity. Try again.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 11/26/2017 8:23 PM

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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

FEEDBACK:

- a. Prescription and nonprescription drugs must be shown to be effective as well as safe.
- b. All labels must be accurate and must include a listing of all active and inactive ingredients. Try again.
- c. The FDA must approve all new products before they are released to the public. Try again.
- d. Warning labels must be present on certain preparations. Try again.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 11/26/2017 8:26 PM

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5. An older adult client is reluctant to take any prescribed medications and questions the nurse about the

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production process and safety of her medications. How should the nurse respond?

- 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

**FEEDBACK:**

- a. Federal laws require all drugs marketed in the United States to meet the minimal standards of strength, purity, and quality.
- b. Medications made out of the United States or illegally are not controlled by drug standards. Try again.
- c. Although pharmaceutical companies do have guidelines, the final authorization for released products is through the FDA. Try again.
- d. Insurance carriers do not manufacture medications. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 8:33 PM

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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

**FEEDBACK:**

- a. The cost to produce a drug is not a category classified by the DEA.
- b. The Drug Enforcement Administration divides controlled substances into five levels or schedules according to their medical value.
- c. Harmfulness of a drug is one criterion that the DEA uses to categorize a drug.
- d. Potential for abuse is one criterion that the DEA uses to categorize drugs.
- e. The popularity of the medication is not considered. The DEA does take into consideration societal problems with medication and that may cause the medication to be moved from one schedule to another.

**POINTS:** 1

**QUESTION TYPE:** Multiple Response

**HAS VARIABLES:** False

**DATE CREATED:** 11/28/2017 2:43 AM

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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

FEEDBACK:

- a. The amendments occurred in 1952, 1962, and 1972.
- b. The amendments did not lessen regulations. Try again.
- c. All prescription and nonprescription drugs must be shown to be effective and safe.
- d. The 1972 amendment established the National Drug Code (NDC) Directory.
- e. It did provide the FDA with a number; however, it is not made up of five parts. Try Again.

POINTS: 1

QUESTION TYPE: Multiple Response

HAS VARIABLES: False

DATE CREATED: 11/28/2017 2:48 AM

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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

FEEDBACK:

- a. The first federal regulation established for consumer protection in the manufacturing of drugs and food was the 1906 Pure Food and Drug Act.
- b. The Controlled Substances Act of 1970 established the Drug Enforcement Administration. Try again.
- c. The Federal Food, Drug, and Cosmetic Act was established in 1938, with amendments in 1951 and 1962. Try again.
- d. The Food and Drug Administration was established under the Department of Health and Human Services as a result of the Federal Food, Drug and Cosmetic Act amendments of 1951 and 1962. Try again.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 11/26/2017 9:05 PM

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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?

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

**ANSWER:** a

**FEEDBACK:**

- a. The USP/NF specifies the official U.S. standards for making each drug.
- b. The FDA was established to ensure that some basic standards would be followed regarding drugs. Try again.
- c. The DEA handles all the needs and safety controls for drugs that are considered more dangerous. Try again.
- d. OBRA mandates that all OTC drugs taken by a client must be documented as part of the medical record. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 9:08 PM

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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

**FEEDBACK:**

- a. The Orphan Drug Act gives the pharmaceutical companies financial incentive to develop medications for diseases that affect only a small number of people. This allows the companies to produce drugs that would otherwise not be developed because of low profitability.
- b. Pharmaceutical companies produce drugs for profit. Try again.
- c. The Orphan Drug Act does not specifically provide incentives for developing medications for orphaned children. Try again.
- d. The Orphan Drug Act does not address the production of medications requested by the local community. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 9:15 PM

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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

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the public.

d. The Drug Enforcement Administration handles all the safety requirements of new products.

**ANSWER:** a

**FEEDBACK:**

- a. The FDA ensures basic standards prior to allowing any drug or new product to be marketed. The FDA can recommend withdrawal of an existing product or medication if it is deemed that the product's or drug's benefit no longer outweighs its risk.
- b. All medications and new products are scrutinized going through many studies and trials prior to marketing. The DEA handles the safety needs associated with controlled substances. Try again.
- c. Pharmaceutical companies do have safety guidelines; however, the ultimate decision of a product's safety rests with the FDA.
- d. The FDA can recommend withdrawal of an existing product or medication if it is deemed that the product's or drug's benefit no longer outweighs its risk.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 9:20 PM

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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

**FEEDBACK:**

- a. Prescription pads should be concealed and in a secure area when not being used. The prescription pad has the provider's DEA registration number and can be used fraudulently.
- b. The prescription pads should be secured when not being used. Try again.
- c. There is no limit to the number of prescription pads a provider can use. Try again.
- d. There are strict restrictions regarding the use of prescription pads as mandated by the DEA. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 9:41 PM

