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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. intentional misuse of a drug intended for medical purposes and recreational use of a prescription or a scheduled drug.

   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. Option B is the definition of *adulteration*.

   DIF: Recall REF: Page 20
   OBJ: ASHP objective: 3.2 Receive, process, and prepare prescriptions/medication orders for completeness, accuracy, and authenticity to ensure safety. | ASHP objective: 3.6 Assist pharmacists in preparing, storing, and distributing medication products including those requiring special handling and documentation.
   MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 1.C.7.f. Diversion and prescription monitoring programs

2. DUE stands for
   a. drug under evaluation.
   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.

   DIF: Recall REF: Page 20
   OBJ: ASHP objective: 3.7 Assist pharmacists in the monitoring of medication therapy.
   MSC: PTCE Domain: 3.3 Issues that require pharmacist intervention (e.g., drug utilization review [DUR], adverse drug event [ADE], OTC recommendation, therapeutic substitution, misuse, adherence, post-immunization follow-up, allergies, drug interactions) | EXCPT: 1.B.1.e. Omnibus Budget Reconciliation Act of 1990 (OBRA 90)

3. Which 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

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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.

DIF: Comprehension REF: Page 21
OBJ: ASHP objective: 5.5 Describe pharmacy compliance with professional standards and relevant legal, regulatory, formulary, contractual, and safety requirements.
MSC: PTCE Domain: 2.5 FDA recall requirements (e.g., medications, devices, supplies, supplements, classifications) | EXCPT: 4.A. Medication Safety and Quality Assurance

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 options are correct.

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.

DIF: Comprehension REF: Page 28
OBJ: ASHP objective: 3.14 Collect payment for medications, pharmacy services, and devices.
MSC: PTCE Domain: none | EXCPT: 3.A.5.c. Types of coverage (for example: Medicare, Medicaid, workers' compensation, HMO, patient assistance programs)

5. Which of the following is a U.S. government–managed entity that oversees safety in the workplace?
   a. Health and Human Services
   b. Occupational Safety and Health Administration (OSHA)
   c. Food and Drug Administration
   d. Safety data sheet (SDS)

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

DIF: Comprehension REF: Pages 20, 51
OBJ: ASHP objective: 5.7 Describe OSHA requirements for prevention and response to blood-borne pathogen exposure (e.g., accidental needle stick, post-exposure prophylaxis).
MSC: PTCE Domain: 2.1 Federal requirements for handling and disposal of non-hazardous, hazardous, and pharmaceutical substances and waste | EXCPT: 1.B.4.o. Organizations/regulators related to pharmacy practice (for example: OSHA, The Joint Commission, FDA)

6. PHI stands for
   a. public health institution.
   b. personal health information.

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c. private health institution.
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.

DIF: Recall REF: Page 20
OBJ: ASHP objective: 2.2 Demonstrate ability to maintain confidentiality of patient information, and understand applicable state and federal laws.
MSC: PTCE Domain: none | EXCPT: 1.B.1.a. Comply with federal laws and regulations applicable to pharmacy practice-Health Insurance Portability and Accountability Act (HIPAA)

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.

DIF: Recall REF: Page 21 OBJ: ASHP objective: none
MSC: PTCE Domain: 2.5 FDA recall requirements (e.g., medications, devices, supplies, supplements, classifications) | EXCPT: 1.B.1.g. Comply with federal laws and regulations applicable to pharmacy practice-Food, Drug and Cosmetic Act

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."

DIF: Recall REF: Page 24
OBJ: ASHP objective: 5.5 Describe pharmacy compliance with professional standards and relevant legal, regulatory, formulary, contractual, and safety requirements.
MSC: PTCE Domain: none | EXCPT: 1.B.1.f. Comply with federal laws and regulations applicable to pharmacy practice-Durham-Humphrey Amendment

9. Which of the following involved the setup of the five-level schedule of controlled substances?

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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.

