Chapter 02: Pharmacy Law, Ethics, and Regulatory Agencies
Elsevier: Mosby's Pharmacy Technician, 4th Edition

MULTIPLE CHOICE

1. Drug diversion can be defined as the:
   a. Intentional misuse of a drug intended for medical purposes
   b. Mishandling of a medication that can lead to contamination or impurity, falsification of contents, or loss of drug quality or potency
   c. Recreational use of a prescription or a scheduled drug
   d. A and C

   ANS: D
   Drug diversion is the intentional misuse of a drug intended for medical purposes; the *Drug Enforcement Administration* (DEA) usually defines *diversion* as the recreational use of a prescription or a scheduled drug. Diversion can also refer to the channeling of the prescription drug supply away from legal distribution to the illegal street market. Answer B is the definition of *adulteration*.

   PTS: 1 REF: Pages 18, 29
   OBJ: ASHP objective: 11.1 (Remembering) Stating definitions of commonly used medical terms

2. DUE stands for:
   a. Drug use examination
   b. Data use evaluation
   c. Data usage evaluation
   d. Drug utilization evaluation

   ANS: D
   DUE is an abbreviation that means *drug utilization evaluation* and is a process designed to ensure that prescribed drugs are appropriately used. The desired outcome is an increase in medication-related efficacy and safety.

   PTS: 1 REF: Page 25
   OBJ: ASHP objective: 11.1 (Remembering) Identifying the correct medical term for a given abbreviation

3. What agency within the U.S. Department of Health and Human Services is responsible for ensuring the safety, efficacy, and security of human and veterinary drugs, biologic products, medical devices, the national food supply, cosmetics, and radioactive products?
   a. DEA
   b. FDA
   c. DUE
   d. USDA

   ANS: B
   The U.S. Food and Drug Administration (FDA) is the agency within the U.S. Department of Health and Human Services responsible for ensuring the safety, efficacy, and security of human and veterinary drugs, biologic products, medical devices, the national food supply, cosmetics, and radioactive products.

PTS: 1 REF: Pages 30-31 OBJ: ASHP objective: none

4. Medicare insures individuals:
   a. Over 65 years of age
   b. Under 65 years of age with long-term disabilities
   c. With end-stage renal disease
   d. All of the above

   ANS: D
   Medicare is a federal- and state-managed insurance program that covers health care costs and prescription drugs for individuals 65 years of age and older, for persons younger than 65 years of age with long-term disabilities, or for those with end-stage renal disease.

   PTS: 1 REF: Page 28
   OBJ: ASHP objective: 31.2 (Understanding) Describing how to verify third-party coverage

5. Which of the following is a U.S. government–managed entity that oversees safety in the workplace?
   a. *Omnibus Budget Reconciliation Act (*OBRA)
   b. Occupational Safety and Health Administration (OSHA)
   c. *Health Insurance Portability and Accountability Act (*HIPAA)
   d. *Material safety data sheet* (MSDS)

   ANS: B
   The purpose of OSHA is to ensure a safe workplace for employees.

   PTS: 1 REF: Page 53
   OBJ: ASHP objective: 22.1 (Understanding) Explaining OSHA regulations regarding pharmacy practice, including regulations for bloodborne pathogens

6. PHI stands for:
   a. Public health information
   b. Personal health information
   c. Private health information
   d. Protected health information

   ANS: D
   Protected health information (PHI) is a phrase used to describe a patient's personal health data. Under HIPAA, this information is protected from being shared or distributed without the patient's permission.

   PTS: 1 REF: Page 25
   OBJ: ASHP objective: 11.1 (Remembering) Identifying the correct medical term for a given abbreviation

7. The FDA is currently under the authority of the:
   a. Department of Health, Education, and Welfare (HEW)
   b. Public Health Service
   c. Department of Health and Human Services
   d. Department of Agriculture

ANS: C
The FDA was under the authority of the U.S. Department of Agriculture until 1940, when the agency became part of the Federal Security Agency. As the FDA continued to regulate new applications for drugs, devices, and other products, the agency was transferred to the Department of HEW in 1953 and was eventually placed under the authority of the U.S. Public Health Service within the Department of HEW in 1968. Ultimately the FDA's final destination occurred in 1980 when it was moved from the Department of HEW to the newly created U.S. Department of Health and Human Services, where it remains today.