**DATE MODIFIED:** 11/26/2017 9:43 PM

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

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d. the Federal Food, Drug, and Cosmetic Act

ANSWER: a

FEEDBACK:

- a. The Omnibus Budget Reconciliation Act mandates client counseling before dispensing prescriptions to a client.
- b. The Pure Food and Drug Act mandates that all drugs marketed in the United States meet minimal standards of strength, purity, and quality.
- c. The Controlled Substances Act sets much tighter controls on drugs that are being abused by society.
- d. The Federal Food, Drug, and Cosmetic Act establishes specific regulations to prevent adulteration of (tampering with) drugs, foods, and cosmetics.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 11/26/2017 9:43 PM

DATE MODIFIED: 11/26/2017 9:45 PM

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

FEEDBACK:

- a. The FDA regulations mandate that all prescriptions must include a listing of all active and inactive ingredients and that certain preparations must include warning labels.
- b. Pharmaceutical companies are required by the FDA to add warning labels. Try again.
- c. The DEA handles issues related to controlled substances. Try again.
- d. Providers are required to educate their clients regarding medications that they are prescribing. Try again.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 11/26/2017 9:45 PM

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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

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- FEEDBACK:**
- a. The FDA is responsible for the approval and removal of products on the market.
  - b. The DEA is not only concerned with controlled substances. Try again.
  - c. The DEA enforces laws against drug activities, including illegal drug use, dealing, and manufacturing. Try again.
  - d. The DEA monitors the need for changing the schedules of abused drugs. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 9:54 PM

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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

- FEEDBACK:**
- a. Medical records should be maintained for 2 years.
  - b. This is not the required length of time for maintaining records. Try again.
  - c. This is not the required length of time for maintaining records. Try again.
  - d. This is not the required length of time for maintaining records. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 9:56 PM

**DATE MODIFIED:** 11/26/2017 9:57 PM

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

- FEEDBACK:**
- a. The Federal Food, Drug, and Cosmetic Act designates which drugs can be sold without a prescription.
  - b. The Pure Food and Drug Act of 1960 was the first established consumer protection act regulating the manufacturing of drugs. Try again.
  - c. The Controlled Substance Act in 1970 was established for specific control over specific drugs, such as those abused by society. Try again.
  - d. The Omnibus Budget Reconciliation Act mandates that all over-the-counter medications be added to the client's medical record and requires that pharmacists provide client



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counseling before dispensing a medication. Try again.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 11/26/2017 9:57 PM

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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

FEEDBACK: 

- a. C-III may be refilled up to five times in six months.
- b. C-V substances have no federal restrictions on refills. Try again.
- c. C-I substances are not approved for medical use in the United States. Try again.
- d. C-II substances can only be refilled with a new prescription. Try again.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 11/26/2017 9:58 PM

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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

FEEDBACK: 

- a. C-II drugs have a high abuse potential and may lead to severe dependence.
- b. All medications have associated risks if used inappropriately. Try again.
- c. C-III drugs may lead to limited dependence. Try again.
- d. C-V drugs have the lowest abuse potential. Try again.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 11/26/2017 9:59 PM

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

Name: \_\_\_\_\_ Class: \_\_\_\_\_ Date: \_\_\_\_\_

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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

**FEEDBACK:**

- a. C-II substances require a new written prescription for a refill.
- b. C-IV substances may be refilled up to five times in six months. Try again.
- c. C-III substances may be refilled up to five times in six months. Try again.
- d. C-V substances have no federal restrictions on refills. Try again.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 11/26/2017 10:02 PM

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Match each name to the definition listed below.

- a. Standards
- b. Controlled (schedule) drug
- c. Legend drug
- d. FDA
- e. DEA

*QUESTION TYPE:* Matching

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:15 AM

*DATE MODIFIED:* 12/4/2017 12:17 AM

1. Requires a prescription but not a DEA number

*ANSWER:* c

*POINTS:* 1

2. These were established by the 1906 Pure Food and Drug Act

*ANSWER:* a

*POINTS:* 1

3. Requires a prescription and DEA number

*ANSWER:* b

*POINTS:* 1

4. Enforcement agency established by the 1970 Controlled Substances Act

*ANSWER:* e

*POINTS:* 1

5. Approval agency established by the 1938 Federal Food, Drug and Cosmetic Act

*ANSWER:* d

*POINTS:* 1

Match each example to the names listed below.

