2018 Multistate Pharmacy Jurisprudence Examination (MPJE) Review Course

Florida Law

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Where to find Florida law

- FL Board of Pharmacy website: http://floridaspharmacy.gov/
- Click on the 'Resources' tab and then click on 'Florida Statutes and Administrative Codes'.
- Please be sure to review the 2017 statutes, Chapters 465, 893, 499, and 456.
- Please also review the Florida Administrative Code (i.e., Rules), Title 64B16 (Board of Pharmacy).
  - You'll want to review each Rule in Chapters: 64B16-25 through 64B16-28 and 64B16-30 through 64B16-32.
  - This session will also address Rules found in 64B8 (Standards of Practice for Medical Doctors) that are related to the practice of pharmacy (https://www.flrules.org/gateway/ChapterHome.asp?Chapter=64B8-9).

RxLaw.org

- **Federal and Florida State: Pharmacy Laws and Regulations. 2018 Study Guide**
  - $ 161.00
- **Florida State Pharmacy Law. 2018 Study Guide**
  - $ 139.00

http://www.rxlaw.org/product-category/study-guides/

2017-2018 Updates

Statutes

Question 1a

- A pharmacist may administer a long-acting antipsychotic medication at the discretion of and within the framework of an established protocol with an MD. In order to be eligible to perform this function, the pharmacist must complete a CE course focusing on the safe and effective administration of behavioral health and antipsychotic medications by injection. **This course must be at least how many hours?**

A. 3
B. 5
C. 8
D. 10
E. 12

Answer to Question 1a

465.1893 Administration of antipsychotic medication by injection

- … (2)(a) A pharmacist seeking to administer a long-acting antipsychotic medication by injection must complete an 8-hour continuing education course …

***This statute is new as of fall 2017

Answer: C

Question 2a

- Please select the BEST response. Unless otherwise authorized, within how long after dispensing a controlled substance must a pharmacy report such dispensing to the Florida Department of Health via the Prescription Drug Monitoring Program database?
  - A. 1 business day
  - B. 3 business days
  - C. 5 days
  - D. 7 days
  - E. 14 business days

Answer to Question 2a

893.055 Prescription drug monitoring program.—

- … (4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but no later than the close of the next business day after the day the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by submitting via the department-approved electronic system the required information concerning each controlled substance that it dispensed.

Answer: A

Question 3a

- To whom may a patient's medical records be disclosed without the patient's written authorization? Select all that apply.
  - A. Patients spouse or adult children, none of whom serving as the patient's legal guardian
  - B. Regional poison control center for purposes of treating a poison episode under evaluation
  - C. Department of Children and Families for the purpose of investigations of abuse
  - D. Parties of a lawsuit involving the patient when compulsory review of such records is made
  - E. Researcher, provided the patient's personal health information is abstracted in such a way as to protect the patient's identity

Answer to Question 3a

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

- (7)(a) Except as otherwise provided … such records may not be furnished to, and the medical condition of a patient may not be discussed with, any person other than the patient, the patient's legal representative, or other health care practitioners and providers involved in the patient's care or treatment, except upon written authorization from the patient. However, such records may be furnished without written authorization under the following circumstances:
  - 1. To any person, firm, or corporation that has procured or furnished such care or treatment with the patient's consent.
  - 2. When compulsory physical examination is made pursuant to Rule 1.360, Florida Rules of Civil Procedure, in which case copies of the medical records shall be furnished to both the defendant and the plaintiff.
  - 3. In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or the patient's legal representative by the party seeking such records.
  - 4. For statistical and scientific research, provided the information is abstracted in such a way as to protect the identity of the patient or provided written permission is received from the patient or the patient's legal representative.
  - 5. To a regional poison control center for purposes of treating a poison episode under evaluation …
  - 6. To the Department of Children and Families, its agent, or its contracted entity, for the purpose of investigations of or services for cases of abuse, neglect, or exploitation of children or vulnerable adults. [This subsection added in fall 2017]

Answer: B-E

Question 4a

- With whom may the Florida Department of Health contract to operate an approved impaired practitioner program? Select all that apply.

A. Licensed Florida physician
B. Licensed Florida pharmacist
C. Licensed Florida advanced registered nurse practitioner
D. Licensed Florida osteopath
E. Licensed Florida naturopath

Answer to Question 4a

456.076 Impaired practitioner programs.—

- (1) As used in this section, the term: (a) "Consultant" means the individual or entity who operates an approved impaired practitioner program pursuant to a contract with the department and who is retained by the department as provided in subsection (2)…
- (2) The department may retain one or more consultants to operate its impaired practitioner program. Each consultant must be:
  - (a) A practitioner licensed under chapter 458 [Medical Practice], chapter 459 [Osteopathic Medicine], or part I of chapter 464 [Nurse Practice Act]…

***Accordingly, an MD, osteopath, or nurse can serve as a consultant. Pharmacists (chapter 465) and Naturopaths (chapter 462) are not eligible to serve as consultants.

Answer: A, C, D

Rules

Question 5a

- Which of the following statements about registered pharmacy technicians is **CORRECT**?

I. Their current registration shall be displayed in a conspicuous place in or near the RX department at their primary practice site.

II. They must wear an ID badge that is visible to patients and identifies them as "registered pharmacy technicians."

III. They must identify themselves as "registered pharmacy technicians" when communicating on the phone.

B. I only
C. III only
D. I & II only
E. II & III only
F. I, II & III

Answer to Question 5a

64B16-27.100 Proof of Licensure; Display of License; Pharmacist, Registered Pharmacy Intern and Registered Pharmacy Technician Identification.

- (1) Proof of licensure. Every pharmacist, pharmacy intern, and registered pharmacy technician must maintain proof of current licensure such that it is readily retrievable upon request by any representative of the Department or the Board or any member of the public. The pharmacy may display the license or registration of each pharmacy employee or alternatively, may display a notice easily accessible to the public that the license or registration of each employee is available for viewing upon request.
- (2) Identification. Every Pharmacist, Pharmacy Intern, or Registered Pharmacy Technician must be identified by means such as a clearly visible identification badge or monogrammed smock showing their name and if they are a pharmacist, pharmacy intern, or registered pharmacy technician. In addition, all registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

Answer: B

Question 6a

- Which of the following immunizations may a Florida pharmacist administer? Select all that apply.
  - A. Influenza
  - B. Zoster Vaccine Recombinant, Adjuvanted
  - C. Meningococcal B (MenB)
  - D. Hepatitis A
  - E. Pneumococcal

Answer to Question 6a

64B16-27.630 Additional Immunizations or Vaccines Which May Be Administered.

- In addition to the immunizations or vaccines listed in the United States Centers for Disease Control and Prevention Adult Immunization Schedule as of February 1, 2015, the Board hereby authorizes administration of the following additional immunizations or vaccines by persons certified pursuant to Section 465.189, F.S.
  - (1) Meningococcal B (MenB).
  - (2) Zoster Vaccine Recombinant, Adjuvanted.
- http://floridaspharmacy.gov/latest-news/house-bill-323-meningococcal-and-shingles-vaccines/
- https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

Answer: A - E

Question 7a

- In which of the following settings may medications dispensed to a patient be returned to the pharmacy for future redispensing to another patient? Select all that apply.

A. Nursing home
B. Hospital (in-patient)
C. Community Pharmacy
D. Short-term, primary care treatment centers
E. Nuclear pharmacy

Answer to Question 7a

64B16-28.118 Unit Dose and Customized Patient Medication Package Returns.

- (1) Definitions. As used herein: … (d) For purposes of this rule, "facility" shall mean any health care institution operating with a Class I, Class II, Modified Class II, or Special ALF permit.
- (2) No pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient *except under the following conditions*:
  - (a) In a *closed drug delivery system* in which *unit dose or customized patient medication packages* are *dispensed to in-patients*, the unused medication may be returned to the pharmacy for redispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system, or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any.

Answer to Question 7a, continued

465.019 Institutional pharmacies; permits.—

- (2) The following classes of institutional pharmacies are established:
  - (a) "Class I institutional pharmacies" are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises … No medicinal drugs may be dispensed in a Class I institutional pharmacy. (nursing homes)
  - (b) "Class II institutional pharmacies" are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution… Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section. (hospitals)
  - (c) "Modified Class II institutional pharmacies" are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. (clinics)

64B16-28.870 Special-ALF.

- (1) The Special-ALF permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

Answer: A, B, D

Question 8a

- Who may witness the destruction of controlled substances in an Institutional Class I Pharmacy (i.e., nursing home)? Select all that apply.

A. Consultant pharmacist or other pharmacist employed by the facility
B. Director of nursing or other nurse employed by the facility
C. Facility administrator
D. Licensed physician or mid-level practitioner (e.g., PA)
E. Sworn law enforcement officer

Answer to Question 8a

64B16-28.301 Destruction of Controlled Substances – Institutional Class I Pharmacies (Nursing Homes).

- (2) For each controlled substance destroyed, documentation must be completed showing the name and quantity of the drug, strength and dosage form, patient's name, prescription number and name of the institution. Destruction of the controlled substance *shall be witnessed by at least two (2) of the following individuals*:
  - (a) Consultant pharmacist;
  - (b) Director of nursing
  - (c) Facility administrator;
  - (d) A licensed physician, mid-level practitioner, nurse, or another pharmacist employed by or under contract or written agreement with the facility, or
  - (e) A sworn law enforcement officer.
- Those individuals witnessing the destruction of the controlled substance shall sign the completed documentation.

***2014 version of this rule required 3 witnesses**

Answer: A-E

Question 9a

- Licensed Florida pharmacists may engage in remote medication order processing (RMOP) for certain types of pharmacies as long as the pharmacists performing the RMOP have access to sufficient patient information to perform prospective drug use review. **Which facilities may utilize RMOP either for themselves or for other facilities they service?** Select all that apply.
  - A. Class I Institutional Pharmacy
  - B. Class II Institutional Pharmacy
  - C. Modified Class II Institutional Pharmacy
  - D. Special- Closed System Pharmacy servicing a Class I Institutional facility
  - E. Special- Sterile Compounding Pharmacy servicing a Class II Institutional facility

Answer to Question 9a

64B16-28.606 Pharmacy Permits Servicing Class I, Class II, Modified Class II, and Special ALF Permitted Facilities.