DIF: Recall REF: Pages 24
OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 1.C.1.c. Differentiate among the controlled substances schedules and the drugs within them-Schedules of controlled substances and drugs within them

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 options are correct

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

DIF: Recall REF: Page 24
OBJ: ASHP objective: 5.5 Describe pharmacy compliance with professional standards and relevant legal, regulatory, formulary, contractual, and safety requirements.
MSC: PTCE Domain: 4.3 Equipment/supplies required for drug administration (e.g., package size, unit dose, diabetic supplies, spacers, oral and injectable syringes) | EXCPT: 1.B.1.j. Comply with federal laws and regulations applicable to pharmacy practice-Poison Prevention Packaging Act (PPPA)

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. No options are correct.

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.

DIF: Comprehension REF: Page 24

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OBJ: ASHP objective: 5.5 Describe pharmacy compliance with professional standards and relevant legal, regulatory, formulary, contractual, and safety requirements.
MSC: PTCE Domain: 4.4 Lot numbers, expiration dates, and National Drug Code (NDC) numbers | EXCPT: 1.B.1.c. Comply with federal laws and regulations applicable to pharmacy practice-Drug Listing Act of 1972 (including elements of the NDC)

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. Second and third sets

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

    DIF: Comprehension REF: Page 24
    OBJ: ASHP objective: 5.5 Describe pharmacy compliance with professional standards and relevant legal, regulatory, formulary, contractual, and safety requirements.
    MSC: PTCE Domain: 4.4 Lot numbers, expiration dates, and National Drug Code (NDC) numbers | EXCPT: 1.B.1.c. Comply with federal laws and regulations applicable to pharmacy practice-Drug Listing Act of 1972 (including elements of the NDC)

13. OBRA '87 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 Congress addressed the problems regarding health care quality for the elderly. With increasing numbers of elderly entering nursing homes, great concern arose over the substandard care being provided, the high nursing personnel-to-patient ratios, and the unhealthy conditions present.

    DIF: Recall REF: Page 25
    OBJ: ASHP objective: 5.5 Describe pharmacy compliance with professional standards and relevant legal, regulatory, formulary, contractual, and safety requirements.
    MSC: PTCE Domain: none | EXCPT: none

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

    DIF: Recall REF: Page 26
    OBJ: ASHP objective: 3.3 Assist pharmacists in the identification of patients who desire/require counseling to optimize the use of medications, equipment, and devices.
    MSC: PTCE Domain: 3.3 Issues that require pharmacist intervention (e.g., drug utilization review

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[DUR], adverse drug event [ADE], OTC recommendation, therapeutic substitution, misuse, adherence, post-immunization follow-up, allergies, drug interactions) | EXCPT: 1.B.1.e. Comply with federal laws and regulations applicable to pharmacy practice-Omnibus Budget Reconciliation Act of 1990 (OBRA 90)

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.

    DIF: Comprehension REF: Page 26
    OBJ: ASHP objective: 3.3 Assist pharmacists in the identification of patients who desire/require counseling to optimize the use of medications, equipment, and devices. | ASHP objective: 5.5 Describe pharmacy compliance with professional standards and relevant legal, regulatory, formulary, contractual, and safety requirements.
    MSC: PTCE Domain: 3.3 Issues that require pharmacist intervention (e.g., drug utilization review [DUR], adverse drug event [ADE], OTC recommendation, therapeutic substitution, misuse, adherence, post-immunization follow-up, allergies, drug interactions) | EXCPT: 1.B.1.e. Comply with federal laws and regulations applicable to pharmacy practice-Omnibus Budget Reconciliation Act of 1990 (OBRA 90)

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 options are correct.

    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 non-compliance. A patient may refuse counseling. Pharmacy technicians are not legally permitted to counsel.