- a. Orphan drug
- b. Drug standards
- c. NDC
- d. USP/NF
- e. OTC

*QUESTION TYPE:* Matching

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:18 AM

*DATE MODIFIED:* 12/4/2017 12:19 AM

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6. Uniform strength, purity and quality

ANSWER: b

POINTS: 1

7. Drug that treats a disease affecting a very small number of people

ANSWER: a

POINTS: 1

8. Directory listing drugs by manufacturer and packaging type(s).

ANSWER: c

POINTS: 1

9. Directory listing of officially approved drugs (was originally two references)

ANSWER: d

POINTS: 1

10. These drugs require no prescription.

ANSWER: e

POINTS: 1

11. The pharmaceutical manufacturer has the authority to add additional active ingredients to a previously approved pharmaceutical product.

ANSWER: False - According to the 1938 Federal Food, Drug, and Cosmetic Act and Amendments of 1951 and 1962, all labels must be accurate and include a listing of all active and inactive ingredients.

POINTS: 1

QUESTION TYPE: Modified True / False

HAS VARIABLES: False

DATE CREATED: 12/4/2017 12:23 AM

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12. Drug strength may vary with each lot number of a medication.

ANSWER: False - The 1906 Pure Food and Drug Act established that all drugs marketed in the United States meet minimal standards of uniform strength, purity, and quality.

POINTS: 1

QUESTION TYPE: Modified True / False

HAS VARIABLES: False

DATE CREATED: 12/4/2017 12:21 AM

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13. The Pure Food and Drug Act of 1906 established drug standards and official drug references.

ANSWER: True

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*POINTS:* 1

*QUESTION TYPE:* Modified True / False

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:23 AM

*DATE MODIFIED:* 12/4/2017 12:23 AM

14. The 1906 Pure Food and Drug Act established consumer protections to prevent the inclusion of “dangerous ingredients” without the knowledge of the consumer.

*ANSWER:* True

*POINTS:* 1

*QUESTION TYPE:* Modified True / False

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:24 AM

*DATE MODIFIED:* 12/4/2017 12:24 AM

15. Medication labels need only include the trade name of the drug.

*ANSWER:* False - Labels must include a listing of all active and inactive ingredients, warning labels on certain preparations, and generic names for the medication

*POINTS:* 1

*QUESTION TYPE:* Modified True / False

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:24 AM

*DATE MODIFIED:* 12/4/2017 12:25 AM

16. The prescriber of the medication is the only health care professional who is responsible for being aware of new medications, laws, and restrictions.

*ANSWER:* False - The health care worker involved in administration of a medication also bears the responsibility of being aware of the laws and restrictions pertinent to that medication.

*POINTS:* 1

*QUESTION TYPE:* Modified True / False

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:25 AM

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17. A double-locked system is the recommended method for maintaining security of controlled substances.

*ANSWER:* True

*POINTS:* 1

*QUESTION TYPE:* Modified True / False

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:25 AM

*DATE MODIFIED:* 12/4/2017 12:26 AM

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18. Health care workers are responsible for maintaining records of all controlled substances received, dispensed, and destroyed.

- a. True
- b. False

*ANSWER:* True

*POINTS:* 1

*QUESTION TYPE:* True / False

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:28 AM

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19. Controlled substance records are to be kept for 10 years.

*ANSWER:* False - Records for the previous 2 years must be available at all times for inspection.

*POINTS:* 1

*QUESTION TYPE:* Modified True / False

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:26 AM

*DATE MODIFIED:* 12/4/2017 12:27 AM

20. The NDC contains the manufacturer, product, and package information for all commercially available products.

- a. True
- b. False

*ANSWER:* True

*POINTS:* 1

*QUESTION TYPE:* True / False

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 12:27 AM

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21. Identify the drug standard in the following list.

- a. Color
- b. Strength
- c. Shape
- d. Taste

*ANSWER:* b

*FEEDBACK:*

- a. Color is not a standard.
- b. Correct!
- c. Shape is not a standard.
- d. Taste is not a standard.

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POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 12/4/2017 1:27 AM

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22. The risk of death from the use of *street drugs* versus *prescription medications* is mostly due to \_\_\_\_.
- a. a lack of control over quality, purity, and strength makes street drugs dangerous
  - b. the risk is the same for both sources of the same substance
  - c. street drugs are approved for use
  - d. the need for a prescription makes drugs hard to obtain

ANSWER: a

- FEEDBACK:
- a. Correct!
  - b. The lack of enforcement of drug standards in illegal street drugs poses a significant danger for the consumer.
  - c. The exact composition of a street drug is unknown, and it may contain dangerous contaminants or undisclosed additional drugs.
  - d. Street drugs are illegal.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 12/4/2017 1:27 AM

DATE MODIFIED: 12/4/2017 1:43 AM

23. Drug standards regulate drug manufacture so that medications of the same name will be of the same \_\_\_\_.
- a. strength, purity, and quality
  - b. shape, color, and taste
  - c. purity, shape, and color
  - d. quality, color, and smell

ANSWER: a

- FEEDBACK:
- a. Correct!
  - b. Standards do not include shape, color or taste.
  - c. Standards do not include shape or color.
  - d. Standards do not include color or smell.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 12/4/2017 1:27 AM

DATE MODIFIED: 12/4/2017 1:44 AM

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24. The 1906 Pure Food and Drug Act includes which of the following provisions?