- (1)(a) "Remote Medication Order Processing" includes any of the following activities performed for a Class II Institutional Pharmacy or for Special Pharmacy Permits servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities from a remote location:
  - 1. Receiving, interpreting, or clarifying medication orders,
  - 2. Entering or transferring medication order data,
  - 3. Performing prospective drug use review,
  - 4. Obtaining substitution authorizations,
  - 5. Interpreting and acting on clinical data,
  - 6. Performing therapeutic interventions,
  - 7. Providing drug information,
  - 8. Authorizing the release of a medication for administration.

Answer to Question 9a, continued

- **Special- Limited Community Pharmacy Permit** are only available to Institutional Class II permittees as an additional permit to allow the facility to provide medications to employees, medical staff and up to a three-day supply of medication to patients being discharged under certain conditions.
- **Special- Parenteral and Enteral Pharmacy Permits** provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. The permittee must provide 24-hour telephone accessibility.
- **Special- Closed System Pharmacy Permits** provide medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, Assisted Living Facilities (ALF's), Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by Agency for Health Care Administration (AHCA) rules. A Special- Closed System Pharmacy may share locations with an establishment that holds a Community Pharmacy Permit, however record keeping and inventory for each permittee must be maintained separately and distinct.

Answer to Question 9a, continued

- **Special- End Stage Renal Dialysis (ESRD) Pharmacy** provides dialysis products and supplies to persons with chronic kidney failure and requires the services of a Consultant Pharmacist.
- **Special- Parenteral/Enteral Extended Scope** is required to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.
- **Special- Assisted Living Facility (ALF)** is an optional permit for those ALF's providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.
- **Special- Sterile Compounding Pharmacy Permit** is required before any pharmacy may engage in the preparation of compounded sterile products.

Answer to Question 9a, continued

- **NOTE:** RMOP is distinguished from the activities conducted remotely by a consultant pharmacist for a Class I, Class II, or Modified Class II facility.

64B16-28.501 Institutional Permit – Consultant Pharmacist of Record.

- … (3) A consultant pharmacist licensed in Florida may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct any services additional or supplemental to regular drug regimen reviews, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations.

Answer: B, D, E

Question 10a

- Generally, a Special Sterile Compounding Permit (SSCP) is required before any pharmacy may engage in the preparation of compounded sterile products. However, one type of pharmacy is exempted from obtaining as SSCP if it only compounds low-risk level compounded sterile preparations and such preparations are for immediate use. **What type of pharmacy?**
  - A. Class I Institutional Pharmacy
  - B. Class II Institutional Pharmacy
  - C. Type A Modified Class II Institutional Pharmacy
  - D. Type B Modified Class II Institutional Pharmacy
  - E. Type C Modified Class II Institutional Pharmacy

Answer to Question 10a

64B16-28.802 Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities.

- … (6) The SSCP is not required for a Type B Modified Class II Institutional Pharmacy under the following conditions:
  - (a) The pharmacy only compounds low-risk level compounded sterile preparations; and
  - (b) The pharmacy only compounds those low-risk level compounded sterile preparations for immediate use pursuant to the provisions the United States Pharmacopeia adopted and incorporated in rule 64B16-27.797, F.A.C.
- Type A Modified Class II Institutional: Not more that 15 drugs stored in bulk
- Type B Modified Class II Institutional: Drugs stored in patient specific form and in bulk form (most common)
- Type C Modified Class II Institutional: Drugs stored in patient specific form only

Answer to Question 10a, continued

64B16-28.702 Modified Class II Institutional Pharmacies.

(1) Modified Class II Institutional Pharmacies … are generally identifiable with short-term or primary care treatment modalities in entities such as primary alcoholism treatment centers, free-standing emergency rooms, rapid in/out surgical centers, certain county health programs, and correctional institutions…

(2) Modified Class II Institutional Pharmacies are categorized according to the type of specialized pharmaceutical delivery system utilized and the following criteria (Categories are designated as Type "A," Type "B," and Type "C"):

(a) The type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and, the quantity of the medicinal drug formulary at the facility.

(b) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist shall provide on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual.

(c) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(d) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide onsite consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual…

Answer: D

Question 11a

- Which of the following activities must a consultant pharmacist perform monthly for an assisted living facility holding a Special- ALF pharmacy permit? Select all that apply.
  - A. Update the facility's Policy and Procedure Manual
  - B. Complete a drug regimen review
  - C. Inspect the facility
  - D. Conduct a medication in-service for nursing staff
  - E. Prepare a written report to be filed at the facility

Answer to Question 11a

64B16-28.870 Special-ALF.

- (3) Consultant Pharmacist of Record.
  - … (b) The consultant pharmacist of record shall be responsible for the preparation of the Policy and Procedure Manual required by subsection 64B16-28.800(2), F.A.C. Policy and Procedure Manuals must provide for the appropriate storage conditions and security of the medicinal drugs stored at the facility.
  - … (d) The consultant pharmacist of record shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility, and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor the facility's system for maintaining medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and or in the monthly facility inspection.

Answer: B, C, E

2016-2017 Updates

Question 12a

- Please select the BEST response. A manufacturer, distributor, or retailer, or its employees and representatives, may not knowingly or willfully sell a finished drug product containing any quantity of dextromethorphan to a person younger than:
  A. 16 years of age.
  B. 18 years of age.
  C. 21 years of age.
  D. 25 years of age.
  E. There is no age limit.

Answer to Question 12a

499.036 Restrictions on sale of dextromethorphan.—

- (2)(a) A manufacturer, distributor, or retailer, or its employees and representatives, may not knowingly or willfully sell a finished drug product containing any quantity of dextromethorphan to a person younger than 18 years of age.
- (b) A person younger than 18 years of age may not purchase a finished drug product containing any quantity of dextromethorphan.
- (3) An employee or representative of a retailer making a retail sale of a finished drug product containing any quantity of dextromethorphan must require and obtain proof of age from the purchaser before completing the sale, unless from the purchaser's outward appearance the person making the sale would reasonably presume the purchaser to be 25 years of age or older…

Answer: B

Question 13a

- Pursuant to an agreement with a nonmilitary health care provider, an active duty military health care practitioner, not licensed in Florida, may be issued a temporary certificate to practice in a nonmilitary setting in Florida in order to develop and maintain the technical proficiency needed to meet the present and future health care needs of the United States Armed Forces. **How long is this temporary certificate valid?**

A. 72 hours
B. 30 days
C. 6 months
D. 1 year
E. 2 years

Answer to Question 13a

456.0241 Temporary certificate for active duty military health care practitioners.—

- (1)(b) "Military platform" means a military training agreement with a nonmilitary health care provider that is designed to develop and support medical, surgical, or other health care treatment opportunities in a nonmilitary health care provider setting to authorize a military health care practitioner to develop and maintain the technical proficiency necessary to meet the present and future health care needs of the United States Armed Forces…
- (2) The department may issue a temporary certificate to an active duty military health care practitioner to practice in a regulated profession in this state if the applicant: (a) Submits proof that he or she will be practicing pursuant to a military platform…
- (3) A temporary certificate issued under this section expires 6 months after issuance but may be renewed upon proof of continuing military orders for active duty assignment in this state and evidence that the military health care practitioner continues to be a military platform participant…

Answer: C

New statute in 2016

456.0361 Compliance with continuing education requirements.—

(1) The department shall establish an electronic continuing education tracking system to monitor licensee compliance with applicable continuing education requirements and to determine whether a licensee is in full compliance with the requirements at the time of his or her application for license renewal. The tracking system shall be integrated into the department's licensure and renewal process.

(2) The department may not renew a license until the licensee complies with all applicable continuing education requirements. This subsection does not prohibit the department or the boards from imposing additional penalties under the applicable professional practice act or applicable rules for failure to comply with continuing education requirements.

(3) The department may adopt rules to implement this section.

HB423

- HB 423 authorizes licensed Physician Assistants (PAs) and licensed Advanced Registered Nurse Practitioners (ARNPs) to prescribe controlled substances (CS).
- Effective January 1, 2017, the bill (codified in 458.347) authorizes PAs to prescribe CS.
  - Formulary to be created of the drugs PAs cannot prescribe. The formulary must limit the prescription of CII drugs to a 7-day supply.
  - Supervising physician may delegate to a PA, the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed on the formulary
- Effective January 1, 2017, the bill (codified in 464.012) authorizes board-certified APRNs (registered nurse anesthetist, psychiatric nurse, or nurse midwife) to prescribe, dispense, administer, or order any drug within an established supervisory protocol.
  - ARNP may prescribe or dispense a CS, only if she has graduated from a program leading to a Master's or Doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills.
  - Board of Nursing to establish a committee to recommend a formulary of CS that an ARNP may not prescribe or may prescribe only for specific uses or in limited quantities.
  - The formulary must also limit the prescribing of CII drugs to a 7-day supply, except that such restriction does not apply to CS that are psychiatric meds prescribed by psychiatric nurses.

General Questions

Question 1

- On January 1, 2018, a pharmacist receives a new RX for Tylenol® No. 3 with codeine, written by an MD that day, with the directions to take as needed, #30 tablets. The MD did not authorize any refills. Because the patient could not afford to receive all 30 tablets at once, the pharmacist dispensed just 15 tablets that day. What is/was the last date in which the balance of this RX may be filled?

A. January 4, 2018
B. January 8, 2018
C. January 31, 2018
D. June 30, 2018
E. December 31, 2018

Answer to Question 1

893.04 Pharmacist and practitioner.—

- (g) A prescription for a controlled substance listed in Schedule III, Schedule IV, or Schedule V may not be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.
  - ****Therefore, no drug may be dispensed after June 30, 2018.**
- NOTE: This is known as the 5-time/6-month rule. Under federal law, this rule is applicable only to refills of CIII and CIV drugs (not CVs!).
- NOTE: A partial fill does NOT count as a refill; however, a CIII medication, like this one, may only be dispensed within 6 months of the date of issue of the RX.