PTS: 1 REF: Pages 30-31 OBJ: ASHP objective: none

8. Which of the following required the labeling, "Caution: Federal law prohibits dispensing without a prescription?"
   a. 1951 Durham-Humphrey Amendment
   b. 1962 Kefauver-Harris Amendments
   c. 1970 Comprehensive Drug Abuse Prevention and Control Act
   d. 1972 Drug Listing Act

   ANS: A
   The 1951 Durham-Humphrey Amendment added more instructions for drug companies and required the labeling "Caution: Federal law prohibits dispensing without a prescription."

   PTS: 1 REF: Page 22 OBJ: ASHP objective: none

9. Which of the following involved the setup of the five-level schedule of controlled substances?
   a. 1951 Durham-Humphrey Amendment
   b. 1962 Kefauver-Harris Amendments
   c. 1970 Comprehensive Drug Abuse Prevention and Control Act
   d. 1972 Drug Listing Act

   ANS: C
   The 1970 Comprehensive Drug Abuse Prevention and Control Act is also known as the *Controlled Substance Act*. The DEA was formed to enforce the laws concerning controlled substances and their distribution. A stair-step schedule of controlled substances was introduced, based on a drug's intended medical use, the propensity of the drug to be abused, and safety and dependency concerns.

   PTS: 1 REF: Page 23
   OBJ: ASHP objective: 20.9 (Remembering) Stating the meaning of the term controlled substance

10. Which of the following are exceptions to the childproof cap requirement set into place by the Poison Prevention Packaging Act of 1970?
    a. Emergency medications such as sublingual *nitroglycerin*
    b. Hospitalized patients' medications
    c. Patient or physician's request
    d. All of the above

    ANS: D
    Exceptions to this act include physicians' requests for nonchildproof caps for their patients, certain legend medications, patients who are hospitalized, or at the specific request of the patient.

PTS: 1 REF: Page 23
OBJ: ASHP objective: 20.5 (Remembering) Describing options for the packaging of products for children and patients who are the physically challenged or aged

11. The first set of numbers of a National Drug Code (NDC) number, which is assigned by the FDA, is the:
    a. Labeler code
    b. Product code
    c. Package code
    d. None of the above

    ANS: A
    The first set of numbers (labeler code) is assigned by the FDA. The second set (product code) identifies the specifics of the product. The third set of numbers (package code) identifies the specifics of the package size and types.

    PTS: 1 REF: Page 23
    OBJ: ASHP objective: 20.2 (Understanding) Explaining the function of an NDC number

12. Which set(s) of numbers in the NDC code is(are) assigned by the drug company?
    a. First set (labeler code)
    b. Second set (product code)
    c. Third set (package code)
    d. B and C

    ANS: D
    Both the second and third sets of code are assigned by the drug company.

    PTS: 1 REF: Page 23
    OBJ: ASHP objective: 20.2 (Understanding) Explaining the function of an NDC number

13. OBRA originally addressed problems regarding the quality of health care for:
    a. Infants and children
    b. Older adults
    c. Disabled individuals
    d. Patients with acquired immunodeficiency syndrome (AIDS)

    ANS: B
    The origins of the **OBRA** are from 1987 when the U.S. Congress addressed the problems regarding health care quality for older adults, especially residents in nursing homes.

    PTS: 1 REF: Page 25 OBJ: ASHP objective: none

14. The OBRA of 1990 *federal* counseling rules specifically state that the pharmacist must offer to counsel all:
    a. Insured persons with new prescriptions
    b. Persons with new prescriptions
    c. Persons with new prescriptions or new instructions for old prescriptions
    d. Medicaid patients who receive new prescriptions

    ANS: D

The OBRA 90 states that a pharmacist must offer to counsel (at the time of purchase) all Medicaid patients who receive new prescriptions.