- a. Regulation of drugs sold in the United States and Canada
- b. Requires labeling to indicate if a medication contained a “dangerous ingredient”
- c. Regulates illicit (illegal) drugs
- d. Requires information regarding medications to be handed down from one practitioner to the next

**ANSWER:** b

**FEEDBACK:**

- a. The Pure Food and Drug Act regulates ALL drugs MARKETED in the United States. If a drug is manufactured in Canada, it must meet USFDA requirements to be marketed here.
- b. Correct!
- c. Illicit drugs are not regulated.
- d. The Pure Food and Drug Act established two references of officially approved drugs, the USP and the NF.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 1:44 AM

25. The Pure Food and Drug Act of 1906 was formulated \_\_\_\_\_.

- a. to control use of drugs being abused by society
- b. as the first government attempt to establish consumer protection in the manufacture of drugs and foods
- c. in order to make drug manufacturing profitable for the drug companies
- d. as a means to identify addicting or abused drugs

**ANSWER:** b

**FEEDBACK:**

- a. This applies to the Controlled Substances Act of 1970.
- b. Correct!
- c. The Pure Food and Drug Act was in answer to a need for consumer safety.
- d. This applies to the Controlled Substances Act of 1970.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 1:45 AM

26. Which act required that drug preparations containing morphine have a label indicating the presence of morphine?

- a. Federal Food, Drug, and Cosmetic Act of 1938
- b. Federal Food, Drug, and Cosmetic Act Amendment of 1965
- c. Controlled Substances Act of 1970
- d. Pure Food and Drug Act of 1906



## Chapter 1 Consumer Safety and Drug Regulations

**ANSWER:** d

**FEEDBACK:**

- a. This act formed the FDA.
- b. There was no amendment in 1965.
- c. The 1970 Controlled Substances Act identified schedules of abused or additive drugs.
- d. Correct!

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 1:45 AM

27. Identify a provision of the Federal Food, Drug, and Cosmetic Act and its Amendments \_\_\_\_\_.
- a. new products are required to be approved by the Food and Drug Administration
  - b. defined schedules for substances that require specific controls
  - c. it set limitations on the use of prescriptions
  - d. established USP

**ANSWER:** a

**FEEDBACK:**

- a. Correct!
- b. This response applies to the 1970 Controlled Substances Act.
- c. Prescription limitations were defined by the 1970 Controlled Substances Act.
- d. USP was established by the 1906 Pure Food and Drug Act.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 1:46 AM

28. What drugs are referred to as “legend” drugs?
- a. Drugs that work so well they become “legendary.”
  - b. Drugs that have been available for over 100 years.
  - c. Drugs that must carry the legend “Caution—federal law prohibits dispensing without a prescription.”
  - d. Drugs that are mentioned in urban legends.

**ANSWER:** c

**FEEDBACK:**

- a. Legend drugs require a prescription from a provider.
- b. Legend drugs may be old or new and require a prescription.
- c. Correct!
- d. Legend drugs require a prescription from a provider

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

## Chapter 1 Consumer Safety and Drug Regulations

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 1:47 AM

29. The Food and Drug Administration was created to \_\_\_\_\_.
- a. oversee testing of all proposed new drugs prior to release into the U.S. market
  - b. inspect plants where food, drugs, medical devices, and cosmetics are made
  - c. remove unsafe drugs from the market
  - d. All of the above.

*ANSWER:* d

*FEEDBACK:*

- a. This is a responsibility of the FDA, but not the only thing the FDA does.
- b. This is a responsibility of the FDA, but not the only thing the FDA does.
- c. This is a responsibility of the FDA, but not the only thing the FDA does.
- d. Correct! All the answers are roles of the FDA.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 1:47 AM

30. The USP/NF (U.S. Pharmacopeia/National Formulary) was established to \_\_\_\_\_.
- a. provide a reference for all officially approved medications
  - b. legalize the manufacture of medications.
  - c. give the public the information needed to safely make their own drugs.
  - d. All of the above.