Question 2

- Generally, RXs written for controlled substance medications in which of the following Schedule(s) must include both a written and a numerical notation of the quantity of drug prescribed. Select all that apply.

A. CI
B. CII
C. CIII
D. CIV
E. CV

Answer to Question 2

893.04 Pharmacist and practitioner.—

- (2)(d) Each written prescription prescribed by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and a numerical notation of the quantity of the controlled substance prescribed on the face of the prescription … A pharmacist may, upon verification by the prescriber, document any information required by this paragraph. If the prescriber is not available to verify a prescription, the pharmacist may dispense the controlled substance but may insist that the person to whom the controlled substance is dispensed provide valid photographic identification. If a prescription includes a numerical notation of the quantity of the controlled substance… but does not include the quantity … written out in textual format, the pharmacist may dispense the controlled substance without verification by the prescriber of the quantity … if the pharmacy previously dispensed another prescription for the person to whom the prescription was written.

Question 3

- A cough preparation contains brompheniramine maleate 3mg, dihydrocodeine bitartrate 5 mg and pseudoephedrine HCl 15 mg per 5 mL. What is the maximum amount that may be sold without an RX to an adult patient in a 48-hour period?

A. 30 mL
B. 40 mL
C. 60 mL
D. 120 mL
E. 240 mL

Answer to Question 3

893.08 Exceptions.—

- (1) The following may be distributed at retail without a prescription, but only by a registered pharmacist:
  - (a) Any compound, mixture, or preparation described in Schedule V.
- … (3) The exemptions authorized by this section shall be subject to the following conditions:
  - (a) The compounds, mixtures, and preparations referred to in subsection (1) may be dispensed to persons under age 18 only on prescription…
  - … (c) The total quantity of controlled substance listed in Schedule V which may be sold to any one purchaser within a given 48-hour period shall not exceed 120 milligrams of codeine, 60 milligrams dihydrocodeine, 30 milligrams of ethyl morphine, or 240 milligrams of opium
- NOTE: 60 mL of the cough product contains 60mg of dihydrocodeine (as well as 180mg of PSE HCl which is far less than the 3.6 g that is allowed to be sold to an adult patient in one day); thus, the CORRECT answer is C.

Question 4

- Which of the following statements about controlled substance RXs is **CORRECT**? Select all that apply.
  - A. An RX written for a medication listed as a controlled substance must contain on its face an RX number.
  - B. After speaking with the prescriber, a community pharmacist may dispense up to a 72-hour supply of a CII drug in an emergency situation.
  - C. A pharmacist cannot dispense more than 30-day's worth of a CIII drug if the RX was phoned in.
  - D. A pharmacy is permitted to mail CII drugs to its patients – but only to those patients who have personally provided the pharmacy with a copy of their driver's licenses.
  - E. When a pharmacy closes it may sell its controlled substances inventory to a manufacturer and/or wholesale distributor, but not to another pharmacy.

Answer to Question 4

893.04 Pharmacist and practitioner.—

- (1)(c) There shall appear on the face of the prescription or written record thereof for the controlled substance the following information:
  1. The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed.
  2. The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.
  3. If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.
  4. The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof.
  5. **The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled.**
  6. The initials of the pharmacist filling the prescription and the date filled.

  ***NOTE: The RX # is *also* required on the label. See 893.04 (1)(e)

- (1)(f) A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply…

Answer to Question 4, continued

893.04 Pharmacist and practitioner.—

- (2)(b) Any pharmacist who dispenses by ***mail*** a controlled substance listed in Schedule II, Schedule III, or Schedule IV is exempt from the requirement to obtain suitable identification for the prescription dispensed by mail if the pharmacist has obtained the patient's identification through the patient's prescription benefit plan…
  - Thus, as long as the pharmacy can ID a patient through the patient's PBM or other benefit plan, the pharmacy does not need to check the patient's ID before mailing the RX.
- (2)(e) A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state…
- (4) The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in controlled substances, may sell said stock to a manufacturer, wholesaler, ***or pharmacy***. Such controlled substances may be sold only upon an order form, when such an order form is required for sale by the drug abuse laws of the United States or this state, or regulations pursuant thereto.

Question 5

- Generally, non-pharmacy practitioners (e.g., physicians, dentists) are NOT permitted to *dispense* controlled substance medications in certain Schedules. What Schedules? Select all that apply.

A. I
B. II
C. III
D. IV
E. V

Answer to Question 5

465.0276 Dispensing practitioner.—

- (1)(a) A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.
- (b) A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03.
  - ***NOTE: Schedule I drugs may not be dispensed under any circumstances
  - ***NOTE: There are a number of exceptions enumerated in this statute. See next two slides

Answer to Question 5, continued

465.0276 Dispensing practitioner.—

- (1)(b) 1. The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug … to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect…
- (1)(b) 2. The dispensing of controlled substances in the health care system of the Department of Corrections.
- (1)(b) 3. *The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply*. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure…

Answer to Question 5, continued

465.0276 Dispensing practitioner.—

- (1)(b) 4. The dispensing of a controlled substance listed in Schedule II or Schedule III *pursuant to an approved clinical trial*. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.
- (1)(b) 5. The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.
- (1)(b) 6. The dispensing of a controlled substance listed in Schedule II or Schedule III *to a patient of a facility licensed under part IV of chapter 400*. (i.e., hospices)

Question 6

- For this question, presume that the controlled substance in question is combined with one or more non-controlled medicinal drugs. **Which of the following drugs could be sold at retail by a pharmacist without an RX?**

A. An elixir containing 200 mg of codeine per 100 mL.
B. A solution containing 200 mg of dihydrocodeine per 100 mL.
C. A syrup containing 200 mg of ethylmorphine per 100 mL.
D. A suspension containing 200 mg of opium per 100 mL.
E. A tablet containing 5 mg of diphenoxylate and 25 mcg of atropine.

Answer to Question 6

893.03 Standards and schedules

- (5)(a) Substances controlled in Schedule V include any compound, mixture, or preparation containing any of the following limited quantities of controlled substances, which shall include one or more active medicinal ingredients which are not controlled substances in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the controlled substance alone:
  - Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
  - Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
  - Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
  - Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
  - Not more than 100 milligrams of opium per 100 milliliters or per 100 grams…

Question 7

- In what category of controlled substances is carisoprodol is classified?
  - A. Schedule II
  - B. Schedule III
  - C. Schedule IV
  - D. Schedule V
  - E. None of the above, as this drug is not classified as a controlled substance.

Answer to Question 7

893.03 Standards and schedules.—

- (4) SCHEDULE IV.—A substance in Schedule IV has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, are controlled in Schedule IV:
  - (jjj) Carisoprodol

Question 8

- A pharmacy conducted its initial controlled substances inventory on June 30, 2016. On which of the following dates is the pharmacy permitted to conduct its next controlled substances inventory? Select all that apply.

A. February 15, 2018
B. January 15, 2019
C. June 30, 2017
D. September 30, 2018
E. June 29, 2018

Answer to Question 8

893.07 Records.—

- (1) Every person who engages in the manufacture, compounding, mixing, cultivating, growing, or by any other process producing or preparing, or in the dispensing, importation, or, as a wholesaler, distribution, of controlled substances shall:
  - (a) On January 1, 1974, or as soon thereafter as any person first engages in such activity, and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The inventory may be prepared on the regular physical inventory date which is nearest to, and does not vary by more than 6 months from, the biennial date that would otherwise apply. As additional substances are designated for control under this chapter, they shall be inventoried as provided for in this subsection…
- **21 CFR §1304.11 Inventory requirements:** (c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is *within two years* of the previous biennial inventory date.

Question 9

- Abuse of which of the following may lead to severe physical or psychological dependence? Select all that apply.
  - A. Hydromorphone
  - B. Clorazepate
  - C. Testosterone
  - D. Levo-alphacetylmethadol (LAAM)
  - E. Ketamine

Answer to Question 9

893.03 Standards and schedules.—

- (2) SCHEDULE II.—A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence. The following substances are controlled in Schedule II:
  - **k. Hydromorphone.**
  - **l. Levo-alphacetylmethadol (also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM)**

Answer to Question 9, continued

893.03 Standards and schedules.—

- (3) SCHEDULE III.—A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. The following substances are controlled in Schedule III:
  - (d)(1)ee Testosterone
  - (e) Ketamine, including any isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

Answer to Question 9, continued

893.03 Standards and schedules.—

- (4) SCHEDULE IV.—A substance in Schedule IV has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III…
  - (k) Clorazepate.

Question 10

- A pharmacy dispenses an RX written for a controlled substance, which warrants the pharmacy report the dispensing of such drug to the state's prescription drug monitoring program (PDMP). What information must the pharmacy add to the PDMP following the dispensing of this RX to the patient? Select all that apply.

A. The credit card number used to pay for the RX
B. The NDC number of the drug
C. The name of the person picking up the drug if it is someone other than the patient
D. The pharmacy's national provider number
E. The pharmacy's DEA number

Answer to Question 10

893.055 Prescription drug monitoring program.—

- … (3) The pharmacy dispensing the controlled substance … shall submit to the electronic system … the following information for inclusion in the database:
  - (a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.
  - (b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does ***not*** authorize the department to include individual credit card numbers or other account numbers in the database.
  - (c) The full name, address, and date of birth of the person for whom the prescription was written.
  - (d) The name, national drug code, quantity, and strength of the controlled substance dispensed.
  - (e) The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.
  - (f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).
  - (g) Other appropriate identifying information as determined by department rule…

Question 11

- A pharmacist must report a prescriber whom he/she believes is involved in the diversion of controlled substances. According to Florida law, the pharmacist ***must*** report the prescriber to the:

A. Florida Department of Health.
B. Police.
C. Drug Enforcement Administration.
D. The American Medical Association.
E. National Association of Boards of Pharmacy.

Answer to Question 11

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

(4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

- ***NOTE: No state law requirement to report the prescriber to the DEA, NABP, AMA, or to the police. A pharmacist may choose, however, to contact the local field office of the DEA, the local authorities, and perhaps even the state board of medicine.