PTS: 1 REF: Page 25
OBJ: ASHP objective: 19.1 (Remembering) Describing the legal obligations for patient counseling, including documentation, as specified in OBRA 90 and in state laws and regulations

15. DUEs required under OBRA 90 must include all of the following *except*:
    a. Possible drug interactions
    b. Appropriateness of dosage and duration of therapy
    c. Evaluation of lower cost therapies
    d. Contraindications

ANS: C
Pharmacists must review drugs for appropriateness, possible drug interactions, contraindications, and correctness of drug dosage and duration of therapy to ensure patient safety.

PTS: 1 REF: Page 25 OBJ: ASHP objective: none

16. Which of the following statements is(are) true of patient counseling?
    a. Most individual states have set higher standards than those in OBRA 90.
    b. A patient can refuse counseling.
    c. A pharmacy technician cannot counsel.
    d. All of the above statements are true.

ANS: D
Although OBRA 90 is specific to **Medicaid** coverage, pharmacies usually counsel all patients on medications that have been prescribed. If these provisions are not met, then the pharmacy cannot receive federal reimbursement for a medication and may face civil liability proceedings. The Board of Pharmacy within each state oversees OBRA 90 compliance and can also impose fines on both pharmacies and pharmacists for noncompliance. A patient may refuse counseling. Pharmacy technicians are not legally permitted to counsel.

PTS: 1 REF: Page 25
OBJ: ASHP objective: 19.1 (Remembering) Describing the legal obligations for patient counseling, including documentation, as specified in OBRA 90 and in state laws and regulations

17. Which of the following is *not* considered a HIPAA-covered entity?
    a. Health care provider
    b. Family member
    c. Health plan
    d. Health care clearinghouse

ANS: B
A HIPAA-covered entity is a health care provider, health plan, or health care clearinghouse and includes entities that process nonstandard health information received from another entity into a standard format (e.g., standard electronic format or data content or vice versa).

PTS: 1 REF: Page 25
OBJ: ASHP objective: 43.1 (Applying) Observing legal and ethical guidelines for safeguarding the confidentiality of patient information

18. Drug errors can be reported to:
    a. MedWatch
    b. The Joint Commission (TJC)
    c. United States Pharmacopeia (USP)
    d. DEA

    ANS: A
    MedWatch is the program under the FDA that allows consumers and health care professionals to report discrepancies or adverse reactions with medications.

    PTS: 1 REF: Page 31
    OBJ: ASHP objective: 35.2 (Understanding) Identifying the role and limitations of the FDA MedWatch program in error reporting

19. Which one of the following product recalls is the most serious?
    a. Class 1
    b. Class 2
    c. Class 3
    d. Class 4

    ANS: A
    Class 1 recalls are the highest level of product recall and deal with products that could cause serious or even fatal harm. This level also includes foods that contain toxins or labels that do not list ingredients that may cause allergies. Only three classifications of product recalls exist—classes 1, 2, and 3.

    PTS: 1 REF: Page 31
    OBJ: ASHP objective: 45.1 (Remembering) Identifying the three classifications of pharmacy recalls

20. Which schedule of medication is considered an exempt controlled substance?
    a. C-II
    b. C-III
    c. C-IV
    d. C-V

    ANS: D
    Schedule C-V medications (referred to as *exempt controlled substances*) may be over-the-counter (OTC) in some states because of the low potential of abuse.

    PTS: 1 REF: Page 36
    OBJ: ASHP objective: 18.2 (Remembering) Stating the schedule for controlled substances and commonly used medications that fall into each category

21. Which of the following is(are) true of schedule C-I drugs?
    a. C-I drugs have no approved medicinal use.
    b. These medications include lysergic acid diethylamide (LSD) and heroin.
    c. C-I drugs are not stocked in pharmacies.
    d. All of the above statements are true.

    ANS: D

The strongest level of abuse potential are schedule C-I drugs. These drugs have been determined to have a high potential for abuse and to have no acceptable medicinal purpose; they are also deemed unsafe for use under medical supervision. Schedule C-I drugs include LSD and heroin. Because C-I drugs do not have any medicinal use in the United States, pharmacies do not stock them and physicians cannot prescribe them for their patients.