*ANSWER:* a

*FEEDBACK:*

- a. Correct!
- b. The USP/NF is a reference with no approval authority.
- c. The USP/NF is a reference.
- d. A is the only correct choice.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 1:48 AM

31. USP is the official abbreviation for \_\_\_\_\_.
- a. U.S. Post office
  - b. U.S. Patrol

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- c. U.S. Police
- d. U.S. Pharmacopoeia

**ANSWER:** d

**FEEDBACK:**

- a. U.S. Post office provides mail services, not pharmacy services.
- b. This is not a pharmacy-related agency.
- c. Remember, the abbreviation would be related to pharmacy.
- d. Correct! United States Pharmacopoeia.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 1:49 AM

32. NF is the official abbreviation for \_\_\_\_\_.
- a. National Football
  - b. National Fortress
  - c. National Food
  - d. National Formulary

**ANSWER:** d

**FEEDBACK:**

- a. Not football, remember this is a related to pharmacology.
- b. Not fortress, it is something to do with pharmacology.
- c. Not food, something related to pharmacy.
- d. Correct! National Formulary

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:14 AM

33. Prior to the 1906 establishment of the U.S. Pharmacopeia, drug information was related by \_\_\_\_\_.
- a. the Internet
  - b. encyclopedias
  - c. passing to the next generation
  - d. schools of medicine and pharmacology

**ANSWER:** c

**FEEDBACK:**

- a. There was no Internet in 1906, and the first drug act was passed this year.
- b. Drug information for medical use is not provided in an encyclopedia.
- c. Correct! Information was passed from one person to another.
- d. There were no drug references available and teaching was very informal prior to 1906.

## Chapter 1 Consumer Safety and Drug Regulations

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:15 AM

34. Which bureau of the Department of Justice was established by the Controlled Substances Act of 1970?

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

*ANSWER:* b

*FEEDBACK:*

- a. U.S. Pharmacopeia
- b. Correct! Drug Enforcement Agency
- c. Food and Drug Administration
- d. National Formulary

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:17 AM

35. The Controlled Substances Act of 1970 set much tighter controls on a specific group of drugs that are \_\_\_\_\_.

- a. at risk of being abused by society
- b. listed in the USP/NF
- c. those that contain herbal components
- d. available over the counter

*ANSWER:* a

*FEEDBACK:*

- a. Correct!
- b. This refers to the 1906 Pure Food and Drug Act.
- c. The FDA does not approve dietary or herbal supplements.
- d. OTCs were outlined in the 1938 Federal Food, Drug, and Cosmetic Act.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:18 AM

36. The Controlled Substances Act may limit \_\_\_\_\_.

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- a. the number of refills that can be filled in a 6-month time frame
- b. at which pharmacies the patient may get the prescription filled
- c. the level of pain control to be maintained
- d. how the patient may maintain or store the medication

**ANSWER:** a

**FEEDBACK:** a. Correct!  
b. The government does not limit where prescriptions may be filled.  
c. The Act does not address pain control.  
d. The government does not regulate where private citizens may keep their medications.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:19 AM

37. The Controlled Substances Act sets tighter controls on \_\_\_\_\_.
- a. common analgesics such as Tylenol or aspirin
  - b. depressants, stimulants, psychedelics, narcotics, and anabolic steroids
  - c. antibiotics, diuretics, antihypertensives, and diabetic medications
  - d. common cold/allergy medications

**ANSWER:** b

**FEEDBACK:** a. Tylenol and aspirin are provided over the counter and access to them is not regulated.  
b. Correct!  
c. These are prescription medications that are not considered to be at risk for abuse.  
d. These currently remain as over-the-counter medications but more controls are being applied.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:20 AM

38. Which of the following is required to have a DEA number?
- a. The provider writing the prescription
  - b. The person receiving the prescription
  - c. All providers working in the physician's office or clinic
  - d. All providers working in the pharmacy

**ANSWER:** a

**FEEDBACK:** a. Correct!

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- b. People receiving the prescription do not need a DEA number.
- c. Only the prescriber needs a DEA number.
- d. Only the pharmacist needs a DEA number.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:21 AM

39. Professionals needing a DEA number are \_\_\_\_\_.

- a. registered nurses (RNs), licensed (vocational) nurses (LPN/LVNs), and certified medication assistants (CMAs)
- b. pharmacists, physicians, and veterinarians
- c. clients who have a professional license
- d. administrators of nursing care facilities, acute care hospitals, and home health care associations

*ANSWER:* b

- FEEDBACK:*
- a. Health care providers administering medications do not need a DEA number.
  - b. Correct!
  - c. No client needs a DEA number, regardless of occupation.
  - d. Administrators of institutions do not need DEA numbers.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:21 AM

40. DEA numbers appear on the \_\_\_\_\_.

- a. prescriber's professional license
- b. prescription for a controlled substance
- c. medication bottle that contains the controlled substance
- d. receipt for the medication