Question 12

- Which of the following acts must be reported to the state prescription drug monitoring program?
  - A. A pharmacist administering a controlled substance (CS) to a resident of a nursing home
  - B. A health care practitioner dispensing a CS to a 16 year-old patient
  - C. A practitioner administering a CS in the ER of a licensed hospital
  - D. A practitioner dispensing a CS in the health care system of the Department of Corrections
  - E. A pharmacist administering a CS to a hospice patient

Answer to Question 12

893.055 Prescription drug monitoring program.—

- … (5) When the following acts of dispensing or administering occur, the following are ***exempt*** from reporting under this section for that specific act of dispensing or administration:
  - (a) A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
  - (b) A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.
  - (c) A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.
  - (d) A practitioner when administering a controlled substance in the emergency room of a licensed hospital.
  - (e) A health care practitioner when administering or dispensing a controlled substance to a person ***under the age of 16***…

Question 13

- Which of the following pairs of drugs may a physician prescribe on the same prescription blank? Select all that apply.

A. Methylphenidate and oxycodone
B. Norco© (hydrocodone/APAP) and Subutex©
C. Lunesta© (eszopiclone) and tramadol
D. Alprazolam and phenobarbital
E. Nalorphine and erythromycin

Answer to Question 13

893.02 Definitions.—

- (24) "Prescription" includes any order for drugs or medicinal supplies which is written or transmitted by any means of communication by a licensed practitioner authorized by the laws of this state to prescribe such drugs or medicinal supplies, is issued in good faith and in the course of professional practice, is intended to be dispensed by a person authorized by the laws of this state to do so, and meets the requirements of s. 893.04... (c) A prescription for a controlled substance may not be issued on the same prescription blank with another prescription for a controlled substance that is named or described in a different schedule [Thus, **Choice A** is permitted because both are CII drugs; Choice B is **not** permitted because Norco is CII and Subutex is CIII; **Choice C** is permitted because both are CIV drugs; **Choice D** is permitted because both are CIV drugs] or with another prescription for a medicinal drug, as defined in s. 465.003(8), that is not a controlled substance.[Thus, Choice E is **not** permitted because nalorphine is CIII and erythromycin is not a controlled substance].

Question 14

- Abuse of which of the following substances may lead to moderate or low physical dependence or high psychological dependence? Select all that apply.
  - A. Lomocot tablet (atropine sulfate 0.025 mg; diphenoxylate hydrochloride 2.5 mg)
  - B. No-Tuss NX liquid (codeine phosphate 10 mg/chlorcyclizine HCl 9.375 mg per 5 mL)
  - C. Fiorinal tablet (aspirin 325 mg/butalbital 50 mg/caffeine 40 mg)
  - D. Donatuss DC syrup (dihydrocodeine bitartrate 7.5 mg/phenylephrine hydrochloride 7.5 mg/guaifenesin 50 mg per 5 mL)
  - E. Zubsolv SL tablet (buprenorphine 11.4 mg/naloxone 2.9 mg)

Answer to Question 14

893.03 Standards and schedules.—

- (3) SCHEDULE III.—A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence…

Answer to Question 14, continued

893.03 Standards and schedules.—

- (3) SCHEDULE III
- (a)(1) Any substance which contains any quantity of a derivative of barbituric acid, including thiobarbituric acid, or any salt of a derivative of barbituric acid or thiobarbituric acid, including, but not limited to, butabarbital and butalbital.
  - ***NOTE: Fiorinal is listed as a CIII drug.
- (c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following controlled substances or any salts thereof:
  - … Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances…
  - Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances…

Answer to Question 14, continued

893.03 Standards and schedules.—

- (5) SCHEDULE V.—A substance, compound, mixture, or preparation of a substance in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.
  - (a) Substances controlled in Schedule V include any compound, mixture, or preparation containing any of the following limited quantities of controlled substances, which shall include one or more active medicinal ingredients which are not controlled substances in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the controlled substance alone:
    - Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
      - ***NOTE: The amount of codeine in No-Tuss NX liq. is 200 mg/100 mL; thus, it is listed as a CV drug
    - Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams…
      - ***NOTE: The amount of dihydrocodeine in Donatuss DC is 150 mg/100 mL; thus, it cannot be listed as a CV drug. It is CIII
    - Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit…
      - ***NOTE: Lomocot tablet is listed as a CV drug
    - (b) Narcotic drugs. Unless specifically excepted or **unless listed in another schedule**, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts: Buprenorphine.
      - ***NOTE: Zubsolv is listed as a CIII drug.

Question 15

- During influenza season, Drug Inc. sponsors a day-long “flu clinic” once a month, and its registered pharmacy interns administer the immunizations. During each 4-hour shift 6 interns staff the clinic. How many pharmacists must also be on duty during each shift?

A. 0
B. 1
C. 2
D. 3
E. 6

Answer to Question 15

465.189 Administration of vaccines and epinephrine autoinjection.—

- (1) In accordance with guidelines of the Centers for Disease Control and Prevention for each recommended immunization or vaccine, a pharmacist, or a registered intern under the supervision of a pharmacist who is certified … may administer … vaccines to an adult within the framework of an established protocol …
  - A registered intern who administers an immunization or vaccine under this subsection must be supervised by a certified pharmacist at a ratio of one pharmacist to one registered intern.

Question 16

- Which of the following statements about the sale of drugs in Schedule V without an RX is **CORRECT**? Select all that apply.

A. Pharmacists must maintain a bound record of all sales.

B. Purchasers must be at least 21 years of age.

C. Pharmacists must see patient IDs before dispensing, even if the pharmacist knows the patient.

D. The maximum amount of codeine that a pharmacist may sell in a given 48-hour period is 120 mg.

E. Pharmacy technicians may dispense such drugs under the direct and immediate supervision of a pharmacist.

Answer to Question 16

893.08 Exceptions.

- (1) The following may be distributed at retail without a prescription, but only by a registered pharmacist [NOTE: Supervised interns may also distribute such drugs]:
  - (a) Any compound, mixture, or preparation described in Schedule V…
- (3) The exemptions authorized by this section shall be subject to the following conditions:
  - (a) The compounds, mixtures, and preparations referred to in subsection (1) may be dispensed to persons under age 18 only on prescription [NOTE: Patients ages 18+ do not need an RX]. A bound volume [aka logbook] must be maintained as a record of sale at retail of excepted compounds, mixtures, and preparations, and the pharmacist must require suitable identification from every unknown purchaser…
  - (c) The total quantity of controlled substance listed in Schedule V which may be sold to any one purchaser within a given 48-hour period shall not exceed 120 milligrams of codeine, 60 milligrams dihydrocodeine, 30 milligrams of ethyl morphine, or 240 milligrams of opium.

Question 17

- Which of the following statements about counterfeit-resistant prescription blanks is **CORRECT**? Select all that apply.
  - A. Such prescription blanks may be transferred.
  - B. Prescriber DEA numbers must be preprinted on such blanks.
  - C. Such prescription blanks must be printed on distinctive, watermarked paper.
  - D. The name of the prescriber may be written on the face of the RX if not preprinted.
  - E. They are to be used by authorized prescribers for prescribing Schedule II-V drugs.

Answer to Question 17

893.065 Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V.—

- The Department of Health shall develop and adopt by rule the form and content for a counterfeit-resistant prescription blank which must be used by practitioners for the purpose of prescribing a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V pursuant to s. 456.42. The Department of Health may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.
  - ***NOTE: The statute states the DOH may require the prescriber's name and DEA number of prescribers to be preprinted on these counterfeit-resistant blanks; however, the DOH did not – it permits DEA numbers to be written in. See 64B-3.005 below:
- **64B-3.005 Counterfeit-Proof Prescription Pads or Blanks for Controlled Substance Prescribing**
- (3) The counterfeit-proof prescription pad or blank must contain the following information: (a) The preprinted name, address and category of professional licensure of the prescribing practitioner or the name and address of the healthcare facility; (b) A space for the prescribing practitioner's name ***if not preprinted*** and federal Drug Enforcement Administration registration number for controlled substances…

Question 18

- Phil's pharmacy is a community pharmacy; however, there is a separate room set up like a call center where medication therapy management (MTM) services take place. Up to how many technicians may one pharmacist supervise in the MTM call center?

A. 1
B. 3
C. 4
D. 6
E. There is no limit

Answer to Question 18

64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio.

- … (6) Six to One (6:1) Ratio:
  - (a) Non-dispensing pharmacies. Any pharmacy which does not dispense medicinal drugs, and the pharmacist(s) employed by such pharmacy, may allow a supervision ratio of up to six (6) registered pharmacy technicians to one (1) pharmacist (6:1), as long as the pharmacy or pharmacist is not involved in sterile compounding.
  - (b) Dispensing pharmacies. A pharmacy which dispenses medicinal drugs may utilize a six to one (6:1) ratio in any physically separate area of the pharmacy from which medicinal drugs are not dispensed. A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.

Question 19

- Which of the following statements about the retail sale of Sudafed® is **CORRECT**? Select all that apply.

A. Purchasers must be 16 years of age or older.

B. A passport is an acceptable form of identification to present in order to buy this drug.

C. No more than 2 packages, regardless of quantity, may be sold in a single sale.

D. No more than 9 grams may be sold to a single purchaser in any 30-day period.

E. All pharmacies must use an electronic recordkeeping system to record/monitor real-time purchases of this drug.

Answer to Question 19

893.1495 Retail sale of ephedrine and related compounds.—

- (2) A person may not knowingly obtain or deliver to an individual in any retail over-the-counter sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds in excess of the following amounts:
  - (a) In any single day, any number of packages that contain a total of 3.6 grams of ephedrine or related compounds;
  - (b) In any single retail, over-the-counter sale, three packages, regardless of weight, containing ephedrine or related compounds; or
  - (c) In any 30-day period, in any number of retail, over-the-counter sales, a total of 9 grams or more of ephedrine or related compounds.
- (3) A person may not knowingly display and offer for retail sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds other than behind a checkout counter where the public is not permitted or other such location that is not otherwise accessible to the general public…

Answer to Question 19, continued

- (5)(a) Any person purchasing, receiving, or otherwise acquiring any nonprescription compound, mixture, or preparation containing any detectable quantity of ephedrine or related compounds must:
  - 1. Be at least 18 years of age.
  - 2. Produce a government-issued photo identification [e.g., driver's license, passport] showing his or her name, date of birth, address, and photo identification number or an alternative form of identification acceptable under federal regulation 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).
  - 3. Sign his or her name on a record of the purchase, either on paper or on an electronic signature capture device.
- (b) The Department of Law Enforcement shall approve an electronic recordkeeping system for the purpose of recording and monitoring the real-time purchase of products containing ephedrine or related compounds and for the purpose of monitoring this information in order to prevent or investigate illegal purchases of these products… A pharmacy or retailer may request an exemption from electronic reporting from the Department of Law Enforcement if the pharmacy or retailer lacks the technology to access the electronic recordkeeping system and such pharmacy or retailer maintains a sales volume of less than 72 grams of ephedrine or related compounds in a 30-day period….