PTS: 1 REF: Pages 35-36
OBJ: ASHP objective: 18.2 (Remembering) Stating the schedule for controlled substances and commonly used medications that fall into each category

22. Individual states cannot establish which of the following?
    a. Storage of certain controlled substances
    b. Record keeping of certain controlled substances
    c. OTC status of some schedule C-V medications
    d. Schedule under which a drug should be placed

ANS: D
Individual states establish certain rules concerning controlled substances, such as storage and record keeping. Schedule C-V medications (referred to as *exempt controlled substances*) may be kept OTC in some states because of the low potential of abuse. The U.S. Attorney General has the authority to decide the schedule under which a drug should be placed.

PTS: 1 REF: Page 36
OBJ: ASHP objective: 42.1 (Understanding) Explaining the importance and role of federal, state, and local laws; regulations; and professional standards

23. Who can sign Form 222 to order schedule C-II narcotics?
    a. Pharmacist who signed Form 224 or the person who has been the legally designated Power of Attorney by that pharmacist
    b. Pharmacist on duty
    c. Store manager
    d. Pharmacy technician

ANS: A
A pharmacy has two ways to obtain schedule C-II controlled substances from a distributor: (1) electronic or paper filing of DEA Form 222, which must be signed by the pharmacist who signed Form 224 or by the person who has been legally designated Power of Attorney by that pharmacist.

PTS: 1 REF: Page 38
OBJ: ASHP objective: 32.1 (Remembering) Describing typical procedures for purchasing pharmaceutical drugs, devices, and supplies

24. Form 222 consists of three copies. Which copy is ultimately sent to the DEA?
    a. Top copy (1)
    b. Middle copy (2)
    c. Bottom copy (#)
    d. B and C

ANS: B
When the medication is shipped, the middle copy (2) is forwarded to the DEA to prove that the medication has been properly received.

PTS: 1 REF: Pages 38-39
OBJ: ASHP objective: 32.1 (Remembering) Describing typical procedures for purchasing pharmaceutical drugs, devices, and supplies

25. How many years does the pharmacy need to retain invoices for scheduled drug purchases?
    a. 1
    b. 2
    c. 3
    d. 7

    ANS: B
    Once the drugs are received, the invoice forms for schedules III to V must be kept for no less than 2 years.

    PTS: 1 REF: Page 39
    OBJ: ASHP objective: 33.10 (Applying) Following established policies and procedures to maintain a record of controlled substances received, stored, and removed from inventory

26. Which DEA form is needed to destroy damaged, outdated, or unwanted controlled substances?
    a. 41
    b. 106
    c. 225
    d. 363

    ANS: A
    DEA Form 41 is needed for authorization to destroy damaged, outdated, or unwanted controlled substances. Retail pharmacies can only request this form from the DEA once a year. (Hospitals may request a "blanket destruction" permission form, which allows them to destroy a controlled substance multiple times throughout the year.)

    PTS: 1 REF: Pages 36, 38
    OBJ: ASHP objective: 33.10 (Applying) Following established policies and procedures to maintain a record of controlled substances received, stored, and removed from inventory

27. Schedule C-II prescriptions cannot be:
    a. Refilled
    b. Partially filled
    c. Transferred
    d. A and C

    ANS: D
    Schedule C-II prescriptions may not be refilled. Schedule II medications are not transferrable because they can only be filled once. Schedule C-II drugs may be partially filled if the pharmacist does not have the full quantity in stock. The pharmacist must note on the prescription the amount filled, and the remaining amount may be dispensed within 72 hours of the first fill.

    PTS: 1 REF: Page 42
    OBJ: ASHP objective: 18.4 (Analyzing) Identifying situations when the technician should notify the pharmacist of potential inappropriateness when screening refills and renewals

28. How often does the DEA require a narcotic inventory?
    a. Every month
    b. Every 6 months
    c. Every year
    d. Every 2 years

    ANS: D
    The DEA requires an inventory to be taken every 2 years but does not require a copy of the inventory. Any discrepancies that are identified must be investigated and explained.