*ANSWER:* b

- FEEDBACK:*
- a. The DEA number does not appear on the professional's license.
  - b. Correct!
  - c. The DEA number does not appear on the medication container.
  - d. The DEA number does not appear on the receipt.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

## Chapter 1 Consumer Safety and Drug Regulations

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:23 AM

41. A DEA number represents \_\_\_\_\_.
- a. the number of times the DEA has cited the person
  - b. the phone number for the local DEA office
  - c. registration with the Drug Enforcement Agency
  - d. the prescriber's professional state license number

*ANSWER:* c

*FEEDBACK:*

- a. DEA number does not provide citation information
- b. DEA number is the individual's registration number assigned by the Drug Enforcement Agency
- c. Correct!
- d. State licensure does not include DEA number

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:24 AM

42. Agencies/persons that are required to have a DEA number are \_\_\_\_\_.
- a. acute care hospitals and nursing homes
  - b. pharmacies, grocery stores, and convenience stores
  - c. drug manufacturers and packaging facilities, pharmacists, and physicians
  - d. schools of nursing, medical assisting, and radiology

*ANSWER:* c

*FEEDBACK:*

- a. The DEA does not regulate hospitals and nursing homes.
- b. The DEA does not regulate grocery stores or convenience stores.
- c. Correct!
- d. The DEA does not regulate schools.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:24 AM

43. The schedule of controlled substances that has the highest risk of abuse potential is \_\_\_\_\_.
- a. Schedule C 2
  - b. Schedule C 3
  - c. Schedule C 4

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d. Schedule C 5

**ANSWER:** a

**FEEDBACK:** a. Correct!  
b. The lower the number the higher potential for abuse.  
c. The lower the number the higher potential for abuse.  
d. The lower the number the higher potential for abuse.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:26 AM

44. Drugs listed in Schedule 1 of Controlled Substances \_\_\_\_\_.

- a. are not approved for medical use in the United States
- b. may be refilled up to five times in 6 months
- c. may have prescriptions phoned in by health care workers
- d. have low abuse potential compared to other schedules

**ANSWER:** a

**FEEDBACK:** a. Correct!  
b. Schedule 1 drugs are not approved for medical use in the United States.  
c. Schedule 1 drugs are not approved for medical use in the United States.  
d. Schedule 1 drugs have the highest risk of abuse or addiction.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:27 AM

45. Prescriptions of the controlled substances listed in these schedules have restrictions about phoning them into the pharmacy \_\_\_\_\_.

- a. Schedule 1
- b. Schedule 2
- c. Schedule 3
- d. All of the above.

**ANSWER:** d

**FEEDBACK:** a. Schedule 1 drugs are illegal for use and are not available to be prescribed in any fashion in the United States.  
b. Schedule 2 drugs may not be called in to the pharmacy unless in cases of emergency, and then only by a physician. The call must be followed by a handwritten prescription within 72 hours.



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- c. Schedule 3 drugs may be phoned in by a physician only.
- d. Correct!

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:28 AM

46. Prescriptions of the controlled substances listed in which of these schedules MAY be called into the pharmacy by health care workers other than the prescriber \_\_\_\_\_.

- a. Schedules 1 and 2 only
- b. Schedules 2 through 4
- c. Schedules 4 and 5 only
- d. Schedules 1 through 3

**ANSWER:** c

**FEEDBACK:**

- a. Schedule 1 is not approved for medical use in the United States. Schedule 2 may be phoned into the pharmacy by a physician in an emergency only, followed by a written prescription within 72 hours.
- b. Schedule 2 may only be phoned in by the physician in an emergency. Schedule 3 may be phoned in by the physician only. Schedules 4 and 5 may be phoned in by an office health care worker.
- c. Correct!
- d. Schedule 3 may be phoned in by the physician only.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:29 AM

47. Prescriptions of the controlled substances listed in these schedules may be refilled up to five times in 6 months \_\_\_\_\_.

- a. Schedules 1 and 2
- b. Schedules 3 and 4
- c. Schedules 3, 4, and 5
- d. Schedules 1, 2, 3, 4, and 5

**ANSWER:** c

**FEEDBACK:**

- a. Schedule 1 drugs are not approved for medical use in the United States. Schedule 2 drugs may not be refilled.
- b. Both may be refilled five times in 6 months, but there is a more complete answer.
- c. Correct!
- d. Schedule 1 drugs are not approved for medical use in the United States. Schedule 2 drugs may not be refilled.