Question 20

- A veterinarian writes an RX for a controlled substance medication for one of her patients. What must appear on the face of this RX? Select all that apply.

A. The full name and address of the owner of the animal
B. The species of the animal
C. The initials of the pharmacist filling the RX
D. The RX number
E. The date the RX is filled

Answer to Question 20

893.04 Pharmacist and practitioner.—

- (1) A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner, under the following conditions…
  - (c) There shall appear on the face of the prescription or written record thereof for the controlled substance the following information:
    - 1. The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed.
    - 2. The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.
    - 3. If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.
    - 4. The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof.
    - 5. The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled [i.e. the RX number].
    - 6. The initials of the pharmacist filling the prescription and the date filled.

Question 21

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- Which of the following drugs is listed on the Florida negative formulary *without regard* to dosage form? Select all that apply.
  - A. Dicumarol
  - B. Chlorpromazine
  - C. Conjugated Estrogen
  - D. Theophylline
  - E. Pancrelipase

Answer to Question 21

64B16-27.500 Negative Drug Formulary.

- The negative drug formulary is composed of medicinal drugs which have been specifically determined by the Board of Pharmacy and the Board of Medicine to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, could produce adverse clinical effects, or could otherwise pose a threat to the health and safety of patients receiving such prescription medications. Except where certain dosage forms are included on the negative drug formulary as a class, all medicinal drugs are listed by their official United States Pharmacopoeia Non-Proprietary (generic) name....The following are included on the negative drug formulary:
  - (1) Digitoxin.
  - **(2) Conjugated Estrogen.**
  - **(3) Dicumarol.**
  - **(4) Chlorpromazine (Solid Oral Dosage Forms).**
  - **(5) Theophylline (Controlled Release).**
  - **(6) Pancrelipase (Oral Dosage Forms).**

Question 22

- At what minimum interval must the stock of a Florida pharmacy be examined to remove outdated pharmaceuticals?
  - A. Every week
  - B. Every two months
  - C. Every two weeks
  - D. Every four months
  - E. Every month

Answer to Question 22

64B16-28.110 Outdated Pharmaceuticals.

- Persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear

Question 23

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- Molly, a second-grade teacher and long-time patient of Jill's pharmacy, comes into the pharmacy and explains to Pharmacist Jill that ever since she has started nursing her son she has experienced several adverse effects such as heartburn and headaches. She also states, "To add insult to injury, a child in my class has head lice, and now I have it!" Which of the following drugs is Jill legally permitted to order for Molly?

  I. Ranitidine syrup for her heartburn
  II. Naproxen tablets for her headache
  III. Lindane shampoo for her head lice

B. I only
C. III only
D. I & II only
E. II & III only
F. I, II & III

Answer to Question 23

64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.

- …[A] pharmacist may order the medicinal drug products listed in Rule 64B16-27.220, F.A.C., subject to the following terms and limitations:
  - (1) Injectable products shall not be ordered by the pharmacist.
  - (2) No ***oral*** medicinal drugs shall be ordered by a pharmacist for a pregnant patient or nursing mother…

64B16-27.220 Medicinal Drugs Which May Be Ordered by Pharmacists.

- A Pharmacist may order and dispense from the following formulary, within their professional judgment, subject to the stated conditions…
  - (11) Medicinal drug shampoos containing Lindane. The pharmacist shall:
    - (a) Limit the order to the treatment of head lice only;
    - (b) Order no more than four (4) ounces per person; and
    - (c) Provide the patient with the appropriate instructions and precautions for use…

Question 24

- Select all that apply. Florida pharmacists are permitted to prescribe:
  A. Up to a 7-day supply of phenazopyridine.
  B. Pyrilamine for patients 5 years of age and older.
  C. Acyclovir ointment for the treatment of herpes simplex infections of the lips.
  D. Meclizine (25 mg) for nausea to an adult taking a CNS depressant.
  E. Naphazoline 0.1% ophthalmic solution for an adult.

Answer to Question 24

64B16-27.220 Medicinal Drugs Which May Be Ordered by Pharmacists.

- A Pharmacist may order and dispense from the following formulary, within their professional judgment, subject to the stated conditions…
  - (2) Urinary analgesics. Phenazopyridine, not exceeding a two (2) day supply. The prescriptions shall be labeled about the tendency to discolor urine…
  - (4) anti-nausea preparations
    - (a) Meclizine up to 25 mg., ***except*** for a patient currently using a central nervous system (CNS) depressant. The prescription shall be labeled to advise the patient of drowsiness and to caution against concomitant use with alcohol or other depressants…
  - (5) Antihistamines and decongestants. The following… may be ordered for a patient above 6 years of age.
    - (a) Antihistamines…
      - … 3. Pyrilamine…
  - (12) Ophthalmics. Naphazoline 0.1% ophthalmic solution…
  - (15) Topical Antiviral.
    - (a) Acyclovir ointment may be ordered for the treatment of herpes simplex infections of the lips…

Question 25

- A prescriber in Florida, on duty in the emergency department of a hospital with only a Class II institutional pharmacy permit, may dispense up to how much drug to a patient, provided the drug is medically necessary and a community pharmacy is not accessible to the patient?

A. None
B. A 24-hour supply
C. A 72-hour supply
D. A 7-day supply
E. There is no limit.

Answer to Question 25

465.019 Institutional pharmacies; permits.

- … (4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a **24-hour supply** of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

Question 26

- Please select the BEST response. A patient presents to the pharmacy requesting a refill of an antihypertensive drug that she has taken for years. The pharmacist discovers that there are no refills remaining, and she cannot reach the prescriber. To make matters worse, the Governor has just declared a state of emergency for the county where the patient resides and where the pharmacy is located. The pharmacist:
  - A. Shall not dispense additional drug to the patient until she receives prescriber authorization.
  - B. Can refill the entire RX since the drug is not a controlled substance.
  - C. Must notify the prescriber of the emergency dispensing within 24-hours after refilling the RX.
  - D. May dispense up to a 30-day supply of the prescribed drug.
  - E. Cannot provide any medication because the drug is not essential to the maintenance of life.

Answer to Question 26

465.0275 Emergency prescription refill.—

- (1) In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense: (a) A one-time emergency refill of up to a 72-hour supply of the prescribed medication…
- (2) If the Governor issues an emergency order …of a state of emergency, the pharmacist may dispense up to a 30-day supply in the areas or counties affected by the order… provided that:
  - (a) The prescription is not for a medicinal drug listed in Schedule II appearing in chapter 893.
  - (b) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition.
  - (c) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.
  - (d) The dispensing pharmacist creates a written order containing all of the prescription information required by this chapter and chapters 499 and 893 and signs that order.
  - (e) The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after such dispensing.

Question 27

- Which of the following statements about an automated pharmacy system (APS) owned by a Florida pharmacy, but housed in a Florida long term care facility (LTCF), is **CORRECT**? Select all that apply.
  - A. All drugs stored in the APS are part of the pharmacy's inventory.
  - B. The Administrator of the LTCF is responsible for supervising the APS.
  - C. Only Florida pharmacists are permitted by law to restock the APS.
  - D. Records of transactions must be maintained for 4 years.
  - E. A pharmacist must be present at the site in order to supervise transactions.

Answer to Question 27

64B16-28.607 Automated Pharmacy System - Long Term Care, Hospice, and Prison.

- (2) Provider Pharmacy Requirements…
  - (c) Supervision of the automated pharmacy system shall be the responsibility of a Florida pharmacist employed by the provider pharmacy.
  - (d) Every medicinal drug stored in the automated pharmacy system shall be owned by the provider pharmacy.
  - (e) An automated pharmacy system shall be under the supervision of a pharmacist employed by the provider pharmacy. The pharmacist need not be physically present at the remote site if the system is supervised electronically…
- (4) Automated Pharmacy System Requirements.
  - (a) A medicinal drug stored in bulk or unit-of-use in an automated pharmacy system is part of the inventory of the provider pharmacy and is not part of the inventory of any other pharmacy permit for the facility…
  - (f) Stocking or Restocking of an Automated Pharmacy System.
    - 1. The stocking or restocking of a medicinal drug in an automated pharmacy system at the remote site shall be completed by a pharmacist or other licensed personnel…
- (7) Record Keeping Requirements… A record of every transaction with the automated pharmacy system shall be maintained for four (4) years.

Question 28

- Jill graduated from an accredited pharmacy school on May 1, 2017. After graduation, Jill backpacked around Europe for about 1 year. Upon her return to the US in early May 2018, she took both the NAPLEX and MPJE, and passed them. Jill expects to receive her FL pharmacist license by the end of the month (May 2018). In summer 2019, Jill will receive a notice in the mail indicating that she needs to renew her pharmacist license by September 30, 2019. To renew her license in 2019, Jill will need to submit to the board of pharmacy evidence of completion of how many CE hours?

A. Ten hours
B. Fifteen hours
C. Thirty Hours
D. Jill will not need to submit CE hours since this is the initial renewal of her pharmacist license.
E. Jill will not need to submit CE hours since she was licensed within 18 months of the biennial renewal date.

Answer to Question 28

64B16-26.103 Continuing Education Credits; Renewal.