    PTS: 1 REF: Page 40
    OBJ: ASHP objective: 33.10 (Remembering) Stating the legal requirements for recording controlled substances received, stored, and removed from inventory

29. Which of the following statements is(are) true of record keeping as it/they apply to controlled substances?
    a. Federal law allows the choice of one of three different prescription-filing methods.
    b. Controlled substances must be logged in and out of the pharmacy stock.
    c. A perpetual inventory must be maintained until an item is no longer stocked.
    d. All of the above statements are true.

    ANS: D
    A pharmacy has three methods of filing controlled substances and legend drugs. Although federal law allows any one of these three methods to be used, a state's Board of Pharmacy may require a specific method. In addition to the filing of controlled medications, every time a controlled substance is issued to a patient or nursing station, it must be logged out of the pharmacy stock as required under state law. This same standard holds true for returning items or adding new stock to the inventory. The pharmacy must maintain a perpetual inventory of these medications.
    ASHP objective: 33.10 (Remembering) Stating the legal requirements for recording controlled substances received, stored, and removed from inventory
    PTCB competency: 2.4 Documentation requirements for receiving, ordering, and returning a controlled substance and for the loss or theft or destruction of a controlled substance (DEA)

    PTS: 1 REF: Page 39-40

30. In which of the following forms can prescriptions for schedules C-II through C-V drugs be accepted by the pharmacy?
    a. Written
    b. Orally
    c. Facsimile
    d. All of the above

    ANS: D
    Schedules C-II through C-V drug prescriptions can be accepted by the pharmacy in written, oral, or facsimile form following certain DEA provisions and/or circumstances. A schedule C-II prescription may be called or faxed ahead of time, but the original prescription, signed by the prescriber, must be presented before the medication is dispensed.

    PTS: 1 REF: Page 41
    OBJ: ASHP objective: 18.1 (Applying) Acting in accordance with state laws and regulations related

to receiving and screening of medication orders

31. What is the maximum number of refills allowed for schedules C-III and C-IV prescriptions?
    a. Whatever the physician writes
    b. None
    c. Five refills within 6 months of the date the prescription was written
    d. Five refills within 6 months of the date of the original fill

    ANS: C
    Schedules C-III and C-IV prescriptions may be refilled up to five times within 6 months after the date the prescription was written, whichever occurs first.

    PTS: 1 REF: Page 42
    OBJ: ASHP objective: 18.4 (Analyzing) Identifying situations when the technician should notify the pharmacist of potential inappropriateness when screening refills and renewals

32. How many times can schedules C-III, C-IV, and C-V prescriptions be transferred?
    a. None
    b. One
    c. Until the refills have expired
    d. None of the above

    ANS: B
    Schedules C-III, C-IV, and C-V prescriptions may be transferred to another pharmacy only one time.

    PTS: 1 REF: Page 42
    OBJ: PTCB competency: 2.3 Controlled substance transfer regulations (DEA)

33. Which of the following statements is *not* true regarding a boxed warning?
    a. A boxed warning is encased in a black border in the manufacturer's insert.
    b. It is required on any medication or product that carries a high risk potential to the consumer.
    c. A boxed warning is required on all medication package inserts.
    d. It is sometimes referred to as a "black box warning."

    ANS: C
    A **boxed warning** is encased in a bold border within the manufacturer's insert. Health care professionals often refer to a boxed warning as a "black box warning," although this labeling term is not official. This type of warning is required on medications and other products that carry a high risk potential to the consumer.

    PTS: 1 REF: Page 45
    OBJ: ASHP objective: 35.1 (Remembering) Defining the term high alert

34. Which pregnancy category has the highest risk of teratogenicity?
    a. X
    b. B
    c. C
    d. D

    ANS: A

Pregnancy category X medications, based on studies in animals or humans, have demonstrated fetal abnormalities and/or positive evidence of human fetal risks, based on adverse reaction data from investigational or marketing experience. The risks involved in the use of the drug in pregnant women clearly outweigh its potential benefits.