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**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:30 AM

48. The *least* desirable information source regarding drugs is a \_\_\_\_\_.

- a. current drug reference
- b. pharmacist
- c. coworker
- d. pharmaceutical company representative

**ANSWER:** c

**FEEDBACK:**

- a. U.S. Pharmacopeia is a reliable source.
- b. The pharmacist is a reliable source.
- c. Correct! A coworker cannot always be considered a reliable source.
- d. Pharmaceutical representatives are considered reliable sources for their products.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:31 AM

49. Which act established the USP and NF?

- a. 1938 Federal Food, Drug, and Cosmetic Act
- b. 1906 Pure Food and Drug Act
- c. 1965 Pharmaceutical Consumer Protection Act
- d. 1962 Amendment to the 1938 Federal Food, Drug, and Cosmetic Act

**ANSWER:** b

**FEEDBACK:**

- a. The 1938 Federal Food, Drug, and Cosmetic Act primarily addressed prevention of tampering with products.
- b. Correct!
- c. The "1965 Pharmaceutical Consumer Protection Act" does not exist.
- d. The 1962 Amendment to the 1938 Federal Food, Drug, and Cosmetic Act was concerned with labeling and assuring that prescription and nonprescription drugs were both effective and safe.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:32 AM

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50. An *orphan drug* is defined as a(n) \_\_\_\_\_.
- a. drug used only in children
  - b. drug used to treat a disease that affects only a small number of people
  - c. lone drug in a specific class of drugs
  - d. unapproved drug used to treat a rare disease

**ANSWER:** b

**FEEDBACK:**

- a. Orphan drugs may treat rare diseases of any age group.
- b. Correct!
- c. Orphan drugs treat uncommon diseases.
- d. Orphan drugs treat rare diseases and there may be exceptions regarding approval but there is a better definition for orphan drug.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:32 AM

51. Which legislation provides for financial incentives to be provided to pharmaceutical companies for the development of medications that would otherwise be unprofitable because they are designed to treat diseases that affect only a small number of people?
- a. 1965 Pure Food and Drug Act
  - b. 1938 Orphan Drug and Cosmetic Act
  - c. 1983 Orphan Drug Act
  - d. OBRA of 1990

**ANSWER:** c

**FEEDBACK:**

- a. Pure Food and Drug Act was passed in 1906.
- b. This act does not exist.
- c. Correct!
- d. This act does not exist.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:33 AM

52. What new requirements were mandated by the Omnibus Budget Reconciliation Act of 1990?
- a. All prescriptions are to be included as part of the permanent medical record.
  - b. Over-the-counter medications are to be entered into the permanent medical record.
  - c. Pharmacists are required to provide drug use review and patient counseling prior to dispensing prescriptions to patients.

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- d. Both B and C are correct.
- e. All of the above.

**ANSWER:** d

**FEEDBACK:**

- a. Prescription medications were previously required to be included in the medical records.
- b. Correct, but there is a more complete answer – OBRA mandated the additional requirement of documenting over-the-counter medications and counseling to be provided by the dispensing pharmacist
- c. Correct, but there is a more complete answer – OBRA mandated the additional requirement of documenting over-the-counter medications and counseling to be provided by the dispensing pharmacist.
- d. Correct! Both B and C are new OBRA requirements.
- e. Not all answers are correct.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/13/2017 12:44 AM

53. Once a drug or device has been approved for use in the United States, the \_\_\_\_\_.

- a. DEA may withdraw approval if a safety concern exists
- b. only action that can be taken is requirement of additional warnings to be added to the labeling and recommendation for voluntary withdrawal by the manufacturer
- c. FDA may reconsider its approval and withdraw it from the market to protect the public safety
- d. DEA may demand withdrawal from the market

**ANSWER:** b

**FEEDBACK:**

- a. The DEA is not involved in approvals or withdrawals.
- b. Correct!
- c. The FDA has the power to review and make recommendations regarding withdrawals of approved drugs, but it cannot enforce a withdrawal.
- d. Withdrawals are made voluntarily by the manufacturer based on safety reports and review.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:36 AM

54. The National Drug Code Directory (NDC) was established in 1972 and provides the FDA with the following information for all drugs commercially distributed \_\_\_\_\_.

- a. the drug name
- b. packaging information

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- c. the manufacturer of the product
- d. All of the above are included in the NDC.

**ANSWER:** d

**FEEDBACK:**

- a. Drug name is included, but there is a more complete answer.
- b. Packaging information is included, but there is a more complete answer.
- c. Manufacturer is included as the first five digits, but there is a more complete answer.
- d. Correct! The NDC has three parts: Manufacturer, product, and packaging.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:38 AM

55. The FDA needs to identify all the packaging options available for a drug, the best reference to locate this information would be \_\_\_\_\_.