- (1) Prior to biennial renewal of pharmacist licensure, a licensee shall complete no less than 30 hours of approved courses of continued professional pharmaceutical education within the 24 month period prior to the expiration date of the license. The following conditions shall apply…
  - … (b) The initial renewal of a pharmacist license will not require completion of courses of continued professional pharmaceutical education hours if the license was issued less than 12 months prior to the expiration date of the license. If the initial renewal occurs 12 months or more after the initial licensure, then 15 hours of continued professional pharmaceutical education hours shall be completed prior to the renewal of the license but no earlier than the date of initial licensure…
    - ***NOTE: If you become licensed on or before 9/30/2018, like Jill here, you will need to submit 15 CE hours upon renewal on 9/30/2019. Two of these hours must involve rules related to the prescribing and dispensing of CS per 64B16-27.83; If, however, you are licensed after 9/30/2018 you will not be required to complete CE until the next biennium (Oct. 2019 – Sept. 2021).

Question 29

- For this question, presume that these adult patients have less than 0.5 ppm of fluoride in their drinking water. Which of the following statements about Florida pharmacists ordering fluoride-containing products for such patients is **CORRECT**?
  - I. Once a pharmacist starts a patient on a fluoride product, she should not substitute it with another manufacturer's product during the course of therapy.
  - II. Pharmacists may dispense up to 264 mg of sodium fluoride at any one time to a single patient.
  - III. Pharmacists are permitted to continue a course of fluoride therapy for a single patient for up to 18 months.

B. I only
C. III only
D. I & II only
E. II & III only
F. I, II & III

Answer to Question 29

64B16-27.230 Fluoride Containing Products That May Be Ordered by Pharmacists.

- Oral medicinal drug products containing fluoride may be ordered by pharmacists for their patients who do not have fluoride supplement in their drinking water, pursuant to the following limitations:
- (1) The fluoride content of drinking water does not exceed 0.5 ppm.
- (2) Once a fluoride treatment has been initiated with one specific fluoride medicinal drug product it should not be interchanged with a product of a different manufacturer for the course of the treatment…
- (3)(b) No more than 264 mg. of sodium fluoride may be dispensed at any one time to a patient.
- (3)(c) Notwithstanding the provisions of subsection 64B16-27.210(3), F.A.C., a pharmacist may continue a course of therapy with fluoride products until appropriate referral to another health care practitioner is indicated or in no event shall the course of therapy be more than one (1) year.

Question 30

- Which of the following statements about a pharmacy compounding non-sterile medications for a physician for "office use" is CORRECT? Select all that apply.

A. No more than 100 grams of a solid or no more than 480 mL of a liquid may be provided to the physician in a 30-day period.
B. The pharmacy and physician enter into a written agreement whereby the physician agrees to include information about the compounded product in the patient's record.
C. The physician may dispense or sell such compounded products to her patients.
D. The label must contain a beyond use date of up to 1 year.
E. The pharmacy must maintain records of products compounded for office use for at least 4 years.

Answer to Question 30

64B16-27.700 Definition of Compounding.

- (3) Office use compounding, "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:
  - (a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;
  - (b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;
  - (c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

Answer to Question 30, continued

64B16-27.700 Definition of Compounding.

- (d) The pharmacy and the practitioner enter into a written agreement. The agreement shall specifically provide:
  - 1. That the compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity,
  - 2. That the practitioner shall include on the patient's chart, medication order, or medication administration record the lot number and the beyond-use-date of any compounded drug administered to the patient that was provided by the pharmacy,
  - 3. That the practitioner will provide notification to the patient for the reporting of any adverse reaction or complaint in order to facilitate any recall of batches of compounded drugs.
- (e) The pharmacy shall maintain readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of four (4) years…

Answer to Question 30, continued

64B16-27.700 Definition of Compounding.

- (f) The pharmacy shall affix a label to any compounded drug that is provided for office use. The label shall include:
  - 1. The name, address, and phone number of the compounding pharmacy,
  - 2. The name and strength of the preparation of a list of active ingredients and strengths,
  - 3. The pharmacy's lot number and beyond-use-date,
  - 4. The quantity or amount in the container,
  - 5. The appropriate ancillary instructions such as storage instructions, cautionary statements, or hazardous drug warning labels were appropriate; and,
  - 6. The statement "For Institutional or Office Use Only – Not for Resale," or if the drug is provided to a veterinarian the statement "Compounded Drug" …

Answer to Question 30, continued

- BEYOND USE DATES: USP Chapter 795 defines Beyond Use Date (BUD) as the date after which a compounded nonsterile preparation (CNSP) should not be used. The BUD is determined from the date the CNSP is compounded. When determining BUD, the pharmacist must take into account stability information regarding the specific drug(s) and specific CNSP. Stability information may come from documentation, literature or stability tests. In the absence of stability information, the maximum BUDs for CNSP packaged in tight, light resistant containers are:
  - Nonaqueous Formulations: no longer than 6 months or the earliest expiration date of any ingredient used, whichever is shorter, and stored at controlled room temperatures.
  - Water Containing Oral Formulations: no longer than 14 days or the earliest expiration date of any ingredient used, whichever is shorter, and stored at controlled cold temperatures. This includes water being added as an ingredient or water is a component of any ingredient used. For example, diphenhydramine syrup has water as a component.
  - Water Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations: no longer than 30 days or the earliest expiration date of any ingredient used, whichever is shorter, and stored at controlled room temperatures. This includes water being added as an ingredient or water is a component of any ingredient used. For example, nystatin cream has water as a component.

Question 31

- Select all that apply. This question pertains to the dispensing of medicinal drugs from pharmacies in hospitals that are registered solely as Class II institutional pharmacies (and are **not** also registered as community pharmacies). Such pharmacies are permitted to dispense medicinal drugs to:
  - A. Individuals treated in the hospital's ER if the patient so chooses.
  - B. Inpatients of their respective institutions for use on the premises.
  - C. Outpatients, generally.
  - D. Community members if their respective hospitals are located in areas proclaimed to be in states of emergency.
  - E. Employees of the institution and their immediate family members.

Answer to Question 31

465.019 Institutional pharmacies; permits.—

- … (2)(b) "Class II institutional pharmacies" are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution…
- (4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted ***and*** that community pharmacy services are not readily accessible, geographically or otherwise, to the patient…

*** RECALL: **Special- Limited Community Pharmacy Permit** are only available to Institutional Class II permittees as an additional permit to allow the facility to provide medications to employees, medical staff and up to a three-day supply of medication to patients being discharged under certain conditions.

Question 32

- Which of the following statements about Modified Class II institutional pharmacies is/are **CORRECT**? Select all that apply.

A. They are located in short-term, primary care treatment centers.
B. They must be under the professional supervision of consultant pharmacists.
C. They are not legally authorized to store medicinal drugs.
D. Medicine and pharmacy (i.e., P & T committee) must adopt an institutional formulary.
E. Drugs may be dispensed to outpatients of such facilities without securing a community pharmacy permit.

Answer to Question 32

465.019 Institutional pharmacies; permits.—

- … (2) (c) "**Modified Class II institutional pharmacies**" are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.
- (3) Medicinal drugs shall be stocked, stored, compounded, dispensed, or administered in any health care institution only when that institution has secured an institutional pharmacy permit from the department…
  - ***NOTE: Medications are permitted in Class I, Class II, and Modified Class II Institutional Pharmacies.
- (4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department…
- (5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist…
- (6) In a Class II institutional pharmacy [NOT a modified Class II], an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs, proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists employed in such institution…

Question 33

- Unless otherwise specified, what is the maximum day supply of medications that can be ordered by a Florida pharmacist for his/her patients?

A. 7
B. 14
C. 30
D. 34
E. There is no limit

Answer to Question 33

64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.

- Pursuant to the authority of the Formulary Committee in Section 465.186, F.S., a pharmacist may order the medicinal drug products listed in Rule 64B16-27.220, F.A.C., subject to the following terms and limitations:
  - (1) Injectable products shall not be ordered by the pharmacist.
  - (2) No oral medicinal drugs shall be ordered by a pharmacist for a pregnant patient or nursing mother.
  - (3) In any case of dispensing hereunder, the amount or quantity of drug dispensed shall not exceed a 34-day supply or standard course of treatment unless subject to the specific limitations in this rule. Patients shall be advised that they should seek the advice of an appropriate health care provider if their present condition, symptom, or complaint does not improve upon the completion of the drug regimen…

Question 34

- Which of the following statements about the donation of cancer drugs is **CORRECT**?

A. Cancer drugs may be donated to a specific patient.

B. Cancer drugs that will expire within 6 months following the date of donation cannot be accepted.

C. Participating facilities accepting donated drugs cannot charge recipient patients any fees whatsoever.

D. The Cancer Drug Donation Program is legally permitted to resell donated drugs at a discounted price.

E. Under no circumstances may a drug be accepted for donation if the outside packaging is opened.

Answer to Question 34

499.029 Cancer Drug Donation Program.—

- … (4) Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program…
- (6)(a) A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.
- (6)(b) A cancer drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled…
- (7)(b) A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. The fee shall be established in rules adopted by the department….

Question 35

- How many hours per week must a community pharmacy in Florida be open?

A. 20
B. 30
C. 40
D. 60
E. 80

Answer to Question 35

64B16-28.1081 Regulation of Daily Operating Hours; Commencement of Operations.

(1) Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment, shall keep the prescription department of the establishment open for a minimum of twenty (20) hours per week…

(2) Any pharmacy that is not open 40 hours a week, must post the days and hours that the pharmacy is open and the information for after-hours access …

Question 36

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- Of the total continuing education hours that pharmacists must complete each biennium to renew their pharmacist licenses, up to how many may be fulfilled by completing ***two*** semester hours of graduate work at an accredited college of pharmacy within the 24 months prior to the expiration date of the license?

A. 2
B. 15
C. 5
D. 10
E. 0

Answer to Question 36

64B16-26.103 Continuing Education Credits; Renewal.