PTS: 1 REF: Pages 45, 48 OBJ: Box 2-9

35. Which of the following is *not* required on a prescription label?
    a. Date the prescription was filled
    b. Name, address, and telephone number of the pharmacy
    c. License or DEA number of the prescriber
    d. Name of the prescriber

    ANS: C
    A prescription label must include the name, address, and telephone number of the pharmacy, the name of the prescriber, the date prescription was filled, the prescription number, and any cautions described or provided on auxiliary labels. The license or DEA number of the prescriber only needs to be on the prescriber's prescription order.

    PTS: 1 REF: Pages 49-50
    OBJ: ASHP objective: 20.6 (Remembering) Describing the information in a complete product label

36. What is the first letter in the DEA number of prescribers who are qualified to prescribe medication to treat opioid addiction?
    a. B
    b. F
    c. M
    d. X

    ANS: D
    Prescribers who are qualified to order medications to treat opioid addiction are assigned an X.

    PTS: 1 REF: Page 50
    OBJ: ASHP objective: 18.2 (Understanding) Explaining the procedure to verify the validity of a prescriber's DEA number

37. Which of the following would be a correct DEA number for Dylan Brown, MD?
    a. MB1234563
    b. BB1234564
    c. AB1234563
    d. MD1234563

    ANS: C
    The method used to verify a DEA number is as follows: The first two characters are composed of letters; the first letter is an A, B, F, M, or X, followed by the first letter of the prescriber's last name. The letter M is assigned to mid-level practitioners such as a nurse practitioner. The next seven digits are composed of numbers that are added together. In this example, $1 + 3 + 5 = 9$ and $2 + 4 + 6 = 12 \times 2 = 24$. $9 + 24 = 33$. The last number of this answer, 3, must be the last number of the DEA number.

    PTS: 1 REF: Pages 50, 52
    OBJ: ASHP objective: 18.2 (Understanding) Explaining the procedure to verify the validity of a

prescriber's DEA number

38. What does the abbreviation REMS mean?
    a. Risk evaluation and management study
    b. Risk evaluation and mitigation strategy
    c. Risk examination and management study
    d. Restricted evaluation and management strategy

    ANS: B
    The Food and Drug Administration Amendments Act of 2007 gave the U.S. FDA the authority to require a risk evaluation and mitigation strategy (REMS) from manufacturers to ensure that the benefits of a drug or biologic product outweigh its risks. Certain drugs are placed in a restricted status for use.

    PTS: 1 REF: Page 52
    OBJ: ASHP objective: 23.5 (Remembering) Defining REMS and its importance

39. No special prescribing requirement exists for which of the following medications?
    a. Methadone
    b. Isotretinoin
    c. Heroin
    d. Suboxone

    ANS: C
    Heroin is a schedule C-I with no medicinal use. The FDA regulates isotretinoin (Accutane, Amnesteem, Claravis, Sotret) under a special program, iPledge, because of the severe adverse effects of the drug. Methadone is a schedule C-II controlled substance and is used to treat persons addicted to opiates. Patients are to receive specialized treatment while taking this medication. No more than 1 day's supply may be filled by a pharmacy, and the medication must be taken in a physician's office or drug treatment center. Suboxone and subutex are schedule C-III controlled substances that require special consent forms to be completed by the patient. Under federal law, prescribers must meet certain criteria. When all conditions are met, the DEA issues a special number with an X identifying them as qualified prescribers.

    PTS: 1 REF: Pages 35-36, 51-52
    OBJ: ASHP objective: 23.5 (Applying) Applying special handling procedures for drugs with mandated REMS

40. The purchase of pseudoephedrine is limited to:
    a. 3.6 g per calendar day
    b. 9 g per 30 days from a retailer
    c. 7.5 g per 30 days by mail order
    d. All of the above

    ANS: D
    The maximum amount of pseudoephedrine sold may not exceed 3.6 g in a calendar day or 9 g per 30 days from a retailer and 7.5 g per 30 days via mail order.

    PTS: 1 REF: Page 28 OBJ: Box 2-5