- a. U.S. Pharmacopoeia
- b. National Drug Code Directory
- c. National Formulary
- d. National Drug Registration Database

**ANSWER:** b

**FEEDBACK:**

- a. U.S. Pharmacopoeia would not be the best choice for packaging information.
- b. Correct! Packaging information is included in the NDC Directory.
- c. National Formulary would not be the best choice for packaging information.
- d. This option does not exist.

**POINTS:** 1

**QUESTION TYPE:** Multiple Choice

**HAS VARIABLES:** False

**DATE CREATED:** 12/4/2017 1:27 AM

**DATE MODIFIED:** 12/4/2017 2:39 AM

56. The Sunshine Act, which is part of the Affordable Care Act, requires reporting of \_\_\_\_\_.

- a. monetary payment a physician receives from a pharmaceutical representative
- b. any compensation or gifts paid to physicians by pharmaceutical representatives
- c. gifts worth over one-hundred dollars a physician receives from pharmaceutical representatives
- d. all samples a physician receives from pharmaceutical representatives

**ANSWER:** b

**FEEDBACK:**

- a. Payments must be reported but there is a more complete answer choice.
- b. Correct! All forms of reward or compensation must be reported.
- c. Gifts must be reported but there is a more complete answer choice.

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- d. The Sunshine Act requires all forms of reward or compensation be reported. Ethical dilemmas can occur when physicians are rewarded for prescribing certain medications.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:39 AM

57. Your friend, Thomas, had a serious adverse reaction to an over-the-counter medication and found that a number of other individuals had similar adverse reactions. Which agency is most likely to investigate this situation and take action if a problem is found?

- a. Food and Drug Administration
- b. United States Pharmacopeia
- c. National Formulary Enforcement
- d. Drug Enforcement Agency

*ANSWER:* a

*FEEDBACK:*

- a. Correct!
- b. USP is a reference only.
- c. National Formulary Enforcement does not exist.
- d. The DEA is not involved in monitoring adverse drug reactions for OTC products.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:40 AM

58. Quinn hears on the news that the FDA has asked a company to withdraw a medication. Under what circumstances can the FDA do this?

- a. When more effective alternatives are available
- b. When it is no longer profitable
- c. Never, because only the DEA can do this
- d. When the benefits of a drug outweigh its risks

*ANSWER:* d

*FEEDBACK:*

- a. Other drug availability would not be a reason to ask for a drug to be withdrawn from the market.
- b. The FDA does not make recommendations based on profitability.
- c. The DEA doesn't make these recommendations.
- d. Correct! The FDA can recommend a company take a drug off the market if complications or adverse events are documented.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

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*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:41 AM

59. Ian, a registered nurse, maintains that he is not a drug abuser, so the 1970 Controlled Substances Act has no relevance for him. Is he right?

- a. Yes, except that his state licensing board may place additional restrictions on him.
- b. No, as long as he is careful to avoid the appearance of impropriety and is generally responsible in his all aspects of life.
- c. Yes, as long as he does not abuse drugs, this act does not impact him.
- d. No, because the act lays out his responsibilities with respect to record keeping and administration of controlled substances.

*ANSWER:* d

*FEEDBACK:*

- a. The Controlled Substances Act is not about licensure of medical professionals.
- b. All medical professionals who work with controlled substances need to know how the Controlled Substances Act applies to the drugs they administer.
- c. If Ian works in a facility providing controlled substances, or works with patients they are prescribed to, he is responsible for following the guidelines.
- d. Correct! As an RN, Ian is responsible for knowing the rules and laws about handling and administering controlled substances.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

*DATE CREATED:* 12/4/2017 1:27 AM

*DATE MODIFIED:* 12/4/2017 2:42 AM

60. You're waiting in line at the pharmacy to get your medication, and decide to take a look at your doctor's handwriting on the prescription. You notice the phrase "DEA Number" followed by a code. What does the phrase "DEA Number" represent?

- a. The code required to determine whether the drug is reimbursable
- b. The physician's license number for your state
- c. The drug standards met by the medication prescribed for you
- d. The registration number for physicians who prescribe controlled substances

*ANSWER:* d

*FEEDBACK:*

- a. DEA stands for Drug Enforcement Agency. The code is related to controlled substances prescribing not insurance reimbursement.
- b. The DEA number is not the same as a physician's licensure.
- c. A DEA number is required on all schedule drug prescriptions.
- d. Correct! Physicians, pharmacists, physician's assistants, nurse practitioners, dentists, and veterinarians who prescribe controlled substances must have a DEA number.

*POINTS:* 1

*QUESTION TYPE:* Multiple Choice

*HAS VARIABLES:* False

Name: \_\_\_\_\_ Class: \_\_\_\_\_ Date: \_\_\_\_\_

## **Chapter 1 Consumer Safety and Drug Regulations**

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