- (1) Prior to biennal renewal of pharmacist licensure, a licensee shall complete no less than 30 hours of approved courses of continued professional pharmaceutical education within the 24 month period prior to the expiration date of the license. The following conditions shall apply.
  - ...(g) Continuing education credit shall be granted for completion of post professional degree programs provided by accredited colleges or schools of pharmacy. Credit shall be awarded at the rate of 5 hours of continuing education credit per semester hour completed within the 24 months prior to the expiration date of the license.

Question 37

- At least how many hours of coursework must a pharmacist or pharmacy intern complete in order to become certified *initially* to administer vaccines?
  - A. 3 hours
  - B. 5 hours
  - C. 12 hours
  - D. 20 hours
  - E. 30 hours

Answer to Question 37

64B16-26.1031 Vaccine Certification Program

… (2) The Board shall approve for initial certification of pharmacist and pharmacy intern administration of vaccines, programs of study not less than 20 hours …

- Note: Pharmacy intern was added to the rule above on 5/29/16
- Coursework includes such topics as: Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration; immunization schedules; vaccine storage and handling; procedures and policies for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS); administration techniques; community immunization resources and programs.

Question 38

- A pharmacist (PharmD), who is not a consultant pharmacist, just completes the initial 3-hour certification course so that she may order and evaluate laboratory tests. How many (if any) of these 3 hours may she apply toward the continuing education requirement for renewal of her pharmacist license?

A. 0 hours
B. 1 hour
C. 1.5 hours
D. 2 hours
E. 3 hours

Answer to Question 38

64B16-26.320 Subject Matter for Continuing Education to Order and Evaluate Laboratory Tests.

- (1) Consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree that wish to order and evaluate laboratory tests … shall successfully complete the requirements of a continuing education course … prior to such practice. Successful completion of the course will certify the pharmacist for this practice for two (2) years from date of completion.
- (2) … Courses approved under this section shall be at least three (3) hours in duration for initial certification and at least one (1) hour for recertification, and shall cover the following subjects:
  - (a) Requirements for monitoring laboratory values,
  - (b) Interpretation of laboratory values,
  - (c) Use of laboratory data to monitor and improve drug therapy,
  - (d) Legal aspects, restrictions, and requirements for obtaining laboratory studies,
  - (e) Use of laboratory data and therapeutic outcomes,
  - (f) Documentation of interventions, and
  - (g) Laboratory studies as an element of complete patient care.
- (3) A consultant pharmacist may apply the three (3) hour initial certification course and the one (1) hour recertification course toward the continuing education requirement for renewal of a consultant pharmacist license … or may apply such continuing education hours toward the continuing education requirement for renewal of a pharmacist license … but may not use the same continuing education hours to satisfy both requirements [***NO double-dipping, if you will!]. A Doctor of Pharmacy who is not a consultant pharmacist may apply the three (3) hour initial certification course and the one (1) hour recertification course toward the continuing education requirement for renewal of a pharmacist license…

Question 39

- Select all that apply. The board of pharmacy may allow a pharmacist to serve as the prescription department manager (PDM) of more than one community pharmacy if it can be shown that the:
  - A. The 2 pharmacies are owned by the same person or entity.
  - B. The pharmacist has been licensed and practicing in Florida for at least 5 years.
  - C. The pharmacist's workload is limited, thus enabling him/her to carry out all the duties/responsibilities required of a PDM.
  - D. The pharmacies are in close proximity to one another.
  - E. The pharmacist carries a minimum of $250,000 of professional liability insurance.

Answer to Question 39

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees.

- … (5) Pursuant to Section 465.018, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy. The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board shall grant an ***exception*** to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

Question 40

144

- What proof must one seeking to become licensed as a pharmacist in Florida by endorsement provide to the board of pharmacy?
  - A. That she has practiced pharmacy in another state for at least 2 of the last 5 years and has completed 30 hours of CE in the last 2 years
  - B. That she has successfully completed a board-approved internship program within the last 2 years
  - C. Either A or B
  - D. Both A and B
  - E. Neither A nor B is required as proof

Answer to Question 40

64B16-26.204 Pharmacist Licensure by Endorsement; Application.

An applicant for licensure by endorsement must be at least 18 years of age received a degree from an accredited U.S. pharmacy or from a program outside the U.S. provided certain conditions are met per 465.007(1)(b)2. The applicant must also have satisfied the board's internship hour requirement (which most earn while in pharmacy school) (see 465.007(1)(c)) and have passed NABP's licensure exam per 465.0075(1)(b). The applicant must:

- (c)1. [Have] two (2) years of active practice, as defined in Section 465.0075(1)(c)1., F.S., within the immediately preceding five (5) years and have completed 30 hours of Board approved continuing education within the two (2) calendar years immediately preceding application…
- 2. Successful completion of board-approved postgraduate training or a board-approved clinical competency examination within the year immediately preceding application, or
- 3. Successful completion of an internship meeting the requirements of Section 465.007(1)(c), F.S., and Rule 64B16-26.2033, F.A.C., within the two (2) years immediately preceding application…

Question 41

- For this question, there is only 1 pharmacist on duty. The pharmacist takes a 30-minute meal break at the restaurant two doors down from the pharmacy. She tells her technician to call her cell phone if he needs her. Which of the following activities is the technician ***unable*** to perform while the pharmacist is on break?
  - I. Restock the pharmacy's automated system
  - II. Count out a controlled medication pursuant to a prescription
  - III. Call a prescriber to clarify the strength of a drug and get a missing DEA number

B. I only
C. III only
D. I & II only
E. II & III only
F. I, II & III

Answer to Question 41

64B16-27.420 Pharmacy Technician – Delegable and Non-Delegable Tasks.

- A pharmacy technician may only assist a pharmacist in executing or carrying out the practice of the profession of pharmacy… (2) Delegable Tasks – The following tasks are delegable:
  - … (d) The counting, weighing, measuring, and pouring of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system;
  - (e) The initiation of communication to confirm the patient's name, medication, strength, quantity, directions, number of refills, and date of last refill;
  - (f) The initiation of communication with a prescribing practitioner or their agents to obtain clarification on missing or illegible dates, prescriber name, brand or generic preference, quantity, license numbers or DEA registration numbers…

Answer to Question 41, continued

64B16-27.1001 Practice of Pharmacy.

- (6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:
  - …(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist ***if the pharmacist is available on the premises during the meal break to respond to questions by the technicians***, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

***NOTE: It is true that the activities listed in choices I-III are those that may be delegated to pharmacy technicians, but, only under the direct and immediate supervision of a pharmacist. Because the pharmacist has left the premises, the technician is not being directly supervised. Also, the technician is not permitted to be in the pharmacy department when the pharmacist is off-site.

Question 42

- On 10/21/2017, a community pharmacy fills an RX for a patient, but the patient does not come to pick up the drug. The manufacturer's expiration date is 6/2019. The pharmacy returns the unclaimed drug to stock on 11/1/17 so that it is available for future patients. What is/was the last date upon which the pharmacy can dispense this drug?

A. 4/21/2018
B. 10/21/2018
C. 11/21/2018
D. 6/1/2019
E. 6/30/2019

Answer to Question 42

64B16-28.1191 Unclaimed Prescriptions.

- Prescriptions that are unclaimed may be retained by a pharmacy and reused for a period up to one year from the date of filling; however, any product reaching the product's expiration date prior to one year or any product subject to a recall shall not be reused.
- ***FYI: USP defines the expiration date as "the time during which the article may be expected to meet the requirements of the pharmacopeial monograph provided it is kept under the prescribed conditions." The expiration date, which limits the time during which the article may be dispensed or used, is based on scientifically sound stability studies carried out by the manufacturer and is usually expressed in terms of the month and year, as stated on the manufacturer's container. This means that the *product can be used or dispensed until the last day of the stated month and year*.

Answer to Question 42, continued

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.

Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

- (1) Definitions.
  - (h) An Expiration Date or Beyond-Use Date: The expiration date must be the date provided by the manufacturer, repackager, or other distributor. The beyond-use date must not exceed the expiration date and it shall not be a date greater than one year from the date the medicinal drug is filled. The board finds that the use of a "discard-after-date" or "do not use after date" to be equivalent of a beyond-use date.

Question 43

- In which of the following instances is a new pharmacy permit required?
  - A. Chain Pharmacy A sells business to Chain Pharmacy B.
  - B. Individual owner of a pharmacy sells it to a partnership.
  - C. Ownership interests of a chain pharmacy is sold from Person A to Person B.
  - D. All of the above
  - E. A and B only

Answer to Question 43

64B16-28.2021 Change of Ownership.

- (1) A pharmacy permit is not transferable. If upon the sale of an existing pharmacy, there is any change in the identity of the natural person, partnership, or business entity which holds the permit, a new application must be filed and a new permit obtained. For purposes of this rule, the test for determining change of identity shall be whether the person or entity's Federal Employer Identification Number (FEIN) remains the same following the sale.
- (2) Permits held by business entities with no change in identity. In those cases where the permit is held by a business entity (e.g. a corporation, limited liability company, limited partnership, etc.) which entity continues to hold the permit without change in identity, the transfer of the ownership interests of said business entity to another person or business entity does not constitute a change of ownership (requiring application for and issuance of a new pharmacy permit)…

Question 44

- Select all that apply. A licensed Florida pharmacy performs RX drug processing for other pharmacies. All pharmacies involved must:
  - A. Be physically located in Florida.
  - B. Be under common ownership.
  - C. Describe in their policy and procedure manuals how they will comply with state/federal laws.
  - D. Utilize a common database.
  - E. Treat such transactions as the transferring of an RX from one pharmacy to another.

Answer to Question 44

64B16-28.451 Pharmacy Common Database.

- (1) A pharmacy licensed under this chapter may perform prescription drug processing for other pharmacies, provided that all pharmacies are under common ownership, utilize a common database, and are properly licensed, permitted or registered in this state or another state. Nothing in this subsection shall prohibit a pharmacist employee of said pharmacies who is licensed in Florida or in another state from remotely accessing the pharmacy's electronic database from outside the pharmacy in order to process prescriptions, provided the pharmacy establishes controls to protect the privacy and security of confidential records…
- (4) Each pharmacy performing prescription drug processing pursuant to this section must maintain a policy and procedure manual, which shall be made available to the Board or its agent upon request. The policy and procedures manual shall include the following information:
  - (a) A description for how each pharmacy will comply with federal and state laws, rules and regulations;
- (5) The prescription drug processing of a prescription by one pharmacy for another pursuant to this section shall not be construed as the transferring of a prescription as set forth in Section 465.026, F.S.