    DIF: Recall REF: Page 26
    OBJ: ASHP objective: 3.3 Assist pharmacists in the identification of patients who desire/require counseling to optimize the use of medications, equipment, and devices. | ASHP objective: 5.5 Describe pharmacy compliance with professional standards and relevant legal, regulatory, formulary, contractual, and safety requirements.
    MSC: PTCE Domain: 3.3. Issues that require pharmacist intervention (e.g., drug utilization review [DUR], adverse drug event [ADE], OTC recommendation, therapeutic substitution, misuse, adherence, post-immunization follow-up, allergies, drug interactions) | EXCPT: 1.B.1.e. Comply with federal laws and regulations applicable to pharmacy practice-Omnibus Budget Reconciliation Act of 1990 (OBRA 90)

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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 non-standard health information received from another entity into a standard format (e.g., standard electronic format or data content or vice versa).

    DIF: Application REF: Page 26
    OBJ: ASHP objective: 2.2 Demonstrate ability to maintain confidentiality of patient information, and understand applicable state and federal laws.
    MSC: PTCE Domain: none | EXCPT: 1.B.1.a. Comply with federal laws and regulations applicable to pharmacy practice-Health Insurance Portability and Accountability Act (HIPAA)

18. Drug errors can be reported to
    a. MedWatch.
    b. The Joint Commission (TJC).
    c. United States Pharmacopeia (USP).
    d. Health and Human Services.

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

    DIF: Comprehension REF: Page 31
    OBJ: ASHP objective: 3.12 Explain procedures and communication channels to use in the event of a product recall or shortage, a medication error, or identification of another problem.
    MSC: PTCE Domain: 3.4 Event reporting procedures (e.g., medication errors, adverse effects, and product integrity, MedWatch, near miss, root-cause analysis [RCA]) | EXCPT: 4.A.f. Follow best practices for quality assurance and medication safety-MedWatch

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.

    DIF: Recall REF: Page 31
    OBJ: ASHP objective: 3.12 Explain procedures and communication channels to use in the event of a product recall or shortage, a medication error, or identification of another problem.
    MSC: PTCE Domain: 2.5 FDA recall requirements (e.g., medications, devices, supplies, supplements, classifications) | EXCPT: 1.A.13.b. Classes of recalls and required actions

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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.

    DIF: Recall REF: Page 36
    OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 2.C.1.e. Controlled Substances-Exempt Narcotics

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

    ANS: D
    The strongest levels 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.

    DIF: Recall REF: Page 30 | Page 36
    OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 1.C.1.c. Differentiate among the controlled substances schedules and the drugs within them-Schedules of controlled substances and drugs within them

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.

    DIF: Comprehension REF: Page 36
    OBJ: ASHP objective: 5.3 Explain that differences exist between states regarding state regulations,

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pertaining to pharmacy technicians, and the processing, handling and dispensing of medications.
MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 1.C. Controlled Substances

23. Who can sign DEA Form 222 to order schedule C-II narcotics?
    a. Pharmacist who signed DEA 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. PTCB certified 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 (2) by the person who has been legally designated Power of Attorney by that pharmacist.

    DIF: Recall REF: Page 39
    OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 1.C.7.d. Order, store, and maintain inventory of controlled substances in accordance with CSA. Procedures for ordering, receiving, storing, and disposing of controlled substances

24. DEA 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. Middle and bottom copies

    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.

    DIF: Recall REF: Page 40
    OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 1.C.7.d. Order, store, and maintain inventory of controlled substances in accordance with CSA. Procedures for ordering, receiving, storing, and disposing of controlled substances

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

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

DIF: Application REF: Page 40
OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 1.C.7.d. Order, store, and maintain inventory of controlled substances in accordance with CSA. Procedures for ordering, receiving, storing, and disposing of controlled substances

26. Which DEA form is needed to destroy damaged, outdated, or unwanted controlled substances?
    a. DEA Form 41
    b. DEA Form 224
    c. DEA Form 225
    d. DEA Form 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.)

DIF: Application REF: Page 38
OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 1.C.7.c. Order, store, and maintain inventory of controlled substances in accordance with CSA. DEA forms

27. Schedule C-II prescriptions cannot be
    a. refilled.
    b. partially filled.
    c. transferred.
    d. refilled and transferred.

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.

DIF: Application REF: Page 42
OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 1.C.4.e. Comply with laws and regulations when filling, partial filling, and refilling prescriptions for controlled substances-Prescription requirements for controlled substances

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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.