Question 45

- Which of the following justifies the use of prescription obesity drugs? Select all that apply.

A. Measurable body fat content ≥ 30% of total body weight for males
B. BMI greater than 27 with at least one comorbidity factor
C. BMI of 30 and above for adults
D. Measurable body fat content ≥ 25% of total body weight for females
E. BMI of 35 and above for children

Answer to Question 45

64B8-9.012 Standards for the Prescription of Obesity Drugs.

The prescription of medication for the purpose of enhancing weight loss should only be performed by physicians qualified by training and experience to treat obesity. All licensees are expected to abide by the following guidelines and standards in the utilization of any drug, any synthetic compound, any nutritional supplement, or herbal treatment, for the purpose of providing medically assisted weight loss.

- (1) To justify the use of weight loss enhancers as set forth above, the patient must have a Body Mass Index (BMI) of 30 or above, or a BMI of greater than 27 with at least one comorbidity factor, or a measurable body fat content equal to or greater than 25% of total body weight for male patients or 30% of total body weight for women. The prescription of such weight loss enhancers is not generally appropriate for children…

Question 46

- Which of the following records must be retained by a pharmacy for a minimum of 4 years after the date of dispensing? Select all that apply.

A. Original RXs (if the pharmacy does not have an authorized electronic imaging system)
B. Electronic images of prescriptions (if the pharmacy has an authorized electronic imaging system)
C. Daily logbook in which pharmacists attest to the correctness of the information entered into the data processing system
D. Original RXs presented to a retail pharmacy, but filled by a central fill pharmacy
E. Name, initials, or ID of persons engaged in remote processing for institutional pharmacy for every medication order remotely processed

Answer to Question 46

64B16-28.140 Record Maintenance Systems for All Pharmacy Permits.

- (1) Requirements for records maintained in a data processing system…
  - (d) Original prescriptions, including prescriptions received as provided for in Rule 64B16-28.1003, F.A.C., Transmission of Prescription Orders, shall be reduced to a hard copy if not received in written form. All original prescriptions shall be retained for a period of not less than four (4) years from date of last filling. To the extent authorized by 21 C.F.R. Section 1304.04, a pharmacy may, in lieu of retaining the actual original prescriptions, use an electronic imaging recordkeeping system, provided such system is capable of capturing, storing, and reproducing the exact image of the prescription, including the reverse side of the prescription if necessary, and that such image be retained for a period of no less than four (4) years from the date of last filling …
- (3) Records of dispensing…
  - (e) In lieu of producing the printout described in paragraphs (b) and (c) of this section, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of four (4) years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand…

Answer to Question 46, continued

64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

- (4) The central fill and originating pharmacy shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:
  - (a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:
    - 4. Maintain the original prescription for a period of four (4) years from the date the prescription was last filled.

Answer to Question 46, continued

64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies or Special Pharmacy Permits Servicing Class I, Class II, Modified Class II, and Special ALF Permitted Facilities.

- (4) Records.
  - (a) A Class II Institutional Pharmacy or Special Pharmacy Permits servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name…
  - (c) The record shall be readily retrievable for at least the past four (4) years. (***Changed from 2 years on 7/19/17)

Question 47

- Select all that apply. A pharmacists attempts to validate an RX written for a controlled substance. She has a question about the RX, so, she calls the prescriber & leaves a voicemail. Her "gut" tells her the RX is valid. The pharmacist:
  - A. Can provide a 72-hour supply of the drug & then verify the RX with the prescriber.
  - B. Must refuse to dispense any drug until she speaks to the prescriber.
  - C. Shall fill the RX if her concerns are eased after speaking with the patient & checking the Prescription Drug Monitoring Program's Database.
  - D. May refuse to fill the RX if the patient refuses to cooperate with her.
  - E. Cannot fill the RX if there is any concern whatsoever about the validity of it.

Answer to Question 47

- **64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.**
- … (2) General Standards for Validating a Prescription … There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

Answer to Question 47, continued

- **64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.**
- … (3) Minimum Standards Before Refusing to Fill a Prescription.
  - (a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and ***shall*** attempt to validate the prescription by performing the following:
    - 1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;
    - 2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.
  - (b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.
  - (c) In the event that a pharmacist is unable to comply with paragraph (a) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required…

Question 48

165

- Which of the following statements about the destruction of controlled substances in a permitted facility (excluding nursing homes) is **CORRECT**?
  - I. Permittees must complete a DEA 41, and forward it on to DEA within 1 business day after the destruction of such drugs.
  - II. Any pharmacist and prescriber employed by the permittee together may conduct the destruction of such drugs.
  - III. When destroying patient-specific drugs in a Modified Institutional Class II B pharmacy, such destruction must be witnessed by the consultant pharmacist, director of nursing, and the facility administrator or his/her designee.

B. I only
C. III only
D. I & II only
E. II & III only
F. I, II & III only

Answer to Question 48

64B16-28.303 Destruction of Controlled Substances All Permittees (Excluding Institutional Class I Nursing Homes).

- … (2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form DEA-41 …This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction requires that a copy of the completed and witnessed Form DEA 41 be mailed to the D.E.A. office in his/her area within one (1) business day after the destruction (NOTE: Old version stated that the form must be sent **"immediately"** after the destruction).
- (3) Another method of destruction shall be conducted by at least two persons: One will be the prescription department manager or the consultant pharmacist of record. The other will be one of the following: medical director or his/her physician designee, director of nursing or his/her licensed nurse designee, or a sworn law enforcement officer. These persons shall serve as the witnesses for the Form DEA-41 and the destruction. This method of destruction requires that a copy of the completed and witnessed Form DEA-41 be mailed to the D.E.A. office in the permittee's area within one (1) business day after destruction.
- … (5) For patient specific controlled substance prescriptions in a Modified Institutional Class II B pharmacy, the destruction method in subsection 64B16-28.301(2), F.A.C., must be followed.

Answer to Question 48, continued

64B16-28.301 Destruction of Controlled Substances – Institutional Class I Pharmacies (Nursing Homes).

- (2) For each controlled substance destroyed, documentation must be completed showing the name and quantity of the drug, strength and dosage form, patient's name, prescription number and name of the institution. Destruction of the controlled substance shall be witnessed by at least two (2) of the following individuals:
  - (a) Consultant pharmacist;
  - (b) Director of nursing
  - (c) Facility administrator;
  - (d) A licensed physician, mid-level practitioner, nurse, or another pharmacist employed by or under contract or written agreement with the facility, or
  - (e) A sworn law enforcement officer.
- Those individuals witnessing the destruction of the controlled substance shall sign the completed documentation.

***64B16-28.303 was modified on 4/20/14 and 64B16-28.301 was modified on 11/5/17**

Question 49

168

- Who is permitted to stock and/or restock automated filling systems in pharmacies? Select all that apply.
  - A. Staff pharmacists
  - B. Prescription Department Managers
  - C. Directly supervised pharmacy interns
  - D. Directly supervised pharmacy technicians
  - E. Non-registered pharmacy clerks (e.g., cashiers)

Answer to Question 49

64B16-28.608 Automated Filling Systems within a Pharmacy.

- …(3) Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or restocked by a pharmacist [any pharmacist!], pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist, as each are defined by subsection 64B16-27.1001(7), F.A.C. …

Question 50

170

- A Special-Limited Community Permit must be obtained by a Class II Institutional Pharmacy that dispenses medicinal drugs to discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs. Before such drugs are dispensed:
  - I. The patient's physician must first write a specific order authorizing that the multi-dose medicinal drug is appropriate to dispense upon discharge.
  - II. The patient or his/her caregiver must be educated on the administration of such drugs.
  - III. The pharmacist must inform the patient that such drugs may only be refilled by the hospital pharmacy filling the original order.

B. I only
C. III only
D. I & II only
E. II & III only
F. I, II & III only

Answer to Question 50

64B16-28.810 Special Pharmacy – Limited Community Permit.

- A Special-Limited Community Permit shall be obtained by a Class II Institutional Pharmacy that dispenses medicinal drugs, including controlled substances to:
- **… (4)** Discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs if the following requirements are met:
  - … (b) The patient is deemed competent to handle and administer the multi-dose medicinal drug.
  - (c) A specific order is written by the patient's physician to authorize that the multi-dose medicinal drug is appropriate to dispense upon discharge.
  - (d) Before the hospital dispenses a multi-dose medicinal drug as specified in paragraph (4) of this section, the hospital shall establish protocols to ensure the following:
    - 1. Infection control during transport and handling of multi-dose medicinal drug containers that have been in contact with a patient;
    - 2. Patient or caregiver education on administration of the multi-dose medicinal drug if necessary on an individual basis.
  - (e) A "multi-dose medicinal drug" as used in this rule means, but is not limited to, commercially available multi-dose packages such as inhalers, ocular products, insulin vials or pens, otic products, bulk antibiotic suspensions, topical agents, and methylprednisolone dose packets dispensed to inpatients, provided in containers that may exceed a three (3) day supply, and are intended to be continued by the patient on an outpatient basis but ***not*** to be re-filled by the hospital. Controlled substances are not considered multi-dose medicinal drugs as defined in this rule.

Florida Law Answer Key

1	D		11	A		21	A, C		31	B, D		41	E
2	B - D		12	B		22	D		32	A, B		42	B
3	C		13	A, C, D		23	B		33	D		43	E
4	A - C		14	C, D, E		24	C, E		34	B		44	B - D
5	A - C		15	E		25	B		35	A		45	B, C
6	A		16	A, D		26	D		36	D		46	A - E
7	C		17	C - E		27	A, D		37	D		47	C, D
8	A, E		18	D		28	B		38	E		48	A
9	A, D		19	B, D		29	C		39	C, D		49	A - D
10	B, E		20	A - E		30	B, E		40	C		50	C