    DIF: Recall REF: Page 40
    OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 1.C.7.a. Order, store, and maintain inventory of controlled substances in accordance with CSA-Controlled Substance Act

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 options are correct.

    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.

    DIF: Recall REF: Pages 40
    OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 1.C.4.i. Comply with laws and regulations when filling, partial filling, and refilling prescriptions for controlled substances-Tracking requirements for perpetual inventory of controlled substances | EXCPT: 1.C.5.c. File all classes of prescriptions appropriately-Filing requirements

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

    ANS: D

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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.

DIF: Application REF: Page 41
OBJ: ASHP objective: 3.2 Receive, process, and prepare prescriptions/medication orders for completeness, accuracy, and authenticity to ensure safety. | ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedule | EXCPT: 1.C.3.a. Verify, on intake, required information is on prescription for controlled substance

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. Six 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.

DIF: Recall REF: Page 42
OBJ: ASHP objective: 3.2 Receive, process, and prepare prescriptions/medication orders for completeness, accuracy, and authenticity to ensure safety. | ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 1.C.4.e. Comply with laws and regulations when filling, partial filling, and refilling prescriptions for controlled substances-Prescription requirements for controlled substances

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. No options are correct.

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

DIF: Recall REF: Page 42
OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 1.C.4.h. Comply with laws and regulations when filling, partial filling, and refilling prescriptions for controlled substances-Laws, regulations, and processes to transfer prescriptions for controlled substances between pharmacies

33. Which of the following statements is *not* true regarding a boxed warning?

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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.

DIF: Recall REF: Page 44
OBJ: ASHP objective: 2.5 Demonstrate basic knowledge of anatomy, physiology and pharmacology, and medical terminology relevant to the pharmacy technician's role.
MSC: PTCE Domain: 2.4 Federal requirements for restricted drug programs and related medication processing (e.g., pseudoephedrine, Risk Evaluation and Mitigation Strategies [REMS]) | EXCPT: 4.A.d Black box warnings

34. 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.

DIF: Recall REF: Page 47
OBJ: ASHP objective: 3.4 Prepare patient-specific medications for distribution. | ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 3.B.6.b. Label medication products packaged in approved containers or, when appropriate, in original packages-Components of a patient prescription label

35. 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.

DIF: Recall REF: Page 49
OBJ: ASHP objective: 3.2 Receive, process, and prepare prescriptions/medication orders for

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completeness, accuracy, and authenticity to ensure safety. | ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 1.C.1.f. Differentiate among the controlled substances schedules and the drugs within them-Elements of and formula for DEA number

36. 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.

    DIF: Recall REF: Page 49
    OBJ: ASHP objective: 3.2 Receive, process, and prepare prescriptions/medication orders for completeness, accuracy, and authenticity to ensure safety. | ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: 1.C.1.f. Differentiate among the controlled substances schedules and the drugs within them-Elements of and formula for DEA number

37. What does the abbreviation REMS mean?
    a. Rapid eye movement 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.

    DIF: Recall REF: Page 50
    OBJ: ASHP objective: 3.6 Assist pharmacists in preparing, storing, and distributing medication products including those requiring special handling and documentation.
    MSC: PTCE Domain: 2.4 Federal requirements for restricted drug programs and related medication processing (e.g., pseudoephedrine, Risk Evaluation and Mitigation Strategies [REMS]) | EXCPT: 3.B.1.b. Identify medications that require special handling procedures-Purpose of Risk Evaluation Mitigation Strategies (REMS) program

38. 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 (Amnesteem, Claravis) 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.

DIF: Application REF: Page 36
OBJ: ASHP objective: 3.6 Assist pharmacists in preparing, storing, and distributing medication products including those requiring special handling and documentation.
MSC: PTCE Domain: 2.2 Federal requirements for controlled substance prescriptions (i.e., new, refill, transfer) and DEA controlled substance schedules | EXCPT: none

39. 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 options are correct.

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.

DIF: Comprehension REF: Page 29
OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.4 Federal requirements for restricted drug programs and related medication processing (e.g., pseudoephedrine, Risk Evaluation and Mitigation Strategies [REMS]) | EXCPT: 1.C.6.d. Comply with federal laws pertaining to the handling of schedule V (exempt narcotics) and regulated (BTC) non-prescription products

40. Which of the following drug classification require package inserts to be provided with the prescription?
a. Estrogens
b. Fertility drugs
c. Retinoids
d. All options are correct

ANS: D
Medications requiring package inserts to accompany the medication includes estrogens, fertility drugs and retinoids.

DIF: Application REF: Page 43
OBJ: ASHP objective: 3.6 Assist pharmacists in preparing, storing, and distributing medication

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products including those requiring special handling and documentation.
MSC: PTCE Domain: 2.4 Federal requirements for restricted drug programs and related medication processing (e.g., pseudoephedrine, Risk Evaluation and Mitigation Strategies [REMS]) | EXCPT: 3.B.8.c. Provide printed patient information leaflets and required medication

41. Which government agency created Safety Data Sheet requirements?
    a. CMS
    b. DEA
    c. FDA
    d. OSHA

    ANS: D
    Occupational Safety and Health Administration (OSHA) is a U.S. government–managed agency that created Safety Data Sheet (SDS) requirements.

    DIF: Application REF: Page 20
    OBJ: ASHP objective: 3.9 Use information from Safety Data Sheets (SDS), National Institute of Occupational Safety and Health (NIOSH) Hazardous Drug List, and the United States Pharmacopeia (USP) to identify, handle, dispense, and safely dispose of hazardous medications and materials.
    MSC: PTCE Domain: 2.1 Federal requirements for handling and disposal of non-hazardous, hazardous, and pharmaceutical substances and waste | EXCPT: 1.B.1. Comply with federal laws and regulations applicable to pharmacy practice

42. Which of the following was *not* covered in OBRA'87?
    a. Individual Privacy Rights
    b. Establishing a minimum standard of care was required
    c. Providing a higher quality of care in nursing homes
    d. Requirements for facilities participating in Medicare and Medicaid programs

    ANS: A
    OBRA'87 set requirements for facilities participating in Medicare and Medicaid programs and addressed enforcement mechanisms. A minimum standard of care was required, and a change began to take place, transitioning nursing homes from uncomfortable institutions to comfortable, home-like environments providing higher quality care. However, the provisions of OBRA'87 did not address individual privacy rights.

    DIF: Comprehension REF: Page 25
    OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: none | EXCPT: 1.B.1. Comply with federal laws and regulations applicable to pharmacy practice

43. Which medication is covered under the I-Pledge program?
    a. Clozaril
    b. Ciprofloxacin
    c. Isotretinoin
    d. Thalidomide

    ANS: C
    The FDA regulates isotretinoin (Amnesteem, Claravis) under a special program called iPledge because of the severe adverse effects of the drug.

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DIF: Application REF: Page 50
OBJ: ASHP objective: 3.6 Assist pharmacists in preparing, storing, and distributing medication products including those requiring special handling and documentation. | ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.4 Federal requirements for restricted drug programs and related medication processing (e.g., pseudoephedrine, Risk Evaluation and Mitigation Strategies [REMS]) | EXCPT: 3.B.1. Identify medications that require special handling procedures

44. A medication is packaged in a container that is defective; what type of drug recall would it be?
    a. Class 1
    b. Class 2
    c. Class 3
    d. Class 4

    ANS: C
    Class 3 recalls are the lowest level, which is used for products that may have a minor defect or other condition that would not harm the patient but that prevents the drugs from being resold. This level includes a drug container defect (e.g., a faulty cap), a product with a strange color or taste, or the lack of English labeling on retail food items.

    DIF: Application REF: Page 31
    OBJ: ASHP objective: 3.12 Explain procedures and communication channels to use in the event of a product recall or shortage, a medication error, or identification of another problem.
    MSC: PTCE Domain: 2.5 FDA recall requirements (e.g., medications, devices, supplies, supplements, classifications) | EXCPT: 1.A.13. Identify and remove recalled products from inventory

45. When a state law conflicts with a federal law, which law must be followed?
    a. Federal law
    b. State law
    c. The most stringent law
    d. The oldest law

    ANS: C
    Many states have laws that differ from federal law; remember that the strictest law is the one you follow.

    DIF: Comprehension REF: Page 52
    OBJ: ASHP objective: 5.3 Explain that differences exist between states regarding state regulations, pertaining to pharmacy technicians, and the processing, handling and dispensing of medications.
    MSC: PTCE Domain: none | EXCPT: 1.B.1. Comply with federal laws and regulations applicable to pharmacy practice

46. Which act defined adulteration and misbranding?
    a. Pure Food and Drug Act of 1906
    b. Federal Food, Drug and Cosmetic Act of 1938
    c. Comprehensive Drug Abuse Prevention and Control Act of 1970
    d. Poison Prevention Packaging Act

    ANS: B

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The Federal Food, Drug and Cosmetic Act described the exact labeling for products and defined misbranding and adulteration as illegal.

DIF: Comprehension REF: Page 23
OBJ: ASHP objective: 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
MSC: PTCE Domain: 2.5 FDA recall requirements (e.g., medications, devices, supplies, supplements, classifications) | EXCPT: 1.B.1. Comply with federal laws and regulations applicable to pharmacy practice

47. By what means is a patient's information protected in an information system?
    a. Backing up files
    b. Use encryption technology
    c. Use of biometrics
    d. Only licensed pharmacists and certified pharmacy technicians have access to it

ANS: B
The sender of electronic PHI is required to use encryption to convert the information into a non-readable format. Decryption is the reverse process. The encryption technology must be approved by the National Institute of Standards and Technologies to ensure its effectiveness in protecting patients' rights.

DIF: Application REF: Pages 26-27
OBJ: ASHP objective: 2.2 Demonstrate ability to maintain confidentiality of patient information, and understand applicable state and federal laws.
MSC: PTCE Domain: none | EXCPT: 1.B.1. Comply with federal laws and regulations applicable to pharmacy practice

48. Which of the following is considered a patient's right under HIPAA?
    a. The right to ask to see and obtain a copy of their health records.
    b. The right to have corrections added to their health information.
    c. The right to obtain a report on when and why their health information was shared for certain purposes.
    d. All options are correct.

ANS: D
Under HIPAA, patients have the following rights: (1) The right to ask to see and obtain a copy of their health records. (2) The right to have corrections added to their health information. (3) The right to receive a notice that tells them how their health information may be used and shared. (4) The right to decide whether they want to give their permission before their health information can be used or shared for certain purposes, such as for marketing. (5) The right to obtain a report on when and why their health information was shared for certain purposes. (6) If patients believe that their rights are being denied or their health information is not being protected, they can:

- File a complaint with their provider or health insurer
- File a complaint with the U.S. government
- Either authorize or not authorize any sharing of their personal or medical information
- Change or rescind this permission any time they desire.

DIF: Application REF: Page 27
OBJ: ASHP objective: 2.2 Demonstrate ability to maintain confidentiality of patient information, and understand applicable state and federal laws.

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MSC: PTCE Domain: none | EXCPT: 1.B.1. Comply with federal laws and regulations applicable to pharmacy practice

49. Which DEA form must a pharmacy possess in order to dispense controlled substances?
    a. DEA Form 41
    b. DEA Form 106
    c. DEA Form 222
    d. DEA Form 224

    ANS: D
    To dispense controlled substances a pharmacy must have a current DEA Form 224, which must be renewed every 3 years using Form 224a.

    DIF: Comprehension REF: Pages 37-38
    OBJ: ASHP objective: 43.1 (Understanding) 5.1 Describe and apply state and federal laws pertaining to processing, handling and dispensing of medications including controlled substances.
    MSC: PTCE Domain: 2.3 Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take-back programs, and loss or theft of) | EXCPT: 1.C.7. Order, store, and maintain inventory of controlled substances in accordance with CSA

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